### UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF ALABAMA NORTHERN DIVISION

BRIANNA BOE et al.,	)
Plaintiffs,	)
and	)
UNITED STATES OF AMERICA,	)
Plaintiff-Intervenor,	)
v.	) No. 2:22-cv-00184-LCB-CWB ) Hon. Liles C. Burke
STEVE MARSHALL, in his official capacity as Attorney General of the	)  REDACTED COPY;
State of Alabama, et al.,	<ul><li>ORIGINAL SUBMITTED</li><li>UNDER SEAL</li></ul>
Defendants.	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

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#### **INTRODUCTION**

When this Court granted a preliminary injunction two years ago, it did so on a necessarily rushed timeline with sparse facts and no guidance from the Eleventh Circuit. Since then, the factual and legal landscapes have changed dramatically. Defendants respectfully submit that those changes entitle them to summary judgment.

The legal rule in the Eleventh Circuit is now clear: the provisions of Alabama's Vulnerable Child Compassion and Protection Act that Plaintiffs and the United States challenge are "subject only to rational basis review." *Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205, 1210 (11th Cir. 2023). Plaintiffs agree. Doc. 489 at 2. However complex the underlying debate may be about how best to care for minors with gender dysphoria, the standard of review makes the legal questions simple. The Act is entitled to a "strong presumption of validity" and must be upheld if "there is any rational basis for" it. *Eknes-Tucker*, 80 F.4th at 1224-25 (citations omitted).

Alabama's Act easily "survive[s] the lenient standard that is rational basis review." *Id.* at 1225. It would also survive heightened review. The facts uncovered in discovery repudiate nearly every claim Plaintiffs made at the preliminary injunction hearing. Are puberty blockers followed by cross-sex hormones "the only safe and effective treatment for gender dysphoria"? Doc. 8 at 13. Emphatically no. Take it from Dr. Marci Bowers, the president of the World Professional Association for Transgender Health (WPATH). Asked whether "reasonable people could conclude that there is not enough evidence to support the safety or clinical effectiveness of puberty blockers," Bowers replied: "There's not enough high level evidence. Yes,

you can – you can – you can say that."1

Or consider England's National Health Service. For the last four years, an independent review commissioned by NHS has examined the safety and efficacy of pediatric transitioning treatments by commissioning 11 systematic evidence reviews, appraising clinical guidelines, parsing through data from the (since shuttered) national pediatric gender clinic, and speaking with clinicians and gender dysphoric youth.<sup>2</sup> The final report was released last month.<sup>3</sup> The chair of the Review, Dr. Hilary Cass, was unsparing in her assessment: "I can't think of another area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."<sup>4</sup>

Commenting on the Review's findings, the editor-in-chief of the *British Medical Journal* went further: "Offering treatments without an adequate understanding of benefits and harms is unethical," particularly when "the treatments are not trivial." Which indeed they are not. Though Dr. Ladinsky promised that puberty blockers are a "pause button," Dr. Cass found that "[t]he[] data suggest that puberty blockers are not buying time to think, given that the vast majority of those who start puberty suppression continue to" cross-sex hormones. That progression results in

<sup>&</sup>lt;sup>1</sup> DX18:252:9-19 (Bowers Dep.). Bowers then argued that there "is evidence," just not "high level." *Id.* 

<sup>&</sup>lt;sup>2</sup> See DX86-96 (Cass evidence reviews).

<sup>&</sup>lt;sup>3</sup> DX84 (Cass Review).

<sup>&</sup>lt;sup>4</sup> DX85:3 (Abbasi *Medication*).

<sup>&</sup>lt;sup>5</sup> DX85:1 (Abbasi *Opportunity*); accord DX5:¶¶148, 153-55 (Hruz Rep.); DX14:¶¶52-97 (Curlin Rep.).

<sup>&</sup>lt;sup>6</sup> Docs. 104 & 105, PI Tr. 105.

<sup>&</sup>lt;sup>7</sup> DX84:176 (Cass Review).

sterility and sexual dysfunction.<sup>8</sup> And unlike when puberty blockers are used to treat precocious puberty, adolescents receiving them for gender dysphoria will *never* go through natural puberty while receiving "gender-affirming care." That is worrisome: Puberty is a "critical period" for brain development, which "may be temporarily or permanently disrupted by the use of puberty blockers." <sup>10</sup>

Does informed consent and Plaintiffs' vaunted "360 assessment" solve the problem? Again, no. No matter how long the assessment period, a "formal diagnosis of gender dysphoria" "is not reliably predictive of whether that young person will have longstanding gender incongruence." That makes sense: Brain "maturation continues into a person's mid-20s, and through this period gender and sexual identity may continue to evolve." That also explains why a 12-year-old who has never experienced puberty is in no position to "assent" to forever foregoing sexual relations or raising children of her own. As the chair of WPATH's Standards of Care, Dr. Eli Coleman, put it, "at their age – they would not know what they want." And make no mistake: whether a procedure is even *recommended* turns on the child's

<sup>&</sup>lt;sup>8</sup> DX7:¶¶90-100, 157-59 (Laidlaw Rep.); DX5:¶¶89-91 (Hruz Rep.); DX10:¶¶5, 59-67 (Thompson Rep.); DX2:¶¶206-09 (Cantor Rep.); DX43:207:23–209:23 (Antommaria Dep.).

<sup>&</sup>lt;sup>9</sup> DX5:¶¶44-45 (Hruz Rep.); DX39:84:3–85:4 (Shumer Dep.); DX2:¶¶68, 228 (Cantor Rep.).

<sup>&</sup>lt;sup>10</sup> DX84:178 (Cass Review); see DX5:¶¶32-33 (Hruz Rep.); DX154:9-10 (Baxendale Neuropsychological Function).

<sup>&</sup>lt;sup>11</sup> PI Tr. 22, 59, 371-72.

<sup>12</sup> DX84:193 (Cass Review); see DX163:4 (Levine Response); DX179:15 (WPATH 6); DX115:3876 (Endocrine Society 2017 Guideline); DX2:¶¶124-26 (Cantor Rep.);

<sup>&</sup>lt;sup>13</sup> DX84:193 (Cass Review); see DX11:¶¶24, 89 (Nangia Rep.); DX39:238:4-6 (Shumer Dep.).

<sup>&</sup>lt;sup>14</sup> DX14:¶¶70-97 (Curlin Rep.); DX11:¶¶71-135 (Nangia Rep.); DX146:3-4 (Cohn Decl.); DX147:1-2 (Cohn What I Wish I'd Known).

<sup>&</sup>lt;sup>15</sup> DX180:59 (WPATH 7); *see* DE128:13 (Hughes *WPATH Transcript*) (WPATH mentor noting that "talk[ing] about fertility preservation with a 14 year old" is like "talking to a blank wall").

wishes. 16 As for the parents, it is deeply unfair—and medically unethical—to ask them to "consent" to procedures that they cannot become "informed" about. 17

What of Plaintiffs' preferred medical organizations that recommend the procedures anyway? Here again the truth is markedly different from what the Court was told. First, though Plaintiffs relied on a listing of 22 domestic medical interest groups that generally support "gender-affirming care," Doc. 91-1, most of those organizations have neither issued nor—as far as WPATH's leaders can tell—endorsed guidelines for such "care." As Plaintiffs note, the exceptions are WPATH and the Endocrine Society (whose guidelines WPATH co-authored). After applying the "most commonly applied and comprehensively validated appraisal tool" to these guidelines, the Cass reviewers found that both guidelines lacked methodological rigor. 19 The guidelines that *did* pass muster—from the Swedish and Finnish health care services—highlighted the *lack* of evidence and recommended restricting pediatric transitioning treatments to research or extraordinary settings. 20 That is just what at least

admitting "we really ARE going on 'what the children say"");

DX116:S59 (SOC-8) (discussing transitioning treatments "requested by the patient");

<sup>;</sup> DX179:15 (WPATH 6) (clinician

<sup>;</sup> DX5:¶56 (Hruz Rep.); DX39:196:9–201:12 (Shumer Dep.).

To DX14:¶¶70-97 (Curlin Rep.); DX11:¶¶71-47 (Nangia Rep.); see DX84:196 (Cass Review); DX164:2-13 (Levine Reconsidering Informed Consent).

<sup>&</sup>lt;sup>18</sup> DX21:255:6–265:3 (Coleman Dep.); DX190:6-7 (WPATH 17).

<sup>&</sup>lt;sup>19</sup> DX84:129-30 (Cass Review); DX86:1-16 (Taylor Guidelines Review).

