UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

STERLING MISANIN, et al., *Plaintiffs*, v. ALAN WILSON, in his official capacity as Attorney General of South Carolina, et al., *Defendants.*	)	Case No. 2:24-cv-04734-RMG

DEFENDANTS' BRIEF IN OPPOSITION
TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

In the last two years, there has been a global reckoning with respect to the purported "science" behind medical and surgical gender transitions. In story after story, the veneer of evidence for these interventions has been exposed as illusory. And most significantly for purpose of this motion, these developments have come to light *years* after the summary-judgment record closed for the Fourth Circuit's decision in *Kadel v. Folwell*, 100 F.4th 122 (4th Cir. 2024) (en banc).

Just days ago, The New York Times published an article explaining that Plaintiffs' expert here, Dr. Olson-Kennedy, "has not published the data" from a long-running study regarding the effectiveness of puberty blockers as a treatment for gender dysphoria that she has conducted with millions of dollars from the National Institutes of Health. Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, N.Y. TIMES (last updated Oct. 24, 2024), https://nyti.ms/3Ascpbb.

Why? Because the data showed that "[p]uberty blockers did *not* lead to mental health improvements," and Dr. Olson-Kennedy did not want that data to be used to support laws like the one at issue here. *Id.* (emphasis added). That remarkable admission—suppressing scientific data to serve an ideological end—is the antithesis of the scientific method.

Remarkably, Dr. Olson-Kennedy is not alone in letting ideology trump the data when it comes to gender transitioning. Indeed, "recent revelations indicate that [the] lodestar" for Plaintiffs' leading authority, the World Professional Association for Transgender Health (WPATH), "is ideology, not science." *Eknes-Tucker v. Gov. of Ala.*, 114 F.4th 1241, 1261 (11th Cir. 2024) (Lagoa, J., concurring in denial of rehearing en banc). Again, the pages of The New York Times tell the story. Documents released earlier this year demonstrated that members of the WPATH group responsible for developing Plaintiffs' vaunted WPATH "Standards of Care 8" (SOC-8) were told by a member of the Biden Administration that, "'based on the rhetoric she is hearing in D.C.,'"

the SOC-8's age limits for gender-transition surgeries "'will result in devastating legislation for trans care,'" and federal officials asked "'if the specific ages can be taken out.'" Azeen Ghorayshi, *Biden Officials Pushed To Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://nyti.ms/4hl0X1L. WPATH ended up removing those age limits. *Id.*

In the same vein, an article in The Economist explains how WPATH sought to suppress studies from the very researcher it hired to help with the SOC-8. Jesse Singal, *Research into Trans Medicine Has Been Manipulated*, ECONOMIST (June 27, 2024), https://econ.st/3Uluz55. Specifically, WPATH had enlisted the help of a researcher at Johns Hopkins University. *Id.* But from the outset, "WPATH expressed a desire to control the results of the Hopkins team's work." *Id.* This issue "flared up" when the Hopkins researchers shared two manuscripts they had developed based on their data. *Id.* The WPATH executive committee warned that "WPATH had 'many concerns' about these papers, and that it was implementing a new policy in which WPATH would have authority to influence the [Hopkins] team's output—including the power to nip papers in the bud on the basis of their conclusion." *Id.*

In contrast to Dr. Olson-Kennedy and WPATH, the researchers and scientists committed to following the evidence have unanimously concluded there is no reliable evidence that justifies the use of puberty blockers, cross-sex hormones, and surgeries as a treatment for gender dysphoria. Specifically, health authorities in the United Kingdom, Sweden, Finland, Norway, and dozens of States have concluded that there is little evidence to support these interventions. And they have taken steps to restrict their use. South Carolina followed suit when it enacted H 4624.

Plaintiffs now seek to preliminarily enjoin enforcement of the Act while this case proceeds. They assert claims under the Equal Protection clause, the Due Process clause, the Affordable Care Act, and the Medicaid Act. But Plaintiffs' request for preliminary injunctive relief stumbles out of

the blocks because they have failed to demonstrate Article III standing for their claims or, alternatively, for various aspects of the relief they seek—including interventions that no Plaintiff seeks, such as puberty blockers. In addition, there is no private cause of action to enforce the provisions of the Medicaid Act that Plaintiffs rely upon here.

Once things turn to the substance, Plaintiffs' arguments fare no better. Although Plaintiffs rely almost exclusively on the Fourth Circuit's decision *Kadel*, that decision does not mechanically dictate the outcome of Plaintiffs' motion for several reasons. First, there is no Due Process right to obtain experimental and harmful medical treatments for minors—an issue that was not before the Court in *Kadel*. Second, with respect to Plaintiffs' Equal Protection claims, the Act survives heightened scrutiny given the total absence of evidence for the medical and surgical interventions at issue—an absence that has been newly and shockingly underscored in the years since the record in *Kadel* was closed. And third, the Act does not violate the Medicaid Act's availability requirement because, unlike West Virginia's policy at issue in *Kadel*, South Carolina does *not* view the prohibited interventions at issue here as "medically necessary."

Finally, for reasons explained more fully in Defendants' accompanying opposition to Plaintiffs' motion for class certification, the numbers and types of claims at issue here are not suitable for class-wide relief. The Court should deny Plaintiffs' motion for a preliminary injunction.

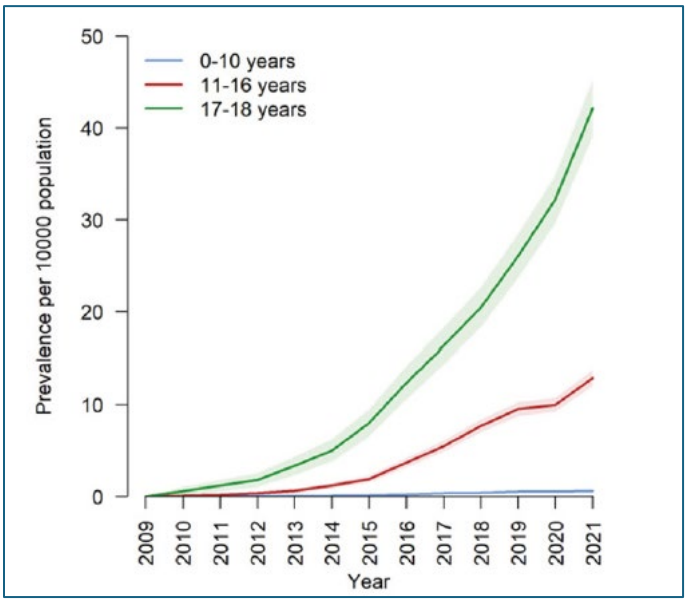
STATEMENT OF FACTS

A. Gender Dysphoria Is A Psychiatric Diagnosis That Is Poorly Understood

There are two human sexes—male and female. Decl. of Dr. Cantor ¶¶ 119-20 ("Cantor Decl.") (attached hereto as Exhibit 1). Distinct from "sex," an individual's "gender identity" is his or her personal sense of being male or female. *See* Cantor Decl. ¶¶ 122. Individuals identify as transgender when their sex is different from their gender identity. *See Kadel*, 100 F.4th at 135-36.

