### UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

DYLAN BRANDT, et al.,

Plaintiffs-Appellees,

V.

### LESLIE RUTLEDGE,

in her official capacity as the Arkansas Attorney General, et al., *Defendants-Appellants*.

On Appeal from the United States District Court for the Eastern District of Arkansas Case No. 4:21-cv-450 JM (Hon. James M. Moody, Jr.)

## BRIEF OF AMICI CURIAE STATE OF ALABAMA AND 18 OTHER STATES SUPPORTING DEFENDANTS-APPELLANTS

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### CORPORATE DISCLOSURE STATEMENT

As governmental parties, amici are not required to file a certificate of interested persons. Fed. R. App. P. 26.1(a).

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#### INTERESTS OF AMICI CURIAE AND SUMMARY OF ARGUMENT<sup>1</sup>

Amici curiae are the States of Alabama, Alaska, Arizona, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia. Like Arkansas, amici are concerned about the surge in recent years of children suffering from gender dysphoria and other forms of gender-related psychological distress. And like Arkansas—and like Plaintiffs—amici are concerned because these vulnerable children are suffering greatly and need help.

The question is how to help them. Relying on an amicus brief filed by the American Academy of Pediatrics and the American Medical Association, among others, in support of Plaintiffs, the district court concluded that the answer is simple and the science settled: "The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care." R. Doc. 64, at 6 (citing Br. of Am. Acad. of Pediatrics et al., R. Doc. 30, at 16 ("AAP Br.")). "Gender-affirming care" in this context means giving children puberty blockers, then cross-sex hormones, then surgical interventions such as "chest reconstruction surgery" (a double

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<sup>&</sup>lt;sup>1</sup> This brief is filed under Federal Rule of Appellate Procedure 29(a)(2).

mastectomy to "masculinize"—their word—a girl's chest). See AAP Br., R. Doc. 30, at 19 n.44.<sup>2</sup>

The problem is that the evidence does not support this approach. That may be an odd thing for a group of States to say in response to a group of medical professionals, but it's true. Spend just a little time with the scientific literature in this field and a few things become abundantly clear: the science in this area is largely unsettled; nearly everyone agrees that far more research is needed; and the currently popular approach to care in the United States is not supported by well-researched, evidence-based studies. What is known, however, is that most cases of gender dysphoria in children resolve naturally with time, and it's impossible to know ahead of time whose dysphoria will persist into adulthood and whose won't. Yet the evidence also shows that nearly all children whose gender dysphoria is treated with puberty blockers to "buy time" will proceed to take cross-sex hormones and seek other medical interventions with irreversible, lifelong consequences—complications such as infertility, loss of sexual function, increased risk of heart attack and stroke, bonedensity problems, risk of altered brain development, social harms from delayed puberty, and mental health concerns. Sadly, but for the "gender-affirming" "care" they received, most of these children would neither suffer from gender dysphoria nor from lifelong medical harm as adults.

<sup>2</sup> Page references are to the ECF-stamped number.

And for what? What are the outcomes for children who undergo Plaintiffs' preferred treatment? Or for the rising tide of adolescent girls, many with autism, who seem to have a new form of sudden-onset gender-related distress? Incredibly, no one really knows. The evidence is distressingly thin. In fact, the lack of evidence in this field is why the Centers for Medicare & Medicaid Services rejected a nationwide coverage mandate for adult gender transition surgeries during the Obama Administration. It is also why hospitals in the United Kingdom, Finland, and Sweden have recently altered their protocols to reduce or eliminate the use of hormone and surgical treatments for minors seeking gender transition. What evidence does exist, though, does not show that long-term mental health outcomes are much improved or rates of suicide much reduced by hormonal or surgical intervention. Yet children are promised relief and asked to "consent" to life-altering, irreversible treatment—and to do so when they are in pain, when they cannot weigh long-term risks the way adults do, when they are not even old enough to vote.

It is no wonder that States have been forced to step in to protect kids from these experimental treatments. The medical establishment has abandoned the field to the political zeitgeist, which labels dissenting opinions as "animus" (or worse) and closes its ears to the tragic and growing chorus of detransitioners who feel betrayed by the adults who should have been caring for them. State legislatures have

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historically played this role, regulating in the face of medical uncertainty. The amici States offer this brief in support of Arkansas's right to do so here.

#### **ARGUMENT**

I. The Experimental Gender Transition Procedures Prohibited By Arkansas Are Fraught With Medical And Scientific Uncertainties.

