No. 23-12155

UNITED STATES 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.

U.S. District Court for the Northern District of Florida, No. 4:22-cv-325 (Hinkle, J.)

DEFENDANTS-APPELLANTS' INITIAL BRIEF

Mohammad O. Jazil Michael Beato HOLTZMAN VOGEL BARAN TORCHINSKY & JOSEFIAK PLLC 119 South Monroe Street, Suite 500 Tallahassee, FL 32301 (850) 270-5938

Counsel for Defendants-Appellants

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 2 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Per Rule 26.1 and Circuit Rule 26.1, Defendants-Appellants certify that the

following have an interest in the outcome of this case:

- 1. Academic Pediatric Association, Amicus
- 2. Alstott, Anne, *Amicus*
- 3. Altman, Jennifer, Counsel for Plaintiffs
- 4. American Academy of Child and Adolescent Psychiatry, *Amicus*
- 5. American Academy of Family Physicians, *Amicus*
- 6. American Academy of Nursing, *Amicus*
- 7. American Academy of Pediatrics, *Amicus*
- 8. American College of Obstetricians and Gynecologists, Amicus
- 9. American College of Osteopathic Pediatricians, Amicus
- 10. American College of Physicians, Amicus
- 11. American Medical Association, *Amicus*
- 12. American Pediatric Society, Amicus
- 13. American Psychiatric Association, Amicus
- 14. Anderson, Barrett, Counsel for Amicus
- 15. Antommaria, Armand, Witness
- 16. Association of American Medical Colleges, Amicus
- 17. Baker, Kellan, *Witness*

C-1 of 7

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 3 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 18. Bardos, Andy, Counsel for Amicus
- 19. Barnes, Brian, Counsel for Amicus
- 20. Beato, Michael, Counsel for Defendants
- 21. Biomedical Ethics and Public Health Scholars, Amicus
- 22. Boergers, Kathleen, Counsel for Amicus
- 23. Boulware, Susan, Amicus
- 24. Bowdre, Alexander, Counsel for Amicus
- 25. Brackett, John Matthew, Witness
- 26. Brown, Louis, Jr., Amicus
- 27. Burleigh, Clifton, Jr., Amicus
- 28. Charles, Carl, Counsel for Plaintiffs
- 29. Chriss, Simone, Counsel for Plaintiffs
- 30. Chuang, Ming, Counsel for Amicus
- 31. Clark, Kaila, Counsel for Amicus
- 32. Coursolle, Abigail, Counsel for Plaintiffs
- 33. Dalton, Ann, Witness
- 34. Debriere, Katherine, Counsel for Plaintiffs
- 35. Dekker, August, *Plaintiff*
- 36. Do No Harm, Amicus
- 37. Doe, Jane, Plaintiff
- 38. Doe, John, Plaintiff

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 4 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 39. Doe, Susan, Plaintiff
- 40. Dunn, Chelsea, Counsel for Plaintiffs
- 41. Edmiston, Kale, Witness
- 42. Endocrine Society, Florida Chapter of the American Academy of Pediatrics, Amicus
- 43. English, Jeffrey, Witness
- 44. Figlio, Erik, Counsel for Amicus
- 45. Florida Agency for Health Care Administration, Defendant
- 46. Florida Chapter of the American Academy of Pediatrics, Amicus
- 47. Florida Policy Institute, Amicus
- 48. Florida Voices for Health, Amicus
- 49. Gonzalez-Pagan, Omar, Counsel for Plaintiffs
- 50. Halley, Ted, Amicus
- 51. Hartnett, Kathleen, Counsel for Amicus
- 52. Helstrom, Zoe, Counsel for Amicus
- 53. Heyer, Walt, Amicus
- 54. Hinkle, Robert, U.S. District Court Judge
- 55. Hruz, Paul William, Witness
- 56. Hussein, Abdul-Latif, Amicus
- 57. Hutton, Kim, Witness
- 58. Isasi, William, Counsel for Amicus

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 5 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 59. Janssen, Aron Christopher, Witness
- 60. Jazil, Mohammad, Counsel for Defendants
- 61. K.F., Plaintiff
- 62. Kaliebe, Kristopher Edward, Witness
- 63. Kamody, Rebecca, Amicus
- 64. Kang, Katelyn, Counsel for Amicus
- 65. Karasic, Dan, Witness
- 66. Kline, Robert, Counsel for Amicus
- 67. Kniffin, Eric, Counsel for Amicus
- 68. Krasovec, Joseph, Counsel for Amicus
- 69. Kuper, Laura, Amicus
- 70. Lannin, Cortlin, Counsel for Amicus
- 71. Lappert, Patrick, Witness
- 72. Laudue, Jade, Plaintiff
- 73. Levine, Stephen, Witness
- 74. Little, Joseph, Counsel for Plaintiffs
- 75. Marstiller, Simone, Former Defendant
- 76. Mauler, Daniel, Counsel for Amicus
- 77. McKee, Catherine, Counsel for Plaintiffs
- 78. McNamara, Meredithe, Amicus
- 79. Meszaros, Marie, Amicus

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 6 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 80. Miller, William, Counsel for Plaintiffs
- 81. Mondry, Emily, Counsel for Amicus
- 82. Morrison, Rachel, Amicus
- 83. National Association of Pediatric Nurse Practitioners, Amicus
- 84. Norohna, Maya, Amicus
- 85. North Central Florida Council of Child and Adolescent Psychiatry, Amicus
- 86. Olezeski, Christy, Amicus
- 87. Olson-Kennedy, Johanna, Witness
- 88. Pediatric Endocrine Society, Amicus
- 89. Perko, Gary, Counsel for Defendants
- 90. Pratt, Christine, Amicus
- 91. Pratt, Joshua, Counsel for Defendants
- 92. Ramer, John, Counsel for Amicus
- 93. Reinhardt, Elizabeth, Counsel for Amicus
- 94. Richards, Jay, Amicus
- 95. Rivaux, Shani, Counsel for Plaintiffs
- 96. Rothstein, Brit, Plaintiff
- 97. Samuels, Valerie, Counsel for Amicus
- 98. Schechter, Loren, Witness
- 99. Scott, Sophie, Witness
- 100. Severino, Roger, Amicus

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 7 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 101. Shaw, Gary, Counsel for Plaintiffs
- 102. Shumer, Daniel, Witness
- 103. Societies for Pediatric Urology, Amicus
- 104. Society for Adolescent Health and Medicine, Amicus
- 105. Society for Pediatric Research, Amicus
- 106. Society of Pediatric Nurses, Amicus
- 107. State of Alabama, Amicus
- 108. State of Arkansas, Amicus
- 109. State of California, Amicus
- 110. State of Georgia, Amicus
- 111. State of Indiana, Amicus
- 112. State of Iowa, Amicus
- 113. State of Kentucky, Amicus
- 114. State of Louisiana, Amicus
- 115. State of Mississippi, Amicus
- 116. State of Missouri, Amicus
- 117. State of Montana, Amicus
- 118. State of Nebraska, Amicus
- 119. State of North Dakota, Amicus
- 120. State of South Carolina, Amicus
- 121. State of Tennessee, Amicus

USCA11 Case: 23-12155 Document: 29 Date Filed: 10/06/2023 Page: 8 of 54 August Dekker et al. v. Secretary, Florida Agency for Health Care Administration No. 23-12155

- 122. State of Texas, Amicus
- 123. State of Utah, Amicus
- 124. State of Virginia, Amicus
- 125. Szilagyi, Nathalie, Amicus
- 126. Thompson, David, Counsel for Amicus
- 127. Veroff, Julie, Counsel for Amicus
- 128. Veta, D. Jean, Counsel for Amicus
- 129. Weida, Jason, Defendant
- 130. World Professional Association for Transgender Health, Amicus

Per Circuit Rule 26.1-2, Defendants-Appellants certify that the CIP contained

herein is complete.

Dated: October 6, 2023

<u>/s/ Mohammad O. Jazil</u> Counsel for Defendants-Appellants

STATEMENT REGARDING ORAL ARGUMENT

Given the important and weighty constitutional and statutory issues in this case, the State asks for oral argument.