"Gender dysphoria," in contrast, is a specific psychiatric diagnosis defined by diagnostic criteria set out in the *Diagnostic and Statistical Manual of Mental Disorders* 5-TR ("DSM-5"). Cantor Decl. ¶ 123. Although its definitions vary slightly for children, adolescents, and adults, all cases are characterized by a strong desire to be the opposite sex and "clinically significant" distress that impairs the individual's ability to function in daily life. *Id.*

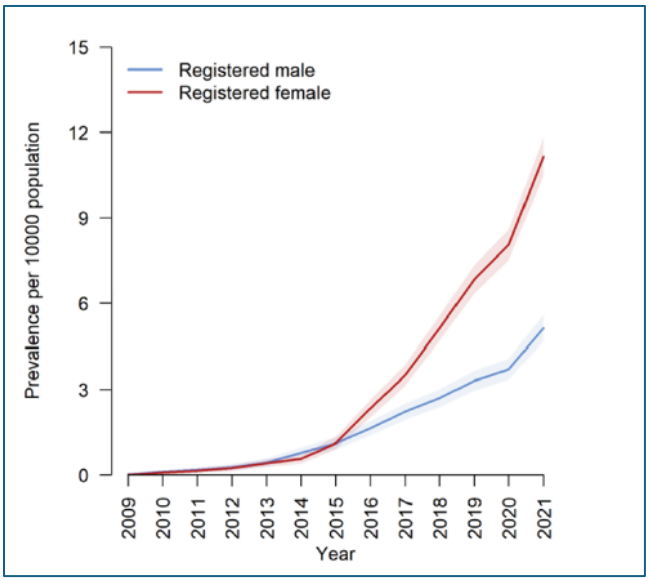
In the last decade, the number of minors diagnosed with gender dysphoria has exploded. *Id.* ¶ 69. This explosion has disproportionately affected adolescents. And as Plaintiffs' own experts have admitted, we do not know why. *See* Olson-Kennedy Dep. 20:7-10, 21:21-22:8 (attached hereto as Exhibit 2). At least part of this uncertainty stems from the fact that "we do not know with certainty what causes gender identity." Shumer Dep. 33:18-21 (attached hereto as Exhibit 3). The following chart displays the increased prevalence of gender dysphoria among different age groups of minors in the United Kingdom based on patient data from general practices across the UK.



Independent review of gender identity services for children and young people: Final report at 87, THE CASS REVIEW (2024), https://bit.ly/3Yxw57r ("Cass Review – Final Report"). As the chart shows, there have been massive increases in the percentage of minors aged 11-18 who have been

diagnosed with gender dysphoria—with a particularly striking increase among minors aged 17-18.

In addition, this recent explosion of gender dysphoria has disproportionately affected adolescent *females*. Cantor Decl. ¶¶ 156-57. Based on the same data, the following chart reflects the increased prevalence of gender dysphoria among male and female minors in the UK:



Cass Review – Final Report at 87. As this chart shows, although there has been a marked increase among all minors, the increase of gender dysphoria diagnoses has been particularly drastic with respect to adolescent females.

Separately, there is an unusually large percentage of patients with gender dysphoria who also have an Autism Spectrum Disorder (ASD). Cantor Decl. ¶ 204. Researchers have noted "the considerable overlap between symptoms of ASD and symptoms of gender variance." *Id.* (internal quotations omitted). Indeed, data shows that minors with an ASD "are more than seven times more likely to have parent-reported gender variance." *Id.* (internal quotations omitted). As Plaintiffs' own experts testified during their deposition, we have no explanation for any of this: They have admitted that the cause, nature, and trajectory of gender dysphoria is not understood. Olson-

Kennedy Dep. 20:7-10, 21:21-22:8, 60:19-23; Shumer Dep. 27:20-28:2, 33:18-25; Antommaria Dep. 30:9-32:4, 42:7-17; 47:3-12 (attached hereto as Exhibit 4). This testimony of Plaintiffs' experts is consistent with the conclusions of health authorities in the UK, Sweden, and Finland, who have noted that the increase in the phenomenon of "later-presenting birth-registered female teenagers" is "unexplained." Cantor Decl. ¶¶ 70-71.

B. The Two Theories On How To Treat Gender Dysphoria Are Psychotherapy Or Drugs And Surgeries To Alter The Patient's Body Appearance.

Psychotherapy is an accepted approach to treating gender dysphoria. *Id.* ¶ 17. Indeed, medical authorities throughout the world "endorse psychotherapy as the treatment of choice for minors." *Id.* And Plaintiff's own expert acknowledged there are times when psychotherapy could be sufficient to resolve gender dysphoria. Shumer Dep. 47:15-23; *see also* Karasic Dep. 17:10-13 (attached hereto as Exhibit 5) (agreeing that "psychotherapy is helpful for many gender dysphoric individuals"). "The intent of psychological intervention is not to change the person's perception of who they are but to work with them to explore their concerns and experiences and help alleviate their distress[.]" Cass Review – Final Report at 150.[1]

In contrast, advocates of so-called "gender-affirming care" promote medically and surgically "transitioning" as a treatment for gender dysphoria. As Plaintiffs explain, under the guidelines from the World Professional Association for Transgender Health (WPATH) and the Endocrine Society, providers prescribe GnRH agonists (puberty blockers) to suppress and

[1] Thus, it is wrong to conflate this type of psychotherapy (often termed "exploratory therapy") with the practice of "conversion therapy." *See* Cantor Decl. ¶¶ 351-52 (noting that the U.K.'s Council for Psychotherapy stresses the distinction between exploratory therapy and conversion therapy); *see also* Olson-Kennedy Dep. 113:6-12 (agreeing "there's a distinction between psychotherapy with the purpose of making someone not transgender and psychotherapy with the purpose of resolving somebody's distress associated with gender dysphoria").

adolescent's natural puberty. Mot. for Prelim. Inj., Doc. 7 at 6-7 (Aug. 30, 2024). This suppression allegedly prevents the distress associated with going through natural puberty. *Id.*

Next, as Plaintiffs also explain, providers prescribe cross-sex hormones. *See id.* at 7. This means that natal females take testosterone, and natal males take estrogen. *Id.* Patients who are prescribed cross-sex hormones for this purpose "will require continuing treatment with cross-sex hormones for life." Cantor Decl. ¶ 290.

Finally, the treatment pathway ends in surgery. Doc. 7 at 5, 7. These surgeries include mastectomy (the removal of a female's breasts), penectomy (the removal of a male's penis), and vaginectomy (the removal of a female's vagina). Eli Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* at S18, S125, INT'L J. TRANSGENDER HEALTH (2022). Once body parts are removed, skin tissue is often used to create body parts that resemble those of the other sex, such as a vaginoplasty (use of skin tissue to create a so-called "neo-vagina") and phalloplasty (use of skin tissue to create something resembling a penis). *See id.* at S125, S154.

1. There Is No Reliable Evidence That "Transitioning" A Patient's Body Resolves Gender Dysphoria.

Not all medical evidence is created equal. Instead, it is well recognized that principles of evidence-based medicine place "systematic reviews" at the top of the hierarchy of medical evidence. Cantor Decl. ¶ 39. Systematic reviews "employ standardized procedures to assess comprehensively all available evidence on an issue, minimizing opportunities for bias in gathering and evaluating research evidence." *Id.* ¶ 40. Specifically, "systematic reviews are designed to prevent researchers from including the studies they favor and other biases." *Id.* ¶ 41.

Plaintiffs' own expert agrees with this bedrock principle of evidence-based medicine. As Dr. Antommaria stated during his deposition, it "would be optimal in medical decision-making to

have such systematic review[s]" of the evidence. Antommaria Dep. 74:2-7. He further agreed that, "ideally, clinical practice guidelines would be based on systematic reviews." *See id.* at 74:9-13.

When it comes to the systematic reviews on this topic, they all say the same thing: There is no reliable evidence showing that medical and surgical interventions reduce gender dysphoria in minors. Researchers from the National Health Service in the United Kingdom, from Swedish health authorities, from Finnish health authorities, and from McMaster University, which "is recognized as a center of expertise in the performance of methodologically sound systematic reviews," have all conducted systematic reviews and concluded that there is no reliable evidence to establish that medical and surgical interventions have any benefit. *See* Cantor Decl. ¶¶ 81-101. One systematic review summed it up succinctly: "Due to important limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria." *Id.* ¶ 90 (internal quotations omitted). This dearth of evidence explains why Plaintiffs' expert Dr. Antommaria could not name "any clinical practice guidelines" recommending those interventions that is "based on a systematic review of the efficacy of either puberty blockers or cross-sex hormones." Antommaria Dep. 84:6-25. It further explains Dr. Karasic's candid admission "that there's limited data on long-term physical, psychological, and neurodevelopmental outcomes to youth" for these interventions. Karasic Dep. 142:18-20.

