No. 23-12155

IN THE UNITED STATES DISTRICT COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

AUGUST DEKKER, et al., *Plaintiffs-Appellees*,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, et al., Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of Florida Case No: 4:22-cv-00325-RH-MA

BRIEF OF AMICI CURIAE HUSSEIN ABDUL-LATIF, REBECCA KAMODY, LAURA KUPER, MEREDITHE MCNAMARA, NATHALIE SZILAGYI, AND ANNE ALSTOTT IN SUPPORT OF AFFIRMING THE DISTRICT COURT'S ORDER

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1–1, the undersigned counsel for *amici curiae* Hussein Abdul-Latif, Rebecca Kamody, Laura Kuper, Meredithe McNamara, Nathalie Szilagyi, and Anne Alstott certify that:

- None of the above-referenced individuals is a corporate entity or has issued stock.
- The following persons and parties, in addition to the above-named amici, may have an interest in the outcome of this case:
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I. <u>STATEMENT OF INTEREST</u>

The *amici* submitting this brief are a group of five scientists and a law professor (collectively, "*Amici*"). The five 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 two Ph.D. child and adolescent psychologists, an M.D. child and adolescent psychiatrist, and two M.D. physicians with specialties in pediatric endocrinology and adolescent medicine. All five scientists are clinicians who treat transgender patients daily. Collectively, *Amici* have over 40 years of clinical practice experience and have treated more than 1,700 transgender patients.

All *Amici* share an interest in the integrity of medicine and science, and all are concerned that Florida Statutes § 286.31(2) (2023) and Florida Administrative Code Rule 59G-1.050(7) set a harmful, national precedent for denying standard medical care to transgender people. *See* Florida Statutes §§ 456.001(9) (2023) and 456.52 (2023) and Fla. Admin. Code r. 64B8-9.019(1)(b) and r. 64B15-14.014(1)(b).

As scientists and clinicians, *Amici* have a strong interest in ensuring that this Court has sound scientific information regarding the medical treatment of gender dysphoria. We submit this brief to encourage this Court to uphold the district court's decision, which holds that Florida Statutes § 286.31(2) (2023) and Florida Administrative Code Rule 59G-1.050(7) are invalid to the extent they categorically ban payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria.

Our goal is to present this Court with sound scientific information and to ensure that the members of this Court, like the district court judge, understand the irreparable harms imposed by the denial of Medicaid coverage for medical care for gender dysphoria. Two of us practice in states with bans on medical treatment for adolescents with gender dysphoria, and we are witnessing firsthand the anxiety and despair that our patients feel when the law requires us to deny them treatment. Our states' bans, like those in Florida, put us in an ethical bind, forcing us to withhold standard medical care from our patients.

We recognize that this Court's opinion in *Eknes-Tucker v. Governor of the State of Ala.*, No. 22-11707, 2022 WL 359111 (11th Cir. Aug. 21, 2023), raises issues of Constitutional law. We do not discuss these questions, which are addressed by Plaintiffs. Instead, consistent with our expertise, we focus on the medical and scientific evidence supporting medical treatment for gender dysphoria.¹

¹The district court opinion does not address Medicaid coverage for gender-affirming surgery, since no plaintiff sought surgery, and the court decided that none of the plaintiffs had standing to challenge the ban on surgery coverage. *Dekker* Opinion at 1, 13-14. Our brief focuses on the evidence regarding the use of medications (puberty blockers and cross-sex hormones) to treat gender dysphoria, and we do not address surgery.

Amici received no funding for this work and have no conflicts of interest to declare. This brief reflects our views and not necessarily those of the University of Alabama, the University of Texas, or Yale University.

II. STATEMENT OF THE ISSUES

Whether the district court correctly determined that the Medicaid Bans violate the Fourteenth Amendment's Equal Protection Clause and of the Affordable Care Act ("Section 1557"), which prohibits discrimination based on sex in health programs or activities.

III. <u>SUMMARY OF ARGUMENT</u>

Adopted in 2022, new Section 59G-1.050(7) of the Florida Administrative Code (the "2022 Regulation") denies Medicaid coverage for standard medical care for individuals with gender dysphoria. Specifically, the 2022 Regulation denies Florida Medicaid coverage for medical services for the treatment of gender dysphoria, including puberty blockers, hormones and hormone agonists, "sex reassignment surgeries," and "any other procedures that alter primary or secondary sexual characteristics" (collectively, "medical care for gender dysphoria").

Adopted in 2023, Florida Statutes § 286.31(2) (2023) (the "2023 Statute") prohibits governmental entities, public postsecondary institutions, and certain managed care plans from expending state funds for "sex-reassignment prescriptions or procedures" as defined in Florida Statutes § 456.001 (2023). Neither the 2022 Regulation nor the 2023 Statute bar coverage of the same medical treatments when offered to people with conditions other than gender dysphoria.