Despite the promise offered by Plaintiffs and their amici and accepted by the district court, "gender-affirming" "care" does not stand on a robust mountain of evidence-based research. And despite their accusation that Arkansas relied on "outdated and now discredited theories," see AAP Br., R. Doc. 30, at 11, it was Plaintiffs and their amici who ignored the most recent research and developments. For not only are record numbers of minors now presenting with gender-related distress, but the patient profile has changed radically in recent years as more teenage girls are suffering from sudden-onset dysphoria that is not typical of the genre.<sup>3</sup> Evidence regarding treatment has not kept up—and, at least for affirmation therapy, was never very good to begin with. As a result, while American organizations have been caught in the political winds, many international experts are urging caution. Here, for instance, is how *The Economist* recently situated Arkansas's law within the global conversation:

Last June, ... Finland revised its guidelines to prefer psychological treatment to drugs. In September Britain launched a top-down review

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<sup>&</sup>lt;sup>3</sup> See L. Littman, Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, PLos ONE 13(8): e0202330.

of the field. In December the High Court of England and Wales ruled that under-16s were unlikely to be able to consent meaningfully to taking puberty blockers, leading [the Gender Identity Development Service at the Tavistock Clinic in London] to suspend new referrals, though a subsequent ruling held that parents could consent on their children's behalf. On April 6th Arkansas passed laws that make prescribing puberty blockers and cross-sex hormones to children illegal. Also in April the Astrid Lindgren Children's Hospital in Stockholm, a part of the Karolinska Institute, announced that it would stop prescribing puberty blockers and cross-sex hormones to those under 18, except in clinical trials.<sup>4</sup>

The Royal Australian & New Zealand College of Psychiatrists recently added its voice to the chorus, lamenting the "paucity of quality evidence on the outcomes of those presenting with Gender Dysphoria," particularly children.<sup>5</sup>

Tellingly, Plaintiffs and their amici mentioned none of this to the district court. They did not explain that most experts in the field agree there is a general paucity of evidence and robust studies. They denied outright one of the few things the research is clear about—that most cases of gender dysphoria in children resolve naturally if transition interventions are not applied. They barely acknowledged the risks such experimental treatments pose. They ignored the fact that children cannot fully understand the long-term risks of these procedures. They threatened that Arkansas's

tion-statements/gender-dysphoria.

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<sup>&</sup>lt;sup>4</sup> Doubts Are Growing About Therapy for Gender-Dysphoric Children, THE ECONOMIST (May 13, 2021) https://www.economist.com/science-and-technology/2021/05/13/doubts-are-growing-about-therapy-for-gender-dysphoric-children.
<sup>5</sup> The Royal Australian & New Zealand College of Psychiatrists, Position Statement 103 (Aug. 2021), https://www.ranzcp.org/news-policy/policy-and-advocacy/posi-

law will result in increased suicides even though the research does not support such a claim. And they asserted that the State's protection of its children is "animus" against transgender youth, even though—among other problems with the statement—most of these children will not identify as transgender as adults since their dysphoria will have resolved naturally so long as they can be protected from experimental treatments.

In sum, Plaintiffs and their amici painted a very misleading picture before the district court.

# A. There is a Paucity of Evidence Regarding Pediatric Gender Transition.

If there is one takeaway from the literature on treating gender-related distress, it's that nearly everyone agrees much more research is needed. This is particularly true when it comes to the experimental transition procedures Arkansas prohibits—puberty blockers, cross-sex hormones, and surgical interventions for minors.

First, a bit of history. Incredibly, there is just one main study that forms the basis for treating gender dysphoric youth with hormones and surgical interventions: the "Dutch Study." The study began with 70 youths who suffered from gender dysphoria since childhood (not just since adolescence); who did not have other mental

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<sup>&</sup>lt;sup>6</sup> See Annelou de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 130 PEDIATRICS, No. 4, 696-704 (Oct. 2014).

health problems; who were given extensive psychological support throughout the study; and who had strong family support.<sup>7</sup> The participants were given puberty blockers after they began puberty (average age of intervention: 13.6 years), cross-sex hormones later in adolescence (16.7 years), and surgical interventions after they reached 18 (20.7 years).<sup>8</sup> Of the 70 children who formed the starting cohort, only 55 completed the study and participated in an assessment a year after surgery.<sup>9</sup> There was no control group that did not receive hormonal or surgical interventions. The study's authors reported two main conclusions. One, gender dysphoria had resolved for the participants when they were surveyed a year after surgery.<sup>10</sup> Two, a year after surgery the participants reported psychological well-being outcomes "comparable to same-age peers."<sup>11</sup>

As others have pointed out,<sup>12</sup> there are many limitations to this study and many questions it did not answer. How did the participants' *pre*-treatment psychological

<sup>&</sup>lt;sup>7</sup> *See id.* at 697.

<sup>&</sup>lt;sup>8</sup> *Id.* at 696.

<sup>&</sup>lt;sup>9</sup> One participant died from a bacterial infection caused by the surgical intervention; four refused to participate; three became ineligible for treatment due to comorbidities; and six had surgery within a year and were ineligible to complete the questionnaire. *Id.* at 697. The outcomes for these patients were thus not included in the study's results. Nor did all of the 55 remaining subjects participate in every aspect of the follow-up assessment; only 32 of them, for instance, provided answers regarding their psychological functioning for all three time periods studied. *Id.* at 700. <sup>10</sup> *Id.* at 701.