Most critically (given the rhetoric around this issue) *every single one* of Plaintiffs' experts admitted they are aware of *no data* demonstrating that medical transition for adolescents reduces the risk of suicide. Dr. Shumer's deposition is illustrative:

> Q. And you agree there is no data linking gender-affirming care to a reduction in suicide, correct?
>
> …
>
> A. Yes, I don't believe that there is strong data linking gender-affirming care in youth to an outcome of less completed suicides.

See Shumer Dep 157:4-10; *see also* Antommaria Dep. 131:15-21 (unable to "name any study demonstrating that medical transition for adolescents reduces the rate of completed suicides among any population of transgender adolescents"); Olson-Kennedy Dep. 99:6-13 (same); Karasic Dep. 136:8-14 (same).

2. The Harms Of Medically And Surgically Transitioning Vastly Outweigh Any Harm Associated With Psychotherapy

Because the objective of medicine is to enhance an individual's health and well-being, a medical intervention is justified only when its probable benefits outweigh its probable risks. Cantor Decl. ¶¶ 77-78. Under this risk-benefit analysis, serious risks associated with a particular intervention cannot be justified "without evidence of correspondingly greater benefit." *Id.* ¶ 51. Therefore, no medical intervention that carries risks should be used unless the probable benefits outweigh the probable risks. *Id.* ¶ 77. In contrast to the weak evidence of benefit, the use of medical and surgical interventions to treat gender dysphoria carry drastic and irreversible risks.

Pubertal Suppression. To start, hormones developed during a person's natural (or "endogenous") puberty "drive important stages of neural development." *Id.* ¶ 273; *see also id.* ¶¶ 276-77. There has been very limited research on the long-term effect of puberty blockers on neurodvelopment. *Id.* ¶ 276-77; *see also* Karasic Dep. 143:4-8 (unaware of any studies showing what the "cognitive impact may or may not be"). Thus, there is "concern" that suppressing the natural hormones that "trigger the opening of a critical period" for the "rewiring of neural circuits underlying executive function" could stunt "maturation of the part of the brain concerned with planning, decision making and judgment." Cantor Decl. ¶ 273 (internal quotation marks omitted).

Plaintiffs' experts have no response to this concern. *See, e.g.*, Karasic Dep. 143:16-18 ("If that question were asked if there is any neurocognitive impact, whether that's known, I would say no."). Indeed, Dr. Antommaria was not even "aware that there were substantial concerns of the effect of [pubertal suppression] on neurodevelopment" of patients "until recently." Antommaria Dep. 130:3-5.

In addition, the use of pubertal suppression may actually *contribute to* an adolescent's mental-health issues. "Undergoing puberty much later than one's peers is also associated with poorer psychosocial functioning and lesser educational achievement." Cantor Decl. ¶ 280. Plaintiffs' own expert agrees that pubertal suppression could contribute to a patient's distress in this way. Shumer Dep. 48:20-49:3.

Pubertal suppression also leads to diminished growth in bone density. Cantor Decl. ¶ 282. And the "long-term effects of the deficient bone growth of people who undergo hormonal interventions at puberty remain unstudied." *Id.* ¶ 284.

Cross-Sex Hormones. Plaintiffs' experts are forced to admit the serious risks associated with cross-sex hormones. Those risks include:

- Heart attack. *See* Antommaria Dep. 48:6-10; Olson-Kennedy Dep. 63:4-8.
- Stroke. *See* Antommaria Dep. 48:12-14; Olson-Kennedy Dep. 63:4-8.
- Blood clots. *See* Antommaria Dep. 48:17-22; Olson-Kennedy Dep. 52:17-21; Shumer Dep. 69:1-4.
- Pulmonary embolism. *See* Olson-Kennedy Dep. 52:23-53:1.
- Diabetes. *See* Olson-Kennedy Dep. 63:10-14.
- Hormone-dependent cancers. *See* Cantor Decl. ¶ 289.
- Infertility. *See* Antommaria Dep. 48:24-49:3; Shumer Dep. 72:21-25.

Significantly, it is *undisputed* that an adolescent who proceeds from pubertal suppression to cross-sex hormones will be infertile. *See* Cantor Decl. ¶¶ 266-67; Antommaria Dep. 49:5-11; Olson-Kennedy Dep. 52:2-11; Karasic Dep. 132:13-19. Plaintiffs' experts have hypothesized that an individual could simply cease taking cross-sex hormones to regain fertility. *See, e.g.*, Shumer Decl., Doc. 7-4, ¶ 80 (Aug. 30, 2024). But they are forced to admit that they are "not aware of particular data" demonstrating that this is possible. Antommaria Dep. 49:13-19; *see also* Shumer Dep. 74:24-75:4 ("Do I have evidence to suggest that a person has used pubertal suppression in Tanner Stage 2 followed by hormones and then as an adult discontinue medications and then achieve a pregnancy? I don't.")

Further questions arise regarding that individual's sexual function for natal males. *See* Cantor Decl. ¶ 272. Specifically, it is uncertain whether that individual will ever be able to experience an orgasm. *Id.* As Plaintiffs' experts concede, answering this question for any particular patient "is currently beyond the scope of our knowledge." Antommaria Dep. 49:20-50:4; *see also* Shumer Dep. 82:15-21 (same).

Surgeries. The permanent removal of healthy and functioning body parts is of course itself a form of harm. In addition, the surgical process can present serious health risks. *See* Karasic Dep. 105:25-106:5 (discussing a minor who died from complications associated with "a vaginoplasty using a colon"). Moreover, removal of these body parts can lead to additional health risks. For example, surgical removal of a female's ovaries leads to "substantially elevated odds of developing parkinsonism." Cantor Decl. ¶ 281. And significantly, subsequently detransitioning will never restore the function that is lost as a result of these surgeries. For example, for an adolescent girl who has her breasts removed as part of a gender transition, "breast-feeding a child will never be possible." *Id.* ¶ 271. Most notably, the American Society of Plastic Surgeons has issued a statement

saying there is "'considerable uncertainty as to the long-term efficacy for the use of chest and genital surgical interventions for the treatment of adolescents with gender dysphoria.'" Karasic Dep. 165:24-166:5.

C. Scientists And Health Authorities Agree That The Severe Risks Outweigh The Limited Demonstrated Benefit Of Transitioning.

1. Officials In The United States And Around The World Have Concluded There Is No Scientific Justification For These Interventions.

Several health authorities have reviewed the evidence and concluded that the demonstrated benefits do not clearly outweigh the risks—especially with respect to minors. Cantor Decl. ¶¶ 17-29. After Swedish health authorities conducted their systematic review of the evidence, they concluded that the "risks of puberty suppressing treatment with GnRH analogues and gender affirming hormonal treatment currently outweigh the possible benefits." *Id.* ¶ 29 (quotations omitted). UK health authorities have banned the use of puberty blockers outside of research for minors. *Id.* ¶¶ 21, 216. Health authorities and researchers in Finland, Norway, France, and Denmark, have expressed similar concerns about these interventions. *Id.* ¶¶ 22-25, 30-34.

Meanwhile, in the United States, the FDA has not approved the use of puberty blockers or cross-sex hormones as a treatment for gender dysphoria. *L.W. v. Skrmetti*, 73 F.4th 408, 418 (6th Cir. 2023) (noting that "the FDA is not prepared to put its credibility and careful testing protocols behind the use" of these drugs for this purpose). And numerous States, following the scientific evidence, have prohibited the practice of these biology-denying interventions on minors and prohibited the use of public funds to obtain these interventions. *See L.W.*, 73 F.4th at 416.

2. South Carolina Likewise Concludes That These Interventions Are Not Justified by The Scientific Evidence.

South Carolina has also followed the evidence and passed H 4624 to protect individuals from interventions that cause known harm and have no reliable evidence of benefit. As Senator

Cash explained during a legislative debate over the Act: "I think gender transition procedures are certainly life-changing, I believe that they are harmful, and I believe a lot of what ends up being puberty blockers followed by cross-sex hormones" in particular "causes irreversible damage. That's based on the book of studies that's in front of me." *Senate Medical Affairs Subcommittee Hearing on H.4624 Before the Senate Med. Affairs Comm.* at 22:15-53*,* 125th Sess. (S.C. 2024) (Statement of Senator Richard J. Cash) ("Feb. 21 Comm. Hr'g").

