No. 22-11707

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PAUL A. EKNES-TUCKER, et al.,
Plaintiffs-Appellees,

&

UNITED STATES OF AMERICA
Intervenor-Plaintiff-Appellee

v.

GOVERNOR, STATE OF ALABAMA, et al.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Alabama
No. 2:22-cv-00184-LCB (Hon. L.C. Burke)

BRIEF OF AMICI CURIAE HUSSEIN ABDUL-LATIF, SUSAN D. BOULWARE, REBECCA KAMODY, LAURA KUPER, MEREDITHE MCNAMARA, CHRISTY OLEZESKI, NATHALIE SZILAGYI, AND ANNE ALSTOTT IN SUPPORT OF PLAINTIFFS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Eleventh Circuit Rule 26.1-26.3, counsel for *amici curiae* Hussein Abdul-Latif, Susan D. Boulware, Rebecca Kamody, Laura Kuper, Meredithe McNamara, Christy Olezeski, Nathalie Szilagyi, and Anne Alstott represent that none of the above-referenced individuals is a corporate entity or has issued stock. Counsel certifies that the following persons and parties may have an interest in the outcome of this case:

1. Abdul-Latif, Hussein – Amicus Curiae;
2. Academic Pediatric Association – Amicus Curiae;
3. Alabama Ch. of the American Academy of Pediatrics – Amicus Curiae;
4. Alaska, State of – Amicus Curiae;
5. Alstott, Anne – Amicus Curiae;
6. Am. Academy of Child and Adolescent Psychiatry – Amicus Curiae;
7. Am. Academy of Family Physicians – Amicus Curiae;
8. Am. Academy of Pediatrics – Amicus Curiae;
9. Am. Academy of Nursing – Amicus Curiae;
10. Am. Ass'n of Physicians for Human Rights, Inc. – Amicus Curiae;
11. Am. Coll. of Obstetricians & Gynecologists – Amicus Curiae;
12. Am. Coll. of Osteopathic Pediatricians – Amicus Curiae;
13. Am. College of Physicians – Amicus Curiae

14. Am. Med. Ass'n – Amicus Curiae;

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16. Am. Psychiatric Ass'n – Amicus Curiae;

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37. Eagan, Melody Hurdle – Counsel for Plaintiffs;

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71. Olezeski, Christy – Amicus Curiae;

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88. Soc'y of Adolescent Health & Medicine – Amicus Curiae;

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107. Wilson, Thomas Alexander – Counsel for Defendants;

108. Woodke, Lane Hines – Counsel for Intervenor-Plaintiff;

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112. Ventiere, Jessica – Defendant;

113. Veta, D. Jean – Counsel for Medical Amici;

114. Walker, Susan R. – Magistrate Judge;

115. Waver, Cynthia Cheng-Wun – Counsel for Plaintiffs;

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STATEMENT OF INTEREST

The amici submitting this brief are a group of seven scientists and a law professor (collectively, "Amici"). The seven scientists on whose behalf this brief is submitted hold academic appointments at the University of Alabama at Birmingham, the University of Texas Southwestern, and Yale University. The law professor holds a tenured position at the Yale Law School. Amici include three Ph.D. child and adolescent psychologists and four M.D. physicians with specialties in pediatric endocrinology, child and adolescent psychiatry, and adolescent medicine.

All seven scientists are also clinicians who treat transgender youth on a daily basis. Collectively, Amici have more than 57 years of clinical practice and have treated more than 2,100 transgender youth.

Dr. Abdul-Latif has a direct interest in the subject of this appeal, because he teaches and practices in the gender clinic at Children's of Alabama. Dr. Abdul-Latif has hundreds of patients who will be adversely affected if this Court grants the Defendants' appeal.

All Amici share an interest in the integrity of medicine and science, and all are concerned that Senate Bill (S.B.) 184, 2002 Leg., Reg. Sess. (Ala. 2022) ("S.B. 184") has set a harmful, national precedent for denying standard medical care to transgender youth. As scientists and clinicians, Amici have a strong interest in ensuring that this Court has sound scientific information at hand, and submit this

brief to rebut the efforts of Defendants and Defendant-aligned amici to confuse this Court with erroneous scientific pronouncements.

SUMMARY OF ARGUMENT

The Amici urge this Court to affirm the District Court's order granting a preliminary injunction. The District Court opinion is based on accurate findings of fact that deserve decisive weight under the "clearly erroneous" standard of review applicable here.

The District Court's findings of fact were grounded in the Court's correct evaluation of the evidence offered by the plaintiffs-appellees and well-supported by reliable scientific evidence.

The District Court correctly found that transitioning medications are standard medical care that have been used safely and with proven benefits for decades and are endorsed by every major medical society in the United States. Defendants mistakenly claim that the District Court "inexplicably deferred" to the medical societies' endorsements, but this objection mischaracterizes the role of authority in medicine. The weight of medical society endorsements does not lie in the "eminence" of these organizations, but rather in their expert evaluation of the scientific evidence on transitioning medications. It is not "eminence-based medicine" (as Defendants claim) to follow medical society endorsements grounded in their careful review of the relevant science.