<sup>&</sup>lt;sup>11</sup> *Id.* at 702.

<sup>&</sup>lt;sup>12</sup> See generally, e.g., Society for Evidence Based Gender Medicine, https://segm.org/.

function compare to their peers? Would the outcomes have been different if the participants were not, on average, already in the healthy psychological range? How did the 13% of the initial cohort who did not or could not participate in the final survey fare? What were the participants' long-term physical and psychological health outcomes? Did the puberty blockers, cross-sex hormones, and surgical procedures cause any physical problems for the participants down the line (other than to the non-reported participant who died from the surgical intervention)? Would the results be similar for youths whose gender-related distress began in adolescence rather than childhood? And most importantly, how do gender dysphoric youth fare if they do not receive the experimental gender transition procedures, and how would that control group compare to the study's experimental cohort?

Some research has been done to try to answer some of these questions. But not as much as one might think. A few recent surveys of the data make this clear.

Centers for Medicare & Medicaid Services Coverage Analysis

In 2016, the Centers for Medicare & Medicaid Services released its national coverage analysis for gender dysphoria and gender reassignment surgery. <sup>13</sup> The analysis looked specifically at whether the data supported surgical interventions to treat gender dysphoria in the Medicare population. The conclusion? "[T]here is not

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<sup>&</sup>lt;sup>13</sup> See Tamara Syrek Jensen, et al., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (CAG-00446N) (Aug. 30, 2016), https://perma.cc/57KK-YKRK.

enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively."<sup>14</sup> The analysis explained:

- "Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a cointervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up." <sup>15</sup>
- "Of the 33 studies reviewed, published results were conflicting—some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population." <sup>16</sup>
- "Clinical evidentiary questions regarding the care of patients with gender dysphoria remain. Many of the publications focused on aspects of surgical technique as opposed to long-term patient outcomes." <sup>17</sup>

To be sure, the CMS analysis looked only at surgical interventions, not hormonal, and determined only whether those interventions were appropriate for the Medicare population, not children. But the lessons are obvious: the district court required Arkansas to allow experimental transitional surgeries *on children* when the CMS found the evidence did not support performing the surgeries on adults.

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<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>&</sup>lt;sup>17</sup> *Id*.

<u>United Kingdom's National Institute for Health and Care Excellence Evidence Reviews</u>

In 2020, Britain's National Institute for Health and Care Excellence (NICE) conducted evidence reviews of two treatment options prohibited by Arkansas: puberty blockers and cross-sex hormones for children and adolescents. Neither inspired much confidence in the procedures. As for the cross-sex hormones, the study cautioned: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria." 19

Other significant findings include:

- "Ten observational studies were included in the evidence review.... No studies directly compared gender-affirming hormones to a control group (either placebo or active comparator). Follow-up was relatively short across all studies, with an average duration of treatment with gender-affirming hormones between around 1 year and 5.8 years."<sup>20</sup>
- "The key limitation to identifying the effectiveness and safety of gender-affirming hormones for children and adolescents with gender dysphoria is the lack of reliable comparative studies."<sup>21</sup>

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<sup>&</sup>lt;sup>18</sup> See Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, Nat'l Inst. for Health & Care Excellence (released Mar. 11, 2021), https://arms.nice.org.uk/resources/hub/1070871/attachment ("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 (released Mar. 11, 2021), https://arms.nice.org.uk/resources/hub/1070905/attachment ("NICE Puberty Blocker Evidence Review").

<sup>&</sup>lt;sup>19</sup> NICE Cross-Sex Hormone Evidence Review, *supra*, at 14.

<sup>&</sup>lt;sup>20</sup> *Id*. at 4.

<sup>&</sup>lt;sup>21</sup> *Id.* at 13.

• "Most studies included in this review did not report comorbidities (physical or mental health) and no study reported concomitant treatments in detail."<sup>22</sup>

Such is the state of the research for the "gender affirming" hormone treatments.

The picture is not much different when it comes to puberty blockers.<sup>23</sup> As the NICE report explained, puberty blockers—gonadotrophin releasing hormone (GnRH) analogues—are used to "suppress puberty by delaying the development of secondary sexual characteristics," with the intent "to alleviate the distress associated with the development of secondary sex characteristics, thereby providing a time for on-going discussion and exploration of gender identity before deciding whether to take less reversible steps."<sup>24</sup> The use of puberty blockers to treat gender dysphoria is off-label in the U.K., as it is in America.<sup>25</sup> (This means that, "[b]ecause they are not licensed for gender medicine, drug firms have done no trials."<sup>26</sup>) Again, the NICE review found that "[a] key limitation to identifying the effectiveness and safety of

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

<sup>&</sup>lt;sup>23</sup> See NICE Puberty Blocker Evidence Review, supra.

<sup>&</sup>lt;sup>24</sup> *Id.* at 3.

<sup>&</sup>lt;sup>25</sup> *Id*.