As relevant here, the Act thus takes a number of actions with respect to these interventions. First, it prohibits their use with respect to minors as of August 1. *See* S.C. CODE ANN. § 44-42-320(A)-(B). For those minors already using these interventions, however, the Act creates a drawdown period that concludes on January 31, 2025. *See id.* § 44-42-320(C). The Act also makes it a crime to knowingly perform a *genital* gender reassignment surgery on minors. *See id.* § 44-42-320(E).

Second, the Act protects the public by refusing to finance these dangerous and unproven interventions. Specifically, it states that "[p]ublic funds may not be used directly or indirectly for gender transition procedures." *Id.* § 44-42-340. It likewise provides that South Carolina's "Medicaid Program shall not reimburse or provide coverage" for them. *Id.* § 44-42-350.

The Act can be enforced a number of ways. First, a person may bring "a claim" for "compensatory damages, injunctive relief, declaratory relief, or any other appropriate relief" in light of "an actual or threatened violation" of the prohibition on gender transitions for minors. *See Id.* § 44-42-360(B). Second, if an individual provides gender transitions to minors, "the appropriate licensing board" will deem it "unprofessional conduct" and the provider will "be subject to discipline by the licensing entity with jurisdiction over the physician, mental health provider, or other medical health care professional." *Id.* § 44-42-360(A). Finally, the Attorney General may

bring an action to enforce compliance with both the prohibition on gender transitions for minors and the prohibition on the use of public funds for gender transition procedures. *See id.* § 44-42-360(F). The Act took effect on May 21, 2024.

Over three months later, the Plaintiffs filed their complaint in this case. *See* Compl., Doc. 1 (Aug. 29, 2023). The complaint seeks injunctive relief against enforcement of the Act in its entirety by the Attorney General, the South Carolina Department of Health and Human Services (DHHS), the Medical University of South Carolina (MUSC), and the South Carolina Public Benefit Authority (PEBA). *See* Doc. 1 ¶¶ 18-45, pp. 58-60 (prayer for relief). Plaintiffs claim that enforcement of the Act violates the Equal Protection Clause, the doctrine of substantive Due Process, the Affordable Care Act (ACA), the Medicaid Act, the Americans with Disabilities Act, and the Rehabilitation Act. *See id.* ¶¶ 198-267.

The Plaintiffs simultaneously filed a motion for a preliminary injunction with respect to some of their claims. *See* Doc. 7. Specifically, they seek preliminary injunctive relief with respect to their Equal Protection, Due Process, ACA, and Medicaid Act claims. *See id.* Defendants now file this opposition to Plaintiffs' motion for a preliminary injunction.

LEGAL STANDARD

"A plaintiff seeking a preliminary injunction must demonstrate 'that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017) (quoting *Winter v. Nat. Res. Def. Defense Council, Inc.*, 55 U.S. 7, 20 (2008)). "A preliminary injunction shall be granted only if the moving party clearly establishes entitlement to the relief sought." *Id.*

ARGUMENT

I. Plaintiffs Have Failed To Demonstrate A Likelihood of Success On The Merits.

A. Plaintiffs Have Failed To Demonstrate Standing For The Preliminary Injunctive Relief They Seek.

A "plaintiff's 'burden of showing a likelihood of success on the merits necessarily depends on a likelihood that plaintiff has standing.'" *Action NC v. Strach*, 216 F. Supp. 3d 597, 630 (M.D.N.C. 2016) (quoting *Obama v. Klayman*, 800 F.3d 559, 565 (D.C. Cir. 2015)) (cleaned up); *see also Waskul v. Washtenaw Cnty. Comm. Mental Health*, 900 F.3d 250, 256 n.4 (6th Cir. 2018) (same). Alternatively, standing could be deemed a threshold issue that precedes the likelihood of success on the merits. *See United States v. South Carolina*, 840 F. Supp. 2d 898, 907 (D.S.C. 2011) (Gergel, J.). In either event, Plaintiffs must have standing to obtain preliminary injunctive relief.

To demonstrate standing, Plaintiffs "'must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Disability Rights S.C. v. McMaster*, 24 F.4th 893, 899 (4th Cir. 2022) (quoting *Deal v. Mercer Cnty. Bd. of Educ.*, 911 F.3d 183, 187 (4th Cir. 2018)). "At the preliminary injunction stage, then, the plaintiff must make a 'clear showing' that she is 'likely' to establish each element of standing." *Murthy v. Missouri*, 144 S. Ct. 1972, 1986 (2024) (quoting *Winter*, 55 U.S. at 22) (emphasis omitted)). "When a preliminary injunction is sought, a plaintiff's burden to demonstrate standing 'will normally be no less than that required on a motion for summary judgment.'" *Cachillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 907 n.8 (1990)); *see also Waskul*, 900 F.3d at 255 n.3 (6th Cir. 2018) (same); *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 912 (D.C. Cir. 2015) (same); *Guilford Coll. v. Wolf*, No. 1:18-cv-891, 2020 WL 586672, at *2 (M.D.N.C. Feb. 6, 2020) (same). "Where, as here, the parties have taken discovery, the plaintiff cannot rest on 'mere allegations,'

but must instead point to factual evidence" to demonstrate standing. *Murthy*, 144 S. Ct. at 1986 (internal quotation marks omitted).

1. Plaintiffs Have Failed To Demonstrate Redressability For Their Challenge To The Prohibition On Gender Transitions For Minors And Their Affordable Care Act Claim.

To demonstrate redressability, plaintiffs must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Widlife*, 504 U.S. 555, 561 (1992) (internal quotation marks omitted). "To determine whether an injury is redressable," the Court must "consider the relationship between the judicial relief requested and the injury suffered." *Murthy*, 144 S. Ct. at 1995 (internal quotation marks omitted). Specifically, the Court must determine whether enjoining *the particular defendants* will actually redress the purported injury. *See Haaland v. Brackeen*, 599 U.S. 255, 293 (2023).

Several recent decisions from the Supreme Court illustrate this principle. In *Brackeen*, the challengers sought "an injunction preventing the federal parties" in the case "from enforcing [the Indian Child Welfare Act] ICWA and a declaratory judgment that the challenged provisions are unconstitutional." 599 U.S. at 292-93. But the Court noted that the federal defendants were not the ones who enforced the relevant statutory provisions. *Id.* Instead, the relevant officials were "nonparties who would not be bound by the judgment." *Id.* at 293. Thus, the requested "injunction would not give petitioners a legally enforceable protection from the allegedly imminent harm." *Id.*

The Court's decision in *Whole Woman's Health v. Jackson*, 595 U.S. 30 (2021), likewise demonstrates this principle in action. There, the plaintiffs sued a number of state officials in an attempt to challenge the constitutionality of a Texas statutory provision that was enforceable primarily through a private cause of action. *See Whole Women's Health*, 595 U.S. at 35-36. As relevant here, the plaintiffs sought "to enjoin the Texas attorney general" from enforcing the statute on the theory that, although the Attorney General could not use the private cause of action, the

Court's injunction would also bind any private party who attempted to do so. *See id.* at 43-44. But the Supreme Court rejected that argument. "Supposing the attorney general did have some enforcement authority" under the statute, the Court held, there was "nothing that might allow a federal court to parlay that authority, or any defendant's enforcement authority, into an injunction against any and all unnamed private persons who might seek to bring their own [statutory] suits." *Id.* at 44. This holding flowed from the "traditional equitable principles" that "no court may lawfully enjoin the world at large or purport to enjoin challenged laws themselves." *Id.* (internal quotation marks omitted).