<sup>&</sup>lt;sup>20</sup> DX84:129-30 (Cass Review 129-30); DX86:5-7 (Taylor *Guidelines Review*); see DX103-108 (Swedish and Finnish summaries and systematic evidence reviews).

six European healthcare authorities have done or recommended doing.<sup>21</sup>

Second, among much else, discovery has revealed that WPATH:

- violated multiple international standards for the creation of clinical guidelines that WPATH itself claimed to follow in Standards of Care 8 ("SOC-8");
- restricted the ability of SOC-8's evidence review team to publish the systematic evidence reviews finding scant evidence for transitioning treatments;
- intentionally used SOC-8 as a political and legal document to increase coverage for transitioning treatments and advance WPATH's political goals;
- caved to outside political pressure by Admiral Rachel Levine and others to remove age minimums for hormones and surgeries in SOC-8; and
- "muzzle[d]" WPATH members who tried to inform the public of their concerns over pediatric transitioning treatments.

In short, neither the Court nor Alabama need treat WPATH as anything other than the activist interest group it has shown itself to be. The Constitution allows States to reject WPATH's model of "care" and protect vulnerable minors from lifealtering transitioning "treatments." The Court should grant Defendants summary judgment.

#### STATEMENT OF UNDISPUTED FACTS

## A. The Legislative Findings Are Supported By Evidence.

1. The Alabama Legislature included legislative findings explaining why it

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<sup>&</sup>lt;sup>21</sup> England's NHS "concluded that there is not enough evidence to support the safety or clinical effectiveness of" puberty blockers "to make the treatment routinely available." DX97:3 (NHS *Puberty Suppressing Hormones*). Scotland's NHS restricted all transitioning treatments for gender dysphoric youth under 18 to research settings "that will"—future tense—"generate evidence of safety and long-term impact for [the] therapies." DX111:1-2 (Scotland Policy); *see also* DX112:1 (Ghorayshi *Scotland*) (Scotland was "the sixth country in Europe to limit such treatments"); DX5:¶¶134-37 (Hruz Rep.); DX2:¶¶16-33 (Cantor Rep.) (discussing recommendations in England, Finland, Sweden, France, and Norway).

enacted the Act, quoted below. Ala. Code § 26-26-2. Those findings are supported by evidence, examples of which are provided in footnotes:

2. "The sex of a person is the biological state of being female or male, based on sex organs, chromosomes, and endogenous hormone profiles, and is genetically encoded into a person at the moment of conception, and it cannot be changed."<sup>22</sup> "Some individuals, including minors, may experience discordance between their sex and their internal sense of identity, and individuals who experience severe psychological distress as a result of this discordance may be diagnosed with gender dysphoria."<sup>23</sup> "The cause of the individual's impression of discordance between sex and identity is unknown, and the diagnosis is based exclusively on the individual's self-report of feelings and beliefs."<sup>24</sup> "This internal sense of discordance is not permanent or fixed, but to the contrary, numerous studies have shown that a substantial majority of children who experience discordance between their sex and identity will outgrow the discordance once they go through puberty and will eventually have an identity that aligns with their sex."<sup>25</sup> "As a result, taking a wait-and-see approach to children who reveal signs of gender nonconformity results in a large majority of those

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 $<sup>^{22}</sup>$  See DX5:  $\P13-17$  (Hruz Rep.); DX2:  $\P106-08$ , 299 (Cantor Rep.); DX7:  $\P15-17$ , 27-31, 40-43 (Laidlaw Rep.); DX10:  $\P25$ , 32 (Thompson Rep.); DX155: 2-7 (Bhargava).

<sup>&</sup>lt;sup>23</sup> DX67:35-38 (DSM-5 TR); DX11:¶¶13-15 (Nangia Rep.); DX2:¶110 (Cantor Rep.).

<sup>&</sup>lt;sup>24</sup> DX2:¶164, 276, 302-03 (Cantor Rep.); DX7:¶¶ 18-23, 53 (Laidlaw Rep.); DX5:¶¶56-58, 129 (Hruz Rep.); DX11:¶¶20-36 (Nangia Rep.); DX39:9:8–10:7, 15:1-6, 23:8–24:20 (Shumer Dep.); DX40:117-18 (Olson *Sex and Gender*); DX41:86 (Shumer *Multidisciplinary Care*); DX24:171:10-16 (Karasic Dep.); DX179:15 (WPATH 6).

<sup>&</sup>lt;sup>25</sup> DX2:¶¶117-20, 270-73 (Cantor Rep.); DX11:¶¶24-25 (Nangia Rep.); DX5:¶¶62, 140 (Hruz Rep.); DX39:68:6-15 (Shumer Dep.); DX164:6-7 (Levine *Reconsidering Informed Consent*); DX38:306 (DSM-5); see generally DX 126 (Zucker *Myth of Persistence*).

children resolving to an identity congruent with their sex by late adolescence."26

3. "Some in the medical community are aggressively pushing for interventions in minors that medically alter the child's hormonal balance and remove healthy external and internal sex organs when the child expresses a desire to appear as a sex different from his or her own."<sup>27</sup> "This course of treatment for minors commonly begins with encouraging and assisting the child to socially transition to dressing and presenting as the opposite sex. In the case of prepubertal children, as puberty begins, doctors then administer long-acting GnRH agonist (puberty blockers) that suppress the pubertal development of the child. This use of puberty blockers for gender nonconforming children is experimental and not FDA-approved."<sup>28</sup> "After puberty blockade, the child is later administered 'cross-sex' hormonal treatments that induce the development of secondary sex characteristics of the other sex, such as causing the development of breasts and wider hips in male children taking estrogen and greater muscle mass, bone density, body hair, and a deeper voice in female children taking testosterone. Some children are administered these hormones independent of

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<sup>&</sup>lt;sup>26</sup> DX2:¶¶115-20 (Cantor Rep.); DX11:¶¶50, 164 (Nangia Rep.); DX5:¶62 (Hruz Rep.); DX7:¶¶224-27 (Laidlaw Rep.).

<sup>&</sup>lt;sup>27</sup> DX129:¶¶9-86 (Reed Affidavit); DX140:6-9 (Conlin Gender Imbalance); DX132:14-17 (Jarvie Abortion Doctor); DX131:3-13 (Pietzke Approve All); DX11:¶25 (Nangia Rep.); DX164:3-6 (Levine Reconsidering Informed Consent); DX148:5 (Vandenbussche Detransition-Related Needs); DX149:14-15 (Littman Detransition and Desistance); DX144:12-13 (Ault Doctors); DX137:8, 11-12 (Kaltiala Dangerous Care); DX134:1-3 (Anderson Health Establishment); DX133:2-4, 13-14 (Shrier Top Trans Doctors); DX130:1-18 (Reed Blowing the Whistle); DX119:4 (Block Professional Disagreement); DX141:3 (Ghorayshi Top Surgery); DX179:12 (WPATH 6) (recognizing "a wave of treatment-on-demand clinics" and "ill informed profiteers taking advantage of troubled youth"), 39 (Bowers noting need to "better safeguard our clientele" from "opportunism by inexperienced and sometimes dangerous providers").

<sup>&</sup>lt;sup>28</sup> DX7:¶¶ 58-89 (Laidlaw Rep.); DX5:¶¶65-80, 148 (Hruz Rep.); DX14:¶¶52-57 (Curlin Rep.); DX2:¶¶121-23, 165-77, 204, 274-75, 292 (Cantor Rep.); DX11:¶ 41 (Nangia Rep.); DX39:88:21–89:15 (Shumer Dep.); DX116:S111 (SOC-8); *see* Doc. 159 ¶¶ 33-34 (Pls' 2d Am. Compl.).

any prior pubertal blockade."<sup>29</sup> "The final phase of treatment is for the individual to undergo cosmetic and other surgical procedures, often to create an appearance similar to that of the opposite sex. These surgical procedures may include a mastectomy to remove a female adolescent's breasts and 'bottom surgery' that removes a minor's healthy reproductive organs and creates an artificial form aiming to approximate the appearance of the genitals of the opposite sex."<sup>30</sup> "For minors who are placed on puberty blockers that inhibit their bodies from experiencing the natural process of sexual development, the overwhelming majority will continue down a path toward cross-sex hormones and cosmetic surgery."<sup>31</sup>

4. "This unproven, poorly studied series of interventions results in numerous harmful effects for minors, as well as risks of effects simply unknown due to the new and experimental nature of these interventions." "Among the known harms from puberty blockers is diminished bone density; the full effect of puberty blockers on brain development and cognition are yet unknown, though reason for concern is

<sup>&</sup>lt;sup>29</sup> DX7:¶¶118-59 (Laidlaw Rep.); DX5:¶¶81-88 (Hruz Rep.); DX40:143-44 (Shumer *Endocrine Care*); DX116:S111 (SOC-8); Doc. 159 ¶ 34 (Pls' 2d Am. Compl.).