We refer to the 2022 Regulation and the 2023 Statute, collectively, as the "Florida Medicaid Bans." We adopt this shorthand while recognizing that the 2023 Statute extends beyond the Medicaid program to ban other uses of public funds to provide coverage for medical treatment for gender dysphoria.

We urge the court to uphold the district court's decision invalidating the Florida Medicaid Bans in order to protect transgender Floridians by ensuring them

access to standard, proven medical care. The district court's decision is based on sound findings of facts, and we encourage this Court to reject Defendants' attempt to misrepresent the scientific evidence and to re-litigate the facts. See Reiterman v. Abid, 26 F.4th 1226, 1234-35 (11th Cir. 2022) ("[Rule] 52(a) allows reviewing courts to set aside trial court findings of fact only when they are clearly erroneous. But '[w]hen findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings..."). That is especially true here, where the district court's findings of fact and conclusions of law were set out following a bench trial. See Regions Bank v. Kaplan, No. 17-15478, 2021 WL 4852268, at *6 (11th Cir. Oct. 19, 2021) ("We review for clear error the district court's bench trial factual findings... If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it.").

Our analysis, below, confirms that the district court opinion is, in every material respect, correct on the science and medicine of treating gender dysphoria. By contrast, the Defendants have mischaracterized the scientific evidence and, in their brief to this Court, have continued to do so.

The district court correctly determined that the Florida Medicaid Bans deny coverage for well-established, evidence-based medical care endorsed by every relevant medical organization in the United States. Defendants claim that transitioning medications are experimental and dismiss the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society as "advocacy organizations." In fact, both are well-respected and authoritative. Their clinical practice guidelines rest on careful examinations of the scientific evidence and prescribe an individualized approach to treatment that includes careful processes to ensure informed consent and to handle complex cases. These guidelines inform our clinical practice and that of other responsible medical providers.

The district court carefully considered the scientific and medical evidence and, with the benefit of a full trial record and testimony by expert witnesses, correctly ruled that Defendants' claims about medical regulation and gender dysphoria are false and misleading. Indeed, as the district court found, the Defendants' claims are so scientifically baseless that they cannot provide even a rational basis for the Florida Medicaid Bans. Our analysis confirms the soundness of the district court's findings on two important issues.

First, the district court correctly determined that the purported scientific "expert" report relied upon by Defendants was produced by a biased process and ignored solid medical evidence in order to reach a pre-ordained result motivated by discriminatory animus. The 2022 Regulation was based on a fatally flawed document issued by Defendant Florida Agency for Health Care Administration ("Florida AHCA") on June 2, 2022. Division of Florida Medicaid, Agency For Health Care Administration, *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, <u>https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_</u> <u>Report.pdf</u> ["AHCA Report"] (last visited Nov. 29, 2023). The 2023 Statute codified the regulation.

As the district court recognized, and as we explained in our comments provided to the Florida AHCA in 2022, the AHCA Report is thoroughly unscientific. Riddled with scientific errors, bias, and unfounded speculation, the AHCA Report provided no sound justification for the 2022 Regulation. It relies on unpublished, non-peer-reviewed reports by purported "experts" with known biases, violating Florida's own administrative standards for determining Medicaid coverage. *See* Fla. Admin. Code Section 59G-1.035(4) (requiring that the AHCA consult "evidencebased clinical practice guidelines" and peer-reviewed scientific publications).

Second, the district court correctly found that a robust and growing body of peer-reviewed research supports medical treatment for gender dysphoria and that the State's arguments about "low-quality" evidence are fundamentally misleading.

As the district court recognized, and as we explain below, "low quality" in this context is a term of art used in a highly technical ranking system. Medical experts recognize that "low quality" evidence can provide a foundation for strong clinical practice recommendations, as it does in the case of transitioning medications.

We urge this Court to uphold the district court's decision. Overturning the district court's ruling would inflict irreparable harm on the many transgender Floridians who rely on Medicaid and other targeted insurance programs for access to standard medical care for gender dysphoria.

IV. <u>ARGUMENT</u>

A. THE DISTRICT COURT CORRECTLY DETERMINED THAT THE FLORIDA MEDICAID BANS DENY COVERAGE FOR WELL-ESTABLISHED, EVIDENCE-BASED MEDICAL CARE ENDORSED BY EVERY RELEVANT MEDICAL SOCIETY AND PRESCRIBED ACCORDING TO CAREFUL PROTOCOLS THAT ENSURE SAFETY AND INFORMED CONSENT.

Medical care for the treatment of gender dysphoria, which can include gonadotropin-releasing hormone agonists ("GnRHa" or "puberty blockers") and hormone therapy, is supported by a firmly established body of scientific research. As the district court found, transitioning medications have been successfully and safely used to treat thousands of patients with gender dysphoria, and the use of these medications has been approved by every relevant major medical association in the United States based on the scientific evidence.