Finally, just last term, the Court decided *Murthy v. Missouri*, 144 S. Ct. 1972 (2024). There, the plaintiffs sought an order enjoining federal officials from pressuring social media platforms to regulate or remove individuals' social media posts and accounts. *See id.* at 1981. But the Court held that the plaintiffs "ha[d] a redressability problem." *Id.* at 1995. Although a "court *could* prevent these Government defendants from interfering with the platforms' independent application of their policies," the Court explained, "the platforms remain free to enforce, or not to enforce, those policies." *Id.* But the platforms were "not parties to the suit, and there is no reason they should be obliged to honor an incidental legal determination the suit produced." *Id.* (internal quotation marks omitted). Thus, the plaintiffs could not show that enjoining *the defendants* would redress the plaintiffs' alleged injury. *See id.*

These three decisions foreclose Plaintiffs' attempt to demonstrate standing sufficient for a preliminary injunction against the prohibition on gender transitions for minors.[2] That prohibition,

[2] Although Plaintiffs' preliminary-injunction motion is broadly framed as a challenge to H 4624 in its entirety, Plaintiffs do not challenge Section 2 of the Act, which is codified at S.C. CODE ANN. § 59-32-36. Thus, that provision will remain in effect regardless of any injunctive relief Plaintiffs obtain.

which appears in S.C. CODE ANN. §§ 44-42-320(A)-(B), is enforceable by (1) private parties via a cause action, *see id.* § 44-42-360(B); (2) "the licensing entity with jurisdiction over" the relevant medical provider or professional, *id.* § 44-42-360(A); and (3) the Attorney General, *see id.* § 44-42-360(F). Of these three entities or persons capable of enforcement, only the Attorney General is a defendant. The Plaintiffs have not sued any private party threatening imminent legal action under S.C. CODE ANN. § 44-42-360(B). Nor have the Plaintiffs sued any relevant licensing entity that would enforce the prohibition on gender transitions for minors through S.C. CODE ANN. § 44-42-360(A). *See also Whole Woman's Health*, 595 U.S. at 45-46 (noting that the plaintiffs could sue those individuals who were "an executive licensing official who may or must take enforcement actions against the petitioners if they violate the terms of" the relevant statute).

The absence of these parties dooms Plaintiffs' attempt to obtain a preliminary injunction with respect to the prohibition on gender transitions for minors. Even if the Plaintiffs obtained an order enjoining the Attorney General from enforcing the prohibition on gender transitions for minors through S.C. CODE ANN. § 44-42-360(F), private parties and the relevant medical licensing boards "remain free to enforce, or not to enforce, those policies." *Murthy*, 144 S. Ct. at 1995. There is "nothing that might allow a federal court to parlay" the Attorney General's "enforcement authority, into an injunction against any and all unnamed private persons who might seek to bring their own [H 4624] suits." *Whole Woman's Health*, 595 U.S. at 44. And Plaintiffs have failed to identify any medical professional in the State of South Carolina who would offer the interventions at issue here while the Act's private cause of action and licensing provision are enforceable. Thus, Plaintiffs' requested "injunction would not give [them] legally enforceable protection from the allegedly imminent harm." *Brackeen*, 599 U.S. at 293. In short, they "have a redressability problem." *Murthy*, 144 S. Ct. at 1995. And they have accordingly failed to demonstrate a likelihood

of success on their Equal Protection and Due Process claims challenging the prohibition on gender transitions for minors.

Plaintiffs face a similar problem with respect to their claims under the Affordable Care Act. For that claim, they have sued PEBA, DHHS, and MUSC. *See* Doc. 1 at ¶¶ 229-42. But the Act expressly permits the Attorney General to enforce the Act's prohibition on the use of "[p]ublic funds" for gender transition procedures in S.C. CODE ANN. § 44-42-340. *See id.* § 44-42-360(F) ("The Attorney General may bring an action to enforce compliance with . . . Section 44-42-340."). And the Plaintiffs have inexplicably failed to bring their ACA claim against the Attorney General. Thus, an injunction against PEBA, DHHS, or MUSC—which is all that Plaintiffs have sought, *see* Doc. 1 at ¶¶ 229-42—would not run against the Attorney General. Yet again, Plaintiffs' requested "injunction would not give [them] legally enforceable protection from the allegedly imminent harm." *Brackeen*, 599 U.S. at 293. And yet again, Plaintiffs "have a redressability problem." *Murthy*, 144 S. Ct. at 1995. Thus, for Plaintiffs' Equal Protection and Due Process challenges to the Act's prohibition on gender transition for minors and for Plaintiffs' ACA challenge, they have failed to demonstrate standing and thus failed to show a likelihood of success on the merits.

2. Plaintiffs Have Failed To Demonstrate An Injury In Fact For Their Challenge To The Prohibition On The Use Of Puberty Blockers Or For Any Surgical Procedures They Are Not Seeking.

Article III "standing is not dispensed in gross." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). Thus, "a plaintiff must demonstrate standing for each claim it seeks to press and for each form of relief that is sought." *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 778 (4th Cir. 2023) (internal quotation marks omitted). As explained above, a Plaintiff must show "an injury in fact that is concrete, particularized, and actual or imminent." *TransUnion*, 594 U.S. at 423. "Requiring a plaintiff to demonstrate a concrete and particularized injury caused by the defendant and redressable by the court ensures that federal courts decide only the rights of individuals and

that federal courts exercise their proper functions" under Article III. *Id.* (internal citations and quotations omitted). Without an Article III injury before it, a federal court may not adjudicate a claim that a statutory provision is unconstitutional. *See id.* ("Under Article III, federal courts do not adjudicate hypothetical or abstract disputes.")

A recent decision from the Supreme Court granting a stay in this very context is on point. *See Labrador v. Poe*, 144 S. Ct. 921 (Mem.) (2024). In *Labrador v. Poe*, a district court had issued injunctive relief enjoining Idaho "from enforcing 'any provision' of" its law prohibiting gender transitions for minors "under any circumstances." 144 S. Ct. at 921 (Gorsuch, J., concurring). "Among other things, this meant Idaho could not enforce its prohibition against surgeries to remove or alter children's genitals even though no party before the court had sought access to those surgeries or demonstrated that Idaho's prohibition for them offended federal law." *Id.* at 922. The Court stayed that injunction to the extent it awarded any injunctive relief that extended beyond "the provision to the plaintiffs *of the treatments they sought below*." *Id.* at 921 (emphasis added). As the lead concurrence explained, "a federal court may not issue an equitable remedy more burdensome to the defendant than necessary to redress the plaintiff's injuries." *Id.* at 923 (Gorsuch, J., concurring) (cleaned up). But in the decision below, the district court had "faced two plaintiffs seeking access to certain specific treatments, yet it issued an order applicable to all potential nonparties and all regulated treatments." *Id.* at 925 n.2. Because district courts may only "issu[e] equitable orders that redress the injuries of the plaintiffs before them," the district court erred. *Id.* at 926.

The principle that equitable relief may only extend to redress the Plaintiffs' Article III injury has two consequences here. First, the Plaintiffs lack standing to seek preliminary injunctive relief against enforcement of the Act's prohibition on the use of puberty blockers as part of a gender

transition. No Plaintiff is taking, has taken, or seeks to take puberty blockers as part of a gender transition. Thus, the administration of those "specific treatments" are not before the Court. *Id.* at 925 n.2. Second, Plaintiffs are not entitled to preliminary injunctive relief for any surgical procedure they have not demonstrated an intent to seek. Thus, even if Plaintiffs prevail on their motion for a preliminary injunction, the injunctive relief may not extend beyond "the treatments they [have] sought" here. *Id.* at 921.[3]

3. Plaintiff Nina Noe Has Failed To Demonstrate An Injury In Fact For The Medicaid Act Claim.

A Plaintiff's "injury in fact" must "be 'concrete'—that is, 'real, and not abstract.'" *TransUnion LLC*, 594 U.S. at 424 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016)). The only Plaintiff bringing a claim under the Medicaid Act is Nina Noe. *See* Doc. 1, ¶¶ 243-48. Notably, Nina's mother, Nancy Noe, does *not* bring a Medicaid Act claim.

Nina's claim for preliminary injunctive for this claim is premised on the loss of "coverage under Medicaid" that will affect "the financial" situation of Nina's family. *See* Doc. 7 at 28. Ordinarily, a monetary harm "is a classic pocketbook injury sufficient" for standing. *Tyler v. Hennepin County*, 598 U.S. 631, 636 (2023). But here, there is a wrinkle. Nina's *father* is the one with the Medicaid policy at issue, and Nina's father is not even a party to the case, let alone asserting a claim under the Medicaid Act. *See* Noe Dep. 13:8-14 (attached hereto as Exhibit 6) ("Q. Okay. And is it—the medical insurance that Nina has, is that provided through her father? A.