<sup>&</sup>lt;sup>30</sup> DX116:S65-66, 129 (SOC-8); DX17:¶28-34 (Lappert Rep.); DX7:¶160-75 (Laidlaw Rep.); DX141:2-3 (Ghorayshi *Top Surgery*); DX19:5-15 (Milrod *Age is Just a Number*).

<sup>&</sup>lt;sup>31</sup> DX17:¶31 (Lappert Rep.); DX7:¶¶56, 94 (Laidlaw Rep.); DX5:¶81 (Hruz Rep.); DX84:171 (Cass Review); DX39:135:4-21 (Shumer Dep.).

DX2:¶¶59-88, 165-205, 229-38 (Cantor Rep.); DX3:¶¶4-31 (Cantor Supp. Rep.); DX7:¶¶59, 113, 141, 158 (Laidlaw Rep.); DX39:156:15–158:15 (Shumer Dep.) (testifying that there is "[n]o literature talking about what happens" to patients' fertility after puberty blockers and cross-sex hormones), 163:14-18, 191:17-24 (testifying that there are "no long-term stud[ies] about" WPATH's current "model of care"); DX43:207:16-21 (Antommaria Dep.) (aware of no fertility studies of those "who started puberty suppression at Tanner Stage 2"); DX5:¶¶130-33, 143-47 (Hruz Rep.); DX59:196:10-16 (McNamara Dep.); DX40:21 (Krishna *GnRH Analogs*); DX103:3 (Swedish Summary); DX104 (Swedish Review); DX108 (Finnish Review); DX162:2-4 (Levine *Current Concerns*); DX84:177-79 (Cass Review); DX88-89 (Cass evidence reviews); DX95-96 (NICE evidence reviews); DX110:1 (Block *Norway's Guidance*); DX164:4-8 (Levine *Reconsidering Informed Consent*); DX158:7-13 (Biggs *Dutch Protocol*).

now present. There is no research on the long-term risks to minors of persistent exposure to puberty blockers. With the administration of cross-sex hormones comes increased risks of cardiovascular disease, thromboembolic stroke, asthma, COPD, and cancer."33 "Puberty blockers prevent gonadal maturation and thus render patients taking these drugs infertile. Introducing cross-sex hormones to children with immature gonads as a direct result of pubertal blockade is expected to cause irreversible sterility. Sterilization is also permanent for those who undergo surgery to remove reproductive organs, and such persons are likely to suffer through a lifetime of complications from the surgery, infections, and other difficulties requiring yet more medical intervention."34 "Several studies demonstrate that hormonal and surgical interventions often do not resolve the underlying psychological issues affecting the individual. For example, individuals who undergo cross-sex cosmetic surgical procedures have been found to suffer from elevated mortality rates higher than the general population. They experience significantly higher rates of substance abuse,

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<sup>33</sup> DX2:¶¶202-26 (Cantor Rep.); DX7:¶¶65-159 (Laidlaw Rep.);

<sup>;</sup> DX5:¶92 (Hruz Rep.); DX39:143:12–144:7 (Shumer Dep.); DX154:9-10 (Baxendale *Neuropsychological Function*); DX103:3 (Swedish Summary); DX104 (Swedish Review); DX108 (Finnish Review); DX162:2-4 (Levine *Current Concerns*); DX84:177-79 (Cass Review); DX88-89 (Cass puberty blocker and cross-sex hormone review); DX95-96 (NICE puberty blocker and cross-sex hormone reviews);

<sup>34</sup> DX10:¶59, 65-66 (Thompson Rep.); DX7:¶90-100, 157-59 (Laidlaw Rep.); DX5:¶80, 89-91 (Hruz Rep.); DX17:¶35-37 (Lappert Rep.); DX2:¶206-07 (Cantor Rep.); DX3:¶58 (Cantor Supp. Rep.); DX39:107:15-18, 121:5-20, 141:9–142:3, 150:13–151:8, 153:13–154:5, 155:24–156:3 (Shumer Dep.); DX40:147 (Shumer Endocrine Care) ("[T]here will never be maturation of sperm or eggs and no opportunity for gamete preservation."); DX18:62:18–63:15, 88:10-14 (Bowers Dep.); DX40:189-90 (T'Sjoen Reproduction); DX43:207:23–209:23 (Antommaria Dep.); DX164:8 (Levine Reconsidering Informed Consent).

depression, and psychiatric hospitalizations."35

5. "Minors, and often their parents, are unable to comprehend and fully appreciate the risk and life implications, including permanent sterility, that result from the use of puberty blockers, cross-sex hormones, and surgical procedures."<sup>36</sup> Thus, "the decision to pursue a course of hormonal and surgical interventions to address a discordance between the individual's sex and sense of identity should not be presented to or determined for minors who are incapable of comprehending the negative implications and life-course difficulties attending to these interventions."<sup>37</sup>

#### B. Plaintiffs' Preferred Medical Interest Groups Are Untrustworthy.

- 6. Against these findings, Plaintiffs rely on guidelines by WPATH and the Endocrine Society. Plaintiffs claim these standards are reliable and have "been adopted by the major medical and mental health associations," including the "American Medical Association" and the "American Academy of Pediatrics." 38
- 7. The Cass Review determined that both guidelines are in fact *un*reliable and methodologically *un*rigorous.<sup>39</sup> The reviewers found that the only reliable clinical guidelines for pediatric gender care were from the Swedish and Finnish health

<sup>&</sup>lt;sup>35</sup> DX2:¶¶152, 194-95, 295-96 (Cantor Rep.); DX156:1-2 (Biggs *Suicidality*); DX84:195 (Cass Review) ("no evidence that gender-affirmative treatments reduce" "deaths by suicide in trans people"); DX5:¶115, 124 (Hruz Rep.); DX39:201:19–203:6 (Shumer Dep.); DX7:¶¶207-19 (Laidlaw Rep.); DX159:4-7 (Dhejne *Long-Term Follow-Up*); DX164:8-9 (Levine *Reconsidering Informed Consent*); DX180:72 (WPATH 7) (Dr. Bowers noting "difficulty in picking an endpoint for therapeutic efficacy and use of" puberty blockers—is it "Reduction in suicidality? Difficult to prove").

<sup>36</sup> DX11:¶¶15-47, 152-62 (Nangia Rep.); DX7:¶¶246-48 (Laidlaw Rep.); DX14:¶¶19, 70-97 (Curlin Rep.); DX5:¶¶106-18 (Hruz Rep.); DX2:¶¶235-36 (Cantor Rep.); DX3:¶58 (Cantor Supp. Rep.); *see* DX141:4-5 (Ghorayshi *Top Surgery*); DX84:195 (Cass Review).

<sup>&</sup>lt;sup>37</sup> DX14:¶19, 70-97 (Curlin Rep.); DX11:¶¶154-76 (Nangia Rep.);

<sup>;</sup> DX10:¶11 (Thompson Rep.); DX17:¶42 (Lappert Rep.); DX7:¶250 (Laidlaw Rep.). <sup>38</sup> Doc. 159 ¶¶28-31.

<sup>&</sup>lt;sup>39</sup> DX84:129-30 (Cass Review); DX86:1-16 (Taylor *Guidelines Review*).

agencies, both of which recommend restricting transitioning treatments to research protocols.<sup>40</sup> That same recommendation has been made by the health agencies of at least six countries.<sup>41</sup> About half the States have also rejected the WPATH model.<sup>42</sup>

- 8. While the Endocrine Society conducted two systematic literature reviews for its guideline, remarkably, neither review "look[ed] at the effect of the interventions on gender dysphoria itself." The Endocrine Society recommended the treatments anyway—an incongruence that caused Dr. Gordon Guyatt, one of the fathers of evidence-based medicine, to note "serious problems" with the guideline.<sup>44</sup>
- 9. WPATH co-sponsored the Endocrine Society guidelines both in 2009 and 2017.<sup>45</sup> According to the Cass Review, early versions of the organizations' guidelines "influenced nearly all the other guidelines."<sup>46</sup> WPATH then laundered those citations as independent support for its own recommendations in SOC-8, "despite these guidelines having been considerably influenced by WPATH 7."<sup>47</sup> The Review concluded: "The circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."<sup>48</sup>

<sup>&</sup>lt;sup>40</sup> DX84:130-32 (Cass Review); DX86:5 (Taylor *Guidelines Review*); *see* DX103 (Swedish Summary); DX104 (Swedish Evidence Summary); DE105 (Swedish Guideline); DE106 (Swedish Review); DE107 (Finnish Summary); DE108 (Finnish Guideline).