TABLE OF CONTENTS

Statement R	Regarding Oral Argument	i
Table of Co	ntents	
Table of Au	thorities	
Introduction	n	1
Jurisdiction	al Statement	2
Statement o	f the Issues	2
Statement o	f the Case and Facts	
Back	ground	
Factu	al History: State Actions Before Lawsuit	11
Proce	edural History	16
Stand	lard of Review	
Summary of	f the Argument	
Argument		
I.	SB 254 and Rule 59G-1.050(7) Are Constitutional Under	r the Equal
	Protection Clause	25
II.	The Challenged Laws Comply with the Affordable Care	Act 36
III.	The Challenged Laws Comply with the Medicaid Act	
Conclusion		
Certificate of	of Compliance	41
Certificate of	of Service	41

TABLE OF AUTHORITIES

Cases

*Adams v. School Board of St. Johns County,		
57 F.4th 791 (11th Cir. 2022)passim		
Andino v. Middleton,		
141 S. Ct. 9 (2020)		
City of Cleburne v. Cleburne Living Center,		
473 U.S. 432 (1985)		
*Dobbs v. Jackson Women's Health Org.,		
142 S. Ct. 2228 (2022)		
*Eknes-Tucker v. Governor, of the State of Alabama,		
2023 U.S. App. LEXIS 21942 (11th Cir. Aug. 21, 2023)passim		
FCC v. Beach Communications,		
508 U.S. 307 (1993)		
Frontiero v. Richardson,		
411 U.S. 677 (1973)		
GBM v. Secretary of Alabama,		
992 F.3d 1299 (11th Cir. 2021)		
Geduldig v. Aiello,		
417 U.S. 484 (1974)		

Jacobson v. Massachusetts,			
197 U.S. 11 (1905)			
Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.,			
299 F.3d 1242 (11th Cir. 2002)24			
League of Women Voters of Florida, Inc. v. Florida Secretary of State,			
32 F.4th 1363 (11th Cir. 2022)			
League of Women Voters of Florida Inc. v. Florida Secretary of State,			
66 F.4th 905 (11th Cir. 2023)24, 26. 34			
L.W. v. Skrmetti,			
73 F.4th 408 (6th Cir. 2023)			
L.W. v. Skrmetti,			
2023 U.S. App. LEXIS 25697 (6th Cir. Sept. 28, 2023)passim			
*Rush v. Parham,			
625 F.2d 1150 (5th Cir. 1980)16, 37			
United States v. Carolene Products Co.,			
304 U.S. 144 (1938)			
University of Georgia Athletic Association v. Laite,			
756 F.2d 1535 (11th Cir. 1985)24			
Village of Arlington Heights v. Metropolitan Housing Development Corp.,			
429 U.S. 252 (1977)25			

Statutes

20 U.S. § 1681
28 U.S.C. § 1291
28 U.S.C. § 1331
42 U.S.C. §§ 1396a
42 U.S.C. §§ 1396d
42 U.S.C. § 18116
Fla. Stat. § 120.5215
Fla. Stat. § 409.90512
Other Sources
Fla. Admin. Code Rule 59G-1.03512
Nondiscrimination in Health & Health Education Programs or Activities,
85 Fed. Reg. 37,160 (Jun. 19, 2020)11

Introduction

This case isn't about what kinds of evidence support puberty blockers and crosssex hormones as treatments for gender dysphoria. The answer is beyond contention: low-quality evidence, a lack of longitudinal studies, and guidance documents from biased advocacy organizations. Instead, this case is about what's to be done with that information; specifically, whether public funds should be used to reimburse for these treatments. It's a health and welfare question; it's a medical policy issue. It's an area where the State gets to draw the line between what's permissible and what isn't.

Here, the State of Florida made its decision in legislation, SB 254, and an administrative rule, Florida Administrative Code 59G-1.050(7). It decided to deny Medicaid reimbursement for the treatments. That's a decision the State gets to make. And given the evidence (or lack thereof) supporting the treatments, its decision was reasonable.

That should have been the end of the matter. Yet the district court decided that it gets to answer that health and welfare question and that it gets to resolve that medical policy issue. Under the auspices of the Equal Protection Clause, the Affordable Care Act, and the Medicaid Act, the district court held that the public *must* reimburse these treatments—despite the State's decision-making authority, and in the face of the serious health risks that accompany these treatments: permanent sterility, cognitive decline, and cardiac complications, to name only a few.

The district court erred. It should therefore be reversed.

Jurisdictional Statement

The district court had jurisdiction under 28 U.S.C. § 1331 (federal-question jurisdiction). This Court has jurisdiction under 28 U.S.C. § 1291 (jurisdiction to review "final decisions of the district courts of the United States"). The district court entered final judgment in Plaintiffs' favor on June 21, 2023. Doc.246.¹ A notice of appeal was timely filed on June 26, 2023. Doc.248.

Statement of the Issues

Plaintiffs challenged section 3 of SB 254 and Rule 59G-1.050(7) under the Equal

Protection Clause of the Fourteenth Amendment, under the Affordable Care Act, and

under the Medicaid Act. As such, this Court must decide:

- 1. Under the Equal Protection Clause, whether the challenged laws survive rational-basis review.
- 2. Under the Affordable Care Act, whether the challenged laws constitute sex-based discrimination.
- 3. Under the Medicaid Act, whether the challenged laws comply with the Act's requirement for early and periodic screening, diagnostic, and treatment services for beneficiaries under age 21.
- 4. Under the Medicaid Act, whether the challenged laws comply with the Act's comparability requirement.

¹ In this brief, "Doc." citations refer to district court docket entries. "Tr." citations refer to the trial transcript. "Tr.*" citations refer to transcript day 4. "P.I. Tr." citations refer to the preliminary-injunction transcript. "Brackett Depo." refers to the State's 30(b)(6) deposition, sections of which were designated by Plaintiffs. Doc.235. "PX" refers to a Plaintiffs exhibit. "DX" refers to a State exhibit. Exhibit page citations refer to the electronic page, which may be different from the typed page number.

Statement of the Case and Facts

Background

A. This case is about whether the taxpayer must pay for certain treatments for gender dysphoria. Gender dysphoria is a psychiatric diagnosis for distress related to incongruence between one's biological sex and one's gender identity. Tr.971:3-7 (Dr. Levine); *see also* Tr.38:17-20, 114:3-9 (Dr. Karasic). Sex is based on biology, but gender is sometimes understood as the culturally constructed attributes associated with being a biological male or a biological female. *See generally* Tr.971:15-25, 1099:18-25 (Dr. Levine); DX24 at 7. Gender identity, in turn, is understood as "a person's deeply felt, inherent sense of being a girl, woman, female, a boy, a man, or male." Tr.120:14-22 (Dr. Karasic).² Unlike biological sex, therefore, gender identity is a psychological concept; it is not based on biology. Tr.971:15-972:2 (Dr. Levine). One's gender identity can change throughout one's life. Tr.165:18-23 (Dr. Karasic). So can transgender status; after all,

² To state the obvious: It's difficult to assess one's "deeply felt, inherent sense of being a girl, woman, female, a boy, a man, or male," separate and apart from having the genetics and anatomy of a female or male. Does this "sense of being" mean, for instance, that there are stereotypical differences between females and males in the way they feel, think, and behave that have no connection to their biological differences? Is it even possible—metaphysically speaking—to be (or have a sense of being) female or male without having female or male genetics and anatomy? For instance, how could a male ever completely know what it feels like to be a female, at least in those respects where males and females are biologically different? Suffice it to say that these highly contested metaphysical questions are a matter for debate within society, not a matter to be decided definitively by federal judges. As such, the district court's finding that "[g]ender identity is real," Doc.246 at 4, reflects a sweeping metaphysical assertion best left to the realm of politics and philosophy, not the courtroom.

detransitioners exist. Tr.81:23-82:14, 164:2-165:23 (Dr. Karasic); DX16 at 43; P.I. Tr.41:17 (testimony from a detransitioner).

As Plaintiffs' experts conceded during the trial, there isn't any "confirmatory laboratory or radiographic study for the diagnosis of gender dysphoria." Tr.400:7-14 (Dr. Antommaria). No "blood test," "X-ray," "MRI," "CT scan," "imaging of any kind," or "gene" can diagnose or establish the existence of gender dysphoria. Tr.114:15-115:4 (Dr. Karasic), Tr.189:14-16 (Dr. Shumer). And while only transgender individuals suffer from gender dysphoria, not every transgender individual has gender dysphoria; some transgender individuals have no distressing incongruence between their gender identity and biological sex. Tr.115:5-119:22 (Dr. Karasic). In other words, someone can be transgender but not have gender dysphoria. Tr.115:5-119:22 (Dr. Karasic).

