No. 22-1721

# In the United States Court of Appeals for the Fourth Circuit

MAXWELL KADEL; JASON FLECK; CONNOR THONEN-FLECK; JULIA MCKEOWN; MICHAEL D. BUNTING, JR.; C.B., by his next friends and parents; SAM SILVANE; and DANA CARAWAY,

Appellees,

v.

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina; and DEE JONES, in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees,

Appellants.

On Appeal from the United States District Court for the Middle District of North Carolina Case No. 1:19-cv-00272

# **Brief of Appellants**

John G. Knepper LAW OFFICE OF JOHN G. KNEPPER, LLC 1720 Carey Ave. Suite 590 Cheyenne, WY 82001 Telephone: (307) 632-2842 Facsimile: (866) 499-6894 john@knepperllc.com Kevin G. Williams Mark A. Jones BELL, DAVIS & PITT, P.A. 100 N. Cherry St. Suite 600 Winston-Salem, NC 27101 Telephone: (336) 722-3700 Facsimile: (336) 722-6558 kwilliams@belldavispitt.com mjones@belldavispitt.com

Counsel for Appellants

August 31, 2022

#### UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

#### **DISCLOSURE STATEMENT**

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. <u>22-1721</u> Caption: <u>Kadel, et al. v. Folwell, et al.</u>

Pursuant to FRAP 26.1 and Local Rule 26.1,

Dale Folwell (in his official capacity as the State Treasurer of North Carolina) (name of party/amicus)

who is <u>Appellant</u>, makes the following disclosure: (appellant/appellee/petitioner/respondent/amicus/intervenor)

- 1. Is party/amicus a publicly held corporation or other publicly held entity? YES VNO
- 2. Does party/amicus have any parent corporations? YES VNO If yes, identify all parent corporations, including all generations of parent corporations:

- 4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ✓NO If yes, identify entity and nature of interest:
- 5. Is party a trade association? (amici curiae do not complete this question) YES NO If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:
- 6. Does this case arise out of a bankruptcy proceeding? YES NO If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? YES NO If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/Mark A. Jones	Date:	7/8/2022	
Counsel for: Dale Folwell (in his official capacity)			

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Pursuant to FRAP 26.1 and Local Rule 26.1,

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Plan for Teachers and State Employees)

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Signature: /s/	Mark A. Jones	Date:	7/8/2022
2	ee Jones (in her official capacity)		

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# STATEMENT OF JURISDICTION

This is an appeal from an order of the United States District Court for the Middle District of North Carolina (Biggs, J.). Plaintiffs/Appellees (hereinafter "*Plaintiffs*") invoked federal question jurisdiction and *Ex Parte Young*, seeking an injunction under the Equal Protection Clause of the Fourteenth Amendment. Upon Plaintiffs' motion for partial summary judgment, on June 10, 2022, the district court issued an injunction that (1) required Defendants/Appellants (hereinafter "*Defendants*") to eliminate one of the Plan's coverage exclusions and (2) mandated that Defendants provide coverage for "medically necessary services for the treatment of gender dysphoria." JA3734. Defendants timely noted this appeal on July 1, 2022. JA3642-3643; *see* Fed. R. App. P. 4(a)(1)(A). This Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1).

# **QUESTIONS PRESENTED**

- I. Plaintiffs challenge the North Carolina State Health Plan's failure to cover certain prescriptions and surgeries. In *Geduldig v. Aiello*, 417 U.S. 484, 494–96 (1974), the Supreme Court held that challenges "related to the asserted underinclusiveness of the set of risks that the State has selected to insure" are subject to rational basis review. Did the district court err when it applied intermediate scrutiny to the Plan's coverage exclusion?
- II. No federal or state law requires the State Health Plan to cover all medically necessary treatments. Did the district court err by concluding that Plaintiffs are "similarly situated" to other Plan

participants who receive treatments for different medical diagnoses?

- III. Does the district court's injunction improperly fail to "state its terms specifically" and "describe in reasonable detail" the "act or acts restrained or required" in the order itself, as required by Fed. R. Civ. P. 65(d)(1)?
- IV. Did the district court improperly admit and rely upon facts outside the record in its order granting summary judgment?
- V. Did the district court abuse its discretion in excluding certain portions of Defendants' expert testimony?