[3] This same analysis follows from the severability provision in H 4624, which provides: "If any section, subsection, paragraph, subparagraph, sentence, clause, phrase, or word of this act is for any reason held to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this act, the General Assembly hereby declaring that it would have passed this act, and each and every section, subsection, paragraph, subparagraph, sentence, clause, phrase, and word thereof, irrespective of the fact that any one or more other sections, subsections, paragraphs, subparagraphs, sentences, clauses, phrases, or words hereof may be declared to be unconstitutional, invalid, or otherwise ineffective." *See* H. 4624 § 3, 125th Sess. (S.C. 2024), https://bit.ly/40tngMH.

It is. Q. Okay. And what medical insurance is that? A. It is Blue Choice Medicaid.") Nor is Nancy Noe somehow representing Nina's father's interest; the two have been separated since 2016. *See id.* at 27:25-28:2. Defendants are aware of no authority recognizing standing in this scenario: A minor asserting a pocketbook injury on behalf of an individual who is not even a party to the case. Thus, Nina Noe has failed to demonstrate standing and thus failed to demonstrate a likelihood of success on the merits for the Medicaid Act claim.

4. Misanin Is Not Suffering An Injury In Fact That Is Traceable To MUSC.

The only Plaintiff bringing a claim against MUSC is Sterling Misanin. And Misanin's claim against MUSC is premised exclusively on a "gender-affirming surgery at a MUSC Health facility," *see* Doc. 1, ¶ 15—specifically, "a hysterectomy," which Misanin seeks for "an eventual phalloplasty," Misanin Decl., Doc. 7-11, ¶ 19 (Aug. 30, 2024).[4] But Misanin has already obtained the hysterectomy. Misanin Dep. 69:7-10 (attached hereto as Exhibit 7). And Misanin obtained hormones from Planned Parenthood, not MUSC. *Id.* at 50:16-23.

That leaves the phalloplasty. But at Misanin's deposition, it was made clear Misanin has no intention of obtaining a phalloplasty at MUSC. Indeed, Misanin does not even believe there is a doctor there who could perform one. *Id.* at 65:24-66:4. Instead, Misanin is already in conversations to obtain that surgery from a doctor in a different state. *Id.* at 63:16-65:23. And Misanin is not considering seeking "any other surgeries or procedures." *Id.* at 72:5-10. Thus, Misanin has no injury in fact that is traceable to MUSC, and Misanin lacks standing to obtain injunctive relief. *See TransUnion*, 594 U.S. at 423.

[4] Plaintiffs' PI memorandum makes on oblique reference to a reduction in "medical privacy" that Misanin has purportedly experienced. *See* Doc. 7 at 31. That is not a concrete and particularized injury that is traceable to any provision of the Act enforced by MUSC. *See TransUnion*, 594 U.S. at 424 (an "abstract" injury is not "concrete" for purposes of Article III).

B. Plaintiffs' Due Process Claim Fails Because There Is No Parental Right To Experimental And Harmful Medical And Surgical Interventions.

Hidden away in the Due Process Clause, the Parent Plaintiffs purport to have discovered a constitutional right to obtain puberty blockers, cross-sex hormones, and gender-transition surgeries for their children. But their analysis falls well short of the Supreme Court's requirements for a substantive Due Process right. That test requires that the right is "fundamental" or "deeply rooted in this Nation's history and tradition." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (internal quotation marks omitted). "But the use of these medications in general—let alone for children—almost certainly is not 'deeply rooted' in our nation's history." *Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205, 1220 (11th Cir. 2023). The "earliest-recorded uses of puberty blocking medication and cross-sex hormone treatment for purposes of treating the discordance between an individual's biological sex and sense of gender identity did not occur until well into the twentieth century." *Eknes-Tucker*, 80 F.4th at 1220-21.

In light of this history, the Parent Plaintiffs seek to raise the level of generality for the right they are asserting. For example, they rely on principles discussed in the Supreme Court's decision in *Parham v. J.R.*, 442 U.S. 584 (1979). *See* Doc. 7 at 21. But courts must "exercise the utmost care whenever" they "are asked to break new ground in th[e] field" of substantive Due Process, so they require "a 'careful description' of the asserted fundamental liberty interest." *Glucksberg*, 521 U.S. at 721 (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)). And "*Parham* does not at all suggest that parents have a fundamental right to direct particular medical treatment for their child that is prohibited by state law." *Eknes-Tucker*, 80 F.4th at 1223.

Indeed, there is not even a "historical recognition of a fundamental right of *adults* to obtain the medications at issue for themselves." *Id.* at 1224 n.18 (emphasis added). Therefore, "it would make little sense for adults to have a *parental* right to obtain these medications for their children

but not a *personal* right to obtain the same medications for themselves." *Id.* And it would make little sense to find a parental right to a pharmacological treatment that the FDA has not even approved for this use. *See L.W.*, 73 F.4th at 417-18. The cases Plaintiffs cite "applying the fundamental parental right in the context of medical decision-making do not establish that parents have a derivative fundamental right to obtain particular medical treatment for their children as long as a critical mass of medical professionals approve." *Eknes-Tucker*, 80 F.4th at 1224; *see also L.W.*, 73 F.4th at 417-18 (citing *Abigail All. for Better Access to Dev. Drugs v. von Eschenbach*, 495 F.3d 695, 703 (D.C. Cir. 2007) (en banc)). In sum, Plaintiffs "have not shown that a right to new medical treatments" such as these "is deeply rooted in our history and traditions and thus beyond the democratic process to regulate." *L.W.*, 73 F.4th at 417 (internal quotation marks omitted).

C. Plaintiffs' Equal Protection and Due Process Claims Fail Because The Act Satisfies Any Level Of Scrutiny.

The Act satisfies any level of scrutiny.[5] There can be no doubt that States "have a compelling interest in protecting children from drugs, particularly those for which there is uncertainty regarding benefits, recent surges in use, and irreversible effects." *Eknes-Tucker*, 80 F.4th at 1225.[6] Similarly, "[p]rotecting public health from ineffective medicine is an important government interest." *Kadel*, 100 F.4th at 156. Thus, the relevant question is whether the challenged provisions are "narrowly tailored" or "substantially related" to serve the compelling

[5] Although Defendants believe the Act should be subject only to rational basis review, *see, e.g.*, *L.W.*, 83 F.4th at 479-89; *Eknes-Tucker*, 80 F.4th at 1227-31, they acknowledge that *Kadel* likely currently forecloses that argument, but Defendants preserve the argument to later contend that heightened scrutiny does not apply.

[6] Assuming that Plaintiffs' Due Process theory is correct, the Court would apply strict scrutiny—and thus assess whether the challenged provisions are "narrowly tailored" to serve a "compelling government interest"—only with respect to the Parent-Plaintiffs' Due Process claim. *See* Doc. 7 at 21. For Plaintiffs' Equal Protection claims, in contrast, the Court would apply lesser scrutiny, asking only whether the statute is substantially related to an important government interest. *See Kadel*, 100 F.4th at 156.

government interest of protecting children, and the public more generally, from ineffective and harmful medicine.