The District Court accurately determined that transitioning medications have been shown by sound scientific evidence to confer significant mental health benefits

and that the denial of these medications to adolescents works irreparable harm. As the Court noted, transitioning medications are well-established, evidence-based treatments for gender dysphoria. The proven benefits of transitioning medications include improvements in anxiety and depression, social functioning, body image, and reductions in suicidal ideation.

Defendants attack the use of transitioning medications by using misleading terminology and sources with little or no scientific credibility. Yet none of the sources cited by Defendants or Defendant-aligned amici refute the scientific evidence supporting the efficacy of transitioning medications. Defendants also incorrectly claim that psychotherapy alone is the appropriate standard of care for adolescent gender dysphoria. Their unsupported speculation is at odds with peer-reviewed, published studies demonstrating that transitioning medications produce benefits over and above those of psychotherapy alone.

The District Court also correctly concluded that gender dysphoria in adolescents persists into adulthood and properly gave little weight to Defendants' unsupported claims, which they repeat before this Court, that there is a new wave of gender dysphoria driven by social media.

ARGUMENT

I. THE DISTRICT COURT'S FINDINGS OF SCIENTIFIC FACT ARE CORRECT, AMPLY SUPPORTED BY THE RECORD, AND DESERVE DECISIVE WEIGHT IN THIS COURT'S DELIBERATIONS.

In the opinion granting Plaintiffs' motion for a preliminary injunction, the District Court carefully and correctly described gender dysphoria and related medical treatments for youth. *See Eknes-Tucker v. Marshall*, 2:22-cv-184-LCB, 2022 WL 1521889 (M.D. Ala. May. 13, 2022) (hereinafter, "Opinion").

This Court should affirm the District Court's order granting a preliminary injunction. This Court's role is to "review the grant of a preliminary injunction for abuse of discretion, reviewing any underlying legal conclusions *de novo* and any findings of fact for clear error." *Gonzalez v. Governor of Ga.*, 978 F.3d 1266, 1270 (11th Cir. 2020); *Alabama v. U.S. Army Corps of Eng'rs*, 424 F.3d 1118, 1129 (11th Cir. 2005). The District Court's findings of fact were grounded in a correct evaluation of the evidence offered by the parties and are well-supported by sound scientific evidence; as a result, this Court should affirm.

The District Court correctly found that there is a strong medical consensus supporting the drug therapies commonly used to treat gender dysphoria in minors.[1]

[1] Following the District Court, we term these "transitioning medications." Transitioning medications may include, depending on the patient, GnRH agonists (sometimes called puberty blockers), estradiol, and testosterone. *See* The World Professional Association for Transgender Health, "Standards of Care for the Health

It also correctly determined that the recommendations of more than twenty medical societies are based on existing scientific evidence, that transitioning medications have been shown by sound scientific evidence to confer significant mental health benefits, and that the denial of transitioning medications to adolescents works irreparable harm.

Defendants invite this Court to re-litigate the facts and to disregard the District Court's sound evidentiary judgments, but Defendants' approach is inconsistent with the standard of review: the District Court's findings of fact are demonstrably correct, based on reliable scientific evidence, and there is no clear error or abuse of discretion.

The District Court reviewed "hundreds of pages of medical evidence" as well as live testimony by several witnesses. *See* Opinion at 8. Based on the written record and the hearing, the District Court judge proceeded to make well-founded factual findings and credibility assessments.

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of Transsexual, Transgender, and Gender Nonconforming People," WPATH (7th ed. 2012), https://wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdfhttp://admin.associationsonline.com/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf [hereinafter "WPATH (2012)" or "WPATH Guidelines"], Wylie C. Hembree et al., "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline", Endocrine Society, 102(11) J. Clinical. Endocrinology. Metabolism. 3869 (2017), https://core.ac.uk/download/153399329.pdf. [hereinafter "Endocrine Society (2017)"].

For example, the District Court properly took a skeptical view of the testimony of Defendants' expert witness, Dr. James Cantor ("Cantor"). The District Court judge correctly "gave [Cantor's] testimony regarding the treatment of gender dysphoria in minors very little weight." Under cross-examination below, Cantor admitted that he only treats adults and has never diagnosed or treated gender dysphoria in a child or adolescent. He also admitted that he had no personal knowledge of the assessments or treatments used at any Alabama gender clinic. *See id.* at 11.

The judge's skepticism about Cantor's expertise is warranted. With no clinical experience treating minors, Cantor cannot evaluate the scientific evidence in light of the realities of clinical practice. Nor has he conducted original empirical research on transitioning medications for minors.[2]

Despite the District Court's clear finding that the Cantor testimony is unreliable, Defendants cite Cantor's declaration twenty-two times in their opening brief to this Court ("Defendants' Br.").[3] This Court should refuse to credit

[2] Cantor's research instead addresses unrelated subjects: adult pedophilia, adult sex addiction, and other adult sexual disorders.

