No. 23-12159

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

JANE DOE, et al.,
Plaintiffs-Appellees,

v.

SURGEON GENERAL, STATE OF FLORIDA, et al.,
Defendants-Appellants.

On Appeal from the United States District Court for the
Northern District of Florida
Case No: 4:23-cv-114-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 PRELIMINARY INJUNCTION

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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:

1. Academic Pediatric Association – Amicus
2. Ackerman, Scot – Defendant
3. American Academy of Child and Adolescent Psychiatry – Amicus
4. American Academy of Family Physicians – Amicus
5. American Academy of Nursing – Amicus
6. American Academy of Pediatrics – Amicus
7. American Association of Physicians for Human Rights, Inc. – 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. Andersen, Alison – Counsel for Amicus

14. Antommaria, Armand – Witness in *Dekker*[1]

15. Archer, Phil – Former Defendant

16. Aronberg, Dave – Former Defendant

17. Association of American Medical Colleges – Amicus

18. Association of Medical School Pediatric Department Chairs, Inc. – Amicus

19. Baker, Kellan – Witness in *Dekker*

20. Bakkedahl, Thomas – Former Defendant

21. Bartlett, Bruce – Former Defendant

22. Basford, Larry – Former Defendant

23. Beato, Michael – Counsel for Defendants

24. Bell, Daniel – Counsel for Defendants

[1] Pursuant to the District Court Order (ECF 90, at 2), "[t]he parties have stipulated to submission of the pending motions based on the written filings in this case and the record compiled in a separate case in this court with overlapping issues, *Dekker v. Weida*, No. 4:22cv325-RH-MAF. A complete bench trial has been conducted in that case." Because the District Court decided the motion at issue in this appeal based, in part, on the trial record in *Dekker*, the witnesses in the *Dekker* case are included in this Certificate of Interested Persons. The *Dekker* case is now on appeal in this Court. 23-12155.

25. Benson, Matthew – Defendant

26. Biggs, Michael – Defendant Witness

27. Blickenstaff, David – Counsel for Amicus

28. Boe, Bennett – Plaintiff

29. Boe, Brenda – Plaintiff

30. Brackett, Matthew – Witness in *Dekker*

31. Brodsky, Ed – Former Defendant

32. Bruggeman, Brittany – Declarant

33. Bruno, Nichole – Plaintiff Gavin Goe's Doctor

34. Campbell, Jack – Former Defendant

35. Cantor, James – Witness in *Dekker*

36. Chriss, Simone – Counsel for Plaintiffs

37. Coe, Carla – Plaintiff

38. Coe, Christina – Plaintiff

39. Coffman, Gregory – Defendant

40. Creegan, Chris – Defendant

41. Cryan, Michael – Counsel for Amicus

42. Derick, Amy – Defendant

43. Di Pietro, Tiffany – Defendant

44. Diamond, David – Defendant

45. Doe, Jane – Plaintiff

46. Doe, Susan – Plaintiff

47. Donovan, Kevin – Witness in *Dekker*

48. Ducatel, Watson – Defendant

49. Dunn, Chelsea – Counsel for Plaintiffs

50. Durrett, John – Former Defendant

51. Edmiston, Kale –Witness in *Dekker*

52. English, Jeffrey – Witness in *Dekker*

53. Erchull, Christopher – Counsel for Plaintiffs

54. Florida Agency for Healthcare Administration – Defendant in *Dekker*

55. Florida Board of Medicine – Defendant

56. Florida Board of Osteopathic Medicine – Defendant

57. Florida Chapter of the American Academy of Pediatrics – Amicus

58. Foe, Fiona – Plaintiff

59. Foe, Freya – Plaintiff

60. Fox, Amira – Former Defendant

61. Garcia, Maria – Defendant

62. Ginsburg, Maya – Counsel for Plaintiffs

63. Gladson, William – Defendant

64. Goe, Gavin – Plaintiff

65. Goe, Gloria – Plaintiff

66. Goldberg, Noah – Counsel for Amicus

67. Haas, Brian – Former Defendant

68. Hart, Joseph – Counsel for Defendants

69. Hinkle, Robert – U.S. District Court Judge

70. Hruz, Paul William – Witness in *Dekker*

71. Hunter, Patrick – Defendant

72. Hutton, Kim – Witness in *Dekker*

73. Isasi, William – Counsel for Amicus

74. Jackson, Valerie – Defendant

75. Jacobs, Arthur – Counsel for Former Defendants & Defendant

76. Janssen, Aron Christopher – Witness in *Dekker* & Declarant in *Doe v. Ladapo*, Case No. 4:23-cv-113-RH-MAF (N.D. Fla.)