It's hard to diagnose gender dysphoria for other reasons as well. Transgender individuals often suffer from other mental health issues, such as autism, anxiety, depression, and suicidality. Tr.108:11-111:11 (Dr. Karasic), 1053:4-1054:17 (Dr. Levine); DX16 at 173. Many factors can influence one's gender dysphoria, including environmental factors, such as social acceptance. Tr.136:16-137:5 (Dr. Karasic). Other conditions, such as body dysmorphic disorder, can also be confused with gender dysphoria. DX24 at 8.

At issue here are two treatments for the difficult-to-diagnose psychiatric condition of gender dysphoria: puberty blockers and cross-sex hormones. Puberty blockers, or GnRH agonists, suppress an adolescent's natural puberty. *E.g.*, DX24 at

12-17. Puberty blockers are then followed by cross-sex hormones—testosterone for biological females and estrogen for biological males—which make an individual undergo the opposite sex's puberty. *E.g.*, DX24 at 17-21. As high as 98% of gender-dysphoric patients who take puberty blockers go on to receive cross-sex hormones. Tr.578:14-20 (Dr. Olson-Kennedy); *see also* Tr.262:14-22 (Dr. Shumer).

These treatments come with significant health risks. Puberty blockers can cause bone-mineralization issues, compromise fertility (if puberty blockers are followed with cross-sex hormones), and have unknown effects on brain development. DX24 at 14. Cross-sex hormones could cause infertility. DX24 at 18. To be sure, these treatments aren't unique to gender dysphoria. Puberty blockers, for example, have been used to treat precocious puberty in minors, though the goal there is to restore endocrine levels to a normal range, not to stop a natural and age-appropriate release of hormones. Doc.246 at 19.

B. Two advocacy organizations are the primary proponents for these genderdysphoria treatments. The first is the World Professional Association for Transgender Health (also called WPATH). It publishes what it calls "standards of care" on treatments for gender dysphoria. DX16. The drafters of these so-called standards of care must be WPATH full members with a marked commitment to furthering transgender rights, Tr.100:18-101:5 (Dr. Karasic) (referring to DX16 at 250); DX17; and they need not be medical professionals; being a parent of a transgender child suffices. Tr.*100:16-21 (Dr. Janssen); DX16 at 250. WPATH is open about the limits and weaknesses of the evidence that purport

to support its treatment recommendations. Consider the following admissions:

- In the adolescent-treatment chapter: "[g]ender-diverse youth should fully understand the reversible, partially reversible, and irreversible aspects of a treatment, *as well as the limits of what is known about certain treatments (e.g., the impact of pubertal suppression on brain development*]]."DX16 at 63 (emphasis added).
- In the adolescent-treatment chapter: "[t]here is, however, limited data on the optimal timing of gender-affirming interventions as well as the long-term physical, psychological, and neurodevelopmental outcomes in youth." DX16 at 67.
- In the adolescent-treatment chapter: "[t]he potential neurodevelopmental impact of extended pubertal suppression in gender diverse youth has been specifically identified as an area in need of continued study." DX16 at 67.
- In the adult-assessment chapter: the "empirical evidence base for the assessment of" transgender and gender diverse adults "is limited." DX16 at 34-35.
- In the adult-assessment chapter: the "intervention-specific risks associated with the presence of specific physical conditions have not been well researched." DX16 at 40.
- In the hormone-therapy chapter: "[t]here are also major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility of" "patients." DX16 at 120.

The second organization is the Endocrine Society. It publishes clinical practice

guidelines on gender-dysphoria treatments, which WPATH co-sponsors, with several

WPATH members serving as contributors to the guidelines. DX24 at 1; Tr.124:11-

125:8 (Dr. Karasic). The guidelines themselves use the Grading of Recommendations,

Assessment, Development, and Evaluation (or GRADE) evidence-rating system.

DX24 at 1, 4-5. GRADE rates the evidence quality for a treatment recommendation:

evidence is either high, moderate, low, or very-low quality. DX24 at 4-5. With higher-

quality evidence comes more confidence that treatments will produce the intended result. Tr.346:4-14 (Dr. Antommaria); DX24 at 4-5. With low-quality evidence, or even very-low-quality evidence, such confidence is either limited or little. Tr.396:21-397:10 (Dr. Antommaria); DX24 at 4-5.

The Endocrine Society's clinical practice guidelines put forth twenty-eight recommendations on gender-dysphoria treatments. DX24 at 2-4. Three are backed by moderate-quality evidence, fourteen are backed by low-quality evidence, five are backed by very-low-quality evidence, and six are backed by no evidence at all. DX24 at 2-5. For example:

- Low-quality evidence backs the following: "[w]e suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty." DX24 at 3.
- Very-low-quality evidence backs the recommendation that "there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years," "even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years." DX24 at 3 (emphasis added).
- The recommendation that "clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment" is backed by no evidence at all. DX24 at 4.

Even beyond WPATH's standards of care and the Endocrine Society's clinical

practice guidelines, gender-dysphoria treatments are backed by limited data and studies.

Plaintiffs' experts concede as much:

• "Limited prospective outcome data exist regarding transgender and nonbinary youth receiving gender-affirming hormones." Tr.586:18-23 (Dr. Olson-Kennedy).

- "Evidence has been lacking from longitudinal studies that explore potential mechanisms by which gender-affirming medical care affects gender dysphoria and subsequent well-being." Tr.586:24-587:5 (Dr. Olson-Kennedy).
- "There are no large-scale studies examining mental health among transgender and nonbinary youth who receive gender-affirming hormone therapy." Tr.588:14-589:4 (Dr. Olson-Kennedy).
- "Knowledge about the effects of puberty suppression on the developing brain of transgender youth is limited." Tr.*38:16-19 (Dr. Edmiston).

The studies relied on by Plaintiffs are also exceedingly weak, often backed by online-survey data, Tr.589:8-19 (Dr. Olson-Kennedy), small sample sizes, Tr.*37:11-39:7 (Dr. Edmiston), a lack of long-term data, Tr.*37:11-39:7 (Dr. Edmiston), and a lack of randomized-sampling data, Tr.143:13-15, 146:3-147:18 (Dr. Karasic) (discussing whether high-quality, randomized gender-dysphoria studies are feasible). In other words, they lack key elements that are necessary to ensure the reliability of a study.

C. States aren't alone in worrying about gender-dysphoria treatments. Other jurisdictions share their concern:

Sweden: Sweden's National Board of Health and Welfare determined that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments," and determined that "[t]reatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered" only "*in exceptional cases.*" DX8 at 3 (emphasis added).

Finland: Finland's Council for Choices in Healthcare urged extreme caution when providing gender transitioning services to children. It says that "[t]he reliability of

the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." DX9 at 7.

United Kingdom: The U.K. National Institute of Health and Care Excellence reviewed studies that purport to support hormone therapy for gender-dysphoric minors. DX11, DX12. The institute concluded that "all small, uncontrolled observational studies" for puberty blockers "are of very low certainty using modified GRADE" and the studies "reported physical and mental health comorbidities and concomitant treatments very poorly." DX11 at 13. As for cross-sex hormones, the institute stated that evidence of their effectiveness was also of a "very low" quality. DX12 at 4. The U.K.'s Cass Review, which reviewed gender-identity services in the country, stated that there's a "lack of consensus" and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response. DX10 at 16.

France: France's Académie Nationale de Médecine concludes that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [of younger people presenting with gender dysphoria] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." DX13 at 1.

Australia & New Zealand: The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of evidence" on the outcomes of those presenting with gender dysphoria. DX14 at 1.

U.S. Federal Government: Within the past two years, the federal government has taken action on treatments for gender dysphoria. On March 2, 2022, the U.S. Department of Health and Human Services issued a notice and guidance on care. DX1. The Department stated that it "stands with transgender and gender nonconforming youth and their families—and the significant majority of expert medical associations—in unequivocally stating that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health." DX1 at 1. It followed the notice and guidance with a Department-issued factsheet that touted the benefits of hormone therapy and surgeries as effective treatments for minors with gender dysphoria. DX2. The Department of Justice then threatened States that limited access to such treatments. DX3.

The federal government's 2022 position was an apparent departure from its prior position. In 2016, the Centers for Medicare and Medicaid Services declined to make a determination "on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population." DX4 at 1. It reached that decision "[b]ased on an extensive assessment of the clinical evidence," concluding "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." DX4 at 48. That 2016 determination memorandum has never been superseded by another. In 2020, the Department of Health and Human Services declined to "take a definitive view on any of the medical questions raised" "about treatments for gender dysphoria"—due to the "lack of high-quality scientific evidence supporting" the treatments and due to the reliance on an "*advocacy group* (WPATH) rather than on independent scientific fact-finding." Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37,160, 37,186-98 (Jun. 19, 2020) (emphasis added).