[3] In a footnote, Defendants claim that the District Court's criticisms of Cantor's qualifications "are irrelevant to his expertise and testimony on the state of the scientific research evidence." *See* Defendants' Br., at 8 n.4. This statement makes light of the District Court's evaluation: Judge Burke specifically and correctly gave "very little weight" to Cantor's credibility and lack of scientific expertise "regarding the treatment of gender dysphoria in minors." The District Court found, and the evidence uncontestably shows, that Cantor lacks relevant expertise to opine on

Defendants' attempt to promote evidence to which the District Court appropriately gave "very little weight." *Id*.

II. THE DISTRICT COURT CORRECTLY FOUND THAT TRANSITIONING MEDICATIONS ARE STANDARD MEDICAL CARE THAT HAVE BEEN USED SAFELY AND WITH BENEFIT FOR DECADES AND ARE ENDORSED BY EVERY MAJOR MEDICAL SOCIETY IN THE UNITED STATES BASED ON A STRONG BODY OF SCIENTIFIC EVIDENCE.

S.B. 184 would impose criminal penalties on physicians who prescribe, and anyone else who "engage[s] in or cause[s]" transitioning medications to be prescribed or administered to a minor. *See* S.B. 184, § 4(a).[4]

S.B. 184 criminalizes what has been, for decades, standard medical care for gender dysphoria in minors. Clinical practice guidelines for the use of transitioning medications have been issued by the World Professional Association for Transgender Health (WPATH) since 1979 and most recently in 2012. *See* WPATH (2012).

The District Court properly focused on the WPATH Guidelines, which are widely followed in clinical practice. The WPATH Guidelines are based on "the best

transitioning medication use in minors. Further, Defendants, contrary to their own statement, cite Cantor's evidence for clinical propositions. *See* Defendants' Br., at 14-15.

[4] This brief does not address the portions of the S.B. 184 that ban surgical procedures, as these are not recommended before the age of majority by standard clinical practice guidelines and are not subject to the preliminary injunction granted by the District Court.

available science and expert professional consensus." WPATH (2012), at 1. The WPATH Guidelines are the product of a careful process that began in 2006 and continued during the next six years, as experts evaluated the relevant scientific evidence. The process also included measures to solicit expert views and ensure that the WPATH Guidelines reflected a true medical consensus. WPATH (2012), at 109-110.

Other expert bodies have independently examined the scientific evidence and have agreed on an approach to transitioning medications that is, in all material respects, the same as that set forth in the WPATH Guidelines. The Endocrine Society, the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry have all issued clinical practice guidelines for the treatment of transgender youth which support the use of transitioning medications. *See* Endocrine Society (2017); Jason Rafferty et al., Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,. 142 (4) Am. Acad. Pediatrics ("AAP") e20182162 (2018), shorturl.at/jpQ57 [hereinafter "AAP (2018)"], Am. Psych. Ass'n (APA), *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am. Psychologist 832 (2015) [hereinafter APA (2015)], Stewart L. Adelson, Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and

Adolescents, 51(9) J. Am. Acad. Child & Adolescent Psychiatry ("AACAP"), 957-974 (2012) [hereinafter "AACAP (2012)"].

Each of these expert bodies conducted its own investigative process. These are not shorthand endorsements of WPATH: they are lengthy and careful reviews of the scientific evidence from the perspective of each medical specialty. *Id.*

Thus, every relevant medical discipline, including endocrinology, pediatrics, psychology, and psychiatry, has independently considered the scientific evidence supporting the use of transitioning medications, and each has recommended their use consistent with the WPATH Guidelines. The degree of agreement across specialties is notable: each of these clinical guidelines approves the use of transitioning medications based on an individualized assessment of each patient. Each set of guidelines recommends the involvement of a mental health provider along with physicians, authorizes the use of transitioning medications only after the onset of puberty, and prescribes a careful process designed to ensure the informed consent of parents or guardians along with the informed assent of the minor. *Id.*

As physicians and psychologists, Amici and others rely on the clinical practice guidelines published by WPATH, the Endocrine Society, the AAP, the APA, and AACAP because these organizations – comprised of Amici's national and international colleagues – have done their research and due diligence.

a. The District Court properly recognized the scientific and medical authority of the WPATH Guidelines, which have been successfully

> used in clinical practice for decades and are updated periodically in light of the best available scientific evidence.

The District Court correctly found that "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." Opinion at 2-3. The Court also accurately referred to WPATH as "an organization whose mission is to promote education and research about transgender healthcare," *id.* at 2, and that, under the WPATH Guidelines, "minors and their parents undergo a thorough screening process and give informed consent before any treatment regimen begins." *Id*. at 9.

The WPATH Guidelines were developed using a structured process designed to incorporate the best scientific evidence. As part of the process, WPATH's working group commissioned a number of original research papers, which were peer reviewed and published in a leading journal in order to generate widespread comment from the scientific community. WPATH (2012), p. 109. Notably, the process was open to comments from experts outside WPATH.

Thus, Defendants are mistaken when they claim that "[t]here is no national or international medical consensus regarding an authoritative standard of care for the

treatment of gender dysphoria or the use of transitioning treatments." Defendants' Br., at 3-4.[5]

b. The recommendations of twenty-two medical societies carry weight with physicians and psychologists because they are based on solid scientific evidence, not because they are "eminent."