For several reasons, the answer is yes. Specifically, there are numerous critical aspects of both gender dysphoria and these interventions that are unknown as the following admissions from Plaintiffs' own experts demonstrate:

- We do not know what causes gender dysphoria. Olson-Kennedy Dep. 20:7-10; Shumer Dep. 33:18-21.
- We have no objective medical test that can detect gender dysphoria. Antommaria Dep. 30:1-7; Olson-Kennedy Dep. 19:18-20:6.
- We cannot determine whether any particular individual with gender dysphoria will continue to be transgender in the future. Shumer Dep. 33:22-25.
- We have no idea what the long-term effects of pubertal suppression are on neurodevelopment. Olson-Kennedy Dep. 60:19-23; Antommaria Dep. 47:3-12; Karasic Dep. 143:4-18.
- We do not understand why there has been a sudden and recent increase in the number of individuals with gender dysphoria. Antommaria Dep. 30:9-31:7; Olson-Kennedy Dep. 21:21-22:8.
- We do not know why this increase has disproportionately affected females. Antommaria Dep. 31:9-32:4.
- We do not know why there is an overrepresentation of individuals with an Autism Spectrum Disorder. Antommaria Dep. 42:7-17; Shumer Dep. 27:20-28:2.
- We do not know if patients' bone mineral density will ever return to normal later in life after taking puberty blockers. Antommaria Dep. 45:17-46:7.
- We have no data or clinical experience regarding patient outcomes after the age of 30 for adolescents who used puberty blockers followed by cross-sex hormones. Olson-Kennedy Dep. 88:1-5 (no "clinical experience related to [her] patient outcomes after 25 years of age"); Shumer Dep. 108:18-21 (no "clinical experience with respect to patient outcomes after 27 years of age"); Antommaria Dep. 53:6-12 ("I'm not aware of any studies" that follow "individuals to their 30th birthday when measuring the safety or efficacy of puberty blockers followed by cross-sex hormones[.]").

The lack of knowledge in this area precludes the possibility of fine-tuning some sort of more narrowly tailored regulatory scheme. Given the host of known harms, the unknowns regarding the cause and etiology of gender dysphoria, and the total lack of reliable evidence demonstrating benefit from these interventions, the Act's provisions are the only way to *adequately* serve the compelling interests of protecting minors and the public more generally from ineffective and dangerous medicine.[7]

Further complicating the analysis is the existence of detransitioners. "Respected national health care systems of several countries have warned of the risk that medical transition of minors can lead to detransition and severe regret due to irreversible physical harms." Cantor Decl. ¶ 175. As Plaintiffs' own experts admit, there is no way to know whether a patient will detransition in the future. *See* Shumer Dep. 33:22-25. Plaintiffs assert there are "low levels of regret" for these interventions. Doc. 7 at 7. But neither the literature nor Plaintiffs' experts' clinical experience can capture this phenomenon yet "[b]ecause detransition (1) can occur several years after transition, (2) is not typically reported to the clinic that provided transition," and (3) "cannot be distinguished by the clinic from dropping out of clinical study for other reasons." Cantor Decl. ¶ 175 (internal citation omitted).

Remarkably, Plaintiffs' memorandum does not even mention the word "detransitioner." This seems to be of a piece with a broader denialism among proponents of medical and surgical interventions. *See, e.g.*, *Eknes-Tucker*, 114 F.4th at 1269 (Lagoa, J., concurring) (recounting WPATH President's statement that some view "talk of the detransition phenomenon as distracting" (cleaned up)). Indeed, Plaintiffs' experts admit they have never even personally spoken with

[7] Any suggestion that a more narrowly tailored option would be limiting the use of these interventions to clinical trials does not help Plaintiffs because they do not seek to perform clinical trials.

someone who has detransitioned. *See* Shumer Dep. 156:24-157:3; Antommaria Dep. 127:18-24. But denying that reality does not make it go away—no matter how inconvenient it may be. And the existence of detransitioners, combined with the impossibility of identifying them ahead of time, makes tailoring impossible in this context.

Plaintiffs' invocation of *Kadel* is no answer. *Kadel* was decided on a summary judgment record that was closed two years ago. *See, e.g.*, *Kadel v. Folwell*, 620 F. Supp. 3d 339 (M.D.N.C. 2022) (granting partial summary judgment on August 10, 2022); *Fain v. Crouch*, 618 F. Supp. 3d 313 (S.D. W. Va. 2022) (granting summary judgment on August 2, 2022). Since that time, there have been numerous developments that have fundamentally changed the understanding of the evidence supporting the use of these interventions as a treatment for gender dysphoria, including the following: (1) The Cass Review published its Final Report, which stated that "[t]his is an area of remarkably weak evidence" and that "we have no good evidence on the long-term outcomes of interventions to manage gender-related distress," Cass Review – Final Report at 13; (2) "England's NHS announced that puberty blockers are no longer available as a routine treatment" because "there is not enough evidence to support the safety or clinical effectiveness" and drastically limited the availability of cross-sex hormones for minors, *Eknes-Tucker*, 114 F.4th at 1260 (Lagoa, J., concurring in denial of rehearing en banc); (3) Researchers from York University in the U.K. published systematic reviews concluding that the WPATH and Endocrine Society Guidelines were not methodologically rigorous and that the evidence for puberty blockers and cross-sex hormones was so weak that no conclusions could be drawn about their effect on gender dysphoria or mental health, Cantor Decl. ¶¶ 96-101; and (4) WPATH was exposed as an organization driven by "ideology, not science," *Eknes-Tucker*, 114 F.4th at 1261 (Lagoa, J., concurring in denial of rehearing en banc). These developments underscore that the Act's provisions are the only way to

adequately serve the compelling interest of "[p]rotecting public health from ineffective medicine." *Kadel*, 100 F.4th at 156.

Finally, Plaintiffs drop a footnote to suggest that the Act lacks a rational basis. *See* Doc. 7 at 13 n.7. This halfhearted argument fails on the law and the facts. On the law, Plaintiffs would need to show the Act "lack[s] any purpose other than a bare desire to harm." *Trump v. Hawaii*, 585 U.S. 667, 705 (2018) (cleaned up). But the Act obviously has another purpose: protecting the public from ineffective and harmful medical and surgical interventions. And the Act, "like other health and welfare laws, is entitled to a strong presumption of validity." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301 (2022) (internal quotations omitted). On the facts, Plaintiffs' argument apparently rests on a footnote elsewhere in their brief that purports to recount allegedly critical statements made by legislators. *See* Doc. 7 at 16-17 n.9. But Plaintiffs' characterization of these statements does not survive even cursory inspection. For example, Plaintiffs state that "[m]embers of the Senate Medical Affairs Committee compared students coming out to their teachers as transgender to students dressing up as animals." *See id.* But the Legislator was referring to an event that *actually happened* at a school in his district: "A young lady was authorized to be a cat and call herself a cat, a feline, and that was encouraged, I've got proof of that . . . that happened in Greenwood county." Feb. 21 Comm. Hr'g at 7:50-8:27. Plaintiffs also fault Representative White for saying that gender dysphoria is "a mental disorder," Doc. 7 at 16 n.9, but that is precisely what the DSM-V says it is. Contrary to Plaintiffs' borderline-frivolous implied assertion of bigotry, Legislators enacted H 4624 because they believed "gender transition procedures" are "harmful" based on the scientific evidence. *Id.* at 22:15-45. Thus, Plaintiffs have not (and cannot) show that the Legislature acted out of any animus or desire to harm. To the contrary, the Legislature acted to protect individuals from these dangerous and unproven interventions.

In sum, given the glaring lack of reliable evidence demonstrating any benefit of these interventions, it is unsurprising that Plaintiffs' own expert *agrees* that "reasonable people can review the same evidence" he has "and reach a contrary conclusion" with respect to the safety and efficacy of these interventions. *See* Shumer Dep. 137:21-138:2.

D. Plaintiff Noe's Medicaid Act Claim Fails.

As explained above, Plaintiff Nina Noe lacks standing to bring a Medicaid Act Claim. *See* I.A.3, *supra*. But even if Nina had standing, the claim would likely fail on the merits because there is no private cause of action to enforce the Medicaid Act's availability and comparability requirements.