Factual History: State Actions Before Lawsuit

A. Against this backdrop, the State of Florida decided to assess for itself whether certain gender-dysphoria treatments were supported by quality science. Brackett Depo.91:20-24. The Florida Department of Health and the Florida Agency for Health Care Administration (or AHCA) were tasked with conducting an independent, evidence-based review of the treatments for gender dysphoria. Brackett Depo.90:5-11-91:1 (AHCA was tasked to "take a" "detailed look at the available medical evidence, or at least the peer-reviewed literature, and to see what it says.").

The Florida Department of Health acted first. On April 20, 2022, it released a factsheet in response to the Department of Health and Human Services' factsheet. Notably, the Florida Department of Health concluded that minors "should not be prescribed puberty blockers or hormone therapy" and that "reassignment surgery should not be a treatment option for children or adolescents." DX5. It based this

conclusion on the "low-quality evidence" supporting such treatments and the international consensus on this issue. DX5.

AHCA's then-Secretary Marstiller subsequently directed Deputy Secretary Wallace to begin the Generally Accepted Professional Medical Standards process—or GAPMS process—to assess whether the State's Medicaid program should reimburse providers of certain treatments for gender dysphoria. DX6 at 48. This process is prescribed in Florida's administrative code, Rule 59G-1.035, and asks whether a health service is consistent with reliable scientific evidence. The State considers several sources of information: evidence-based clinical practice guidelines, medical reports and articles, and recommendations by subject-matter experts, to name a few. Tr.1190:5-11 (Brackett); *see also* Fla. Stat. § 409.905(9) (barring payment for services that are "clinically unproven" or "experimental").

The GAPMS process to evaluate gender-dysphoria treatments began with no result in mind. Brackett Depo.90:12-16. It was to be an independent review. Ann Dalton, the AHCA Bureau Chief of Medicaid Policy, recommended that Matt Brackett draft the GAPMS Report. Tr.1155:18-22, 1159:15-18 (Dalton). She also recommended that two other employees, Devona Pickle, an AHCA program director, and Nai Chen, a pharmacist, assist Mr. Brackett. Tr.1159:15-18 (Dalton).

According to Ms. Dalton, Mr. Brackett would be a good drafter, because he "had a lot of historical knowledge with the GAPMS process" and he "could work independently and would deliver a really good product in a short amount of time." Tr.1159:19-1161:9 (Dalton). Ms. Dalton stated that Ms. Pickle had "been with" AHCA "for a long time," "gives good direction," and she's "a great manager." Tr.1161:10-18 (Dalton). Ms. Dalton admitted that she hadn't worked with Mr. Chen as much as other members of the team, but she knew all three to have been part of the Canadian Prescription Drug Importation Program, a multifaceted and important State policy initiative. Tr.1161:19-1162:1, Tr.1158:25-1159:14 (Dalton).

Work then began on the GAPMS Report. Tr.1195:24-1196:7 (Brackett). Mr. Brackett drafted the GAPMS Report, with Ms. Pickle and Mr. Chen providing secondary assistance. Tr.1197:8-10 (Brackett). He "comb[ed] the literature" and started "gathering the materials and start[ed] reading them," "letting the research guide" him. Tr.1196:1-17 (Brackett).

Then he started drafting. Tr.1196:18-20 (Brackett). Alone. Tr.1197:3-7, Tr.1198:12-16 (Brackett). He considered Medicaid programs in different States, approaches in Western European countries, WPATH and the Endocrine Society treatment recommendations, and peer-reviewed studies. Tr.1198:25-1202:9 (Brackett). Mr. Brackett was generally aware of prior GAPMS reports—two being drafts—that dealt with gender-dysphoria treatments, but he opted not to read them so he could "take a look at the evidence with fresh eyes" and not let "any other analyst" influence his decision. Tr.1207:15-1208:10 (Brackett).

AHCA also hired Dr. Miriam Grossman and Dr. Andre Van Mol to assist Mr. Brackett. It's not unusual for AHCA to hire outside consultants. Tr.1216:3-14 (Brackett). Both provided Mr. Brackett with articles and resources, but neither influenced or affected Mr. Brackett's ultimate conclusions. Tr.1202:13-1204:22 (Brackett). Nor did they write any portion of the GAPMS Report. Tr.1202:13-1204:22 (Brackett).

At the same time Mr. Brackett was drafting the GAPMS Report, AHCA asked medical professionals to provide additional perspective, such as a review of the evidence supporting the excluded treatments. Brackett Depo.131:1–132:19. The experts were Dr. Romina Brignardello-Petersen, Dr. James Cantor, Dr. Quentin Van Meter, Dr. Patrick Lappert, and Dr. G. Kevin Donovan. DX6 at 3.

Dr. Romina Brignardello-Petersen's report is notable. She's a Canadian researcher with a Ph.D. in clinical epidemiology and health care research, who conducted a systematic review of relevant medical studies through April 2022. DX6 at 52. That review could have cut against Mr. Brackett's review of the literature. But after reviewing "the best available evidence regarding the effects of" gender-dysphoria treatments, she "found low and very low certainty evidence suggesting improvements in gender dysphoria, depression, anxiety, and quality of life." DX6 at 55. AHCA didn't make substantive edits to the experts' reports; at most, style and grammar edits were made. Brackett Depo.145:4-16.

In the end, Mr. Brackett concluded that, in relevant part, "[e]vidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality." DX6 at 39. He also concluded that "[e]vidence suggesting that cross-sex hormones provide benefits to mental health and prevents [sic] suicidality is low or very low quality. Rather, evidence shows that cross-sex hormones cause multiple irreversible physical consequences as well as infertility." DX6 at 39. These treatments, Mr. Brackett concluded, are experimental. DX6 at 39.

B. AHCA finalized the GAPMS Report on June 2, 2022. Tr.1211:2-5 (Brackett). The State's Administrative Procedures Act requires that "each agency statement of general applicability that implements, interprets, or prescribes law or policy" be "adopted pursuant to the requirements of s. 120.54." Fla. Stat. § 120.52(16), (20). AHCA thus initiated the rulemaking process to exclude puberty blockers, cross-sex hormones, and gender-reassignment surgeries as treatments for gender dysphoria. Rulemaking can "move very quickly," and because the GAPMS Report was completed, and DOJ had already threatened related litigation against the State, the process moved along. Brackett Depo.170:4-171:5.

AHCA solicited public comments as part of the process. It received around 600 comments, and AHCA read every one. Brackett Depo.189:12-16. Particular attention was given to comments from Yale faculty, the Endocrine Society, and the American Academy of Pediatrics. Tr.1213:23-1214:16 (Brackett).

AHCA also held a public rulemaking hearing on July 8, 2022. Tr.1212:7-1213:20 (Brackett). There the agency heard impassioned public testimony from all sides of the issue, Tr.1213:17-20 (Brackett), and AHCA employees Jason Weida, Shena Grantham,

and Mr. Brackett, served as panelists, Tr.1213:2-5 (Brackett). Dr. Van Mol, Dr. Grossman, and Dr. Van Meter also served as panelists for good measure. Tr.1213:6-16 (Brackett). At this point, the State's position on the excluded treatments expressly conflicted with the federal government's position. The State finalized what became Rule 59G-1.050(7), which became effective August 21, 2022. It states:

(7) Gender Dysphoria.

(a) Florida Medicaid does not cover the following services for the treatment of gender dysphoria:

1. Puberty blockers;

2. Hormones and hormone antagonists;

3. Sex reassignment surgeries; and

4. Any other procedures that alter primary or secondary sexual characteristics.

(b) For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

Procedural History

A. Plaintiffs, two adults—August Dekker and Brit Rothstein—and two minors—S.D. and K.F.—sued the AHCA Secretary and AHCA, and sought to enjoin the enforcement of Rule 59G-1.050(7). Doc.1. Plaintiffs alleged that the rule violates the Equal Protection Clause, the Affordable Care Act, and the Medicaid Act. Doc.1.

Plaintiffs then moved for a preliminary injunction, which the district court denied. Doc.64. Sidestepping the constitutional issues, Doc.64 at 5-6, the district court relied on a Medicaid case from the old-Fifth Circuit, *Rush v. Parham*, 625 F.2d 1150 (5th Circ. 1980). Doc.64 at 4. According to the district court, *Rush* provided the controlling

question: "whether, based on current medical knowledge, the state's determination that" certain gender-dysphoria "treatments are experimental is reasonable." Doc.64 at 4. The district court noted that Plaintiffs didn't move for a preliminary injunction on their Medicaid claims, but it nevertheless held that they didn't "show[] a likelihood of success on the merits on the constitutional and ACA claims." Doc.64 at 6. Plaintiffs also failed to show irreparable harm because, in part, they failed to provide the district court with their medical records. Doc.64 at 6.