The best scientific evidence shows that gender dysphoria is real, that untreated gender dysphoria leads predictably to serious, negative psychological consequences,

and that medical care for gender dysphoria significantly improves mental health outcomes.

The district court made precisely these findings, concluding that "gender identity is real." *Dekker v. Weida*, No. 4:22cv325-RH-MAF, 2023 WL 4102243, at *4 (N.D. Fla. June 21, 2023) ("*Dekker* Opinion"), at 4. And the district court judge admonished the Defendants for "dog whistles" signaling that gender identity and gender dysphoria are "made up." *Id.* at 2 (finding "an unspoken suggestion running just below the surface in some of the proceedings that led to adoption of the rule and statute at issue ... is that transgender identity is not real, that it is made up").

As the district court noted, the American Psychiatric Association recognizes gender dysphoria in its Diagnostic and Statistical Manual of Mental Disorders ("DSM-5"), the standard reference for the diagnosis of mental health conditions. The DSM-5 sets forth criteria for diagnosis, including "a marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics" and "a strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)." To meet diagnostic criteria, an individual must also exhibit "clinically significant distress or impairment in social, occupational, or other important areas of functioning." Am. Psychiatric Ass'n, *Diagnostic and Stat. Manual of Mental Disorders* 21, 452 (5th ed. 2013).

"In other words, individuals who live in a manner that is physically and socially incongruent to their gender identity can experience gender dysphoria — a clinically significant psychological distress that can lead to depressed mood, suicidal ideation and attempts, and disordered eating." See 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 Sch. of Scientific Claims, Yale Med. (Apr. 28, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/biased-science/ ["Boulware (2022)"], at 12-13.

Defendants' brief claims that gender dysphoria cannot be reliably diagnosed and that "[p]laintiffs' experts conceded during the trial [that] there isn't any 'confirmatory laboratory or radiographic study for the diagnosis of gender dysphoria.'" Defs.'-Appellants' Initial Br. at 4. But that argument proves too much, because the same is true of many psychiatric conditions, including depression, anxiety, and schizophrenia. Psychiatrists routinely diagnose these conditions — and prescribe medications when appropriate — without any lab test or imaging tool. Indeed, the entire fields of psychiatry and clinical psychology are devoted to the careful diagnosis and treatment of mental health conditions, typically without confirmatory laboratory or radiographic evidence. Gender dysphoria can have serious adverse effects if untreated. As the district court recognized, "there are risks attendant to not using [transitioning medications], including the risk—in some instances, the near certainty—of anxiety and depression and even suicidal ideation." *Dekker* Opinion at 16. The court's observation is correct: suicidal ideation and attempts have been found to be significantly higher among transgender adolescents who cannot obtain or do not receive gender-affirming care than among their cisgender peers: "40% of trans individuals who do not receive hormones will attempt or complete suicide in their lifetime," a much higher rate than is found in the cisgender population. Boulware (2022), *supra*, at 12-16.

Treatment for gender dysphoria is possible, and it is effective. Reliable research has shown that transitioning medications have major benefits, including improvements in anxiety and depression, social functioning, body image, and reductions in suicidal ideation. These findings have been well documented in numerous peer-reviewed studies published in authoritative journals and confirmed by years of clinical experience.

The district court correctly found that "well-qualified doctors" have treated thousands of transgender patients with transitioning medications and "have achieved excellent results." *Dekker* Opinion at 8. The court also found "no evidence" in the

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record to prove that transitioning medications have "caused substantial adverse clinical results in properly screened and treated patients." *Id.* at 8.

For the sake of brevity, Amici offer a few recent examples of the research that supports the use of transitioning medications, but we note that the literature spans a decade or more and that there are detailed summaries in the WPATH Standards of Care, the Endocrine Society Guidelines, and the clinical practice guidelines published by the American Academy of Pediatrics (the "AAP"), the American Psychological Association (the "APA") and the American Academy of Child and Adolescent Psychiatry ("AACAP"). See Standards of Care for the Health of Transgender and Gender Diverse People 23 World Pro. Ass'n for Transgender Health, (8th ed. 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9553112/ ["WPATH Standards of Care"]; Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102(11) J. Clinical Endocrinology & Metabolism 3869 (2017), https://pubmed.ncbi.nlm.nih.gov/28945902/ ["Endocrine Society Guidelines"]; Jason Rafferty, et al., Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142(4) Pediatrics (Oct. 2018), ["AAP https://pubmed.ncbi.nlm.nih.gov/30224363/ Guidelines"]; American Psychological Association, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70 Am. Psych. 832 (2015),

https://www.apa.org/practice/guidelines/transgender.pdf ["APA Guidelines"]; 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 957 (Sept. 2012), https://pubmed.ncbi.nlm.nih.gov/22917211/ ["AACAP Guidelines"]. *See also* Boulware (2022), *supra*, at 11-17 (summarizing the scientific evidence supporting medical care for gender dysphoria).