#### **INTRODUCTION**

The North Carolina State Health Plan spends nearly \$4 billion each year for health care services. The Plan's structure is not financially sustainable: costs increase by 7% per year, while funding increases by only 4% per year. JA171. Defendants and other Plan officials have focused on reducing costs as one strategy to preserve the Plan's fiscal health. JA167. Defendants prioritize coverage for "basic health" needs affecting a large portion of Plan members, such as diabetes, orthopedic issues, rheumatoid arthritis, and cancer. JA171-173. The Plan declines requests to expand covered benefits unless the changes benefit the overall health of the Plan's population or the new benefits are required by law. *Id.* This is possible, in part, because no federal or state law requires large employer-sponsored group health plans, like the State Health Plan, to cover every medically necessary treatment for members, and the Plan does not. JA164-165.

Plaintiffs are Plan members who are either transgender or parents of transgender minors. Plaintiffs also have been diagnosed with gender dysphoria, which is a psychiatric condition that can affect transgender, cisgender, and gender-non-binary individuals alike. JA207; JA209-211, JA204-205. Plaintiffs assert that certain prescription drugs and surgeries—such as hormone supplements and cosmetic surgeries, among others—are medically necessary treatments for gender dysphoria.

This case pits Plaintiffs' desire for the Plan to pay for these treatments against one of the Plan's longstanding coverage exclusions. Since the 1990s, the Plan has not covered "[t]reatment or studies leading to or in connection with sex changes or modifications and related care." JA181.<sup>1</sup> Plaintiffs may obtain these treatments on their own, regardless of whether the State Health Plan will provide coverage for them.

<sup>&</sup>lt;sup>1</sup> The Plan suspended this exclusion for the 2017 calendar year, awaiting the outcome of litigation over a federal regulation mandating such coverage. The federal regulation was enjoined, and the Plan's exclusion returned to effect at the conclusion of the oneyear suspension.

Nevertheless, Plaintiffs view this exclusion not as a limitation of coverage benefits, but rather as an impermissible classification of Plan participants.

However, the State Health Plan provides every Plan participant with the same health benefits to protect against the same health risks. For example, the State Health Plan covers reconstructive breast surgery following a mastectomy, regardless of whether the recipient Plan member is transgender or cisgender. See N.C. Gen. Stat. § 135-48.50(7). Likewise, the State Health Plan does not cover acupuncture treatments, regardless of whether the recipient Plan member is transgender or cisgender. The health risks covered and the premiums charged are identical for every North Carolina state employee. Because the Plan provides the same health coverage regardless of sex, gender or transgender status, and because the district court's judgment does not hold that the Plan exclusion is the result of discriminatory intent, the disputed coverage exclusion does not violate the Equal Protection Clause.

#### STATEMENT OF THE CASE AND OF THE FACTS

# I. The North Carolina State Health Plan for Teachers and State Employees

The North Carolina State Health Plan for Teachers and State Employees (the "State Health Plan" or the "Plan") is the largest purchaser of healthcare and pharmaceuticals in North Carolina, JA154, funding healthcare for more than 740,000 teachers, legislators, state and local government employees, retirees, and their dependents. JA159-160; JA167. Until 2018, Plan members paid no premiums for their own health coverage, and enacting the current scheme, with a \$50 monthly employee premium for the most comprehensive plan, "was a herculean effort." JA173-174. The North Carolina General Assembly appropriates money for the remaining costs of employee healthcare, but this appropriation currently increases by only 4% per year while healthcare costs are rising by 7% per year. JA171.

Plan members can purchase coverage for their spouses and children by paying the unsubsidized cost of the increased coverage. For the most comprehensive plan, adding children results in an additional payroll deduction of \$255/month, adding a spouse costs an additional \$650/month, and adding both a spouse <u>and</u> children costs an additional

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\$670/month. JA177. At a total cost of \$720 per month (\$50 for the employee plus \$670 for the spouse and family), lower-paid employees who purchase family coverage must "work one week out of a month just to cover their Health Plan for their family." JA173. These high premiums further undermine Plan solvency; they discourage healthy families from enrolling in the Plan unless they already know they are about to incur significant healthcare costs.

Defendants Dale Folwell, in his official capacity as State Treasurer of North Carolina, and Dee Jones, in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees, are state officials involved in the operation of the State Health Plan.

# II. The Plaintiffs and Gender Dysphoria

Plaintiffs either are, or were, enrolled in the State Health Plan. Plaintiffs are either transgender individuals or the legal guardians of two transgender minors. Plaintiffs also suffer from gender dysphoria, which is a diagnosed mental illness. A person with gender dysphoria has a "cognitive discontent" leading to "distress" from the "incongruence between one's experienced or expressed gender and one's assigned

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gender." AMERICAN PSYCHOLOGICAL ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 451 (5th ed. 2013). Transgender identity is not mental illness. *Id*.