B. Realizing that Plaintiffs would rely on WPATH, the Endocrine Society, and medical organizations' positions on treatments for gender dysphoria, the State of Florida sought documents from the organizations, and corporate depositions from WPATH, the Endocrine Society, and the American Academy of Pediatrics. In particular, the State wanted to know *why* the organizations support puberty blockers and cross-sex hormones as treatments for gender dysphoria, and *how* the organizations reached this position.

The organizations resisted and sought to quash document and deposition subpoenas in the D.C. District Court. *In re Subpoenas Served on AAP*, 23-mc-00004 (D.D.C. 2023). The D.C. District Court ultimately ordered the organizations to produce documents and ordered WPATH, the Endocrine Society, and the American Academy of Pediatrics to sit for corporate depositions. The organizations moved for a stay with the district court, which the court denied. The organizations then moved for a stay with the D.C. Circuit, which it granted. 23-7025 (D.C. Cir. 2023). The State was thus prevented from obtaining additional documents and deposition testimony to test the credibility and reliability of these organizations' public positions on the treatment of gender dysphoria.

That decision had spillover effects on discovery. The State took the deposition of Dr. Kale Edmiston, one of Plaintiffs' experts. In his expert report, he stated that his "opinions are based on," in part, "my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8." Doc.120-27 ¶ 13.

Yet, when the State deposed Dr. Edmiston and tried to ask him about his authorship of a WPATH standards-of-care chapter—which formed part of his expert opinion, Doc.120-27 ¶ 13—Plaintiffs' counsel instructed Dr. Edmiston to not answer these questions, to the extent that the answers wouldn't "violate" the stay granted by the D.C. Circuit Court or violate a heretofore unknown confidentiality agreement imposed on WPATH standards-of-care authors. Doc.120-36 18:5-48:7 (Dr. Edmiston deposition transcript). Specifically, Plaintiffs' counsel contended that the State:

[C]an't go into the issues that are currently addressed in the [D.C. Circuit Court] order that stays the discovery relating to internal processes of WPATH. So as long as it's not going into that, it's fine just depending on the question, but I guess that's the concern that I have is just not to violate that court order or to violate any nondisclosure agreement. You can ask anything that's about public information but nothing internal or private to WPATH that would violate that court order or require Dr. Edmiston to violate his confidentiality agreement. Doc.120-36 19:13-20:1.³

C. The case then proceeded to a bench trial. Plaintiffs solicited testimony from several expert witnesses: Dr. Dan Karasic, a psychiatrist and WPATH member, Tr.18, 96:4-5; Dr. Daniel Shumer, an endocrinologist, Tr.174; Dr. Loren Schechter, a surgeon and WPATH member, Tr.291, 294:7-11; Dr. Armand Antommaria, a pediatrician, Tr.325; Dr. Kellan Baker, an expert on insurance coverage, Tr.461; Dr. Johanna Olson-Kennedy, a physician and WPATH member, Tr.520, 575:2-3; Dr. Kale Edmiston, a neuroscientist and former WPATH member, Tr.*4, 39:14-17; and Dr. Aron Jannsen, a psychiatrist and WPATH member, Tr.*66, 70:1-2. Despite Plaintiffs' stance in discovery, their WPATH-affiliated experts testified about their experiences with WPATH and drafting the standards of care. E_{cg} , Tr.*39:14-45:15 (Dr. Edmiston). Plaintiffs also solicited testimony from Jeffrey English, a former AHCA employee, Tr.410; and Kim Hutton, an individual who once interacted with one of the State's experts, Tr.*46.

The adult Plaintiffs, August Dekker and Brit Rothstein, testified. Jane Doe (S.D.'s mother) and Jade Ladue (K.F.'s mother) also testified.

August Dekker: August Dekker suffers from rheumatoid arthritis, a history of sexual assault, PTSD, a major depressive disorder, and anxiety. Tr.650:11-12, 658:15-

³ Plaintiffs also sought the deposition of Jason Weida, the current AHCA Secretary. The State sought a protective order, but the district court compelled his testimony. Doc.118. The State sought a writ of mandamus from this Court, but this Court denied that request. 23-11126 (11th Cir. 2023).

23, 659:1-2, 659:25-660:2, 661:1-10. He doesn't have a relationship with his mother. Tr.651:12-16, 652:2-6. He also suffers from gender dysphoria.⁴

Mr. Dekker was informed about risks of cross-sex hormone treatments: a decrease in fertility, baldness, cardiac issues, higher blood pressure, a decrease in organ function, kidney and liver issues. Tr.662:23-663:4. This risk-related conversation lasted around 25 minutes. Tr.675:17-24.

Regarding his top surgery, he obtained approval letters from two individuals, one of which was a medical intern, with ten hours of gender dysphoria training. Tr.675:25-676:10. Mr. Dekker didn't recall whether the intern was supervised by anyone. Tr.678:13-679:6. He ended up getting the top surgery. Tr.672:24-25.

Brit Rothstein: Brit Rothstein suffers from anxiety, depression, and autism. Tr.628:1-4, 645:15-25. His mother was not supportive. Tr.624:11-15. He has hypertension and only one kidney. Tr.631:15-632:2. He also suffers from gender dysphoria. A non-MD (and hypnotherapist) diagnosed him with gender dysphoria. Tr.627:15-25, 646:1-647:5.

He was informed that puberty blockers could "stop[] my period and stop[] chest growth from continuing," and could lead to "hot flashes" and "bone density" issues. Tr.634:1-9. He was also informed that cross-sex hormones have "effects like a deeper voice, body fat redistribution, facial hair growth," "stopping [] puberty—stopping the

⁴ For sake of consistency with the trial record, this brief uses the pronouns Plaintiffs' counsel used before the district court.

period and chest growth," "increased blood pressure," "increased" "blood cholesterol," and fertility issues. Tr.635:4-636:3. He didn't recall whether he was informed about the specific affects of cross-sex hormones on his solitary kidney. Tr.647:22-648:2.

Susan Doe: Susan Doe's adopted mother, Jane Doe, testified. Jane explained that Susan suffers from anxiety, depression, and ADHD. Tr.602:4-10, 616:21-617:23. Susan's birth mother struggled with drug abuse during pregnancy and neglected Susan after her birth. Tr.616:21-617:23. Susan also suffers from gender dysphoria. Jane and Susan were told that gender-dysphoria treatments might carry risks of bone-density issues and permanent infertility. Tr.617:25-618:8.

K.F.: Jade Laude, K.F.'s mother, testified. K.F. suffers from anxiety. Tr.689:10-690:15, 704:9-15. K.F. also suffers from gender dysphoria. Jade Laude and K.F. were informed that gender-dysphoria treatments could lead to osteoporosis, bone-density issues, infections, and the body rejecting the treatments. Tr.699:18-24.

D. The State relied on experts as well: Dr. Paul Hruz, an endocrinologist, Tr.137; Dr. Stephen Levine, a psychiatrist and former WPATH member, Tr.966, 975:25-978:1; Dr. Patrick Lappert, a surgeon, Tr.1058; Dr. Kristopher Kaliebe, a psychiatrist, Tr.1095; and Dr. Sophie Scott, a British neuroscientist, Tr.1267. Ms. Dalton, Tr.1155, and Mr. Brackett, Tr.1187, testified about the GAPMS process.

E. While the bench trial was proceeding, the Florida Legislature passed, and the Governor signed into law, SB 254. The bill addressed gender-dysphoria treatments. In relevant part, section 3 states that:

286.31 Prohibited use of state funds.-

 (1) As used in this section, the term "governmental entity" means the state or any political subdivision thereof, including the executive, legislative, and judicial branches of government; the independent establishments of the state, counties, municipalities, districts, authorities, boards, or commissions; and any agencies that are subject to chapter 286.
(2) A governmental entity, a public postsecondary educational institution as described in s. 1000.04, the state group health insurance program, a managing entity as defined in s. 394.9082, or a managed care plan providing services under part IV of chapter 409 may not expend state funds as described in s. 215.31 for sex-reassignment prescriptions or procedures as defined in s. 456.001.