For instance, a 2020 meta-analysis of nine studies found positive outcomes from transitioning medications, 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(1) Child Adolescent Mental Health 3, (Feb. 2021), https://pubmed.ncbi.nlm.nih.gov/33320999/. 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, 3. (Feb. 7 1. 2022). https://pubmed.ncbi.nlm.nih.gov/35212746/ ["Tordoff (2022)"]. A 2020 study found that transitioning medications were associated with "large 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, 5 (Apr. 2020), <u>https://pubmed.ncbi.nlm.nih.gov/32220906/</u> ["Kuper (2020)"].

Additional longer-term data is now emerging, with one study demonstrating improved self-worth and satisfaction with physical appearance an average of six years after initiating transitioning medication in adolescence and a second study demonstrating little to no ongoing gender dysphoria after nine or more years since initiating transitioning medication in adolescence. Marijn Arnoldussen, et al., Self-Perception of Transgender Adolescents After Gender-Affirming Treatment: A Follow-Up Study into Young Adulthood, 9(4) LGBT Health 238 (May 26, 2022), https://doi.org/10.1089/lgbt.2020.0494; B.B. de Rooy Frédérique, et al., Long Term Follow-Up of Gender and Sexuality in Early Treated Transgender Adolescents, 20(4)J. Sexual Med. 062 (July 6, 2023), https://doi.org/10.1093/jsxmed/qdad062.088.

Further studies in the last year have provided yet more evidence that transitioning medications are effective. *See* Anna L. Olsavsky, et al., *Associations Among Gender-Affirming Hormonal Interventions, Social Support, and Transgender Adolescents' Mental Health*, 72(6) J. Adolescent Health 860 (Apr. 6, 2023), <u>https://doi.org/10.1016/j.jadohealth.2023.01.031</u>; Diane Chen, et al.,

Psychosocial Functioning in Transgender Youth after 2 Years of Hormones, 388(3)

New Eng. J. Med. 240 (Jan. 19, 2023), https://pubmed.ncbi.nlm.nih.gov/36652355/.

1. The district court correctly found that standard medical care for gender dysphoria is conducted according to wellestablished clinical practice guidelines and has been endorsed, based on careful reviews of the scientific evidence, by every relevant medical organization in the United States.

Two authoritative scientific organizations, WPATH and the Endocrine Society, have published detailed clinical practice guidelines for treating gender dysphoria. *See* WPATH Standards of Care, *supra*, and the Endocrine Society Guidelines, *supra*.

As recognized by the district court, the WPATH and the Endocrine Society clinical practice guidelines are "well-established" and "widely accepted." *Dekker* Opinion at 6, 10, 16-18. The district judge credited "the abundant testimony in this record that these standards are widely followed by well-trained clinicians" and insurance companies and are endorsed by the United States Department of Health and Human Services. *Id.* at 6.

These clinical guidelines are based on rigorous, structured processes. Each involves the work of a committee of scientific experts and peer review by additional experts. For example, the authors of the WPATH guidelines include more than 90 leading researchers in the field of transgender medicine. *See* WPATH Standards of Care, *supra*. The WPATH Standards of Care and the Endocrine Society Guidelines

are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments. "These longstanding clinical practice guidelines have been used by clinicians for decades." Meredithe McNamara, et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, Yale Sch. Med. (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida-medicaid/ ["McNamara (2022)"], at 5.

Defendants attempt to dismiss WPATH and the Endocrine Society as "advocacy organizations." Defs.'-Appellants' Initial Br. at 1, 5. But the district court correctly rejected that claim, finding that "[t]he overwhelming majority of doctors are dedicated professionals whose first goal is the safe and effective treatment of their patients. There is no reason to believe the doctors who adopted these standards were motivated by anything else." *Dekker* Opinion at 17.

Moreover, the scientific and medical consensus supporting medical treatment for gender dysphoria extends well beyond WPATH and the Endocrine Society. As the district court recognized, these "standards have been unanimously endorsed by reputable medical associations, even though not unanimously endorsed by all the members of the associations." *Id.* at 17.

More than 20 major medical associations, including the AAP, the APA, and AACAP, have endorsed the use of transitioning medications. *See* AAP Guidelines;

APA Guidelines; AACAP Guidelines; Brief of Amici Curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations, *Dekker v. Weida* (4:22-CV-00325).

The district court was correct in finding that the endorsements of transitioning medications by more than 20 medical societies should carry great weight. These endorsements are not the work of a couple of advocacy groups: they reflect careful reviews of the scientific evidence by experts in each medical specialty. Every relevant medical discipline has independently validated the scientific evidence supporting standard medical care for gender dysphoria.

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. These organizations set the standards by which medicine is practiced in the United States and, in the case of WPATH, across the world.