<sup>&</sup>lt;sup>41</sup> DX2:¶¶16-33, 77-88 (Cantor Rep.); DX7:¶¶241-44 (Laidlaw Rep.); DX109:5 (Norway Recommendation); DX97:3 (NHS *Puberty Suppressing Hormones*); DX98:2 (NHS *Gender Affirming Hormones*); DX111 (Scotland Policy); DX112:1 (Ghorayshi *Scotland*).

<sup>&</sup>lt;sup>42</sup> Movement Advancement Project, https://tinyurl.com/275zrznp (last visited May 26, 2024).

<sup>&</sup>lt;sup>43</sup> DX119:3 (Block *Professional Disagreement*); DX115:3873 (Endocrine Society 2017 Guideline); DX2:¶¶90-93 (Cantor Rep.).

<sup>&</sup>lt;sup>44</sup> DX119:2-3 (Block *Professional Disagreement*); see DX2:¶¶90-93 (Cantor Rep.); DX3:¶¶83-85 (Cantor Supp. Rep.); DX5:¶¶98-101 (Hruz Rep.); DX7:¶¶192-201 (Laidlaw Rep.).

<sup>&</sup>lt;sup>45</sup> DX115:3869 (Endocrine Society 2017 Guideline); DX86:5 (Taylor Guidelines Review).

<sup>&</sup>lt;sup>46</sup> DX84:130 (Cass Review); DX86:5 (Taylor Guidelines Review).

<sup>&</sup>lt;sup>47</sup> DX84:130 (Cass Review); see DX86:5-7 (Taylor Guidelines Review).

<sup>&</sup>lt;sup>48</sup> *Id.*; see DX86:5-7 (Taylor *Guidelines Review*).

10. WPATH leaders also appear to be at a loss about the "apparent consensus." Dr. Coleman, who chaired both SOC-7 and SOC-8, admitted he had "no idea how it was ever said that so many medical organizations have endorsed SOC 7."<sup>49</sup> After publishing SOC-8, WPATH lobbied medical organizations to endorse the new guideline.<sup>50</sup> As of May 2024, Dr. Coleman knew of only two that had—both international sexual health organizations.<sup>51</sup> The AAP, Dr. Coleman said, rejected WPATH's requests to endorse SOC-8.<sup>52</sup> The American Medical Association also declined to "endorse or support" SOC-8, leading WPATH's president to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."<sup>53</sup>

11. While WPATH claimed to follow international standards for guideline creation,<sup>54</sup> it did not meet these standards.<sup>55</sup> For instance, the standards on conflicts of interest that WPATH cite recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review. <sup>56</sup> Dr. Cass is a good example: When appointed to run the NHS review, she was a well-respected pediatrician, but not one

<sup>&</sup>lt;sup>49</sup> DX190:7 (WPATH 17); see DX21:262:1-24 (Coleman Dep.).

<sup>&</sup>lt;sup>50</sup> DX21:256:22-25–257:1-4 (Coleman Dep.); DX18:243:22-25 (Bowers Dep.); DX189:1-22, 39 (WPATH 16).

<sup>&</sup>lt;sup>51</sup> DX21:261:5-12, 262:4-8 (Coleman Dep.); see DX190:6 (WPATH 17).

<sup>&</sup>lt;sup>52</sup> DX21:261:5-24 (Coleman Dep.); DX187:338 (WPATH 14); DX188:152 (WPATH 15); DX190:6 (WPATH 17).

<sup>&</sup>lt;sup>53</sup> DX189:13 (WPATH 16); DX21:259:4-10 (Coleman Dep.).

<sup>&</sup>lt;sup>54</sup> DX116:S247-51 (SOC-8); DX21:202:10-15 (Coleman Dep.).

<sup>55</sup> DX84:129-32 (Cass Review); DX86:6-7 (Taylor *Guidelines Review*); DX2:¶¶94-104 (Cantor Rep.); *see generally* DX166 (JHU 1); DX174 (WPATH 1); DX175 (WPATH 2).

<sup>&</sup>lt;sup>56</sup> DX116:S246 (SOC-8); DX3:¶¶98-101, 102, 107, 111-14, 116-17 (Cantor Supp. Rep.); DX22:307-08, 334-40 (Institute of Medicine Guidelines); DX22:363-80 (WHO Handbook).

who provided transitioning treatments.<sup>57</sup> The standards suggest ways for guideline committees to benefit from clinicians with financial or intellectual conflicts while being transparent about the conflicts and limiting those clinicians' involvement.<sup>58</sup>

12. WPATH ran the opposite way, expressly limiting SOC-8 authorship to existing WPATH members.<sup>59</sup> Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria." Dr. Bowers agreed it was "absolutely" "important for someone to be an advocate for [transitioning treatments] before the guidelines were created." Bowers also admitted to making "more than a million dollars" last year from transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing as an author of a guideline recommending those surgeries. Dr. Karen Robinson, the chair of the Johns Hopkins evidence review team WPATH hired to help with SOC-8, was more realistic: "We would expect many, if not most, SOC-8 members to have competing interests." Dr. Coleman agreed that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts

 $<sup>^{57}</sup>$  DX74:115:16-18 (Goodman Dep.); DX18:255:21–256:14 (Bowers Dep.); DX2:¶12 (Cantor Rep.).

<sup>&</sup>lt;sup>58</sup> DX22:307-08, 334-40 (Institute of Medicine Guidelines); DX22:363-80 (WHO Handbook); *see* DX21:201:2–219:3 (Coleman Dep.).

<sup>&</sup>lt;sup>59</sup> DX116:S248 (SOC-8); *see* DX21:201:2–223:24 (Coleman Dep.).

<sup>&</sup>lt;sup>60</sup> DX21:228:14-19 (Coleman Dep.).

<sup>&</sup>lt;sup>61</sup> DX18:121:7-11 (Bowers Dep.).

<sup>&</sup>lt;sup>62</sup> DX18:37:1-13, 185:25–186:9 (Bowers Dep.). Notably, Dr. Bowers also admitted to performing "medically necessary" penile inversion vaginoplasty surgeries on minors when SOC-7 restricted such procedures to adults. *Id.* at 34:19-35; *see* DX19:26-27 (SOC-7).

<sup>&</sup>lt;sup>63</sup> DX166:1 (JHU 1). Dr. Robinson also noted that "[d]isclosure, and any necessary management of potential conflicts, should take place prior the selection of guideline members," but lamented that, "[u]nfortunately, this was not done here." *Id*.

of interest."<sup>64</sup> Publicly, WPATH assured readers that "[n]o conflicts of interest [among the authors] were deemed significant or consequential."<sup>65</sup>

13. WPATH also boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations." According to WPATH, Dr. Robinson's evidence review team conducted systematic evidence reviews, "assigned evidence grades using the GRADE methodology," and "presented evidence tables and other results of the systematic review" to SOC-8 authors. Chapter members then graded the recommendation statements based on the evidence.

14. The reality did not match what WPATH told the world. As Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."<sup>69</sup> The lead of the mental health chapter testified that, rather than rely on systematic reviews, drafters simply "used authors … we were familiar with."<sup>70</sup> SOC-8 abandoned the GRADE notations disclosing the quality of evidence for each treatment recommendation.<sup>71</sup> Authors admitted that they used

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<sup>&</sup>lt;sup>64</sup> DX21:230:17-23 (Coleman Dep.). Dr. Coleman even thought "it would be ethically justifiable" for an SOC-8 author "who was actively serving as an expert witness [to] advocate for language changes [in SOC-8] to strengthen his position in court." *Id.* at 158:17-25; *see* DX174:7 (WPATH 1) (author opining that "[e]veryone involved in the SOC process has a non-financial interest").

<sup>&</sup>lt;sup>65</sup> DX116:S177 (SOC-8). Coleman was unaware of any author removed from SOC-8 because of a conflict of interest. DX21:232:13-15 (Coleman Dep.); *accord* DX14:¶¶44-46 (Curlin Rep.).

<sup>&</sup>lt;sup>66</sup> DX116:S250 (SOC-8); see generally DX2:¶¶44-45 (Cantor Rep.).