Section 4 defines "sex-reassignment prescriptions or procedures" to be puberty

blockers and cross-sex hormones for the treatment of gender dysphoria.⁵

Plaintiffs orally amended their complaint to challenge 59G-1.050(7) and section

3 of SB 254. Doc.233. Both are challenged under the Equal Protection Clause, the

Affordable Care Act, and the Medicaid Act. Doc.233. During trial, Plaintiffs didn't introduce evidence specific to SB254—for example, the record includes no legislative transcripts and no evidence of legislative history.

F. The district court entered judgment in favor of Plaintiffs. Doc.246. It held that S.D. and K.F. had standing to challenge "Florida's denial of Medicaid payment for puberty blockers," and that all four Plaintiffs had standing to challenge the denial of payment for cross-sex hormones. Doc.246 at 13. No Plaintiff had standing to challenge the denial of payment for surgeries. Doc.246 at 13-14.

⁵ Other SB 254 provisions are challenged in a different case before this Court, *Doe v. Surgeon General*, No. 23-12159.

Adhering to *Rush*, the district court concluded that "based on current medical knowledge," the State unreasonably determined that puberty blockers and cross-sex hormones to treat gender dysphoria are experimental. Doc.246 at 15. The district court relied on WPATH's standards of care, the Endocrine Society's clinical practice guidelines, and Plaintiffs' experts testimony about their clinical experience. Doc.246 at 16-21, 26.

Instead of sidestepping the constitutional and Affordable Care Act issues, the district court waded into them. It held that the challenged laws were sex-based and transgender-based discrimination, which subjected the laws to heightened constitutional scrutiny. Doc.246 at 26-36. The district court then marched through each State interest and called them all pretextual—the State's concern for low-quality evidence, concern about treatment risks, concern about bias in the medical organizations, concern about malpractice, and concern about the continuation of treatment, to name a handful. Doc.246 at 38-51. The district court assumed bad-faith action whenever it could.⁶

⁶ E.g., Doc.246 at 9 ("The new GAPMS process was, from the outset, a biased effort to justify a predetermined outcome, not a fair analysis of the evidence."); Doc.246 at 10 ("AHCA conducted a well-choreographed public hearing that was an effort not to gather facts but to support the predetermined outcome."); Doc.246 at 38 ("The rule and statute at issue were motivated in substantial part by the plainly illegitimate purposes of disapproving transgender status and discouraging individuals from pursuing their honest gender identities."); Doc.246 at 44 (noting that one state legislator referred to transgender individuals as "mutants" and "demons"); Doc.246 at 37 ("Dissuading a person from conforming to the person's gender identity rather than to the person's natal sex is not a legitimate state interest."); Doc.246 at 37 (the State disapproves of

In the end, the district court found for Plaintiffs on their Equal Protection, Affordable Care Act, and Medicaid Act claims. Doc.246 at 51-52.

Standard of Review

"In reviewing a judgment following a bench trial," this Court reviews "de novo both conclusions of law and the application of the law to the facts," and reviews "findings of fact for clear error." *League of Women Voters of Fla. Inc. v. Fla. Sec'y of State*, 66 F.4th 905, 921 (11th Cir. 2023). "The facts found by a district court are 'clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed."" *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1246 (11th Cir. 2002) (quoting *Univ. of Ga. Athletic Ass'n v. Laite*, 756 F.2d 1535 (11th Cir. 1985)).

Summary of the Argument

Federal district courts don't get to make medical policy judgments. Those judgments belong to the State of Florida through the Florida Legislature, the Governor of Florida, and AHCA. Courts presume that States act in good faith. *League of Women Voters*, 66 F.4th at 923. States are entitled to great deference, and their laws a strong presumption of validity. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). Yet the district court afforded the State neither a presumption of good faith nor

transgender status, which "was a substantial motivating factor in enactment of the challenged rule and statute").

deference. The district court instead seized the State's medical-policymaking mantel for itself.

That's error, as this Court recently decided in *Eknes-Tucker v. Gov., of the State of Ala.*, No. 22-11707, 2023 U.S. App. LEXIS 21942 (11th Cir. Aug. 21, 2023). In that case, this Court held that gender-dysphoria-treatment regulations are subject to rationalbasis review, not heightened scrutiny. Such regulations aren't transgender-based discrimination, either. *Id.* at *43. And pretext, on this record, can't be proven. *See Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252 (1977).

The district court's statutory conclusions fail as well. The challenged laws don't violate the Affordable Care Act; they aren't sex-based regulations. *Adams v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 811 (11th Cir. 2022) (en banc). And the Medicaid Act isn't violated; under *Rush*, the State reasonably determined that puberty blockers and cross-sex hormones, as gender-dysphoria treatments, are experimental.

As such, this Court should reverse the district court's final judgment.

Argument

I. SB 254 and Rule 59G-1.050(7) Are Constitutional Under the Equal Protection Clause.

The district court's constitutional analysis committed three errors. First, it didn't provide the State with a presumption of good faith and didn't give the challenged laws any presumption of validity. Second, the district court wrongly subjected the laws to heightened review, instead of rational basis review. Third, the district court's pretext analysis is legally deficient.

A. It's blackletter law that State "health and welfare laws" are "entitled to a strong presumption of validity" and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests." *Dobbs*, 142 S. Ct. at 2284 (quotation marks omitted). Regulations on gender-dysphoria treatments are health and welfare laws. *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *40-41. They are also entitled to a presumption of good faith. *League of Women Voters*, 66 F.4th at 923. It's error not to afford that presumption. *League of Women Voters of Fla., Inc. v. Fla. Sec'y of State*, 32 F.4th 1363, 1373-74 (11th Cir. 2022) (per curiam) (stay panel).

Here, the district court afforded no presumption of validity or presumption of good faith. When evaluating the State's governmental interests—preventing citizens from receiving low-quality-backed treatments with serious medical consequences, to name a few—the district court didn't defer to the State.⁷ Instead, the district court made

⁷ From the district court: Doc.246 at 40-41 ("When facing a binary decision to use or not use GnRH agonists or hormones, a reasonable decisionmaker would consider the evidence on the yes side, as well as the weaker evidence on the no side."); Doc.246 at 43 ("Risks attend many kinds of medical treatment, perhaps most."); Tr.1369:20-1370:1 ("When you have someone who may need treatment, the decision whether to get treatment or not is going to be made because it has to be made at that point. So who's going to make the decision? Is it going to be the parent and child in consultation with a doctor who does this all the time and knows all about it or is the decision going to be made by the legislature and Governor?"); Tr.1355:17-20 ("Why is it that the State of Florida—that the Legislature and the Governor get to decide the medical care that an individual gets when even your own expert says this kind of care is

its own policy judgments based on WPATH and the Endocrine Society's perspective as the benchmark. Doc.246 at 16.

The district court assumed bad faith whenever it could. For example, it concluded that the "new GAPMS process was, from the outset, a biased effort to justify a predetermined outcome, not a fair analysis of the evidence." Doc.246 at 9. Its only evidence: that Mr. Brackett "testified he did not know the preferred outcome" of the GAPMS process. Doc.246 at 9 n.21. That's it.

The district court stated that "AHCA conducted a well-choreographed public hearing." Doc.246 at 10. Its evidence: none cited. The district court also stated that the State's motivation in enacting the challenged laws isn't a "desire to achieve the best possible medical treatment" for gender-dysphoric citizens. Doc.246 at 26. Its evidence: none cited.

B. *Eknes-Tucker* further confirms that the district court erred in concluding that the challenged laws are subject to heightened sex-based scrutiny. No. 22-11707, 2023 U.S. App. LEXIS 21942, at *45-58. The Equal Protection Clause affords heightened scrutiny to laws that make distinctions based on immutable characteristics like race, ethnicity, or national origin. *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality op.). Biological sex triggers heightened scrutiny because it too is an immutable characteristic. *Adams*, 57 F.4th at 807-08. But biological sex isn't the same as gender

sometimes needed?"); Tr.1374:10-12 ("Why isn't the solution to that imposing better standards rather than prohibiting the treatment?").

identity or transgender status; gender identity and transgender status are mutable characteristics as this Court and Plaintiffs' experts have recognized. *Id.*; Tr.165:18-23 (Dr. Karasic); *see also* Tr.81:23-82:14, 164:2-165:17 (Dr. Karasic). So the challenged laws can't be subject to heightened scrutiny based on some immutable characteristic theory. *L.W. v. Skrmetti*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *59-60 (6th Cir. Sept. 28, 2023) ("*L.W. II*"). Nor do the challenged laws discriminate based on sex. The relevant distinction is one based on a diagnosis for gender dysphoria.