77. Jazil, Mohammad – Counsel for Defendants

78. Justice, Nicole – Defendant

79. Kaliebe, Kristopher Edward – Witness in *Dekker*

80. Karasic, Dan – Witness in *Dekker*

81. Kirsh, William – Defendant

82. Kramer, Brian – Former Defendant

83. Ladapo, Joseph – Defendant

84. Laidlaw, Michael – Witness in *Dekker*

85. Lannin, Cortlin – Counsel for Amicus

86. Lappert, Patrick – Witness in *Dekker*

87. Larizza, R.J. – Former Defendant

88. Levi, Jennifer – Counsel for Plaintiffs

89. Levine, Stephen – Witness in *Dekker*

90. Loe, Linda – Plaintiff

91. Loe, Lisa – Plaintiff

92. Lopez, Susan – Former Defendant

93. Madden, Ginger – Former Defendant

94. Mandelbaum, Sara – Counsel for Plaintiffs

95. Marstiller, Simone – Former Defendant in *Dekker*

96. Minter, Shannon – Counsel for Plaintiffs

97. Mondry, Emily – Counsel for Amicus

98. Moody, Ashley – Former Defendant

99. Mor, Yuval – Counsel for Amicus

100. Mortensen, Monica – Defendant

101. Nangia, Geeta – Witness in *Dekker*

102. National Association of Pediatric Nurse Practitioners – Amicus

103. Nelson, Melissa – Former Defendant

104. Olson-Kennedy, Johanna – Witness in *Dekker*

105. Pages, Luz – Defendant

106. Patel, Ami – Counsel for Plaintiffs

107. Pediatric Endocrine Society – Amicus

108. Peral, Stephanie – Counsel for Plaintiffs

109. Percival, James – Counsel for Defendants

110. Perko, Gary – Counsel for Defendants

111. Pimentel, Eleonor – Defendant

112. Poe, Patricia – Plaintiff

113. Poe, Paul – Plaintiff

114. Popkin, Kelly – Counsel for Plaintiffs

115. Pratt, Joshua – Counsel for Defendants

116. Pryor, Harold – Former Defendant

117. Redburn, Thomas, Jr. – Counsel for Plaintiffs

118. Romanello, Nicholas – Defendant

119. Fernandez-Rundle, Katherine – Former Defendant

120. Schechter, Loren – Witness in *Dekker*

121. Scott, Sophie – Witness in *Dekker*

122. Shumer, Daniel – Witness in *Dekker* & Declarant in *Doe*

123. Silverman, Lawrence – Counsel for Plaintiffs

124. Societies for Pediatric Urology – Amicus

125. Society for Adolescent Health and Medicine – Amicus

126. Society for Pediatric Research – Amicus

127. Society of Pediatric Nurses – Amicus

128. Stafford, William, III – Counsel for Defendants

129. Starr, Jason – Counsel for Plaintiffs

130. Stoll, Christopher – Counsel for Plaintiffs

131. Van Meter, Quentin – Witness in *Dekker*

132. Van Mol, Andre – Witness in *Dekker*

133. Veta, D. Jean – Counsel for Amicus

134. Vila, Hector – Defendant

135. Ward, Dennis – Former Defendant

136. Wasylik, Michael – Defendant

137. Weaver, Cynthia – Counsel for Plaintiffs

138. Weida, Jason – Defendant in *Dekker*

139. Whitaker, Henry – Counsel for Defendants

140. Williams, Gregory – Defendant

141. World Professional Association for Transgender Health – Amicus

142. Worrell, Monique – Former Defendant

143. Zachariah, Zachariah – Defendant

144. Zanga, Joseph – Witness in *Dekker*

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I. STATEMENT OF INTEREST

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 youth daily. Collectively, *Amici* have over 40 years of clinical practice experience and have treated more than 1,700 transgender youth.