To determine whether particular statutory requirements are enforceable by private parties under 42 U.S.C. § 1983, courts first ask whether the statutory provisions "*unambiguously* confer individual federal rights." *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 180 (2023). But even for provisions that do confer individual rights, courts must also ensure that Congress did not intend to preclude the use of Section 1983 to enforce those provisions in equity. *See id.*[8] For example, the Supreme Court has previously held that Congress had expressed an intent to foreclose equitable relief for a particular provision of the Medicaid Act for two reasons. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 328 (2015). "First, the sole remedy Congress provided for a State's failure to comply with Medicaid's requirements" was "the

[8] Although *Kadel* held that similar exclusions in West Virginia violated the availability and comparability requirements of the Medicaid Act, the Court was not presented with—and thus did not pass upon—the question whether those requirements may be enforced by private parties in the first place. Defendants are thus unaware of any controlling authority on this question. Although other Courts have held that there is a private right of action to enforce these provisions, those Courts did not grapple with the remedial aspect of the *Armstrong* test but rather focused on the rights-creating language. *See Davis v. Shah*, 821 F.3d 231, 255 n.12 (2d Cir. 2016) (comparability provision); *Waskul v. Washtenaw Cnty. Comm. Mental Health*, 979 F.3d 426, 446-48 (6th Cir. 2020) (focusing on the "promptness" language not at issue here).

withholding of Medicaid funds by the Secretary of Health and Human Services." *Id.* at 328 (citing 42 U.S.C. § 1396c). Second, that exclusive remedy "combined with the judicially unadministrable nature of [the provision's] text" "preclude[d] the availability of equitable relief" through "private enforcement." *Id.* at 328-29.

Here, *Armstrong* counsels against finding a private cause of action to enforce the availability and comparability requirements of the Medicaid Act. The availability provision requires participating States to "provide . . . for making medical assistance available" to individuals, "including at least" an enumerated list of "care and services." *See* 42 U.S.C. § 1396a(10)(A). That list "includes broad categories of care, like 'inpatient hospital services,' 'outpatient hospital services,' 'rural health clinic services,' 'laboratory and X-ray services,' and others." *See Kadel*, 100 F.4th at 188-89 (Richardson, J., dissenting) (quoting relevant provisions). The comparability provision states that the "medical assistance" described above offered "to any individual" "shall not be less in amount, duration or scope than the medical assistance made available to any other such individual." *See* 42 U.S.C. § 1396a(10)(B). These provisions establish a "judgment-laden standard." *Armstrong*, 575 U.S. at 329. "For instance, what does it mean that a state's Medicaid program must 'provide for making inpatient" and outpatient hospital services available'?" *Kadel*, 100 F.4th at 189 (Richardson, J., dissenting). "Explicitly conferring enforcement of [these] judgment-laden standard[s] upon the Secretary alone" strongly suggests Congress sought to utilize "'the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decisionmaking" and avoid "the comparative risk of inconsistent interpretations and misincentives that can arise out of an occasional inappropriate application of the statute in a private action.'" *Armstrong*, 575 U.S. at 328-29 (quoting *Gonzaga Univ. v. Doe*, 536 U.S. 273, 292 (2002) (Breyer, J., concurring)). Thus, the

"sheer complexity associated with enforcing" these provisions "coupled with the express provision of an express administrative remedy, shows that the Medicaid Act precludes private enforcement" of these provisions "in the courts." *Id.* (internal citation omitted).

Separately, even if Nina Noe had standing and had a cause of action, the Act does not violate the availability provision. As even *Kadel* acknowledged, "States can 'place appropriate limits on a service based on such criteria as medical necessity.'" 100 F.4th at 161 (quoting 42 C.F.R. § 440.230(d)). The issue in *Kadel*, however, was that the State of "West Virginia relie[d] on a third party" to determine "which services are medically necessary," *id.* at 161 n.29, and that third-party *had determined* that "surgery to treat gender dysphoria is medically necessary," *id.* at 139. Here, in contrast, the State of South Carolina, through enactment of the Act, has concluded that medical and surgical gender transitions are *not* medically necessary. Thus, the Act does *not* prohibit "coverage of all surgeries to treat gender dysphoria, *regardless of medical necessity*." *Id.* at 162. Instead, the State has made the decision that the prohibited interventions are not, in fact, medically necessary at all. That conclusion does not violate the Availability requirement.

Nor can Plaintiffs assert that their experts' (or WPATH's) determination of medical necessity is based on rigorous scientific analysis. As it turns out, Plaintiffs' expert, Dr. Karasic, *helped write* the statement of medical necessity in WPATH's SOC-8. *See* Karasic Dep. 173:24-174:8, 174:25-175:6. And as part of internal discussions in WPATH regarding that statement, Dr. Karasic stressed that the medical-necessity statement was critical in part because there were "lawsuits in the U.S. trying to reverse the position of trans healthcare by asserting that it is categorically not medically necessary." *See id.* at 182:19-183:7. Even Plaintiffs' expert Dr. Shumer agrees "that clinical guidelines should not be written with the goal of obtaining an advantage in litigation." Shumer Dep. 140:22-25. Apparently, that is precisely the goal of WPATH's medical-

necessity statement. And yet again, it appears "WPATH's lodestar is ideology, not science." *Eknes-Tucker*, 114 F.4th at 1261 (Lagoa, J., concurring).

E. Plaintiffs' ACA Claim Fails With Respect To Pubertal Suppression.

As explained above, Plaintiffs lack standing for their ACA claims. *See* I.A.1, *supra*. But even if they have standing for some aspect of those claims, and even if they somehow have standing to challenge the Act's prohibition on the use of puberty blockers as part of a gender transition, *but see* I.E, *supra*, their request for preliminary-injunctive relief under the ACA would fail with respect to puberty blockers.

Kadel's reading of Section 1557 turned on the Supreme Court's decision in *Bostock v. Clayton County*, 590 U.S. 644 (2020). *See Kadel*, 100 F.4th at 164. In *Bostock*, the Court held that a classification based on transgender status constituted sex discrimination because an individual's sex was a but-for cause of the discrimination. *See* 590 U.S. at 656. The "but-for test" from *Bostock* "directs us to change one thing at a time and see if the outcome changes." *Id.* If a change in sex leads to change in outcome, sex is a but-for cause. *See id.* But a patient's sex is not a but-for cause in the denial of puberty suppression because *the same drug* is used for both boys and girls. Thus, changing the patient's sex changes nothing, and *Bostock*'s but-for test is not triggered. As a result, the Act's prohibition on the use of public funds to pay for puberty blockers as part of a gender transition does not violate the ACA.

II. Plaintiffs Have Failed To Meet The Remaining Preliminary-Injunction Factors.

South Carolina "will suffer irreparable harm from its inability to enforce the will of its legislature, to further the public-health considerations undergirding the law, and to avoid irreversible health risks to its children" and its public-funding recipients. *L.W.*, 73 F.4th at 421. Moreover, as catalogued above, Plaintiffs have failed to provide evidence showing that the benefits of these treatments outweigh the harms associated with them. Indeed, the *entire point* of the Act is

to *prevent* irreparable harm to individuals from these specific interventions. South Carolina acknowledges that Plaintiffs disagree about how best to treat gender dysphoria, but South Carolina's "elected representatives made these precise cost-benefit decisions" in adopting the Act. *Id.* at 421. Moreover, the Act's drawdown period "'lessens the harm' to minors 'who wish to continue receiving treatment'" until then. *Doe 1 v. Thornbury*, 75 F.4th 655, 657 (6th Cir. 2023) (per curiam) (quoting *L.W.*, 73 F.4th at 421).

When the government is a party, the balance of equities and public-interest "factors merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, South Carolina's "interests in applying the law to its residents and in being permitted to protect its children [and citizens] from health risks weigh heavily in favor of the State at this juncture." *L.W.*, 73 F.4th at 421-22. If the Act is enjoined, individuals in South Carolina will face lasting harm and irreversible damage to their bodies. Plaintiffs have not shown they are entitled to an injunction imposing that harm to the public.

III. Plaintiffs Have Failed To Show An Entitlement To Class-wide Relief.

For the reasons explained in Defendants' opposition to Plaintiffs' motion for class certification, the Plaintiffs have failed to show an entitlement to class-wide preliminary injunctive relief. Specifically, they have failed to demonstrate standing to support a class action, failed to satisfy the requirements of numerosity, commonality, typicality, and adequacy of Rule 23(a), and have failed to satisfy Rule 23(b)(2). The Court should thus deny Plaintiffs' request for preliminary class-wide relief for the same reasons it should deny their motion for class certification.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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