2. The district court correctly found that authoritative clinical practice guidelines guide an individualized approach to treatment, including careful processes to ensure informed consent and to address complex cases.

The WPATH and the Endocrine Society guidelines recommend careful processes to ensure informed consent by adult patients (and, in the case of minors, by parents and informed assent by adolescents). Patients undergo a multidisciplinary team assessment, beginning with a thorough psychosocial assessment of each patient by a mental health provider and involving specialist physicians, as appropriate, at each decision point. *See* WPATH (2022), *supra*, and the Endocrine Society (2017), *supra*.

Both sets of guidelines emphasize that treating gender dysphoria requires an individualized approach. Not all patients with gender dysphoria receive medication, because it is not appropriate in every case. There is no medical treadmill that sets patients on a pre-determined course of treatment. Instead, physicians and mental health providers work together to consider how best to address each patient's individual presentation.

Nor is the process a rushed one. A recent study of one gender clinic found that the median time between initial contact and the first administration of transitioning medications was nearly a year (307 days). Diana M. Tordoff, et al., *Factors Associated with Time to Receiving Gender-Affirming Hormones and Puberty Blockers at a Pediatric Clinic Serving Transgender and Nonbinary Youth*, 8(5) Transgend Health 420 (Oct. 4, 2023), <u>https://pubmed.ncbi.nlm.nih.gov/37810940/</u>.

Contrary to Defendants' arguments, that many patients continue hormone treatment once they start does not prove that that medication and surgery are inevitable once gender dysphoria is diagnosed. Rather, it shows that when WPATH and the Endocrine Society guidelines for eligibility, assessment, and counseling are followed, most patients are happy with the results. Pranav Gupta, et al., *Adherence to Gender Affirming Hormone Therapy in Transgender Adolescents and Adults: A Retrospective Cohort Study*, 108(11) J. Clinical Endocrinology & Metabolism (Oct. 18, 2023), <u>https://pubmed.ncbi.nlm.nih.gov/37246711/</u> (showing less than 2% discontinuation of hormone treatment in a sample of adolescents and adults treated according to WPATH and the Endocrine Society guidelines).

Defendants also question the capacity of medical providers to diagnose gender dysphoria. They claim that "[i]t's hard to diagnose gender dysphoria … Transgender individuals often suffer from other mental health issues, such as autism, anxiety, depression, and suicidality. Many factors can influence one's gender dysphoria as well, including environmental factors, such as social acceptance. Other conditions, such as body dysmorphic disorder, can also be confused with gender dysphoria." Defs.'-Appellants' Initial Br. at 4 [internal citations omitted]. This assertion is another attempt to persuade the Court that gender dysphoria is an imagined byproduct of mental illness or social contagion.

While some individuals with gender dysphoria also have anxiety, depression, and other mental health conditions, it is well-documented that these conditions often reflect the social stress and discrimination of being transgender. McNamara (2022), *supra*, at 25-27.

Further, that individuals with gender dysphoria also suffer other forms of psychological distress is not a reason to deny them medical care. Any population of individuals—cisgender or transgender—includes some with mental health concerns. In response, the WPATH Standards of Care and the Endocrine Society Guidelines require a careful psychological assessment of each patient. WPATH, for example, specifically states that transitioning medications are appropriate for an adolescent with gender dysphoria only if:

- Gender diversity/incongruence is "marked and sustained over time,"
- The patient has "the emotional and cognitive maturity required to provide informed consent/assent for the treatment and diagnosis of gender dysphoria,"
- The adolescent's "mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and/or gender-affirming medical treatments have been addressed."

WPATH (2022), supra, at 560-63.

The WPATH guidelines pay special attention to patients with co-occurring mental health conditions, advising that "it is critical" to differentiate gender dysphoria from other mental health conditions (including obsessions and compulsions, autism, broader identity problems, or psychotic thoughts): "Mental health challenges that interfere with the clarity of identity development and genderrelated decision-making should be prioritized and addressed." *Id.* at 563.

These cautions do not imply that patients with co-occurring conditions are incapable of assenting to medical treatment for gender dysphoria. Medical experts have established that patients — including transgender youth with co-occurring mental health conditions — can express informed assent to complex medical decisions when well-supported by parents and professionals. *See* Lieke J. Vrouenraets, et al., *Assessing Medical Decision-Making Competence in Transgender Youth*, 148(6) Pediatrics e2020049643 (Dec. 1, 2021), https://pubmed.ncbi.nlm.nih.gov/34850191/.

The district court correctly determined that these informed consent and assent procedures protect patients, finding that "the ability of the adult plaintiffs... [and] the minor plaintiffs and their parents to evaluate the benefits and risks of [transitioning medications] far exceeds the ability of the State of Florida to do so." *Dekker* Opinion at 10.

3. The district court correctly found that the Florida Medicaid Bans inflict irreparable harm on patients with gender dysphoria and criminalize transitioning medications only for transgender patients, ignoring the fact that the same treatments are used commonly and safely by cisgender patients.