All *Amici* share an interest in the integrity of medicine and science, and all are concerned that Florida's newly adopted statutes and rules set a harmful, national precedent for denying standard medical care to transgender people. *See* Florida Statutes §§ 456.001(9), 456.52 (2023) and Fla. Admin. Code R. 64B8-9.019(1)(b), R. 64B15-14.014(1)(b) (2023). 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 granting Plaintiffs a preliminary injunction against enforcement of Florida's statutes and rules.

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 these Florida regulations and statutes. 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 (11th Cir. Aug. 21, 2023), raises issues of Constitutional law. We do not discuss these questions, which will be addressed by Plaintiffs. Instead, consistent with our expertise, we focus on the medical and scientific evidence supporting medical treatment for gender dysphoria in adolescents.

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 enjoined Defendants-Appellants from enforcing Rules 64B8-9.019 and 64B15-14.014 of the Florida Administrative Code.

III. SUMMARY OF ARGUMENT

Effective in 2023, Florida's Board of Medicine and Board of Osteopathic Medicine adopted Fla. Admin. Code R. 64B8-9.019(1)(b) and Fla. Admin Code R. 64B15-14.014(1)(b). These regulations (the "Regulatory Ban") prohibit medical providers from providing minors with medical services for the treatment of gender dysphoria, including puberty blockers and hormones (collectively, "transitioning medications"). Also in 2023, the state legislature passed Florida Statutes §§ 456.001(9) and 456.52 (the "Statutory Ban") imposing criminal and civil penalties, including professional discipline and loss of licensure, for providing such treatments to minors.

The "Regulatory Ban" and "Statutory Ban" are collectively referred to as the "Florida Bans" in this brief.

The Florida Bans deny long-established, evidence-based medical care to thousands of Florida adolescents with gender dysphoria.

The district court's preliminary injunction suspending enforcement of the Florida Bans was based on an unusually robust factual record: the court had heard a full trial on closely related issues in *Dekker v. Weida*, No. 4:22cv325-RH-MAF, 2023 WL 4102243 (N.D. Fla. June 21, 2023), and the parties stipulated to the use of the trial record in *Dekker* in this case. *See Doe* Opinion at 2. We urge the Court to uphold the district court's preliminary injunction, which is based on sound findings

of fact, and to reject Defendants' attempt to misrepresent the scientific evidence and re-litigate the facts.

The Court reviews a district court's grant of a preliminary injunction for an abuse of discretion, and the State cannot meet this high bar. *See Robinson v. Attorney Gen.*, 957 F.3d 1171, 1177 (11th Cir. 2020) (holding that the state failed to make the necessary strong showing, under the deferential abuse of discretion standard, that the district court abused its discretion in granting preliminary injunction)."[A]s its name implies, the abuse-of-discretion standard allows a range of choices for the district court." *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1247 (11th Cir. 2016) (quotation marks omitted). Because there was no abuse of discretion here, the district court's decision should be affirmed.

Amici urge this Court to uphold the district court's preliminary injunction in order to protect transgender adolescents in Florida by ensuring them access to standard, evidence-based medical care. 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, Defendants mischaracterized the scientific evidence in the district court and continue to do so in their brief to this Court.

The district court correctly determined that the Florida Bans criminalize well-established, evidence-based medical care that has been endorsed by every relevant

major medical organization in the United States, and that the Florida Bans would inflict irreparable harm on adolescents with gender dysphoria by denying them standard medical care. Deferring treatment for gender dysphoria until age 18 is not "doing nothing" or "waiting," as Defendants claim: it effectively sentences adolescents with gender dysphoria to extreme distress. As the district court correctly found, gender dysphoria, if left untreated, can lead to anxiety, disordered eating, and suicidality as the adolescent is forced to undergo puberty that is discordant with their gender identity.

That result is reserved for transgender youth alone. The State of Florida does not require adolescents with other serious health conditions to defer medical treatment until adulthood; it trusts physicians, parents, and teens to exercise their judgment and give informed consent and assent.