The District Court correctly found that "the record shows that at least twenty-two major medical associations in the United States endorse transitioning medications as well-established, evidence-based treatments for gender dysphoria in minors." Opinion, at 18.

Defendants mistakenly claim that the District Court "inexplicably deferred to Plaintiffs' healthcare amici, making an eminence-based medical judgment." Defendants' Br., at 5. This allegation badly mischaracterizes the role of scientific authority in medicine.

The weight of the medical society endorsements does not lie in the "eminence" of these organizations, but rather in their expert evaluation of the entire body of available evidence on the use of transitioning medications in minors. It is

[5] One Defendant-aligned amicus, the Ethics and Public Policy Center ("EPPC"), goes further, incorrectly characterizing WPATH as "an advocacy group." EPPC Amicus Br., at 8. WPATH's members include thousands of experts from around the world. It organizes the leading scientific conferences on the treatment of transgender patients and adopts guidelines only after a methodical process that involves peer review and consultation within and outside WPATH. Characterizing WPATH as an "advocacy group" thus grossly misrepresents its important role in medicine.

not "eminence-based medicine" for medical societies to endorse treatments based on solid, peer reviewed scientific evidence. Amici have the highest respect for the WPATH Guidelines and consult them in their medical and psychological practices.

EPPC attempts to attack the WPATH Guidelines based on a review by Dahlen et al. (2021). *See* EPPC Br. at 14 (citing Sara Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment*, 11 BMJ Open e048943 (2021), https://bmjopen.bmj.com/content/bmjopen/11/4/e048943.full.pdf [hereinafter "Dahlen"]). They characterize the study as a "first-of-its-kind systematic analysis of international [clinical practice guidelines]" that concluded that "WPATH [2012] cannot be considered 'gold standard.'" *Id*.

In fact, the EPPC characterization of Dahlen is inaccurate and misleading. The Dahlen study does not evaluate the scientific evidence base for the WPATH recommendations. Instead, the study attempts only to assess the presentation and user-friendliness of the WPATH Guidelines along with several other clinical practice guidelines.

Specifically, Dahlen adopts the so-called AGREE method, which evaluates the clarity and presentation of clinical practice guidelines, and not the underlying science. The foundational paper for AGREE states expressly that AGREE *"does not assess the clinical content of the guideline nor the quality of evidence that*

underpins the recommendations." See The AGREE Collaboration, *Development and Validation of an International Appraisal Instrument for Assessing the Quality of Clinical Practice Guidelines: the AGREE Project*, 12 BMJ Quality & Safety 18 (2003), https://qualitysafety.bmj.com/content/qhc/12/1/18.full.pdf (emphasis added). Instead, the AGREE method considers whether guidelines clearly explain their development process and are presented in a user-friendly way. *Id.*, *see also* Melissa C. Brouwers et al., *AGREE II: Advancing Guideline Development, Reporting, and Evaluation in Healthcare*, 182 Can. Med. Assoc. J. E839, E841 (2010).[6] The ratings produced by AGREE are subjective, based on each reviewer's impression of the specific guidelines.

Thus, the Dahlen study includes no information about the *scientific quality* of the WPATH Guidelines. It provides only an assessment of the usability of the Guidelines based on the subjective impressions of six authors, none of whom appear to have clinical or research expertise in treating gender dysphoria.

c. The District Court correctly recognized that Defendants offered no evidence to suggest that physicians and healthcare organizations are "aggressively pushing" transitioning medications on minors.

[6] For example, the questionnaire asks whether the objective of the guideline is specifically described and whether key recommendations are easily identifiable. The instrument includes a section on "rigour [sic] of development," but it inquires only into the transparency of the evidence review process. AGREE II Instrument (2017), at 1-2.

S.B. 184 asserts that "[s]ome in the medical community are aggressively pushing for [medical] interventions on minors." S.B. 184, § 2(6). After examining the record and questioning expert witnesses on both sides, however, the District Court correctly found that "nothing in the record shows that medical providers are pushing transitioning medications on minors." Opinion, at 23.

Despite the District Court's findings, Defendants persist in arguing that physicians are subjecting children to cookie-cutter medical treatments. Defendants claim, for example, that "the use of puberty blockers and cross-sex hormones sets children on a pathway to surgical interventions." Defendants' Br., at 18.

Contrary to the Defendants' claims (and the record below), there is no rush to prescribe transitioning medications to adolescents. The WPATH Guidelines – and all other major clinical guidelines – recommend transitioning medications only when medically necessary to treat gender dysphoria in adolescence.[7] Further, WPATH and all other major clinical guidelines require an individualized approach based on the needs of each patient.