The district court correctly found that the Florida Medicaid Bans would inflict grave harm on patients with gender dysphoria by denying them standard medical

care. "The loss of Medicaid payment for the needed treatments is an injury in fact; it is concrete and particularized; and it is actual or imminent, not conjectural or hypothetical." *Id.* at 12.

Defendants refer to transitioning medications as "risky and poorly supported medical procedures," Defendants' brief at 35, but the medications used to treat gender dysphoria are used commonly and safely in cisgender patients as well as transgender patients. Puberty blockers are the primary treatment for central precocious puberty. Estrogen is prescribed for patients to manage fertility and reduce heavy menstrual bleeding (to give just two examples of its many uses). Testosterone is prescribed to treat hypogonadism and is routinely prescribed to cisgender men with testosterone deficiency. *See* McNamara (2022), *supra*, at 22, 24.

But the Florida Medicaid Bans do not bar the use of transitioning medications when prescribed to cisgender patients. The District Court confirmed these facts, finding that "[c]isgender individuals can be and routinely are treated with GnRH agonists, testosterone, or estrogen, when they and their doctors deem it appropriate, and the treatments are covered by Medicaid." *Dekker* Opinion at 35.

B. THE DISTRICT COURT CORRECTLY DETERMINED THAT THE PURPORTED SCIENTIFIC EVIDENCE OFFERED BY THE STATE IS SO BIASED AND FLAWED THAT IT FAILS TO

PROVIDE EVEN A RATIONAL BASIS FOR THE FLORIDA MEDICAID BANS.

The district court correctly determined that the purported scientific evidence offered by the State as justification for the Florida Medicaid Bans was produced by a biased process that ignored solid medical evidence in order to reach a pre-ordained result fueled by discriminatory animus. *Id.* at 14 (finding that the Florida Medicaid Bans "were motivated in substantial part by the plainly illegitimate purposes of disapproving transgender status and discouraging individuals from pursuing their honest gender identities. This was purposeful discrimination").

From the start, the Florida Medicaid Bans were based on faulty and misleading characterizations of the science. On June 2, 2022, the Florida Agency for Health Care Administration ("Florida AHCA") issued a lengthy report concluding that transitioning medications and gender-affirming surgeries for minors and adults are "experimental." Division of Florida Medicaid, Agency for Health Care Administration, *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, https://ahca.myflorida.com/content/download/4869/file/AHCA_GAPMS_June_20 22_Report.pdf ["AHCA Report"] (last visited Nov. 29, 2022). On the basis of that report, the Florida AHCA promulgated the Florida Medicaid Bans.

But the State's efforts to prohibit the use of transitioning medications did not end with the Medicaid prohibition. Later in the summer of 2022, the Florida Boards of Medicine and Osteopathic Medicine began the process that led to the adoption of the Regulatory Ban, and in 2023, the legislature codified and criminalized those rules in the Statutory Ban.

Amici, along with other medical experts, submitted timely comments in opposition to the Regulatory Ban. *See* Letter from Anne Alstott, et al., to David Diamond, Chair, Florida Board of Medicine (July 14, 2022), *available at* <u>https://transgender.agency/files/08052022_FB2_Publicbook.pdf</u>. ["Alstott Letter"].

As we observed in our comments, the AHCA Report does not represent sound scientific evidence. It relies upon "expert" reports that are unpublished, not peerreviewed, and written by authors whose expertise has been successfully challenged in legal proceedings and whose backgrounds raise red flags for bias.

The AHCA Report is lengthy and full of scientific and medical jargon and may appear, to a non-expert reader, to be a serious evaluation of the evidence. Any such appearance is deceiving. The AHCA Report violated the standards of scientific inquiry and distorted the scientific evidence to reach a pre-ordained result: to deny coverage of medical care for gender dysphoria. Here, we summarize some of the major flaws in the AHCA Report; we do so comprehensively in the Alstott Letter, *supra*, and in McNamara (2022), *supra*.

The AHCA Report concluded that transitioning medications and genderaffirming surgery are "experimental" based on five attached documents that, the report claims, constitute "clinical and technical expert assessments." AHCA Report, *supra*, at 2. Despite this billing, the attachments to the AHCA Report are unreliable and violate the standards of scientific inquiry in several ways.

First, neither the AHCA Report nor any of its attachments met standard criteria for expert scientific investigations, because none is published or peer reviewed. Contrary to these accepted standards, the AHCA Report repeatedly cites unreliable sources, including journalism, a student blog, a website, and letters to the editor. McNamara, *supra*, (2022), at 16-17; *see also* Catherine Lockmiller, *Decoding the Misinformation-Legislation Pipeline: an Analysis of Florida Medicaid and the Current State of Transgender Healthcare*, 111(4) J. MED. LIB. ASS'N 750, 752-755 (Oct. 2023), <u>https://jmla.pitt.edu/ojs/jmla/article/view/1724</u> (identifying and analyzing the unreliable sources used by the Florida AHCA report).