<sup>&</sup>lt;sup>26</sup> Little Is Known About the Effects of Puberty Blockers, THE ECONOMIST (Feb. 18, 2021), https://www.economist.com/science-and-technology/2021/02/18/little-is-known-about-the-effects-of-puberty-blockers.

GnRH analogues for children and adolescents with gender dysphoria is the lack of reliable comparative studies."<sup>27</sup> To wit:

- "The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly." 28
- "Many of the studies did not report statistical significance or confidence intervals."<sup>29</sup>
- "In the observational, retrospective studies providing evidence on bone density, participants acted as their own controls and change in bone density was determined between starting GnRH analogues and follow up. Observational studies such as these can only show an association with GnRH analogues and bone density; they cannot show that GnRH analogues caused any differences in bone density seen. Because there was no comparator group and participants acted as their own controls, it is not known whether the findings are associated with GnRH analogues or due to changes over time." 30

In sum: "The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning), in children and adolescents with gender dysphoria are of very low certainty."<sup>31</sup>

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<sup>&</sup>lt;sup>27</sup> NICE Puberty Blocker Evidence Review, *supra*, at 12.

<sup>&</sup>lt;sup>28</sup> *Id.* at 13.

 $<sup>^{29}</sup>$  *Id*.

 $<sup>^{30}</sup>$  *Id*.

 $<sup>^{31}</sup>$  *Id*.

### Sweden's Literature Review and Policy Change at the Karolinska Institute

In December 2019, the Swedish Agency for Health Technology Assessment and Assessment of Social Services published a "scoping review of the literature on gender dysphoria in children and adolescents." Once again, the results do not support the district court's narrative. From the report's summary: "There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery. Studies on long-term effects of gender affirming treatment in children and adolescents are few.... Almost all identified studies are observational.... No relevant randomised controlled trials in children and adolescents were found." 33

This review caused the Astrid Lindgren Children's Hospital at Karolinska University Hospital in Sweden to change course and prohibit the use of puberty blockers and cross-sex hormones in minors except in clinical trial settings.<sup>34</sup> The Hospital's guideline document explained that the studies conducted on puberty blockers and cross-sex hormones to treat gender dysphoria in children have been

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<sup>&</sup>lt;sup>32</sup> Swedish Agency for Health Tech. Assessment and Assessment of Soc'l Servs., *Gender Dysphoria in Children and Adolescents: An Inventory of the Literature* (Dec. 20, 2019), https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/.

<sup>33</sup> *Id*.

<sup>&</sup>lt;sup>34</sup> See Guideline Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn – Astrid Lindgren Children's Hospital (ALB), https://perma.cc/Y54Z-Z6RA.

"small, uncontrolled observational studies providing low quality evidence that the treatments have the desired effect." Accordingly, the study found, "we have very little knowledge about their safety in the long term," and the "treatments are potentially fraught with extensive and irreversible adverse consequences such as cardio-vascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis." This makes it challenging to assess the risk/benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments."

### Finland's Council for Choices in Healthcare in Finland Policy Change

In June 2020, Finland's Council for Choices in Healthcare in Finland also suggested changing its treatment protocols.<sup>38</sup> Though allowing for some reversible hormonal interventions under certain conditions, the Council lamented the lack of evidence and urged caution:

- "As far as minors are concerned, there are no medical treatment[s] that can be considered evidence-based."<sup>39</sup>
- "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system. In trans girls, early pubertal suppression inhibits penile growth, requiring the use of

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<sup>&</sup>lt;sup>35</sup> *Id*.

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>37</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> See Palveluvalikoima, *Recommendation of the Council for Choices in Health Care in Finland*, https://perma.cc/EQ4B-RUWZ . <sup>39</sup> *Id*.

alternative sources of tissue grafts for a potential future vaginoplasty. The effect of pubertal suppression and cross-sex hormones on fertility is not yet known."<sup>40</sup>

- "In cases of children and adolescents, ethical issues are concerned with the natural process of adolescent identity development, and the possibility that medical interventions may interfere with this process. It has been suggested that hormone therapy (e.g., pubertal suppression) alters the course of gender identity development; i.e., it may consolidate a gender identity that would have otherwise changed in some of the treated adolescents. 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." 41
- "Professionals, for their part, consider it important to ensure that irreversible interventions, which may also have significant adverse effects, both physical and mental, are only performed on individuals who are able to understand the permanence of the changes and the potential for harm, and who are unlikely to regret such interventions. It is not known how the hormonal suppression of puberty affects young people's judgement and decision-making." 42
- "A lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment." 43

The Council concluded: "Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported." 44

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<sup>&</sup>lt;sup>40</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>41</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>42</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>43</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>44</sup> *Id*.