The current guidelines all recommend a staged process that takes into account the presentation of gender dysphoria in each minor, along with their medical history and psychological functioning. As always in medicine, the priority is to treat the patient as an individual and to address each patient's physical and mental health

[7] Transitioning medications are not administered to pre-pubertal children.

needs holistically. WPATH, for example, expressly states that, "[b]efore any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken …. The duration of this exploration may vary considerably depending on the complexity of the situation." WPATH (2012), at 16.

d. The District Court correctly recognized that there is no foundation for the assertion that "[m]inors, and often their parents, are unable to comprehend and fully appreciate the risk and life implications" of these treatments.

S.B. 184 states that "the decision to pursue a course of hormonal and surgical interventions … 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." S.B. 184, § 2(16).

This claim is misleading, because it ignores the careful procedures followed by psychologists, physicians, and other health-care providers to ensure informed consent by parents and informed assent by adolescents to the use of transitioning medications.

Concretely, the WPATH Guidelines and other clinical practice standards require the participation of a qualified mental health practitioner, who confirms that the adolescent has demonstrated a lasting and intense pattern of gender dysphoria and that gender dysphoria worsened with the onset of puberty. The mental health

provider, along with a physician, also determines that any coexisting psychological, medical, or social problems that could interfere with treatment have been addressed, so that the adolescent is functional and stable enough to begin hormone treatment. The WPATH Guidelines and other clinical practice guidelines also require informed assent by adolescents and (if under the age of majority) informed consent by their parents, and they require the involvement of a physician to ensure that medication is warranted and that there are no medical contraindications. WPATH (2012), at 13-16, 18-21; Endocrine Society (2017), at 3876-3879.

These procedures reflect the significant body of research in child and adolescent psychiatry, child psychology, and adolescent medicine demonstrating that youth can assent, with parental consent, to complex medical decisions. *See e.g.* Beth A. Clark & Alice Virani, *This Wasn't a Split-Second Decision: An Empirical Ethical Analysis of Transgender Youth Capacity, Rights, and Authority to Consent to Hormone Therapy*, 18 J. Bioethical Inquiry 151 (2021), Lieke J. Vrouenraets et al., *Assessing Medical Decision-Making Competence in Transgender Youth*, 148(6) Pediatrics e2020049643 (2021), shorturl.at/dEGLU , Megan S. O'Brien, *Critical Issues for Psychiatric Medication Shared Decision Making with Youth and Families*, 92 Families in Society 310 (2011), Mary Ann McCabe, *Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations*, 21 J. Pediatric Psychology 505 (1996).

III. THE DISTRICT COURT CORRECTLY CONCLUDED THAT TRANSITIONING MEDICATIONS HAVE BEEN SHOWN BY SOUND SCIENTIFIC EVIDENCE TO CONFER SIGNIFICANT MENTAL HEALTH BENEFITS AND THAT THE DENIAL OF TRANSITIONING MEDICATIONS TO ADOLESCENTS WORKS IRREPARABLE HARM.

The District Court correctly found that gender dysphoria is a recognized condition and that untreated gender dysphoria may "lead to anxiety, depression, eating disorders, substance abuse, self-harm, and suicide." Opinion, at 2. These conclusions are based on a significant body of medical research. *See e.g.* Susan D. Boulware et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*, Yale School of Medicine (April 28, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/biased-science/ [hereinafter "Boulware (2022)"], pp. 11-13. The District Court rightly gave credence to Plaintiffs' experts, who "testified that, without these medications, minors with gender dysphoria suffer significant deterioration in their familial relationships and educational performance." Opinion at 9.

The District Court also accurately concluded that "transitioning medications are well-established, evidence-based methods for treating gender dysphoria in minors." Opinion, at 10. The benefits of these medications include improvements in anxiety and depression, social functioning, body image, and reductions in suicidal ideation. Boulware (2022), at 13-16.

The scientific evidence showing the benefits of transitioning medications has been well documented in a body of peer-reviewed studies published in high-impact journals. For the sake of brevity, Amici offer just a few examples, but there are careful summaries of this significant literature in Endocrine Society (2017), AAP (2018), APA (2015), AACAP (2012), and Boulware (2022).

A 2020 meta-analysis of nine studies found positive outcomes from puberty blockers including "decreased suicidality in adulthood, improved affect and psychological functioning, and improved social life." *See* Lynn Rew et al., *Review*: *Puberty Blockers for Transgender and Gender Diverse Youth-A Critical Review of the Literature*, 26 Child. Adolesc. Ment. Health 3, 3 (2021). A 2022 study found that transitioning medications were "associated with 60% lower odds of moderate to severe depressive symptoms and 73% lower odds of self-harm or suicidal thoughts over a 12-month follow-up." *See* Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5(2) JAMA Network Open e220978, at 7 (2022) [hereinafter "Tordoff (2022)"]. A 2020 study found that transitioning medications were associated with "important improvements in body dissatisfaction over the first year of treatment." *See* Laura E. Kuper et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145(4) Pediatrics e20193006, at 7 (2020) [hereinafter "Kuper (2020)"].

Defendants incorrectly claim that the evidence supporting transitioning medications is recent and based on a single study that has not been replicated. *See* Defendants' Br. at 1 ("the seminal study on transitioning children was published less than a decade ago (and has not been replicated)"). This is false. More than fifteen studies have documented the mental health benefits of transitioning medications for adolescents. *See e.g.* Boulware (2022), at 13-15; Meredithe McNamara et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, Yale School of Medicine (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida-medicaid/ [hereinafter "McNamara (2022)"], at 5-6, 15-21.