Critically, not all transgender individuals suffer from gender dysphoria. JA207; JA209-211. Inversely, "there may be people who have symptoms of gender dysphoria, but they personally don't identify as transgender." JA204-205, JA209-211. There is no evidence in the record about what proportion of transgender individuals suffer from gender dysphoria; one of Plaintiffs' experts has stated that "no one knows the answer to that [question]." JA213.

Plaintiffs pay the exact same premiums, deductibles, and copays, and are provided coverage for the same health risks, as every other enrollee in the Plan. JA177.

### **III.** State Health Plan Benefits and Exclusions

#### A. Plan Benefits

The Plan provides coverage for thousands of diagnoses, but it is not required by any law to, cannot, and does not cover every medically necessary procedure. JA161; JA165. For each Plan coverage option, the Plan's benefits booklet describes the covered and non-covered

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diagnoses and services. JA172. The booklet specifically states that coverage does not extend to "[a]nything specifically listed in this benefits booklet as not covered or excluded, regardless of medical necessity." JA178. The Plan does not cover any treatments that are not medically necessary. JA161; JA165.

# **B.** Coverage Exclusions affecting Plaintiffs

As established through discovery, the Plan provides counseling for gender dysphoria on the same terms as any other diagnosed mental illness. JA191 ¶28. Since the 1990s, the Plan has had coverage exclusions that limit other treatments for gender dysphoria. JA158-159; JA175-176. Even if medically necessary, the Plan does not cover:

> Cosmetic services, which include the removal of excess skin from the abdomen, arms or thighs, skin tag excisions, cryotherapy or chemical exfoliation for active acne scarring, superficial dermabrasion, injection of dermal fillers, services for hair transplants, electrolysis and <u>surgery for</u> <u>psychological or emotional reasons</u>, except as specifically covered by the Plan.

> Treatment or studies leading to or in connection with sex changes or modifications and related care.

> The following drugs or medications: ... Experimental medication or any medication or device not approved by the Food and Drug

Administration ("*FDA*") for the applicable diagnosis or treatment.

JA179-182 (emphasis added).

The Plan benefits booklet provides guidance to members about covered benefits. Blue Cross/Blue Shield of North Carolina ("**BCBS**"), the Plan's current Third-Party Administrator, uses the Plan booklet's guidance to determine the precise benefits available to Plan members using the health care industry's medical coding system. JA184-185 at  $\P\P6-7,11$ . CVS/Caremark ("**CVS**"), the Plan's pharmacy benefit manager, uses the Plan booklet to guide its management of the Plan's prescription drug coverage. JA156; JA197-200.

## C. Implementation of the Plan's Coverage Exclusions

The Plan, BCBS, and CVS do not identify whether a participant is transgender. JA170; JA187 ¶; JA191 ¶28; JA224-225. BCBS does not consider a patient's sex when reviewing claims connected to gender dysphoria, and BCBS does not code or track whether a Plan participant is transgender, cisgender, non-binary, or otherwise. JA190-191 ¶¶22,28.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> The Plan admittedly allows members to identify their gender upon enrollment, but members decide what information to provide and can switch their identified gender at any time. This information is

Payment for covered healthcare is based solely on the diagnosis and procedure codes provided with the patient's claim. When BCBS receives a claim from a healthcare provider, it reviews whether the claim is for (1) a Plan member with (2) a covered diagnosis and (3) is for a covered procedure. If all three requirements are met, then BCBS pays for the treatment. If one of these three variables is missing, then the claim is denied. JA184-185 ¶¶6-9.

Many of the treatments identified by Plaintiffs are considered "cosmetic procedures" under BCBS guidelines and are automatically denied for all Plan members, including several treatments that Plaintiffs have identified as "medically necessary" for the treatment of gender dysphoria, such as shoulder shaping, chin contouring and implants, mandible reduction, and chondrolaryngoplasty (tracheal shave). JA190-191 ¶25; *compare* JA4255-4256. BCBS also denies coverage for four surgical procedures that are used only to treat gender dysphoria. JA188-189 ¶20. Some other surgical procedures, such as mastectomies, are covered for certain diagnoses, but are not covered when the

used to perform statistical analysis of the health of the plan population, not to make coverage decisions. JA168-170.

accompanying diagnosis indicates the procedures relate to treatment for gender dysphoria. JA189-190  $\P{21}$ .