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The reality these evidence reviews describe is starkly different from the promises Plaintiffs and their amici offered below. "[N]ecessary, effective[,] and safe." Pls' Br., R. Doc. 12, at 9. "[R]obust body of empirical evidence." AAP Br., R. Doc. 30 at 10. "[S]upported by medical evidence that has been subject to rigorous study." DOJ Statement, R. Doc. 19, at 21. None of these statements are true. Yet this is what children and their parents are told. They are assured relief with little downside. Given that children rely on such false promises, the truth is terrifying: In the words of Finland's Council for Choices in Healthcare, "[i]n light of available evidence, gender reassignment of minors is an experimental practice." Arkansas had every reason to prohibit such experimentation on vulnerable minors.

# B. The Evidence That Does Exist Shows That Most Cases of Gender Dysphoria Resolve Naturally by Adulthood.

"Gender dysphoria during childhood does not inevitably continue into adult-hood." Given the insistence of Plaintiffs' amici that Arkansas's reliance on this truth "rests on incorrect facts and outdated and discredited theories," AAP Br., R. Doc. 30, at 9, one might think this statement comes from an anti-transgender group or is at least controversial in the literature. In fact, neither is true. The statement comes from the World Professional Association for Transgender Health's "Standards of

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<sup>&</sup>lt;sup>45</sup> *Id*.

Care" v.7<sup>46</sup>—one of two medical protocols Plaintiffs relied on below. *See* R. Doc. 12, at 12-13. The other protocol comes from the Endocrine Society, *id.*, which reports similar findings: "Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called 'desisters')."<sup>47</sup>

In recognizing that "[g]ender dysphoria during childhood does not inevitably continue into adulthood," WPATH reported that "in follow-up studies of prepubertal children (mainly boys) who were referred to clinics for assessment of gender dysphoria, the dysphoria persisted into adulthood for only 6–23% of children." "Newer studies, also including girls, showed a 12–27% persistence rate of gender dysphoria into adulthood." The Endocrine Society's findings were similar: "In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal

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<sup>&</sup>lt;sup>46</sup> WPATH, Standards of Care for the Health of Transsexual, Transgender, and Gender-Conforming People 11 (7th Version) (2012) (citations omitted), https://www.wpath.org/publications/soc ("WPATH Standards of Care").

<sup>&</sup>lt;sup>47</sup> Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guidelines*, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3876 (Nov. 2017) ("Endocrine Society Guidelines").

<sup>&</sup>lt;sup>48</sup> WPATH Standards of Care, *supra*, at 11.

<sup>&</sup>lt;sup>49</sup> *Id.* (citations omitted).

children with a childhood diagnosis did not remain GD/ gender incongruent in adolescence."50

To be sure, WPATH posited that "[i]n contrast" to childhood gender dysphoria, "the persistence of gender dysphoria into adulthood appears to be much higher for adolescents." But the study it cited was the Dutch Study discussed above—in which (as WPATH recounted) the adolescents "who were diagnosed with gender dysphoria and given puberty-suppressing hormones[] all continued with actual sex reassignment, beginning with feminizing/masculinizing hormone therapy." 52

There are at least two problems with WPATH's conclusion that the Dutch Study shows that adolescents with gender dysphoria will always suffer from dysphoria unless they medically transition. The first is one WPATH recognized in the sentence directly following its hypothesis: "No formal prospective studies exist." (This might be how amici could claim that there are "no studies" to support a contrary view. AAP Br., R. Doc. 30, at 14-15.) The second problem is that whether a child who is given puberty blockers and cross-sex hormones proceeds to surgical transition tells us nothing about what would happen to a child who is *not* given puberty blockers and cross-sex hormones. All it shows is that puberty blockers and

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<sup>&</sup>lt;sup>50</sup> Endocrine Society Guidelines, *supra*, at 3879 (citations omitted).

<sup>&</sup>lt;sup>51</sup> WPATH Standards of Care, *supra*, at 11.

<sup>&</sup>lt;sup>52</sup> *Id.* (emphasis added) (citing de Vries et al., *supra*).

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

cross-sex hormones are "two stages of one clinical pathway and once on that pathway it is extremely rare for a child to get off it."<sup>54</sup> What we are left with is precisely what the Arkansas legislature found: "For the small percentage of children who are gender nonconforming or experience distress at identifying with their biological sex, studies consistently demonstrate that the majority come to identify with their biological sex in adolescence or adulthood." *See* SAFE Act, § 2(4).<sup>55</sup>

# C. Plaintiffs' Preferred Experimental Procedures Come With Serious, Lifelong Risks That Children Cannot Fully Understand.

As detailed above, the benefits, if any, of puberty blockers, cross-sex hormones, and surgical interventions to treat gender-related distress are not well understood or studied.<sup>56</sup> But the risks associated with the interventions are serious and often irreversible. As the Swedish literature review found, "these treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and

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<sup>&</sup>lt;sup>54</sup> Bell v. Tavistock & Portman Nat'l Health Serv. Foundation Trust, 2020 EWHC (Admin) 3274, ¶ 136, set aside by 2021 EWCA (Civ) 1363.