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 in *Dekker*, 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 Bans.

Our analysis confirms the soundness of the district court's findings on two important issues.

First, the district court correctly determined that the Florida Bans rely on purported scientific evidence that is flawed, unscientific, and produced by a biased process engineered to reach a pre-ordained result motivated by discriminatory animus.

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 complaints 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 strongly urge this Court to uphold the district court's decision. Overturning the preliminary injunction would inflict irreparable harm on Florida adolescents with gender dysphoria.

IV. ARGUMENT

A. THE DISTRICT COURT CORRECTLY DETERMINED THAT THE FLORIDA BANS CRIMINALIZE "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 for adolescents 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 adolescents 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 these findings, concluding that "gender identity is real." *Doe* Opinion, at 3. And the district court judge admonished the Defendants for "dog whistles" signaling that gender identity and gender dysphoria are "made up." *Doe* Opinion, at 5-6 (finding that "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 Scientific Claims*, Yale Sch. of 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 "plaintiffs' experts conceded during the *Dekker* trial [that] there isn't any 'confirmatory laboratory or radiographic study for the diagnosis of gender dysphoria.'" Defs.'-Appellants' Corrected Initial Br. at 5. 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." *Doe* Opinion, at 31. 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." *Doe* Opinion, at 12. The court also found "no evidence" in the record to prove that transitioning medications have "caused substantial adverse clinical results in properly screened and treated patients." *Doe* Opinion, at 13.

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), https://pubmed.ncbi.nlm.nih.gov/30224363/ ["AAP 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, 7 (Feb. 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), https://pubmed.ncbi.nlm.nih.gov/32220906/ ["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), https://doi.org/10.1016/j.jadohealth.2023.01.031; 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 well-established 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 and Endocrine Society Guidelines.

As recognized by the district court, the WPATH and Endocrine Society clinical practice guidelines are "well-established" and "widely accepted." *Doe* Opinion, at 7, 32. 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. *Doe* Opinion, at 7.

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. 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' Corrected Initial Br. at 6. 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." *Doe* Opinion, at 34.

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." *Doe* Opinion, at 34.

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*.

Defendants attempt to minimize the significance of these endorsements by repeating to this Court their claim that "[m]edical organizations aren't accountable to anyone. Yet they have forced themselves into the political debate …." Defs.'-Appellants' Corrected Initial Br. at 29.

But the district court, having examined the evidence and heard testimony by experts on both sides, correctly rejected Defendants' claim: "[D]efendants say, in

effect, that [medical organizations] were dominated by individuals who pursued good politics, not good medicine. If ever a pot called a kettle black, it is here. The statute and the rule were an exercise in politics, not good medicine." *Doe* Opinion, at 32-33.

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.

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 Endocrine Society guidelines recommend careful processes to ensure informed consent by parents and informed assent by adolescents. Patients undergo a multi-disciplinary 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 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 adolescents 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), https://pubmed.ncbi.nlm.nih.gov/37810940/.

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 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), https://pubmed.ncbi.nlm.nih.gov/37246711/ (showing less than 2% discontinuation of hormone treatment in a sample of adolescents and adults treated according to WPATH and 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' Corrected Initial Br. at 5 [internal citations omitted]. This assertion is another attempt to persuade the Court that gender dysphoria is an imagined by-product of mental illness or social contagion.

While some youth 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 adolescent. 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 gender-related decision-making should be prioritized and addressed." *Id*. at 563.

These cautions do not imply that adolescents with co-occurring conditions are incapable of assenting to medical treatment for gender dysphoria. Medical experts

have established that youth — 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 youth and their parents, finding that "the ability of 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." *Doe* Opinion, at 16-17.

3. The district court correctly found that the Florida Bans inflict irreparable harm on adolescents 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 Bans would inflict grave harm on adolescents with gender dysphoria by denying them standard medical care. "The plaintiffs' adolescent children will suffer irreparable harm—the unwanted and irreversible onset and progression of puberty in their natal sex—if they do not promptly begin treatment with GnRH agonists." *Doe* at 39-40.