Defendants attempt to cast doubt on the scientific evidence supporting transitioning medications by noting that the FDA "has not approved puberty blockers to treat gender dysphoria." Defendants' Br., at 15. *See also* S.B. 184, § 4(7) (stating that the use of transitioning medications is "not FDA-approved"). Defendants imply that the absence of FDA approval renders a treatment unauthorized and experimental, but this is false.

The lack of FDA approval means that the use of a medication is technically "off-label." But this term has a narrow meaning in medicine: a drug is used off-label if the FDA has not specifically approved a particular medication for a particular use in a specific population. The off-label use of medications for children is quite

common and often necessary, because an "overwhelming number of drugs" have no FDA-approved instructions for use in pediatric patients. Kathleen A. Neville et al., *Off-label Use of Drugs in Children*, American Academy of Pediatrics, Committee on Drugs 133 Pediatrics 563, 563 (2014).

The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs, noting that "[t]he purpose of off-label use is to benefit the individual patient" and that "the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use." *Id*. Indeed, off-label use is so common in pediatrics that off-label drugs are prescribed in about 20% of patient visits. *See* Diya Hoon et al., *Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015*, 144(4) Pediatrics 1, 1 (2019).[8]

a. Defendants rely on misleading terminology and sources with little or no scientific credibility to support their claim that transitioning medications are experimental.

Defendants and Defendant-aligned amici repeatedly claim that the evidence supporting transitioning medications is "low quality." This claim is false and rests on a misleading use of technical terminology.

Defendants principally rely on a June 2022 report issued by the Florida Agency for Health Care Administration ("Florida AHCA"). *See* Florida AHCA,

[8] For a range of examples of off-label drug use in pediatrics, see McNamara (2022), at 19-21.

Division of Florida Medicaid, *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria* (June 2022), https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf [hereinafter "AHCA Report"]; Defendants' Br., at 14. Amici submitting this brief have addressed the distortions and scientific errors in the AHCA Report at length elsewhere. *See* McNamara (2022). Stated plainly: nothing in the AHCA Report calls into question the scientific evidence supporting the use of transitioning medications.

The linchpin of the AHCA Report is an unpublished, non-peer-reviewed report written by two epidemiologists. AHCA Report (2022). The analysis purports to be a review of all the relevant scientific evidence, and it boldly – but incorrectly – concludes that there is "no evidence" for the benefits of medical care for gender dysphoria.

The analysis underpinning the AHCA Report is deceptive, because it dismisses existing studies of transitioning medications as "low quality," without explaining that this is a highly technical term that conveys primarily that the underlying studies are observational (rather than randomized controlled trials). In fact, many consensus procedures and treatments in medicine are based on technically "low-quality" evidence; these include mammograms, many surgical procedures, and the anti-cholesterol medications known as statins. *See* McNamara (2022), at 15-16.

The term "low quality," used in this technical sense, does not mean that the underlying studies are poorly-conducted or unreliable. Indeed, the drafters of the quality rating system relied on by the Florida AHCA are quite clear that "a particular level of quality does not imply a particular strength of [clinical] recommendation. *Sometimes, low or very low quality evidence can lead to a strong recommendation.*" *See* Howard Balshem et al., *GRADE Guideline: 3. Rating the Quality*, 64 J. Clinical Epidemiology 401, 402 (2011) (emphasis added).

The Florida AHCA finding thus signifies only that there are no randomized controlled trials (RCTs) on the benefits of transitioning medications. But RCTs are not, and cannot be, the sole method for medical research on gender dysphoria, because RCTs in this context would be prohibited for ethical reasons. This ethical limitation actually reflects the solidity of the clinical consensus supporting transitioning medications for youth: it is unethical to conduct an experiment that denies proven medical care to a control group when the efficacy of the care is well established. Because the benefits of transitioning medications are well-established, it would be unethical to randomly deny them to some adolescents with gender dysphoria. By analogy, it would be unethical to conduct an RCT that administered placebos instead of insulin to patients with juvenile diabetes, because insulin is a proven treatment. It is thus a mischaracterization of medical research for the Florida

AHCA to claim that the absence of RCTs means that there is "no evidence" for the efficacy of transitioning medications.

The AHCA Report thus provides no scientific foundation for Defendants' claim that transitioning medications are unsupported by scientific evidence.

b. Defendants incorrectly claim that psychotherapy alone is the appropriate standard of care for adolescent gender dysphoria, but evidence has shown that transitioning medications produce benefits over and above those of psychotherapy.

Defendants speculate, without evidence, that adolescents with gender dysphoria should not be offered transitioning medications but should receive psychotherapy alone. Defendants' Br., at 14-15 (citing Cantor declaration for the clinical claim that youth should undergo psychotherapy "while waiting to see whether the dysphoria will continue before experimenting with irreversible interventions").