<sup>&</sup>lt;sup>55</sup> These findings raise the question about precisely what Plaintiffs and amici mean by their oft-repeated phrase "gender-affirming care." When the clear majority of children who experience gender discordance desist from this discordance by adulthood, is a child's gender really being "affirmed" by treatments that make long-lasting discordance more likely?

<sup>&</sup>lt;sup>56</sup> See also R. Doc. 49, at 30-33 (surveying the evidence supporting Plaintiffs' claim that "gender-affirming care" prevents suicides and concluding that Plaintiffs' preferred treatment would "likely inflict more injury").

thrombosis."<sup>57</sup> And even for puberty blockers—which Plaintiffs' amici treat as the least-dangerous intervention, calling them "reversible" with "well known efficacy and side-effect profiles," AAP Br., R. Doc. 30, at 18—the Endocrine Society's Guidelines warn that pubertal suppression "may include adverse effects on bone mineralization ..., compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development."<sup>58</sup> Then the Guidelines note: "Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence."<sup>59</sup> The AAP's own policy statement admits the same: "Research on long-term risks, particularly in terms of bone metabolism and fertility, is currently limited."<sup>60</sup>

As Finland's Council for Choices in Healthcare has explained, "[i]n a situation where a minor's identification with the opposite sex causes longterm and severe dysphoria, it is important to make sure that he/she understands the realistic potential of gender reassignment treatments to alter secondary sex characteristics, the reality of a lifelong commitment to medical therapy, the permanence of the effects, and the possible physical and mental adverse effects of the treatments. *Although patients* 

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<sup>&</sup>lt;sup>57</sup> See Swedish Agency for Health Tech. Assessment, supra.

<sup>&</sup>lt;sup>58</sup> Endocrine Society Guidelines, *supra*, at 3882.

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

<sup>&</sup>lt;sup>60</sup> Jason Rafferty et al., *AAP Policy Statement*, 142 PEDIATRICS No. 4 (Oct. 2018), https://doi.org/10.1542/peds.2018-2162.

may experience regret, after reassignment treatments, there is no going back to the non-reassigned body and its normal functions."<sup>61</sup>

There is very little reason to think that a child in early adolescence can properly weigh these lifetime risks, particularly when the popular narrative so distorts what the evidence shows. As the Endocrine Society Guidelines recognize, there are not even "formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning genderaffirming treatment."62 How is an 11-year-old girl feeling uncomfortable in her body to weigh the probabilities that her gender-based distress will resolve without hormonal or surgical intervention? (The Endocrine Society's Guidelines admit that, "[w]ith current knowledge," not even medical professionals "can predict the psychosexual outcome for any specific child."63) How is she to know whether she will want to have children in twenty years? Whether she will want to breastfeed them? Whether she will come to regret her deepened voice and irreversible mastectomy? What it would have been like to develop and go through puberty with her peers? Whether it would all be worth it? These are tough questions for anyone. They are unfair questions to ask a child.

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<sup>&</sup>lt;sup>61</sup> See Palveluvalikoima, supra (emphasis added).

<sup>&</sup>lt;sup>62</sup> Endocrine Society Guidelines, supra, at 3879.

<sup>&</sup>lt;sup>63</sup> *Id.* at 3876.

Many of Plaintiffs' amici once echoed this truth, noting in another context that minors are "less capable of mature judgment than adults" and "more vulnerable to negative external influences." See, e.g., Br. of Am. Psych. Ass'n et al. at 7, 15, Miller v. Alabama, 567 U.S. 460 (2012) (No. 10-9646) ("Miller APA Brief"); Br. of Am. Med. Ass'n et al. at 2-4, 5-7, 36-37, Miller v. Alabama, 567 U.S. 460 (2012) (No. 10-9646) ("Miller AMA Brief"). "Sound judgment requires both cognitive and psychosocial skills," these amici explained, Miller APA Br. at 14, but minors tend to lack these skills because "the brain continues to develop throughout adolescence and young adulthood in precisely the areas and systems that are regarded as most involved in impulse control, planning, and self regulation," id. at 10 (citations omitted). Adolescents thus "overvalue short-term benefits and rewards." *Miller* AMA Br. at 2-3. And because they have "less life experience on which to draw" and cannot "envision the future consequences of [their] actions," they are "less likely [to] fully apprehend ... potential negative consequences." APA Br. at 12, 14 (citations omitted). Research has also "shown that personality traits change significantly during the developmental transition from adolescence to adulthood, and the process of identityformation typically remains incomplete until at least the early twenties." *Id.* at 14 (footnotes omitted).