<sup>&</sup>lt;sup>67</sup> DX116:S249-50 (SOC-8).

<sup>&</sup>lt;sup>68</sup> DX116:S250 (SOC-8).

<sup>&</sup>lt;sup>69</sup> DX190:8 (WPATH 17); see DX182:157-58 (WPATH 9).

<sup>&</sup>lt;sup>70</sup> DX24:66:2–67:5 (Karasic Dep.).

<sup>&</sup>lt;sup>71</sup> DX7:¶189-90 (Laidlaw Rep.); 23 (Antommaria Dep.); DX182:62 (WPATH 9).

"recommend"—a term of art that, per SOC-8, was to be reserved for strong recommendations based on "high quality" evidence, "few downsides," and "a high degree of acceptance among providers and patients" to describe controversial treatment recommendations with low-quality evidence. WPATH members even acknowledged "that a global consensus on 'puberty blockers' does not exist." Bowers said, "I'm not a fan." SOC-8 recommended them still.

15. As if to drive home how unscientific the enterprise was, SOC-8 included an entire chapter on "eunuchs"—men who "wish to eliminate masculine physical features, masculine genitals, or genital functioning." Dr. Coleman admitted no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.<sup>78</sup> And

<sup>&</sup>lt;sup>72</sup> DX116:S250 (SOC-8); *see* DX3:¶¶59-65 (Cantor Supp. Rep.).

<sup>&</sup>lt;sup>73</sup> DX24:106:3–109:8 (Karasic Dep.); DX183:14-16, 61, 93 (WPATH 10). It is hard to overstate WPATH's disregard for evidence-based medicine when it made strong ("recommend") treatment recommendations for controversial, life-altering medical decisions while intentionally hiding the quality of evidence supporting those recommendations. "Low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available. DX28:53 (Balshem GRADE Guidelines). Given that the estimated effect is therefore likely to be wrong for low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, "[e]videncebased medicine warns against strong recommendations based on low quality evidence." DX3:¶¶59-65 (Cantor Supp. Rep.). That WPATH intentionally rejected these standards should be disqualifying. See DX86:7 (Taylor Guidelines Review) ("[t]he WPATH and Endocrine Society international guidelines ... lack developmental rigour and transparency"). Even more shocking, it appears that WPATH hid the evidence for a reason: WPATH's own systematic evidence review found that, "[a]mong adolescents," there was "no difference in [quality of life] scores after a year of endocrine interventions" and concluded that the "strength of evidence" in this area was "low." DX118:8 (Baker Hormone Therapy). WPATH strongly recommended the interventions anyway.

<sup>&</sup>lt;sup>74</sup> DX180:63 (WPATH 7); see

<sup>75</sup> DX133:4 (Shrier Top Trans Doctors).

<sup>&</sup>lt;sup>76</sup> DX116:S113-14 (SOC-8).

<sup>&</sup>lt;sup>77</sup> DX116:S88 (SOC-8) (emphasis added).

<sup>&</sup>lt;sup>78</sup> DX21:172:19–173:25 (Coleman Dep.); *see* DX182:96 (WPATH 9) ("This Chapter is very high on speculation and assumptions, whilst a robust evidence base is largely absent.").

WPATH's president admitted that not every member of the WPATH board read the eunuch chapter before approving it for publication.<sup>79</sup> No matter: WPATH recognizes the identity and recommends castration as "medically necessary" treatment.<sup>80</sup>

16. Though the SOC-8 authors didn't seem to have much use for them,<sup>81</sup> the Johns Hopkins evidence review team did create systematic evidence reviews—"dozens!"—for SOC-8.<sup>82</sup> The results were concerning. The head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS: "[W]e found little to no evidence about children and adolescents."<sup>83</sup> On September 1, 2020, HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."<sup>84</sup> That did not stop the United States from representing to the Supreme Court on November 6, 2023, that "overwhelming evidence establishes that … puberty blockers and hormones directly and substantially improve[] the physical and psychological wellbeing of transgender adolescents with gender dysphoria."<sup>85</sup>

17. Dr. Robinson also told HHS that she was "having issues with this

<sup>&</sup>lt;sup>79</sup> DX18:147:9–148:4 (Bowers Dep.).

<sup>&</sup>lt;sup>80</sup> DX116:S90 (SOC-8). This is not an exaggeration: When asked whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct." DX21:198:23–199:5 (Coleman Dep.).

<sup>&</sup>lt;sup>81</sup> WPATH's president never even saw the reviews and thus relied on a much older, non-systematic review of the effects of transitioning treatments on *adults* to publicly advocate for the safety and efficacy of transitioning treatments for *minors*. DX18:185:4-6; 292:12–293:10 (Bowers Dep.).

<sup>82</sup> DX173:22-25 (HHS 5).

<sup>83</sup> DX173:22-25 (HHS 5). The World Health Organization likewise recently agreed: "the evidence base for children and adolescents is limited and variable regarding the longer-term outcomes of gender affirming care for children and adolescents." DX113:3 (WHO Development FAQ); DX3:¶67-68 (Cantor Supp. Rep.)

<sup>&</sup>lt;sup>84</sup> *Id.* at 22.

<sup>85</sup> Cert. Pet. at 7, United States v. Skrmetti, No. 23-477 (U.S. filed Nov. 6, 2023).

sponsor"—WPATH—"trying to restrict our ability to publish."<sup>86</sup> Days earlier, WPATH had rejected the team's request to publish two manuscripts based on the reviews because the team failed to comply with WPATH's policy for using SOC-8 data. Among other things, that policy required Johns Hopkins to seek "final approval" of the proposed article from an SOC-8 leader and "at least one member of the transgender community." WPATH explained that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense"—as WPATH defined it.

18. WPATH's scuttling of the evidence reviews was consistent with advocacy concerns that animated the drafting of SOC-8.90 Some authors chose *not* to seek evidence reviews from the Johns Hopkins team precisely so they wouldn't have to report the results: "Our concerns, echoed by the social justice lawyers we spoke with, is that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits." Another author drew on his experience as an expert witness in "recent federal cases" to raise "concern[] about

<sup>&</sup>lt;sup>86</sup> DX173:22 (HHS 5).

<sup>87</sup> DX167:86-88 (JHÚ 2).

<sup>&</sup>lt;sup>88</sup> DX167:75-81 (JHU 2).

<sup>&</sup>lt;sup>89</sup> DX167:91 (JHU 2). While the Johns Hopkins team eventually published two manuscripts, it is unclear what happened to the remainder of the "dozens!" of systematic reviews it conducted. *See* DX118 (Baker *Hormone Therapy*); L. Wilson et al., *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391-401 (2020). Even so, the United States recently told the Supreme Court that WPATH publishes "evidence-based practice guidelines" that "reflect[] the consensus of the medical community." Cert. Pet. at 4, No. 23-477. <sup>90</sup> *See* DX16:¶¶57-102 (Kaliebe Supp. Rep.); DX5:¶104 (Hruz Rep.); DX184:24 (WPATH 11) ("My hope with these SoC is that they land in such a way as to have serious effect in the law and

policy settings ... even if the wording isn't quite correct....").

91 DX174:1-2 (WPATH 1); see DX16:¶¶57-75 (Kaliebe Supp. Rep.).

language such as 'insufficient evidence,' 'limited data,' etc." that would "empower" groups "trying to claim that gender-affirming interventions are experimental." <sup>92</sup>

19. WPATH's public positions were likewise influenced by its ideological and political goals. Asked to endorse a critique of Alabama's law—authored by Plaintiffs' "misinformation" expert Dr. McNamara and relied on by Plaintiffs at the PI hearing<sup>93</sup>—WPATH initially noted its disagreement with the document's strong implication that genital surgeries were not provided to minors.<sup>94</sup> The sponsor replied: "After consultation with those involved in the Alabama lawsuit, the consensus appeared to be that quoting the standards of care"—and omitting facts about the *actual* provision of surgeries to minors—"would be most helpful for the case." WPATH endorsed the critique it knew was misleading.<sup>96</sup>

20. Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for practically any "embodiment goal" a patient has by labelling it "medically necessary." That label was given to a staggeringly broad list of treatments, seemingly without regard to the evidence base. 98 One author explained: "I think it is clear

<sup>&</sup>lt;sup>93</sup> See Doc. 78-19; M. McNamara et al., Combating Scientific Disinformation on Gender-Affirming Care, 152 PEDIATRICS (Sept. 2023).

<sup>&</sup>lt;sup>94</sup> DX184:49-53 (WPATH 11).