This argument rests on the mistaken premise, examined in depth *infra*, that adolescent gender dysphoria will resolve without any treatment. In fact, gender dysphoria in the vast majority of adolescents does not resolve without medical treatment, as Defendants' own putative expert, Cantor, admitted on the stand. *See* Prelim. Injunct. Tr., at 329-330.

Further, it is false to claim that psychotherapy alone is as effective as transitioning medications. Medical studies have shown that transitioning

medications produce positive effects on mental health that are not associated with psychotherapy alone. *See* McNamara (2022), at 17-19, 27-28.

For example, a 2022 study published in *Pediatrics*, one of the top medical journals in the world, found that youth with gender dysphoria reported better outcomes if they received transitioning medications, even after controlling for the effects of psychotherapy. The authors found that transitioning medications are associated with significant improvements in depression and suicidality in a population of transgender youths aged 13 to 20. The authors controlled for whether teens received mental health therapy "other than for the purpose of a mental health assessment to receive a gender dysphoria diagnosis." Tordoff (2022), at 3.

IV. THE DISTRICT COURT ACCURATELY CONCLUDED THAT GENDER DYSPHORIA IN ADOLESCENCE PERSISTS INTO ADULTHOOD AND PROPERLY GAVE LITTLE WEIGHT TO UNSUPPORTED CLAIMS THAT THERE IS A NEW WAVE OF GENDER DYSPHORIA DRIVEN BY SOCIAL MEDIA.

The District Court correctly found that, although gender dysphoria in young children may resolve without treatment, gender dysphoria that persists into or arises in adolescence is likely to last into adulthood. Opinion, p. 2.

As the Court recognized, the key distinction is between adolescence and pre-pubertal children. Transitioning medications are offered only after puberty begins, and only to adolescents whose dysphoria worsens with puberty. Thus, medication

is used only with adolescent patients whose gender dysphoria is extremely likely to continue into adulthood.

The course of gender dysphoria is different in young children, a population not subject to the S.B. 184, because they do not receive transitioning medications. When prepubertal children experience gender dysphoria, some will find that their dysphoria resolves before adolescence. Based on older evidence, the American Psychological Association estimated that around 50% of prepubertal children will not persist in identifying as transgender into adolescence and adulthood. APA (2015), at 841-2. An important recent study suggested that rates of "desistance" are much lower, finding that after an average of 5 years of social transition, only 2.5% of youth identified as the gender assigned to them at birth. Kristina R. Olson et al., *Gender Identity Five Years After Social Transition*, Pediatrics e2021056082, at 6 (preprint, May 2022).

Gender dysphoria in adolescents, by contrast, has long been found to be persistent into adulthood. When an adolescent presents with severe gender dysphoria worsened by the onset of puberty (whether originally diagnosed in childhood or in adolescence), it is highly unlikely that their dysphoria will resolve on its own. APA (2015), at 843; WPATH (2012), at 11; Stephanie Wagner et al., *Progression of Gender Dysphoria in Children and Adolescents: A Longitudinal Study*, 148 Pediatrics e2020027722, at 8 (2021).

Indeed, Defendants' own putative expert witness, James Cantor, admitted that adolescents rarely "desist." *See* Prelim. Injunct. Tr., at 329-330. At trial, Plaintiffs' counsel asked whether "the majority of kids who continue to feel trans after puberty rarely cease?" Cantor replied, "That does seem to be the case, yes." *Id*.

a. Defendants incorrectly claim that "the vast majority of youth suffering from gender dysphoria will not identify as transgender as adults."

Defendants repeatedly misstate the scientific evidence by grouping young children together with adolescents. For example, Defendants claim that "[i]f not given medical interventions to transition—and that is an important "if"—most children with gender dysphoria grow up to identify as gay or lesbian and do not suffer from gender dysphoria as adults." Defendants' Br., at 11.

Defendants also mislead this Court when they state that "practitioners have no way of knowing *ex ante* whether the treatments would benefit any particular child because (among other things) there is no proven way for a clinician to separate the minority of persisters from the majority of desisters." Defendants' Br., at 56-57.

In fact, physicians need not predict the course of gender dysphoria in young children. Instead, following the WPATH Guidelines and other clinical practice guidelines, they wait until adolescence before considering transitioning medications. At that time, a multidisciplinary team evaluates each adolescent, recommending

medications only for those who present with lasting and intense gender dysphoria and for whom medication is medically necessary. *See* McNamara (2022), at 17-18.

b. There is no evidence to support Defendants' speculation that there is a wave of patients with gender dysphoria who cannot reliably be treated with transitioning medications.

Defendants claim that "what was once a trickle of children presenting with gender related distress has become a tsunami" and that "adolescent girls have now become the default patient, and their dysphoria is associated with peer clusters and social media use." Defendants' Br. at 1, 43. Defendants argue that transitioning medications have not been shown to be effective in this purportedly new population. *Id*.