No wonder some children suffering from gender dysphoria feel betrayed by the adults to whom they turned for help. Because the evidence in this entire field is

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so poor, no one really knows how many patients come to regret their transition, but the number is not insignificant. One of the few studies to look at the needs of detransitioners was published earlier this year.<sup>64</sup> The author surveyed 237 participants who detransitioned back to their natal gender. Seventy percent reported that they detransitioned because they "realized that [their] gender dysphoria was related to other issues"; half reported that "[t]ransition did not help with [their] dysphoria"; and over a third reported that their "[d]ysphoria resolved itself over time."<sup>65</sup> Only 13% reported that a lack of support from social surroundings contributed to their detransition.<sup>66</sup> Most participants reported needing help with "learning to cope with feelings of regret."<sup>67</sup>

Plaintiffs and their amici preferred to ignore these needs, promising the district court that hormonal and surgical interventions for gender dysphoric youth are medically necessary and safe. But the reality is that (1) no one really knows what percentage of children who transition come to regret their transition, and (2) we do know that most cases of gender dysphoria in children would have resolved naturally but for medical intervention. With the stakes so high, the harms so great, and the

<sup>64</sup> See Elie Vandenbussche, Detransition-Related Needs and Support: A Cross-Sectional Online Survey, JOURNAL OF HOMOSEXUALITY (Apr. 30, 2021), https://doi.org/10.1080/00918369.2021.1919479.

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<sup>&</sup>lt;sup>65</sup> *Id*. at 6.

<sup>&</sup>lt;sup>66</sup> *Id*.

<sup>&</sup>lt;sup>67</sup> *Id*.

known benefits so paltry, the Arkansas legislature did not have to embrace an experimental path in lieu of the one that has served the medical profession so well for so long: First, do no harm.

# II. States—Not The Political Interest Groups The District Court Deferred To—Have Broad Authority To Regulate In Areas Fraught With Medical Uncertainties.

When confronted with this murky intersection of medicine and social health, the district court should have deferred to the Arkansas legislature, which has "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007). Instead, it deferred to unelected and unaccountable medical organizations. *See* R. Doc. 64, at 6-8.

States routinely regulate the medical profession, and routinely update their regulations as new problems arise.<sup>68</sup> They can do so because, as the Supreme Court has recognized, "the State has a significant role to play in regulating the medical profession." *Gonzalez*, 550 U.S. at 157; *see Washington v. Glucksberg*, 521 U.S. 702, 731 (1997) (The government "has an interest in protecting the integrity and ethics of the medical profession.").

The legislature's role is particularly important when the science is unsettled or varying factions disagree about the best course of treatment, as is the case here.

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<sup>&</sup>lt;sup>68</sup> E.g., Nat'l Conf. of State Legislatures, *Prescribing Policies: States Confront Opioid Overdose Epidemic* (June 30, 2019), https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.

"In fact, it is precisely where such disagreement exists that legislatures have been afforded the widest latitude in drafting such statutes." *Kansas v. Hendricks*, 521 U.S. 346, 360 n.3 (1997); *see Abigail All. For Better Access to Development Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (en banc) ("Our Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.").

The State's power is likely at its zenith when it acts to protect children. *See Bellotti v. Baird*, 443 U.S. 622, 634 (1979). Indeed, children's "inability to make critical decisions in an informed, mature manner" makes legislation to protect them particularly appropriate. *Id.*; *see Miller* AMA Br. at 2-3 ("[T]he average adolescent cannot be expected to act with the same control or foresight as a mature adult.").

The district court violated these principles by instead deferring to the amicus brief filed by the American Academy of Pediatrics and the American Medical Association. *See* R. Doc. 64, at 6. But "[n]othing in the Constitution mechanically gives controlling weight to one set of professional judgments." *Cameron v. Tomes*, 990 F.2d 14, 20 (1st Cir. 1993). That truth makes all the more sense when it comes to political organizations posing as neutral arbiters of science.

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Take the American Medical Association. The AMA counts only 12.6% of physicians who have completed their training as members, <sup>69</sup> yet claims to speak for "substantially all physicians, residents, and medical students," R. Doc. 30, at 30-31. To be sure, the AMA does do a lot of speaking—since 1998, it has been the fourth-largest spender on political lobbying in the United States. <sup>70</sup> But like any trade organization, when it speaks, it does so with its own interests in mind. In the past, that has generally included financial interests tied to opioid or tobacco manufacturers or to Medicare coding that benefits doctors. <sup>71</sup> In recent years, however, as its membership has skewed "younger and less conservative," the organization has waded more frequently into the culture wars. <sup>72</sup> It now files amicus briefs in support of abortion providers, <sup>73</sup> and recently released a language guide for "advancing health equity."

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<sup>&</sup>lt;sup>69</sup> Miriam J. Laugesen, *How the American Medical Association's Rent-Seeking Strategy Compensated for Its Loss of Members*, 44 J. OF HEALTH POLITICS, POLICY & LAW 67-85 (2019), https://doi.org/10.1215/03616878-7206731.

<sup>&</sup>lt;sup>70</sup> Top Spenders, OPEN SECRETS, https://www.opensecrets.org/federal-lobbying/top-spenders?cycle=a.