<sup>&</sup>lt;sup>95</sup> DX184:49 (WPATH 11).

<sup>&</sup>lt;sup>96</sup> DX184:49 (WPATH 11); see

<sup>&</sup>lt;sup>97</sup> See DX116:S18 (SOC-8); DX16:¶¶64-75 (Kaliebe Supp. Rep.); DX180:11 (WPATH 7) (advocating using SOC-8 to further an "individual's embodiment goals").

<sup>&</sup>lt;sup>98</sup> See DX116:S18 (SOC-8).

as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) of TGD people who pursue treatment (in its broadest sense) for their gender dysphoria (because it refers to the symptoms of distress – which is a very very broad category and one that any 'goodwilling' clinician can use for this purpose (or in the unescapable medical lingo we, as physicians are stuck with: those who fulfill a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."99

21. Outside political actors also exercised influence. Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published" because "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration. <sup>100</sup> After WPATH provided Levine exclusive access to the near-final draft of SOC8, <sup>101</sup> Levine asked WPATH to remove the recommended age minimums for transitioning treatments. <sup>102</sup> WPATH leaders voiced two main concerns. The first, as voiced by WPATH's current president, was "that without specific age requirements, insurers may not grant authorization" for the treatments. <sup>103</sup> The second, as voiced by WPATH's former president, was "that politics always trumps common sense and what is best for patients." <sup>104</sup> A member of the adolescent chapter

<sup>&</sup>lt;sup>99</sup> DX181:36 (WPATH 8); see DX16:¶75 (Kaliebe Supp. Rep.).

<sup>&</sup>lt;sup>100</sup> DX184:54 (WPATH 11); see DX18:193:2–195:5, 226:8–229:22 (Bowers Dep.); DX16:¶¶79-90 (Kaliebe Supp. Rep.); DX185:1 (WPATH 12) ("the US Department of Health is very keen to bring the trans health agenda forward"); *id.* at 10, 25.

<sup>&</sup>lt;sup>101</sup> DX189:13 (WPATH 16).

<sup>&</sup>lt;sup>102</sup> DX186:11 (WPATH 13) ("We sent the document to Admiral Levine.... She asked us to remove" the age minimums); *id.* at 50, 57.

<sup>&</sup>lt;sup>103</sup> DX186:57 (WPATH 13); *id.* ("If we don't put ages, the insurances companies specify 18 years old, hence the main reason to list the ages."); *see* DX16:¶85 (Kaliebe Supp. Rep.). <sup>104</sup> DX186:25 (WPATH 13).

put it this way: "I don't know how I feel about allowing US politics to dictate international professional clinical guidelines." WPATH initially insisted that the age minimums could not be removed because they had been approved by SOC-8's consensus process. (Indeed, Dr. Coleman said the consensus was "[t]he only evidence [they] had." WPATH thus responded to Levine: "[W]e heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion." Levine immediately requested—and received—more meetings with WPATH leaders.

22. Days before SOC-8 was to be published, the AAP likewise demanded that WPATH remove the age recommendations. Despite holding AAP's recommendations in low esteem, WPATH leaders saw the political threat. As Dr. Coleman wrote, AAP was "a MAJOR organization" that "is typically very pro-

<sup>&</sup>lt;sup>105</sup> DX186:31 (WPATH 13); *see id.* ("[W]e have a very high up politician telling us that having the ages specified front and center would politically lead to more attacks and legislative efforts. I see no reason not to trust that assessment is accurate."); *id.* ("I'm also curious how the group feels about us making changes based on current US politics."); *id.* ("I think it's safe to say that we all agree and feel frustrated ... that these political issues are even a thing and are impacting our own discussions and strategies."); *id.* ("I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda.").

<sup>&</sup>lt;sup>106</sup> DX186:17 (WPATH 13).

<sup>&</sup>lt;sup>107</sup> DX186:57 (WPATH 13).

<sup>&</sup>lt;sup>108</sup> DX186:17 (WPATH 13).

<sup>&</sup>lt;sup>109</sup> DX186:73, 88-91 (WPATH 13); DX18:226:8–229:18 (Bowers Dep.).

<sup>&</sup>lt;sup>110</sup> DX16:¶¶91-98 (Kaliebe Supp. Rep.); DX187:13-14 (WPATH 14); *id.* at 109 ("The AAP comments asked us to remove age[s]"); *id.* at 188; DX21:292:3-9 (Coleman Dep.) (AAP was "not going to support SOC-8 if it contained minimum ages for surgeries").

<sup>111</sup> See DX187:100 (WPATH 14) ("As far as I can tell they are asking for us to remove anything that does not fit into their narrative.... The AAP guidelines that they mentioned so many times have a very weak methodology, written by few friends who think the same."); id. at 107 ("I have also read all the comments from the AAP and struggle to find any sound evidence-based argument(s) underpinning these. I am seriously surprised that 'reputable' association as the AAP is so thin on scientific evidence."); DX16:¶94 (Kaliebe Supp. Rep.); accord DX122:1 (Ghorayshi Research Review); DX121:1-3 (Mason Dubious Science); DX120:10-14 (Sibarium Hijacking).

transhealth/gender affirming care"; "[c]learly, if AAP were to publicly oppose the SOC8, it would be a major challenge for WPATH."<sup>112</sup> "WPATH leadership" thus agreed to remove the age minimums—and did so without sending the change through the SOC-8 consensus process. <sup>113</sup> After deleting the age minimums (SOC-8 still falsely proclaims "all statements" were voted on by "[e]very member of the SOC"<sup>114</sup>), WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."<sup>115</sup> They settled on a public explanation focused on "individualized care" and a promise of "strengthened criteria."<sup>116</sup> In reality, the change was purely political: "It led to [AAP] not opposing the SOC. Yes this is highly confidential."<sup>117</sup>

23. WPATH's lack of transparency could be because leaders view any inquiry into the safety and efficacy of the procedures they recommend as an "attack." Per Dr. Coleman, "[t]rans health care is not only under attack by politicians, but by:" (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "increasing number of regret cases" who "blame clinicians for allowing them[] to transition," and (4) "continuing pressure in health care to provide evidence-based care." This is one clear reason why

 $<sup>^{112}</sup>$  DX187:191 (WPATH 14); see DX16:  $\P95-96$  (Kaliebe Supp. Rep.); DX21:290:7–295:16 (Coleman Dep.).

<sup>113</sup> DX187:338 (WPATH 14) ("[W]e have agreed to remove the ages.... I hope that by doing this AAP will be able to endorse the SOC8...."); see [DX21:293:25–295:16 (Coleman Dep.) ("[W]e did not submit that change to Delphi at the end.").

<sup>&</sup>lt;sup>114</sup> DX116:S250 (SOC-8); accord DX21:293:25–295:16 (Coleman Dep.).

<sup>&</sup>lt;sup>115</sup> DX188:120 (WPATH 15); *see id.* at 113 ("I do think we need to speak more as a cohesive voice"); *see* DX16:¶¶97-98 (Kaliebe Supp. Rep.).

<sup>&</sup>lt;sup>116</sup> DX188:113 (WPATH 15); id. at 116.

<sup>&</sup>lt;sup>117</sup> DX188:152 (WPATH 15).

<sup>&</sup>lt;sup>118</sup> See DX16:¶¶99-110 (Kaliebe Supp. Rep.).

<sup>119</sup> DX190:5 (WPATH 17) (emphasis added); see DX16:¶103 (Kaliebe Supp. Rep.).

SOC-8 rejected the standards of "evidence-based care."

24. WPATH also sought to prevent its own members from raising concerns publicly. For instance, at the behest of trans-activist protestors, USPATH cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria have the dysphoria "desist" by adulthood. PA few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments. PATH even issued a formal statement "oppos[ing] the use of the lay press, either impartial or of any political slant or viewpoint, as a forum for the scientific debate" about "the use of puberty delay and hormone therapy for transgender and gender diverse youth." As WPATH's president explained it: "[T]he public ... doesn't need to sort through all of that."

25. The result of WPATH's prioritization of ideology over truth and patient welfare was predictable. One of the authors of the adolescent chapter of SOC-8 was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source." Or as one of

<sup>&</sup>lt;sup>120</sup> DX16:¶¶9-13 (Kaliebe Supp. Rep.); DX21:29:8-11 (Coleman Dep.) (Dr. Zucker is "a careful and serious researcher"); *id.* at 130:19–131:1; DX24:184:24–222:4 (Karasic Dep.); *see* DX178:5, 22, 82-85 (WPATH 5); DX125:300-05 (Ciszek *Discursive Stickiness*).