CVS reviews prescription drug claims for the Plan. When a prescription drug is not subject to prior authorization, CVS only considers four questions: whether the beneficiary is an eligible Plan participant, whether the drug is covered for any purpose by the Plan, whether the pharmacy is in-network, and whether the prescription is within quantity limits. CVS never inquires, and never learns, the patient's diagnosis or whether the member is transgender. Accordingly, the Plan covers many medications that Plaintiffs seek (*e.g.* estrogen or spironolactone). JA216-223.

However, some medications are expensive or subject to abuse. For these medicines, CVS requires the treating physician to obtain prior authorization before filling a prescription. Once the healthcare provider has submitted its request for prior authorization, CVS approval is based on the supporting diagnosis. Seven medications identified by Plaintiffs for treatment of gender dysphoria require prior authorization. None of these medications are FDA-approved for treatment of gender dysphoria, so CVS denies coverage for them unless the Plan specifically directs otherwise. JA224-225.

#### D. The 2017 Plan Year

In December 2016, the Plan expanded its benefits to cover treatment of gender dysphoria. At that time, the U.S. Department of Health and Human Services had issued a regulation (later rescinded) that required the Plan, as a recipient of federal funding, to provide coverage for treatment of gender dysphoria. JA4684. See generally Health Plan Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376 (May 18, 2016); replaced by Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160 (June 19, 2020).

The Plan's leadership was told that failure to expand its benefits could lead to either suspension or termination of federal funding or private lawsuits against the Plan. JA4684. At the same time, as the Board of Trustees noted, litigation was ongoing that challenged the new federal regulation. JA4686. The Board of Trustees suspended its coverage exclusions specifically tied to or affecting gender dysphoria for the 2017 Plan year only. JA4689-4690. By late 2017, the HHS regulation was enjoined by a federal court, and the Plan's 2016 suspension (which authorized coverage for gender dysphoria) lapsed by its own terms, with no further action by Defendants or the Board of Trustees.

#### **IV.** Procedural History

Plaintiffs' complaint raises claims against Defendants under the Equal Protection Clause, the Affordable Care Act ("ACA"), and Title VII of the Civil Rights Act of 1964. JA80-91. The district court denied Defendants' motion to dismiss Plaintiffs' Equal Protection Clause and ACA claims, see JA20-21 (Doc. Nos. 32, 45), and this Court affirmed a portion of the district court's decision, holding that the Plan itself had waived sovereign immunity for ACA-related claims, on interlocutory appeal, see Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps., 12 F.4th 422 (4th Cir. 2021) (No. 20-1409), as amended (Dec. 2, 2021), cert. denied, 142 S. Ct. 861 (2022).

Plaintiffs moved for summary judgment on all three claims, *see* JA278-79, and Defendants moved for summary judgment on the ACA and Title VII claims, *see* JA106-107. A group of third-party medical associations sought leave to file an *amicus curiae* brief in support of

Plaintiffs' motion for summary judgment, *see* JA95-101, which the district court granted over Defendants' objection, *see* JA466-476, JA3535-3538; JA3539-3558. Plaintiffs also moved to exclude Defendants' expert testimony on grounds of qualification, relevance, and reliability. *See* JA1092-3129.

The district court granted partial summary judgment to Defendants on Plaintiffs' Title VII claims, JA3714-3720, and reserved ruling on the parties' motions regarding the ACA claims, JA3726-3727. The district court granted partial summary judgment to Plaintiffs on their equal protection claims, holding that "Defendants Folwell and Jones, in their official capacities, are permanently enjoined from enforcing the Plan's exclusion and are ordered to reinstate coverage for 'medically necessary services for the treatment of gender dysphoria.""<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> The district court's order initially indicated that the State Health Plan itself was also subject to this injunction, in violation of *Ex Parte Young*, 209 U.S. 123 (1908). The district court granted the State Health Plan's motion to correct the order. *See* JA3645-3648; JA3649-3654; JA3658-3662; JA3663-3735. Accordingly, this Court has granted the State Health Plan's motion to voluntarily dismiss its interlocutory appeal of the district court's injunction. *See Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, No. 22-1730 (4th Cir. Aug. 11, 2022) (ECF Nos. 33, 34).

JA3734 (cleaned up). In reaching this conclusion, the district court excluded one of Defendants' expert witnesses entirely and limited the scope of Defendants' other expert testimony. JA3674-3699. The district court also repeatedly relied upon factual assertions from the *amicus* brief. *See* JA3665; JA3669; JA3671; JA3674; JA3705. Defendants timely noted this interlocutory appeal. JA3642-3643.