<sup>&</sup>lt;sup>71</sup> See generally Julia Lurie, The Untold Story of Purdue Pharma's Cozy Relationship With the American Medical Association, MOTHER JONES (Aug. 5, 2021), https://www.motherjones.com/politics/2021/08/purdue-pharma-american-medical-association-relationship-opioid-crisis-public-health/.

<sup>&</sup>lt;sup>72</sup> Julie Rovner, *American Medical Association Wades into Abortion Debate with Lawsuit*, NPR (July 2, 2019), https://www.npr.org/sections/health-shots/2019/07/02/738100166/american-medical-association-wades-into-abortion-debate-with-lawsuit.

 $<sup>^{73}</sup>$  *Id*.

<sup>&</sup>lt;sup>74</sup> AMA, *Advancing Health Equity: A Guide to Language, Narrative and Concepts* (2021), https://perma.cc/A2MD-LD7H.

According to the guide, physicians should use "equity-focused language that acknowledges root causes of inequities."<sup>75</sup> Thus, the guide suggests, instead of stating that "[1]ow-income people have the highest level of coronary artery disease in the United States," a physician should try: "People underpaid and forced into poverty as a result of banking policies, real estate developers gentrifying neighborhoods, and corporations weakening the power of labor movements, among others, have the highest level of coronary artery disease in the United States."<sup>76</sup>

The AMA's language guide is clearly a work of politics, not medicine. And whether one agrees with the organization's suggestions or not, it is easy to recognize them as political because the conversation over language is, however ungracefully, unfolding in public. Yet while the conversation concerning medical treatment for children suffering from gender dysphoria is less accessible, given the overstatements and false promises it makes, it is nonetheless clear that the AMA's amicus brief is equally a work of politics, not medicine.

Moreover, the discussion in the medical community concerning gender dysphoria is highly politicized, not open and free. So while "[t]he cosmetics company L'Oreal and the National Peanut Board" can host booths at the annual conference for the American Academy of Pediatrics, for instance, the Society for Evidence-

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<sup>&</sup>lt;sup>75</sup> *Id.* at 15, 20.

<sup>&</sup>lt;sup>76</sup> *Id*.

Based Gender Medicine—"a group of clinicians and researchers who want to present evidence that pediatric gender treatments rest on a foundation of questionable evidence"—cannot even rent a booth.<sup>77</sup> And even though 80% of responding pediatricians voted in favor of a resolution "asking the AAP [to] re-evaluate its commitment to affirmative care in light of the growing international skepticism," the AAP leadership took no action.<sup>78</sup> Instead, it continues to file amicus briefs that misrepresent the evidence and gloss over the dissenting voices in its own ranks.

So much more could be said. Stories of how "activists who can make a loud enough racket can get research retracted that wouldn't be retracted otherwise."<sup>79</sup> How once-respected psychologists are fired for urging caution rather than affirming the "gender-affirming" "care" model for young children.<sup>80</sup> How conferences for transgender health care cancel panels discussing detransition or alternative methods of treating dysphoria.<sup>81</sup> But the takeaway is this. At the end of the day, it was the

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<sup>&</sup>lt;sup>77</sup> Abigal Shrier, *A Pediatric Association Stifles Debate On Gender Dysphoria*, WALL STREET JOURNAL (Aug. 9, 2021), https://www.wsj.com/articles/pediatric-association-gender-dysphoria-children-transgender-cancel-culture-11628540553.

<sup>78</sup> *Id.* 

<sup>&</sup>lt;sup>79</sup> Jesse Singal, *Can Science Ever Debate Trans Issues*, UNHERD (June 3, 2020), https://unherd.com/2020/06/eneuro/.

<sup>&</sup>lt;sup>80</sup> Jesse Singal, *How the Fight Over Transgender Kids Got a Leading Sex Researcher Fired*, THE CUT (Feb. 7, 2016), https://www.thecut.com/2016/02/fight-over-transkids-got-a-researcher-fired.html.

<sup>&</sup>lt;sup>81</sup> Katie Herzog, *Philly Trans Health Conference Cancels Sessions on Detransitioning*, The STRANGER (Aug. 30, 2017), https://www.thestranger.com/slog/2017/08/30/25382933/philly-trans-health-conference-cancels-sessions-on-detransitioning.

responsibility of the Arkansas legislature to determine the best way to help children suffering from gender dysphoria and other forms of gender-related psychological distress. And based on the evidence, the legislature reasonably determined that the use of puberty blockers, cross-sex hormones, and surgical interventions are still experimental in nature and that the risks of such procedures outweigh their benefits. That determination does not discriminate against children suffering from gender dysphoria, but seeks to protect them. This Court should defer to the legislature's constitutional determination rather than the unelected medical organizations to whom the district court deferred.

#### **CONCLUSION**

The order granting the preliminary injunction should be reversed.

Respectfully submitted,

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s/ Edmund G. LaCour Jr.

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I certify that on November 19, 2021, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such filing to any CM/ECF participants.

s/ Edmund G. LaCour Jr. Edmund G. LaCour Jr. Counsel for Amici Curiae

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