There is, in fact, no credible evidence to support these claims, and there is good reason to believe they are wild exaggerations. To begin, the data show no massive explosion in the percentage of transgender adolescents. A 2022 study found that, using an expansive definition of "transgender," about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people in the entire United States. *See* Jody L. Herman et al., *How Many Adults and Youth Identify as Transgender in the United States?*, U.C.L.A. School of Law Williams Institute, at 1 (June 2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Jun-2022.pdf. This is not a large percentage or a large absolute number.

Further, Defendants' own evidence is inconsistent with the claim that there is a "tsunami" of transgender youth obtaining medical treatment. Defendants' brief presents a graph showing an increase in referrals to the U.K.'s Gender Identity Development Service (GIDS) from 2009 through 2016. According to the graph, there were a total of 1,766 referrals to GIDs in 2016, the most recent year shown. That is a large percentage increase over the 51 patients seen in 2009, but it is a low absolute number. GIDS is the only pediatric gender clinic run by the UK National Health Service, and 1,766 patients represents about one-tenth of one percent of the UK under-18 population. *See* Office for National Statistics, Ethnicity Facts and Figures, Age Groups (last updated August 17, 2020), https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/age-groups/latest#main-facts-and-figures. Further, the increase is not surprising, since the social climate in the U.K., as in the U.S., has become more accepting of gender nonconformity in this period.

Data do substantiate that younger people today are more likely to identify as transgender than older people are, but this fact does not lend support to the idea of gender dysphoria spreading rapidly by social contagion. The increase may be due to the growing social acceptance of gender diversity (i.e., older people grew up in a more transphobic social environment) and the availability of standard medical care when appropriate.

Importantly, adolescent presentation of transgender identity has long been observed and should not be pathologized. In the largest U.S. sample of transgender adults, over half reported first starting to realize that they were transgender in adolescence (57% ages 11-20), and roughly half (47%) started to disclose their identity during this time frame. *See* Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey*, at 46 (December 2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

The hypothesis that there is a new wave of adolescent gender dysphoria driven by social media has been widely covered in the media, but no clinical studies have found that a new form of gender dysphoria exists, and no professional organization has recognized a new diagnosis or distinct clinical condition. Indeed, in 2021, the American Psychological Association and other national and international medical societies issued a position statement emphasizing that "[t]here are no sound empirical studies of [the claimed new type of gender dysphoria] and it has not been subjected to rigorous peer-review processes that are standard for clinical science. Further, there is no evidence that [the claimed "rapid-onset" gender dysphoria] aligns with the lived experiences of transgender children and adolescents." *See* Coalition for the Advancement & Application of Psychological Science, *CAAPS Position Statement on Rapid Onset Gender Dysphoria (ROGD)*, 2021, https://www.caaps.co/rogd-statement.

The only proffered evidence for Defendants' sensational claims is a single study that has been discredited by subsequent research. The cited study, Littman (2018), contained such serious errors that the journal in which it was published mandated an extensive correction, an unusual step taken only when it would be unscientific to allow the originally published findings to stand. *See* Lisa Littman, *Correction: Parent Reports of Adolescents and Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, 14(3) PLoS One 1 (2019), *see also* Boulware (2022), at 20-21.

Recent studies have found no evidence of a new type of gender dysphoria driven by social media or social contagion. An important 2022 study published in *Pediatrics* analyzed 173 youth presenting to a Canadian gender clinic. *See* Greta R. Bauer et al., *Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?*, 243 J. Pediatrics 224 (2022). The researchers hypothesized that if rapid gender dysphoria and social contagion were real phenomena, then teens who had more recently begun identifying as transgender would also be more likely to report online support and engagement from their peers for their gender identity. *Id*. The researchers found no such correlations. *Id*. Contrary to Defendants' claims, teens with more recent awareness of being transgender were not significantly more likely to have gender-supportive online

friends, general support from online friends or transgender friends, or gender support from parents. *See* Bauer (2022), at 225-26.

V. CONCLUSION

For the reasons stated herein and in the voluminous scientific record before the District Court below, the Court should affirm the District Court's order granting a preliminary injunction.

Respectfully submitted,

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Dated: August 12, 2022.

CERTIFICATE OF COMPLIANCE

1. I certify that this brief complies with the type-volume limitations set forth in Fed. R. Civ. App. P. 32(a)(7)(B)(i) and Fed. R. Civ. App. 29(a)(5). This brief contains 6,491 words, including all headings, footnotes, and quotations, and excluding the parts of this submission exempted under Fed. R. App. P. 32(f).

2. In addition, this response complies with the typeface and type style requirements of Fed. R. App. P. 33(a)(5) and (6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

3. Pursuant to Fed. R. App. P. 29(a)(4)(E), I certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person other than the amici curiae or their counsel contributed money that was intended to fund preparing or submitting the brief. Amici received no funding for this work and have no conflicts of interest to declare. The views expressed are Amici's own and not those of the University of Alabama, the University of Texas, or Yale University.

4. Counsel for the Amici Curiae sought and received the consent of all parties to file this amicus brief, pursuant to Fed. R. App. P. 29(a)(2).

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CERTIFICATE OF SERVICE

I certify that on August 12, 2022, I electronically filed this document using the Court's CM/ECF system, which will serve counsel of record.

/s/ Alison Andersen
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