The district court disagreed. It concluded that the challenged laws discriminate on the basis of sex. Doc.246 at 30. "If one must know the sex of a person to know whether or how a provision applies to the person," the district court stated, "the provision draws a line based on sex." Doc.246 at 30. The district court explained its reasoning:

Consider an adolescent Medicaid patient, perhaps age 16, that a physician wishes to treat with testosterone. Under the challenged [laws], is the treatment covered by Medicaid? To know the answer, one must know the adolescent's sex. If the adolescent is a natal male, the treatment is covered. If the adolescent is a natal female, the treatment is not covered. This is a line drawn on the basis of sex, plain and simple.

Doc.246 at 30-31. From this, the district court stated "that the reason for the treatment—the diagnosis—is different for the natal male and natal female. Indeed it is. But this does not change the fact that this is differential treatment based on sex." Doc.246 at 31. Thus, according to the district court, heightened scrutiny applies. The district court erred. Badly. Start with the basis for the distinction actually made under Florida law: a psychiatric diagnosis of gender dysphoria. Both biological males and biological females can be diagnosed with it. *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *50-51. The challenged laws apply to both biological sexes, thereby precluding any claim of sex-based discrimination. *Id.*; *cf. Adams*, 57 F.4th at 810 (the challenged bathroom policy divided students based on biological sex, thereby subjecting it to heightened scrutiny).

Consider puberty blockers. Under the challenged laws, neither a biological male nor a biological female can obtain them to treat gender dysphoria. There's no sex-based discrimination; the challenged laws apply equally to both sexes. The same is true with cross-sex hormones. Neither a biological male nor a biological female can obtain them to treat gender dysphoria. *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *50-51; *L.W. v. Skrmetti*, 73 F.4th 408, 419 (6th Cir. 2023) (stay panel) ("*L.W. P*").

The district court tried to get around this by contending that to know whether providing testosterone is legal, "one must know the adolescent's sex. If the adolescent is a natal male, the treatment is covered. If the adolescent is a natal female, the treatment is not covered." Doc.246 at 30-31. That's not right.

Under Florida law, the natal female remains free to receive testosterone so long as it's not to treat the incongruence between her biological sex and her perception of herself—so long as it's not to treat gender dysphoria. The diagnosis is what matters. It makes no difference that biological males can't obtain estrogen injections to treat gender dysphoria, and biological females can't obtain testosterone injections to treat gender dysphoria. "The reality that the" hormones "correspond to sex in these understandable ways and that" the State "regulates them does not require skeptical scrutiny." *L.W. I*, 73 F.4th at 419; *see also Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *51.

To put a point on it: the challenged laws pertain to "sex-transition treatments," "regardless of sex." *L.W. II*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *42. The laws don't "prefer one sex over the other"; they don't "include one sex and exclude the other"; they don't "bestow benefits or burdens based on sex"; and they don't "apply one rule for males and another for females." *Id.* at *42-43. In short, the laws aren't based on sex.

C. The district court held that, in addition to sex-based discrimination, the challenged laws discriminate based on transgender status and are thus subject to heightened scrutiny. Doc.246 at 31. It explained its reasoning:

To confirm this, consider a Medicaid-eligible child that a physician wishes to treat with GnRH agonists to delay the onset of puberty. Is the treatment covered? To know the answer, one must know whether the child is [nontransgender] or transgender. The treatment is covered if the child is [nontransgender] but not if the child is transgender, because the [challenged laws] exclude coverage of GnRH agonists only for transgender children, not for anyone else. The theoretical but remote-to-the-point-ofnonexistent possibility that a child will be identified as transgender before needing GnRH agonists for the treatment of central precocious puberty does not change the essential nature of the distinction. Doc.246 at 32. The district court then cited United States v. Carolene Products Co., 304 U.S. 144 (1938), and City of Cleburne v. Cleburne Living Center, 473 U.S. 432 (1985), as bases to hold that transgender status is subjected to heightened scrutiny. Doc.246 at 32-33. In particular, the district court likened racial discrimination to discrimination on the basis of transgender status and concluded (without any factual basis or record citations) that transgender individuals lack political access and suffer from "widespread private opprobrium." Doc.246 at 33-34.

This Court effectively foreclosed the district court's conclusion when it said the following in two recent cases: "we have grave 'doubt' that transgender persons constitute a quasi-suspect class." *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *55 (quoting *Adams*, 57 F.4th at 803 n.5). This Court even cited *City of Cleburne* to reach that conclusion. *Adams*, 57 F.4th at 803 n.5. This Court went on to say that "the regulation of a course of treatment that, by the nature of things, only transgender individuals would want to undergo would not trigger heightened scrutiny unless the regulation is a pretext for invidious discrimination against such individuals." *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *55.

More fundamentally, the district court again ignored that the challenged laws make a distinction based on a diagnosis, not transgender status. It bears emphasis that not every transgender individual suffers from gender dysphoria. Tr.115:5-119:22 (Dr. Karasic). And, under the challenged Florida provisions, both transgender and nontransgender individuals *can* obtain puberty blockers and cross-sex hormones, just not to treat gender dysphoria. Just as in *Geduldig v. Aiello*, where "men and women were treated the same," because "nobody had health coverage for pregnancy," Doc.246 at 35 (referencing *Geduldig v. Aiello*, 417 U.S. 484 (1974)), here too non-transgender and transgender individuals are treated the same because nobody can obtain puberty blockers and cross-sex hormones to treat gender dysphoria.

The district court's puberty blockers example is unavailing as well. In fact, the court acknowledged the fatal flaw in its own argument: a transgender individual can obtain puberty blockers to treat precocious puberty under the challenged laws. Implicit here is a recognition that the challenged laws turn on the diagnosis, not transgender status. The court attempted to minimize this scenario by calling it a "theoretical" and "remote-to-the-point-of-nonexistent possibility," citing no record evidence in the process. Doc.246 at 32. The fact remains, though, that the challenged laws don't turn on transgender status.

The district court also tried to distinguish *Dobbs v. Jackson Women's Health Organization.* Doc.246 at 35. According to the district court, unlike the abortion regulation in *Dobbs*, this case:

involves treatments that all individuals can undergo; the state has simply chosen to make the treatment legal for some and illegal for others, depending on sex or transgender status. The *Dobbs* statement about procedures only one sex can undergo is simply inapplicable—and would not help the defendants anyway, because this case involves invidious discrimination against transgender[individuals].

Doc.246 at 36.

Again, the district court gets things wrong. The challenged laws make a distinction based on a medical diagnosis, not transgender status. And it again bears emphasis that not every transgender individual suffers from gender dysphoria. Tr.115:5-119:22 (Karasic).

Nor do *Carolene Products* and *City of Cleburne* elevate transgender status to a protected status. The district court is wrong that racial discrimination is like transgender discrimination. To reiterate, the Equal Protection Clause provides greater protections for immutable characteristics. *Adams*, 57 F.4th at 807-08. Race is immutable. Biological sex is also immutable. Transgender status isn't. Even the experts admit this; after all, detransitioners exist. Tr.81:23-82:14, 164:2-165:17 (Dr. Karasic); P.I. Tr.41:17-45:6.

The district court also failed to cite any factual bases to support its conclusion. It couldn't. Transgender individuals aren't a politically powerless group. "The President of the United States," the Department of Health and Human Services, and "the Department of Justice support the Plaintiffs." *L.W. II*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *60; *see also E.g.*, DX1, DX2, DX3. "A national anti-discrimination law, Title VII, protects transgender individuals in the employment setting." *L.W. II*, No. 23-5600, No. 23-5600, No. 23-5609, at *60. "The major medical organizations support the Plaintiffs." *Id.* at *60; *see also* Doc.246 at 18. And "the only large law firms to make an appearance in the case all entered the controversy in support of the Plaintiffs. *These are not the ballmarks of a skewed or unfair*

political process." *L.W. II*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *60 (emphasis added).

D. Nor are the laws pretext for invidious discrimination. The district court concluded differently. In its level-of-scrutiny-application analysis, the district court points solely to a Florida Department of Health fact sheet that states, in part, that minors shouldn't socially transition. Doc.246 at 37. Later on, in a different section, the district court mentions some statements from a single member of the Florida House. Doc.246 at 44. That's it.

But the Florida Department of Health's recommendation that gender-confused children—the majority of whom grow out of any dysphoria—should not be made to socially transition to the opposite sex as a treatment for such dysphoria is not alone evidence of invidious discrimination. In any event, the district court did not and cannot explain how a different State agency's fact sheet or a single legislator's statements can speak for the Florida House, the Florida Senate, the Governor, and AHCA. This kind of evidence is insufficient to satisfy the *Arlington Heights* test for invidious discrimination—to overcome the good faith to which political actors are entitled. *See League of Women Voters*, 66 F.4th at 932 (holding that a statement from one legislator isn't dispositive of discriminatory intent).