Second, the AHCA Report does not disclose how its "experts" were identified or by what criteria their expertise was assessed. This is troubling because the qualifications and credibility of several of the experts have been successfully challenged in litigation, as the district court correctly found. At trial, the district court determined that the "AHCA retained only consultants known in advance for their staunch opposition to gender-affirming care." *Dekker* Opinion at 9. "The new [process for evaluating medical treatments for gender dysphoria] was, from the outset, a biased effort to justify a predetermined outcome, not a fair analysis of the evidence." *Id.*

For all these reasons, the district court properly discounted the AHCA Report and the other evidence offered by the State to support the Florida Medicaid Bans, concluding that "[t]he State of Florida's decision to ban payment for [transitioning medications] for transgender individuals is not rationally related to a legitimate state interest" and the State's "laundry list of purported justifications" is "largely pretextual." *Id.* at 14.

In their brief to this Court, Defendants advance these same misleading claims. Below, we review two of the district court's most important findings and show that the court correctly rejected Defendants' positions.

1. The district court correctly found that robust, peer-reviewed research supports medical treatment for gender dysphoria and that the State's arguments about "low-quality" evidence are fundamentally misleading.

Defendants' brief attempts to undermine the scientific evidence supporting medical treatment for gender dysphoria in two ways. First, Defendants quote the Plaintiffs' experts out of context and make cherry-picked criticisms of individual studies. *See* Defs.'-Appellants' Initial Br. at 7-8. They fail to acknowledge that the literature as a whole strongly supports medical treatment for gender dysphoria. By contrast, the district court evaluated the evidence presented by both sides and correctly concluded that "there is now extensive clinical experience showing

excellent results from treatment with GnRH agonists and cross-sex hormones." *Dekker* Opinion at 15.

Scientific knowledge is cumulative and refined over time, but that does not make it unreliable, and it does not mean physicians should not act on the evidence furnished by existing research. In the aggregate, at least 20 studies show that transitioning medications benefit patients with gender dysphoria. *See* Exhibit 1. These studies have demonstrated benefits as measured by a variety of outcomes (inter alia, body satisfaction, mental health, and suicidality). They evaluate diverse study populations and use a diverse array of methods (including retrospective report, cross-sectional, longitudinal, and qualitative). McNamara (2022), *supra*, at 18; Chen, et al. (2023), *supra*; and Olsavsky, et al. (2023), *supra*.

Notably, none of these studies has shown that transitioning medications harm transgender patients. It is thus unscientific and misleading to launch cherry-picked criticisms at individual studies and to quote experts, out of context, as saying that more research is needed. Defendants' brief engages in exactly this kind of misdirection without acknowledging the overwhelming weight of the evidence and that the studies reach consistent results.

Second, Defendants mischaracterize the scientific evidence showing the benefits of transitioning medications as "low quality" and therefore unreliable. Defs.'-Appellants' Initial Br. at 7.

This criticism is grossly misleading. "Low quality" is a technical term describing the type of studies that have been done, not a negative judgment about the reliability of the conclusions they have reached. The district court correctly gave Defendants' "low quality" evidence argument little weight, finding that "[i]t is commonplace for medical treatments to be provided even when supported only by research producing evidence classified as 'low' or 'very low' on this scale." *Dekker* Opinion at 15.

To understand why "low quality" evidence can be and often is relied upon in clinical practice, it is important to know that there are essentially two types of studies that evaluate the effects of medical treatments. Randomized controlled trials, or RCTs, divide patients randomly into a control group (which receives no treatment) and a treatment group (which does). In an RCT, both doctors and patients are ideally "blind" to whether the patient has received treatment. In contrast, an observational study records information about patients in a real-world setting, such as a cohort of patients treated at a clinic. Although observational studies do not have a strict control group the way RCTs do, they allow researchers to study the treatment group over time and, in some studies, compare outcomes between the treatment group and similar patients who did not take transitioning medications.

The technical GRADE rating system for medical studies, which Defendants invoke and which features prominently in the AHCA Report, generally codes only

RCTs as "high quality" evidence. Because the studies showing the benefits of transitioning medications are not RCTs, they are therefore coded as "low quality."

That is not a criticism of the studies' conclusions. In fact, the drafters of the GRADE system emphasize that technically "low quality" evidence can support a strong clinical treatment recommendation. Howard Balshem, et al., *GRADE Guideline: 3. Rating the Quality*, 64(4) J. Clinical Epidemiology 401, 402-404 (Apr. 2011), https://pubmed.ncbi.nlm.nih.gov/21208779/.