### SUMMARY OF ARGUMENT

The threshold question on appeal is the proper equal protection analysis. In *Geduldig v. Aiello*, the Supreme Court held that the Equal Protection Clause does not require a government insurance plan to cover pregnancy, even though that particular condition is inextricably linked to sex. Excluding pregnancy "does not exclude anyone from benefit eligibility because of gender but merely removes one physical condition pregnancy—from the list of compensable disabilities." 417 U.S. 484, 496 n.20 (1974). Such benefit exclusions receive only rational basis review. *Id.* at 494–95.

The district court below distinguished *Geduldig* by concluding that one of the Plan's coverage exclusions, which references "sex changes or modifications," is a facial sex classification.<sup>4</sup> The district court reasoned that because one cannot implement the coverage exclusion without knowing the patient's sex, intermediate scrutiny is required. This analysis is incorrect. To violate the Equal Protection Clause, the government must treat one person differently from others with whom he or she is similarly situated. The Plan's coverage exclusion applies to all participants, and the mere fact that a policy can "only be stated or effectuated [by] referencing sex," JA3704, does not trigger heightened scrutiny.

Second, the District Court erred by framing the equal protection analysis in a manner that impermissibly relaxed Plaintiffs' burden of proof. "To succeed on an equal protection claim, a plaintiff must first demonstrate that he has been treated differently from others with whom he is similarly situated and that the unequal treatment was the result of

<sup>&</sup>lt;sup>4</sup> Because the district court found a facial classification, it concluded that it did not need to consider evidence from Plaintiffs or Defendants about the underlying purpose for the coverage exclusion. JA3702. Claims that the Plan's coverage limitation is motivated by a discriminatory purpose to harm transgender individuals are unproven and incorrect, and they cannot form a basis for finding a violation of equal protection at this time.

intentional or purposeful discrimination." *Morrison v. Garraghty*, 239 F.3d 648, 654 (4th Cir. 2001).

Thus, at summary judgment, Plaintiffs were obligated to establish they are similarly situated to other Plan members. No physician or health benefits plan can determine whether a treatment is "medically necessary" without reference to the specific diagnosis that the physician intends to treat. This distinction is inherent within the definition of "medically necessary" that the district court adopted, *sua sponte*, from a North Carolina law regulating private insurers. The concept of medical necessity links together diagnosis and treatment.

Therefore, a similarly situated person for purposes of Plaintiffs' equal protection claim must be another Plan member who has the same medical diagnosis. By using the term "medically necessary" healthcare without this connection, the district court erroneously concluded that Plaintiffs are similarly situated to other Plan members (whether cisgender, transgender, gender-fluid, or gender-non-binary) even when seeking treatments for totally different medical conditions.

Third, the district court's injunction is unlawfully vague and unlawfully broad. The district court's injunction does not simply prohibit the Plan from enforcing the specific coverage exclusion at issue in this case. The injunction goes further, requiring the Plan to "reinstate coverage for 'medically necessary services for the treatment of gender dysphoria." JA3734. The injunction does not define or otherwise explain what services are medically necessary or how the Plan is to determine compliance. Rule 65 requires every injunction, in the text of the order itself, to "state its terms specifically" and "describe in reasonable detail" the "act or acts restrained or required," without reference to any other document. Fed. R. Civ. P. 65(d)(1). The Court should reverse the injunction as a violation of Rule 65.

Fourth, the district court's opinion relied in part on an *amicus* brief submitted by several medical organizations at summary judgment, over Defendants' objection. This is improper. Summary judgment must be granted based on "materials in the record." Fed. R. Civ. P. 56(c)(1). District courts are not independent fact-finding bodies, and they cannot supplement the summary judgment record with inadmissible factual evidence on disputed issues. Defendants objected to the *amicus* brief as unsworn, untested expert testimony offered by a non-party outside of the record.

Finally, the district court excluded portions of expert testimony from Defendants' expert witnesses and excluded one witness altogether. This ruling is reviewed for abuse of discretion, but its analysis contains reversible legal and factual errors. First, the court adopted a narrow application of *Daubert*, looking not to the experts' credentials as scientists and physicians, but rather to their treatment of transgender patients. In doing so, the court mischaracterized the qualifications of two experts, concluding they have no familiarity with health care for transgender patients despite explicit evidence to the contrary. Finally, the district court excluded one expert witness as irrelevant, even though his opinion and expertise demonstrate a core flaw with the district court's equal protection analysis. The district court's evidentiary decisions should be reversed and remanded for the proper analysis.