Even if the district court considered the *Arlington Heights* factors, they wouldn't support a showing of pretextual discrimination. Putting AHCA's rule aside, Plaintiffs didn't introduce, and the district court never considered, any *Arlington Heights* evidence

related to SB 254. The bill was passed during the bench trial, and Plaintiffs didn't introduce any bill-specific evidence, such as the sequence of events leading up to its passage, its procedural departures, or its substantive departures from the usual legislative process. *See generally GBM v. Sec'y of Ala.*, 992 F.3d 1299, 1321 (11th Cir. 2021). That evidence would be introduced for the first time on appeal.

All told, there's no evidence of pretext.

E. Rational basis thus applies. Under this level of review, the law is entitled to a *strong* presumption of validity. *FCC v. Beach Comm'ns*, 508 U.S. 307, 314-15 (1993). The State need not "articulate its reasons for enacting" the law; instead, the law can be based on "rational speculation unsupported by evidence or empirical data." *Id.* at 315. Those "attacking the rationality of the" challenged law have "the burden to negative *every* conceivable basis which might support it." *Id.* (emphasis added).

Rational basis is easily satisfied. *Eknes-Tucker*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *43-45. The challenged laws turn on a medical diagnosis, not sex and not transgender status. The State has a compelling governmental interest in protecting its citizens from risky and poorly supported medical procedures for the treatment of a difficult-to-diagnose condition where there is "uncertainty regarding benefits" of the treatments, serious "irreversible effects" from the treatment like sterility, and a host of unknowns like the effects on cognition. *Id.* at 43. The State also has "an abiding interest in protecting the integrity and ethics of the medical profession, and preserving and promoting the welfare of" its residents, particularly children. *L.W. II*, No. 23-5600, No.

23-5609, 2023 U.S. App. LEXIS 25697, at *24 (cleaned up). These interests are heightened "in areas of medical and scientific uncertainty." *Id.* (same)

II. The Challenged Laws Comply with the Affordable Care Act.

The district court also concluded that the challenged laws violate the Affordable Care Act. That's not right. Under section 1557, "an individual shall not, on the ground prohibited under" "title IX of the Education Amendments of 1972," "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." 42 U.S.C. § 18116. Title IX prohibits discrimination "on the basis of sex." 20 U.S. § 1681.

This Court has already interpreted "on the basis of sex" in Title IX. And it did so en banc in a transgender-related case: "sex" means "biological sex." *Adams*, 57 F.4th at 815. And as explained above, the challenged laws turn on a medical diagnosis gender dysphoria—that both biological males and biological females suffer. *Supra*. As such, the challenged laws comply with the Affordable Care Act.

III. The Challenged Laws Comply with the Medicaid Act.

In addition, the district court concluded that the challenged laws violate two Medicaid reimbursement requirements: the early and periodic screening, diagnostic, and treatment service (EPSDT) requirement, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5), and the comparability requirement. 42 U.S.C. § 1396a(a)(10)(B)(i). Not so.

A. Under *Rush v. Parham*, the State need not reimburse payments for experimental treatments. 625 F.2d at 1150. Whether the State's determination concerning the excluded treatments is "reasonable" is governed by "current medical opinion, regardless of the prevailing knowledge at the time" the State adopted the exclusions. *Id.* at 1157 n.13. *Rush*'s standard is thus closer to a rational-basis standard than a mean-ends tailoring standard; after all, courts aren't state medical boards. *L.W. I*, 73 F.4th at 416.

Both rational-basis review and *Rush* ask whether the State acted reasonably. *Rush*, 625 F.2d at 1157 n.13; *Beach Comm'ns*, 508 U.S. at 314-15. It would make little sense, in reviewing the record and in resolving essentially the same legal question, for a court to determine that the State's actions are reasonable under rational-basis review but unreasonable under *Rush*. So goes one, so goes the other.

The State meets *Rush*'s deferential standard. As detailed above, the weight and quality of the evidence backing these treatments don't support the use of puberty blockers and cross-sex hormones to treat gender dysphoria. Caution is instead the watchword. There's no certainty that the excluded treatments are reversible. The chances are great that those prescribed with the treatments suffer from other comorbidities. Thus, a cautious approach aligns with the growing global consensus.

The State's approach also aligns with the Centers for Medicare and Medicaid Services' guidance that States "are not required to provide any items or services" that the State determines "are not safe and effective or which are considered experimental." Doc.120 at 27.

True, Plaintiffs' experts provide an alternative approach to treatment. At best, however, it's just that: an alternative perspective that can't supersede the State's decision to take a more cautious approach. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905). At worst, it's the product of an untested and flawed approach based on low-quality evidence and sanctioned by WPATH and the Endocrine Society, both of which have assiduously sought to prevent scrutiny of their decision-making process. Either way, the State's conclusion concerning the excluded treatments is reasonable. *Supra*.

The rub is this: gender dysphoria is a "relatively new diagnosis" with relatively new treatment options. *L.W. II*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *4-10, 71-72. The diagnosis was established in the second half of the twentieth century, as were its treatment options of puberty blockers and cross-sex hormones. *Id.* at *4-10; *Eknes-Tucker*, No. 22-11707 2023 U.S. App. LEXIS 21942, at *35 n.11 & 12. Using those treatments on children for gender dysphoria began "just before the millennium." *L.W. II*, No. 23-5600, No. 23-5609, 2023 U.S. App. LEXIS 25697, at *8. The medical community is still in disagreement over the efficacy of these treatments, but no one can "dispute]] that these treatments carry risks or that the evidence supporting their use is far from conclusive." *Id.* at *36, 65. That makes these treatments experimental, and the State acted reasonably in denying reimbursement for them. **B.** Nor can Plaintiffs establish comparability. Medicaid requires that services "made available" to an eligible person "shall not be less in amount, duration, or scope" than services "made available to any other" eligible person. 42 U.S.C. $\int 1396a(a)(10)(B)(i)$. There must be some "equivalence between" "Florida-Medicaid-eligible service[s] and" the excluded treatments for gender dysphoria. Doc.64 at 4-5.

Although the district court held that Plaintiffs didn't have standing to challenge the laws' surgery provisions, a surgical example is appropriate: a mastectomy is an effective and appropriate treatment for breast cancer, where diseased breast tissue is removed from the body. Tr.1082:13-23 (Dr. Lappert). The efficacy of mastectomies for breast cancer treatment, however, says nothing about their efficacy of removing healthy breast tissue to treat gender dysphoria.

Accepting a false equivalency between a treatment approved for a specific malady and a treatment desired for a completely different malady is inappropriate, for the reasons expressed above. Plaintiffs' expert testimony contained little to no information on this front. Plaintiffs didn't show an equivalence.

In sum, the challenged laws are Medicaid-Act compliant.

Conclusion

The "Constitution principally entrusts the safety and the health of the people to the politically accountable officials of the State." *Andino v. Middleton*, 141 S. Ct. 9, 10 (2020) (Kavanaugh, J., concurral) (cleaned up). The Constitution doesn't entrust that duty to federal courts.

Here, the Florida Legislature, the Governor, and AHCA made a reasonable choice: the public shouldn't fund risky and experimental treatments that are backed by low-quality evidence and that could lead to potential infertility. The district court should have respected that reasonable decision. Because it didn't, it should be reversed.

* * *

Dated: October 6, 2023

Respectfully Submitted,

/s/ Mohammad O. Jazil

Mohammad O. Jazil Michael Beato HOLTZMAN VOGEL BARAN TORCHINSKY & JOSEFIAK PLLC 119 South Monroe Street, Suite 500 Tallahassee, FL 32301 Phone: (850) 270-5938 Facsimile: (850) 741-1023 mjazil@holtzmanvogel.com mbeato@holtzmanvogel.com *Counsel for Defendants-Appellants*

CERTIFICATE OF COMPLIANCE

This brief contains 9,678 words, excluding the parts that can be excluded. This

brief also complies with Rule 32(a)(5)-(6) because it's prepared in a proportionally

spaced face using Microsoft Word 2016 in 14-point Garamond font.

Dated: October 6, 2023

<u>/s/ Mohammad O. Jazil</u> Mohammad O. Jazil

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing was filed using this Court's CM/ECF, which will automatically serve a copy to all counsel of record.

Dated: October 6, 2023

<u>/s/ Mohammad O. Jazil</u> Mohammad O. Jazil