<sup>&</sup>lt;sup>121</sup> DX176:107, 113-14 (WPATH 3); DX16:¶14-17 (Kaliebe Supp. Rep.); DX18:279:3–281:14 (Bowers Dep.); DX133:13 (Shrier *Top Trans Doctors*).

<sup>&</sup>lt;sup>122</sup> DX117 (WPATH Jt. Letter); DX18:283:1–289:1 (Bowers Dep.).

<sup>123</sup> DX18:287:18-22 (Bowers Dep.); see id. at 293:17–304:15; DX16:¶25-35 (Kaliebe Supp.).

<sup>&</sup>lt;sup>124</sup> DX176:152 (WPATH 3); DX16:¶¶23-24 (Kaliebe Supp. Rep.); see DX133:3-4 (Shrier Top Trans Doctors).

Defendants' experts, a practicing child and adolescent psychiatrist, put it:

# C. Minors in Alabama Are Harmed by Transitioning Treatments.

26. As even WPATH recognizes, the population of gender dysphoric youth has changed radically in recent years. <sup>126</sup> For decades—and when the foundational studies were conducted—the average minor patient suffering from gender dysphoria was a prepubescent boy whose dysphoria was likely to "desist." <sup>127</sup> In recent years, the average minor patient has transformed to an adolescent girl without a diagnosis of gender dysphoria in childhood. <sup>128</sup> And the numbers have skyrocketed—by thousands of percent. <sup>129</sup> No one knows why, though researchers are concerned that the increase appears to be "associated with very high rates of social media use, among youth with other mental health issues, and in association with peers expressing gender dysphoria issues." <sup>130</sup> Though WPATH publicly attacks the idea of "Rapid-Onset"

<sup>126</sup> DX116:S43-45 (SOC-8).

<sup>127</sup> DX2:¶¶114-36 (Cantor Rep.); DX5:¶¶127-28 (Hruz Rep.); DX84:89, 177-78 (Cass Review).

<sup>&</sup>lt;sup>128</sup> DX116:S43 (SOC-8); DX5:¶128 (Hruz Rep.); DX2:¶¶137-39 (Cantor Rep.); DX165:4 (Littman *Rapid Onset*); *see* DX39:251:7-24 (Shumer Dep.); DX139:1 (Bazelon *Battle*); DX137:5-6 (Kaltiala *Dangerous Care*).

DX5:¶127-29 (Hruz Rep.); DX2:¶137-39 (Cantor Rep.); DX15:¶26-33 (Kaliebe Rep.); DX84:84-89 (Cass Review); DX164:2-3 (Levine Reconsidering Informed Consent); DX143:12 (Card Transgender Patients); DX138:1 (Kaltiala Psychiatric Needs); DX119:1 (Block Professional Disagreement).

<sup>130</sup> DX2:¶137 (Cantor Rep.); see DX3:¶¶32-54 (Cantor Supp. Rep.); DX11:¶¶16-36 (Nangia Rep.); DX15:¶¶32-55 (Kaliebe Rep.); DX165:30-40 (Littman Rapid Onset); DX135:1-4 (Anderson Losing Our Way); DX133:12-13 (Shrier Top Trans Doctors); DX129:¶¶20-22 (Reed Affidavit).

Gender Dysphoria,"<sup>131</sup> its members confess privately that they "cannot outright dismiss the fact that social factors" "impact identity development and decision making in adolescents."<sup>132</sup> "There do not yet exist any cohort studies of people with adolescent-onset gender dysphoria," though that hasn't stopped WPATH from recommending hormones and surgeries for the unstudied group. <sup>133</sup>

27. Many minors suffering from gender dysphoria also struggle with other mental health disorders like depression, anxiety, ADHD, and autism.<sup>134</sup> Many have experienced trauma as well.<sup>135</sup> Psychotherapy is thus particularly important for youth with gender dysphoria.<sup>136</sup> Unlike transitioning treatments, psychotherapy "entails minimal risk and does not require life-long alteration of one's body."<sup>137</sup> It also helps prevent "diagnostic overshadowing"—the "single focus on gender" that many patients experience from their "gender-affirming" clinicians.<sup>138</sup>

28. Those clinicians are not foreign to Alabama. To take one particularly

<sup>&</sup>lt;sup>131</sup> DX116:S45 (SOC-8); see DX124:1-7 (Wright Scientific Scandal); cf. Bowers, Frequently Asked Questions, https://perma.cc/GYP5-U5TN.

<sup>&</sup>lt;sup>132</sup> DX179:40 (WPATH 6); *id.* at 41 ("What the explanation for this increase is, is unknown and also methodologically challenging to study; social factors likely play a role."); *see* DX4:¶126 (Cantor Supp. Rep. App. A); DX84:117-27 (Cass Review).

<sup>&</sup>lt;sup>133</sup> DX2:¶138 (Cantor Rep.); DX116:S110-36 (SOC-8).

<sup>&</sup>lt;sup>134</sup> DX15:¶153 (Kaliebe Rep.); DX5:¶¶130, 149 (Hruz Rep.); DX2:¶¶33, 156-63 (Cantor Rep.); DX11:¶¶136-47 (Nangia Rep.); DX39:46:7-25 (Shumer Dep.); DX40:75 (Shumer Serving Transgender Youth); DX129:¶16 (Reed Affidavit); DX84:91-96 (Cass Review).

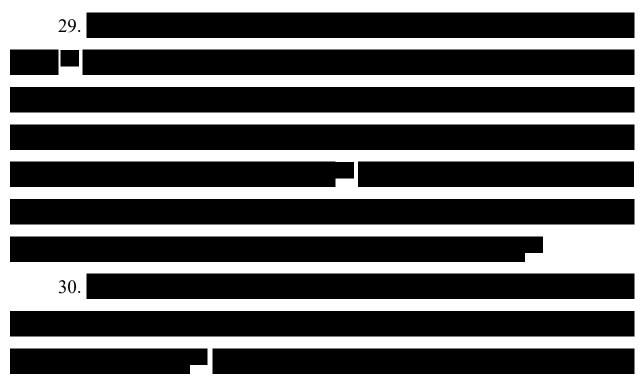
<sup>&</sup>lt;sup>135</sup> DX11:¶¶143-44 (Nangia Rep.); DX84:26, 119-20, 226 (Cass Review).

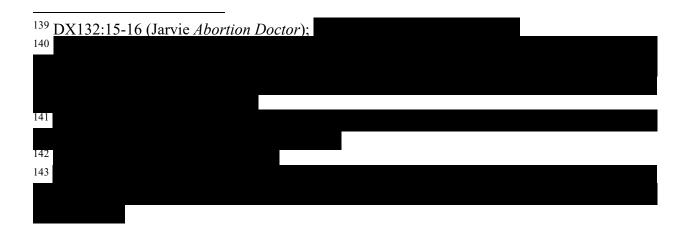
<sup>&</sup>lt;sup>136</sup> DX11:¶¶57-60, 146-47, 163-70 (Nangia Rep.); DX15:¶¶153-67 (Kaliebe Rep.); DX39:75:10–79:7 (Shumer Dep.); DX107:1 (Finland Summary); DX84:150-55 (Cass Review).

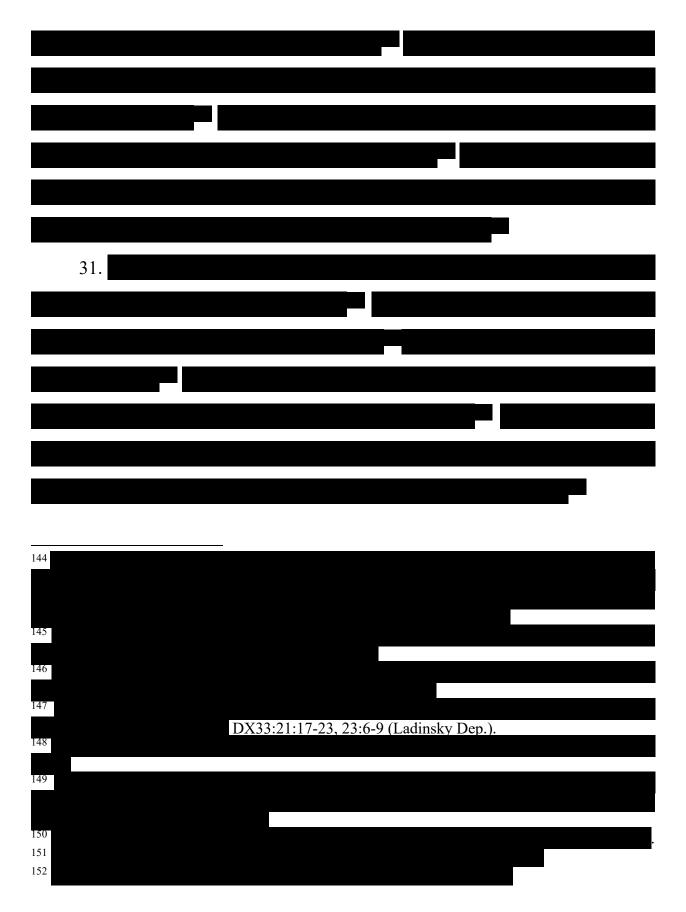
<sup>&</sup>lt;sup>137</sup> DX15:¶174 (Kaliebe Rep.); DX39:169:6-25 (Shumer Dep.).