#### **ARGUMENT**

## I. Standard of Review

This Court reviews a grant of summary judgment *de novo. Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc.*, 673 F.3d 94, 299 (4th Cir. 2012). "Summary judgment cannot be granted merely because the court believes that the movant will prevail if the action is tried on the merits." Jacobs v. N.C. Admin. Off. of the Cts., 780 F.3d 562, 568 (4th Cir. 2015). Therefore, in assessing the district court's reliance on specific facts, this Court does not consider whether it is "more likely than not" the conclusions are correct. Rather, all evidence is seen "in the light most favorable" to Defendants, with the facts themselves and "all reasonable inferences" drawn in Defendants' favor. *Harris v. Pittman*, 927 F.3d 266, 272 (4th Cir. 2019). "To the extent that the district court's injunction relied upon weighing evidence or credibility determinations, then Defendants will prevail on appeal." *Jacobs*, 780 F.3d at 569.

The district court's evidentiary rulings are reviewed for an abuse of discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997). The abuse of discretion standard, however, "does not preclude an appellate court's correction of a district court's legal or factual error." *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 572 U.S. 559, 563 n.2 (2014). "A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence." *Id.* 

# II. The district court's order disregards binding Supreme Court precedent in *Geduldig v. Aiello*.

The district court held that the Plan's decision not to provide additional coverage for "[t]reatment or studies leading to or in connection with sex changes or modifications and related care" is a <u>facially</u> discriminatory classification. This is a question of law, which this Court reviews *de novo*.

# A. The district court incorrectly concluded that the coverage exclusion for treatments leading to "sex changes or modifications" is a facial classification.

A facially discriminatory classification must "explicitly classif[y] people based on sex." Adkins v. Rumsfeld, 464 F.3d 456, 468 (4th Cir. 2006); see also Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc., 499 U.S. 187, 199 (1991) (Facial discrimination depends "on the explicit terms of the discrimination."). The distinction between individuals based on sex must form the basis for the government's differential treatment.

The district court found a facial classification in the text of the Plan's coverage exclusion simply because it contains the word "sex." This is incorrect. The Equal Protection Clause does not require intermediate scrutiny when government policy cannot be understood without knowing the concepts of sex or gender. JA3704. Instead, the Equal Protection Clause is implicated when individuals receive different treatment "because of" their sex, gender or transgender status. *Cf. Pers. Adm'r of Massachusetts v. Feeney*, 442 U.S. 256, 279 (1979). To constitute a facial classification, the coverage exclusion must treat a person "differently from others with whom he is similarly situated" <u>on the basis of sex or</u> <u>gender</u>. *Kerr v. Marshall Univ. Bd. of Governors*, 824 F.3d 62, 82 (4th Cir. 2016) (quoting *Morrison*, 239 F.3d at 654). *See Adkins v. Rumsfeld*, 464 F.3d 456, 468 (4th Cir. 2006) (Statute that defines "spouse" as "husband or wife" is facially gender-neutral).

The district court's understanding—that government policies that reference gender or sex in any way are automatically subject to intermediate scrutiny—rests on a misapplication of *Grimm v*. *Gloucester County School Board*, 972 F.3d 586, 608 (4th Cir. 2020). *See* JA3703. In *Grimm*, the Fourth Circuit considered a policy that expressly distinguished based on sex: "the school district will provide male and female restroom and locker room facilities in its schools." In *Grimm*, however, the policy dictated which restrooms the students could use, and it directed students to <u>different</u> restrooms after considering their sex.<sup>5</sup>

In contrast, the Plan's coverage exclusion does not distinguish between biological male and biological female participants. Nor does the exclusion distinguish between transgender and cisgender participants. The coverage exclusion applies to all Plan members. Transgender Plan members are in both the group that suffers from gender dysphoria, for which Plaintiffs allege these treatments are medically necessary, and the group that does not suffer from gender dysphoria, who do not require these procedures. JA207; JA209-211.<sup>6</sup> Accordingly, the "fiscal and

<sup>&</sup>lt;sup>5</sup> The district court also erroneously invoked the Supreme Court's political-process doctrine for its sweeping assertion that heightened scrutiny applies whenever a policy uses "gendered" language. JA3702-3703. *Washington v. Seattle Sch. Dist. No. 1* addresses "the right to full participation in the political life of the community," 458 U.S. 457, 467 (1982); it has no application here. *See also Lewis v. Governor of Alabama*, 896 F.3d 1282, 1297 (11th Cir. 2018), *on reh'g en banc*, 944 F.3d 1287 (11th Cir. 2019) (noting a majority of the Supreme Court has questioned this line of authority).