Evidence that the GRADE system classifies as "low quality" is commonly used in medicine for exactly that purpose. In fact, a recent study of a large sample of systematic reviews found that fewer than 10% of medical treatments are supported by what GRADE calls "high quality" evidence. *See* Jeremy Howick, et al., *The Quality Of Evidence For Medical Interventions* Does *Not Improve Or Worsen: A Metaepidemiological Study Of Cochrane Reviews*, 126 J. Clinical Epidemiology154 (Oct. 2020), https://pubmed.ncbi.nlm.nih.gov/32890636/.

Medical practitioners can and do make frequent use of so-called "low quality" evidence because, in many contexts (including gender dysphoria), it would be impossible or unethical to conduct an RCT. *See* Florence Ashley, et al., *Randomized-Controlled Trials are Methodologically Inappropriate in Adolescent Transgender Healthcare*, Int'l J. Transgender Health, (June 24, 2023),

https://www.tandfonline.com/doi/citedby/10.1080/26895269.2023.2218357?scroll =top&needAccess=true.

Given the medical consensus and solid evidence supporting transitioning medications, it would be unethical to conduct an RCT that would deny the control group standard medical care. By analogy, it would be equally unethical to conduct an RCT on the treatment of juvenile diabetes by randomizing some participants to receive insulin and others to receive no medication at all.

There are also practical obstacles to RCTs in this context. Transitioning medications have obvious physical effects, and so it would be impossible to "blind" the participants in the study. Patients and providers would notice whether a patient's pubertal development had ceased (in the case of patients receiving puberty blockers) or whether cross-sex development had occurred (such as the development of a low voice in a transgender boy or breasts in a transgender girl). These bodily changes are highly sought by individuals with gender dysphoria, so many members of the control group would likely drop out and seek medication elsewhere, invalidating the research design. *See id*.

These issues of study design are not unique to medical treatment for gender dysphoria. Similar issues leave many areas of consensus medicine supported primarily by observational studies (and not RCTs). Yet the State of Florida permits them without legal restriction. If the State consistently prohibited procedures supported only by observational studies, the result would be a massive disruption in medical care.

For example, if the State of Florida criminalized all medical care supported by technically "low quality" evidence, it would ban post-menopausal hormone replacement therapy and mammography screening for breast cancer. Many common surgical procedures also rest on a technically "low quality" evidence base, including minimally invasive gall bladder surgery. McNamara (2022), *supra*, at 16.

For all these reasons, the district court correctly rejected Defendants' "lowquality evidence" argument. *Dekker* Opinion at 15.

V. <u>CONCLUSION</u>

The district court's findings of scientific fact are clear and correct. Transitioning medications have been used safely and effectively for years to treat gender dysphoria.

We strongly urge this Court to affirm the district court's decision invalidating the Florida Medicaid Bans in order to protect transgender Floridians by ensuring them access to standard, proven, and critically important medical care.

Respectfully submitted,

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AMICI CURIAE'S EXHIBIT 1

No. 23-12155

IN THE UNITED STATES DISTRICT COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

AUGUST DEKKER, et al., *Plaintiffs-Appellees*,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION et al., Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of Florida Case No: 4:22-cv-00325-RH-MA

AMICI CURIAE'S EXHIBIT 1

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<u>AMICI CURIAE'S EXHIBIT 1. Twenty studies finding benefits of</u> <u>transitioning medications in transgender patients.</u>

Citation

Annelou L C de Vries et al., *Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study*, 8(8) J.Sexual Med. 2276 (Aug. 2011), <u>https://pubmed.ncbi.nlm.nih.gov/20646177/</u>.

Annelou L C de Vries et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134(4) Pediatrics 696 (Oct. 2014), https://pubmed.ncbi.nlm.nih.gov/25201798/.

Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*,12(11) J. Sexual Med. 2206 (Nov. 2015), <u>https://pubmed.ncbi.nlm.nih.gov/26556015/</u>.

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<u>CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT,</u> TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENT

1. As required by Fed. R. App. P. 32(a)(7)(B)(i), I certify that this brief is proportionally spaced and contains 6272 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). I relied on my word processor, Microsoft Office Word, to obtain this count.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Office Word in Times New Roman Style, 14 point font.

I certify that the foregoing information is true and correct to the best of my knowledge and belief formed after a reasonable inquiry.

/s/ David C. Blickenstaff David C. Blickenstaff

<u>CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE</u> <u>REQUIREMENT</u>

Pursuant to Fed. R. App. P. 29(a)(2), counsel for *amici* contacted counsel for the parties on October 3, 2023, and asked whether they consent to the filing of *amici*'s brief. Counsel for both Plaintiffs-Appellees (on October 6, 2023) and Defendants-Appellants (on October 3, 2023) indicated that they did not object to the filing.

<u>/s/ David C. Blickenstaff</u> David C. Blickenstaff

CERTIFICATE OF SERVICE

I hereby certify that, on December 1, 2023, this notice was filed through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

<u>/s/ David C. Blickenstaff</u> David C. Blickenstaff

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