Deferring treatment for gender dysphoria until age 18 is not "doing nothing" or "waiting" as Defendants claim: it sentences adolescents with gender dysphoria to extreme distress, which may include anxiety, depression, suicidality, and disordered eating as adolescents are forced to undergo puberty that is discordant with their gender identity. Denied standard medical care, these teens will face more difficult social interactions and may be more subject to bullying. The delay in treatment also makes an adult gender transition more difficult because someone who has gone through puberty may have to undergo more intrusive and complex procedures in adulthood (such as a mastectomy) to reverse pubertal changes. Some changes will be lifelong and will be permanently distressing (such as a deep voice in a transgender girl assigned male gender at birth).

By contrast, the State of Florida does not require adolescents with other serious health conditions to delay medical care until adulthood. By analogy, consider a teen with a cleft palate who wants corrective surgery, and suppose that the teen and their family have given informed assent and consent. Even though the surgery makes permanent physical changes and carries risk, including the risks of anesthesia and surgical complications, the State of Florida does not require that teen to forgo treatment and to live out their teen years with an appearance that they find highly distressing.

Nor does the State of Florida require an adolescent diagnosed with juvenile diabetes to wait until adulthood before taking daily insulin. Delaying treatment would subject such a patient to the complications of untreated diabetes, which can include severe weight loss, muscle weakness, and a deadly condition called ketoacidosis. But taking insulin also carries risks and requires careful management. In this case too, the State trusts the physician, the teen, and their parents to determine what kind of treatment is appropriate and to weigh the possible risks and benefits.

Defendants refer to transitioning medications as "risky medical procedures," Defs.'-Appellants' Corrected Initial Br. at 1, 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, which occurs when the onset of puberty is unusually early. And estrogen is prescribed for adolescent and adult patients to manage fertility and reduce heavy menstrual bleeding (to give two examples of its many uses). Testosterone is prescribed to treat hypogonadism and is routinely prescribed to cisgender males with testosterone deficiency. *See* McNamara (2022), *supra*, at 22, 24.

But the Florida Bans do not bar the use of transitioning medications when prescribed to cisgender patients.

As the district court found, "[c]isgender individuals can be and routinely are treated with GnRH agonists, testosterone, or estrogen, when they and their doctors deem it appropriate." *Doe* Opinion, at 24.

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 BANS.

The district court correctly determined that the purported scientific evidence offered by the State as justification for the Florida Bans was produced by a biased process that ignored solid medical evidence in order to reach a pre-ordained result fueled by discriminatory animus. *Doe* Opinion, at 26 (finding that the Florida 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 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_2022_Report.pdf ["AHCA Report"] (last visited Sept. 30, 2022).

On the basis of that report, the Florida AHCA promulgated a regulation denying Medicaid coverage for medical treatment for gender dysphoria. Florida Administrative Code Rule 59G-1.050(7), *later codified in* Florida Statute § 286.311. These are the statutes and rules challenged by the plaintiffs in *Dekker*.

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* https://transgender.agency/files/08052022_FB2_Publicbook.pdf. ["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 peer-reviewed, 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 gender-affirming 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), https://jmla.pitt.edu/ojs/jmla/article/view/1724 (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. In the *Dekker* 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 Bans, concluding that "[t]he State of Florida's decision to ban [transitioning medications for adolescents] is not rationally related to a legitimate state interest" and the State's "laundry list of purported justifications" is "largely pretextual." *Doe* Opinion, at 25, 27.

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 complaints 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' Corrected Initial Br. at 8-9. 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." *Doe* Opinion, at 29.

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* Appendix 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." Defs.'-Appellants' Corrected Initial Br. at 1 ("[l]ow-quality evidence supports the use of these treatments, meaning that they might not work").

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." *Doe* Opinion, at 29.

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 adolescents 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' "low-quality evidence" argument. *Doe* Opinion, at 29.

V. CONCLUSION

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 preliminary injunction protect transgender adolescents in Florida by ensuring them access to standard, proven, and critically important medical care.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT, 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 6498 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
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CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

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 do not object to the filing.

/s/ David C. Blickenstaff
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CERTIFICATE OF SERVICE

I hereby certify that, on November 6, 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.

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