<sup>&</sup>lt;sup>6</sup> One cannot even assume that a majority of transgender individuals seek treatment for gender dysphoria. When asked how many transgender individuals suffer from gender dysphoria, Plaintiff experts testified "no one knows the answer to that [question]." JA213. Nor is it true that only transgender people suffer from gender dysphoria; patients with gender dysphoria may not identify as transgender at all. JA204-205; JA209-211. Accordingly, this case

actuarial benefits of the [Plan] thus accrue to members of both sexes," and to those who identify as cisgender and transgender. *Geduldig*, 417 U.S. at 496 n.20.

The district court concluded that the facial classification discriminates "between medically necessary treatments that align with the member's sex" and "medically necessary treatments . . . that do not." JA3703-3704. Under equal protection, however, "[t]he proper comparator is the provision of the medical benefit in question," not the policyholder's identity or the effect of the medical benefit on a particular class. *In re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 944 (8th Cir. 2007) (upholding exclusion for contraception); *see also Alexander v. Choate*, 469 U.S. 287, 303 (1985) (Medicaid's "package of services has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered—not 'adequate health care.").

The Supreme Court first reached this conclusion in *Geduldig v*. *Aiello*, holding that California's short-term disability insurance plan did

presents an even clearer application of the principles articulated in *Geduldig* than did the facts in that case itself, where the coverage exclusion affected exclusively members of one sex.

not discriminate when it excluded coverage for pregnancy. 417 U.S. 484 (1974). Like Plaintiffs here, the *Geduldig* dissenters argued that whenever "the State employs a legislative classification that distinguishes between beneficiaries solely by reference to gender-linked disability risks, the Court is not . . . free to sustain the statute on the ground that it rationally promotes legitimate governmental interests." *Id.* at 503 (Brennan, J., dissenting).

The Court held otherwise: "[w]hile it is true that only women can become pregnant, it does not follow that every legislative classification concerning pregnancy is a sex-based classification." State officials can exclude coverage "on any reasonable basis" as with "any other physical condition." *Id.* at 496 n.20. Like California, Defendants are entitled to decide "not to create a more comprehensive insurance program" through the "selection of the risks insured by the program." *Id.* at 496. Heightened scrutiny does not apply so long as "[t]here is no risk from which men are protected and women are not," and "there is no risk from which women are protected and men are not." *Id.* at 496–97. The same is true here: there is no equal protection violation because there is no risk from which cisgender plan members are covered and transgender plan members are not, and *vice versa*.<sup>7</sup>

In a recent case with strikingly similar facts, a Georgia district court recognized that "[w]ith *Geduldig*, 'the Supreme Court has foreclosed" Plaintiffs' argument—and the district court's conclusion below—that the coverage exclusion "facially discriminates on the basis of sex." *Lange v. Houston Cnty., Georgia*, 2022 WL 1812306, at \*7–8 (M.D. Ga. June 2, 2022). The *Lange* court correctly set forth the application of *Geduldig* as follows:

> [Plaintiffs here have] the same coverage as other [Plan participants] because the [e]xclusion[s] appl[y] equally to a male seeking to become a woman or a woman seeking to become a man. And even if transgender individuals are entitled to protection under the Equal Protection Clause as a separate and distinct class from that of males and females, the same logic would apply. In other words, the [e]xclusion[s] create[] two groups those that want ["treatments that lead to or are

<sup>&</sup>lt;sup>7</sup> The Supreme Court reaffirmed *Geduldig* earlier this year in *Dobbs v. Jackson Women's Health Org.*: "The regulation of a medical procedure that only one sex can undergo does not trigger heightened constitutional scrutiny unless the regulation is a 'mere pretext designed to effect an invidious discrimination against members of one sex or the other." 142 S. Ct. 2228, 2245–46 (2022) (quoting *Geduldig*, 417 U.S. at 496 n.20).

connected to sex changes or modifications" (JA3709)] and those that do not. Both groups contain transgender members and non-transgender members, so a "lack of identity" exists between the policy and transgender status. Thus, in the context of the Equal Protection Clause, the Exclusion does not facially discriminate on the basis of sex.

Lange, 2022 WL 1812306 at \*8.