<sup>138</sup> DX84:200 (Cass Review); see DX15:¶¶152-77, 180 (Kaliebe Rep.); DX131:3-13 (Pietzke Approve All); DX130:1-18 (Reed Blowing the Whistle); DX129:¶¶9-86 (Reed Affidavit); see also DX179:15 (WPATH 6) ("[T]here's no assessment tool that captures all the ways internal signals can sometimes be misread as related to gender when they're not."); accord DX136:2 (Edwards-Leeper Mental Health Establishment) ("find[ing] evidence every single day" that the field is "one where every problem looks like a medical one that can be solved quickly with medication").

galling example, the *LA Times* profiled an OB/GYN in Tuscaloosa, Dr. Leah Torres, who began providing transitioning treatments when her abortion revenue dried up after *Dobbs*. "Torres does not believe adolescents seeking hormones require mental health evaluations," so she had no trouble prescribing cross-sex hormones via telehealth to a teenager with "a history of depression and anxiety" whose "pediatrician and staff at a psychiatric hospital" had refused the teen's request. <sup>139</sup>







32. Then there is the issue of informed consent. Even if it were theoretically possible, <sup>153</sup> informed consent, according to SOC-8, should begin with an assessment of "the emotional and cognitive maturity" of the patient and continue with a discussion of "all potential risks and benefits," "fertility options," and "the limits of what is known about certain treatments." <sup>154</sup>

33. The result, at least for some patients, is likely significant harm. The clinic does not track its patients, so it does not know how many patients have already regretted their treatments or sought to detransition. But across America—across the Western world—heartbreaking instances of regret and detransition are occurring. 160

<sup>&</sup>lt;sup>153</sup> But see DX11:¶¶119-35, 154-62 (Nangia Rep.); DX14:¶¶70-97 (Curlin Rep.).

DX116:S61 (SOC-8).

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159 DX33:150:9–151:2 (Ladinsky Dep.);

<sup>&</sup>lt;sup>160</sup> See DX146 (Cohn Decl.); DX129:¶53 (Reed Affidavit); DX147 (Cohn What I Wish I'd Known); DX150 (Littman Survey); DX149 (Littman Detransition); DX148 (Vandenbussche Detransition-Related Needs); DX144:12-13 (Ault Doctors); DX140:6-8 (Conlin Gender Imbalance);

There is no reason to think Alabama's children have been spared.

#### **ARGUMENT**

### I. The Act Passes Rational-Basis Review.

On both claims here—substantive due process and equal protection—the Act is "subject only to rational basis review." Eknes-Tucker, 80 F.4th at 1224, 1230 (cleaned up). "Under this deferential standard, the question" "is simply whether the challenged legislation is rationally related to a legitimate state interest." Id. at 1224-25 (cleaned up). "Such a relationship may merely be based on rational speculation and need not be supported by evidence or empirical data." *Id.* at 1225 (cleaned up). It makes no difference "if the government's proffered explanation is irrational," "if it fails to offer any explanation," id. (cleaned up), or if its explanation "may not be true at all," Gregory v. Ashcroft, 501 U.S. 452, 473 (1991). "[T]he burden is on the one attacking the law to negate every conceivable basis that might support it, even if that basis has no foundation in the record." Leib v. Hillsborough Cnty. Pub. Transp. Comm'n, 558 F.3d 1301, 1306 (11th Cir. 2009) (cleaned up). The "actual purposes" of the law or "improper motive[s]" "are not relevant." Haves v. City of Miami, 52 F.3d 918, 923 (11th Cir. 1995). "As long as [Defendants] can present at least one plausible, arguably legitimate purpose for the [law], summary judgment for [Defendants] is appropriate unless [Plaintiffs] can demonstrate that the legislature could not *possibly* have relied on that purpose." *Id.* (emphasis added).

"Here, it seems abundantly clear that [the Act] classifies on the basis of age

DX137:9-10 (Kaltiala *Dangerous Care*); DX84:187-89 (Cass Review); DX179:14 (WPATH 6) ("de/retransitioners have always been a part of my community, and to a lesser degree my medical practice"); DX190:5 (WPATH 17) (acknowledging "increasing number of regret cases").

in a way that is rationally related to a legitimate state interest." *Eknes-Tucker*, 80 F.4th at 1230. "Alabama has a legitimate"—indeed, "compelling"—"interest in safeguarding the physical and psychological well-being of minors." *Id.* (cleaned up); *id.* at 1225. The Act expresses that interest. *See* Ala. Code §§ 26-26-1, -2. And the Act "furthers that interest by restricting the prescription and administration of puberty blockers and cross-sex hormone treatment to minors" for gender transition "based on the rational understanding that many minors may not be finished forming their identities and may not fully appreciate the associated risks." *Eknes-Tucker*, 80 F.4th at 1230. "Although rational speculation is itself sufficient to survive rational basis review," "the record evidence is undisputed that the medications at issue present *some* risks." *Id.* at 1225. And "there is at least rational speculation that some families will not fully appreciate those risks." *Id.* 

Given that each of the sixteen legislative findings is amply supported by the record, *see supra* 5-10, Plaintiffs cannot show that the Legislature could not have even "hypothe[tically]" relied on the very bases it included in the Act. *United States v. Castillo*, 899 F.3d 1208, 1213 (11th Cir. 2018). Because no material factual dispute exists about whether the Act has "at least one plausible, arguably legitimate purpose," Defendants are entitled to summary judgment. *Haves*, 52 F.3d at 923.

### II. The Act Would Also Survive Heightened Scrutiny.

Though the Eleventh Circuit rejected the application of heightened scrutiny to the Act, the Act would survive that scrutiny too. As Judge Brasher suggested and the evidence confirms, the State "has an 'exceedingly persuasive justification' for regulating these drugs differently when they are used to treat a discordance between an individual's sex and sense of gender identity than when they are used for other purposes." *Eknes-Tucker*, 80 F.4th at 1235 (concurring). Again, the State's interest in protecting children is "compelling." *Id.* at 1225 (opinion of the Court). The State cannot regulate the uses of these drugs covered by the Act "without drawing the lines it has drawn." *Id.* at 1236 (Brasher, J., concurring). And the undisputed evidence shows that these uses—for transitioning a child's gender—*are* particularly dangerous and fraught with uncertainty. *See supra* 5-27. The use of these drugs puts impossibly unfair decisions before a child and her parents. And the only guidelines issued with scientific rigor have confirmed the lack of evidence and recommended restricting these uses because "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits." <sup>161</sup>

The Act is, at a minimum, substantially related to protecting children from these unproven drug uses. The State did not ban these uses for adults, and it expressly protected safer treatments for gender dysphoria. Ala. Code § 26-26-6. The Act also exempts minors born with certain "medically verifiable disorder[s] of sex development," recognizing that these unique cases may involve different treatment considerations. *Id.* § 26-26-4(b). Thus, the Act provides "enough of a fit' between the means and the asserted justification" to satisfy heightened scrutiny. *Eknes-Tucker*, 80 F.4th at 1226; *see id.* at 1235-36 (Brasher, J., concurring).

### **CONCLUSION**

The Court should grant Defendants summary judgment.

<sup>&</sup>lt;sup>161</sup> DX103:3 (Swedish Summary).

<sup>&</sup>lt;sup>162</sup> See DX11:¶¶48-60, 163-70 (Nangia Rep.); DX5:¶63 (Hruz Rep.); DX39:169:6-25 (Shumer Dep.).

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## **CERTIFICATE OF SERVICE**

I certify that on May 27, 2024, I electronically filed this document using the Court's CM/ECF system, which will serve counsel of record.

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