When the Government distinguishes among individuals using their membership in a protected class, then it is using a facial classification. See Nguyen v. INS, 533 U.S. 53, 56-57 (2001). In contrast, when the Government distinguishes "between medically necessary treatments," JA3703, this classification is subject to rational basis review even when the excluded benefit is primarily, or even exclusively, significant to members of a protected class. Such coverage exclusions merely "relate [] to the asserted underinclusiveness of the set of risks that the State has selected [to] insure." Geduldig, 417 U.S. at 494. Under rational basis review, the Equal Protection Clause does not forbid the discretionary, actuarial benefits coverage decisions made by the State Health Plan, including the decision not to cover certain treatments for gender dysphoria, unless Plaintiffs prove that the Plan

<u>intended</u> to harm Plaintiffs based on their sex or transgender identities.<sup>8</sup>

# B. The district court's analysis of which medical conditions may only be defined "with reference to sex" straightforwardly contradicts <u>Geduldig</u>.

To avoid confronting *Geduldig*, the district court created an artificial and inconsequential distinction between medical "conditions" (such as normal pregnancy in *Geduldig*) and the medical "treatments" requested by Plaintiffs (in connection with the medical <u>condition</u> of gender dysphoria). JA3708. This misunderstands the factual context of *Gelduldig*. The insurance plan in *Geduldig* covered "conditions" and not "treatments" because it was a short-term disability plan, not a health benefits plan. 417 U.S. at 486.

The district court's order further semantically distinguishes Geduldig by suggesting that the status of being pregnant can be described without consideration of one's biological sex. JA3709 ("Pregnancy can be described without reference to sex, gender, or

<sup>&</sup>lt;sup>8</sup> Again, the district court did not find impermissible discriminatory intent in its opinion below. JA3702 (noting that "[n]o inquiry into [] purpose is necessary" for facial classifications).

transgender status."). This is an attempt to sidestep *Geduldig* rather than to obey it. The *Geduldig* Court explicitly defined pregnancy with "reference to sex" ("only women can become pregnant") and went on to hold that this connection does not have constitutional significance: "it does not follow that every legislative classification concerning pregnancy is a sex-based classification." 417 U.S. at 496 n.20. "Absent a showing that distinctions involving pregnancy are mere pretexts designed to effect an invidious discrimination against the members of one sex or the other, lawmakers are constitutionally free to include or exclude pregnancy from the coverage of legislation such as this on any reasonable basis, just as with respect to any other physical condition." *Id*.

The Plan did not move for summary judgment on Plaintiff's Equal Protection claim, recognizing that it is for a jury to determine whether the Plan's coverage limitation is a pretext "designed to effect an invidious discrimination," *Geduldig*, 417 U.S. at 496 n.20.

### C. The district court improperly applied Title VII principles to its equal protection analysis.

Finally, the Supreme Court's decision in Bostock v. Clayton County,
140 S. Ct. 1731 (2020), does not reduce the controlling effect of Geduldig.
JA3706-3707; see Dobbs, 142 S. Ct. at 2245–46 (quoting Geduldig,

417 U.S. at 496 n.20). The district court cited *Bostock* in support of its conclusion that a facial classification exists because "one cannot explain gender dysphoria without referencing sex or a synonym." JA3706-3707. But *Bostock* only applies in the statutory context of Title VII, not to an interpretation of the Fourteenth Amendment's Equal Protection Clause. Therefore, *Bostock* does not affect the validity of *Geduldig*.

The Supreme Court expressly limited its holding in *Bostock* to Title VII claims involving employers who fired employees because of their gay or transgender status: "An employer who fires an individual merely for being gay or transgender defies the law." 140 S. Ct. at 1754. The Bostock Court held that Congress made a policy choice in the Title VII statute when it commanded that "[a]n individual employee's sex is 'not relevant to the selection, evaluation, or compensation of employees." Id. at 1741 (quoting Price Waterhouse v. Hopkins, 490 U.S. 228, 239 (1989) (plurality)). The Supreme Court did not hold that the drafters and ratifiers of the Fourteenth Amendment made the same policy choice. "[S]tatutory prohibitions often go beyond the principal evil to cover reasonably comparable evils." Oncale v. Sundowner Offshore Servs., Inc., 523 U.S. 75, 79 (1998).

The Supreme Court has "never held that the constitutional standard for adjudicating claims of invidious racial [or gender] discrimination is identical to the standards applicable under Title VII." (1976).Washington v. Davis. 426 U.S. 229, 239Purposeful discrimination under the Constitution "requires more than intent as volition or intent as awareness of consequences." Ashcroft v. Iqbal, 556 U.S. 662, 676 (2009) (quoting Feeney, 442 U.S. at 279). Plaintiffs must prove that the Plan has undertaken a course of action "because of, not merely in spite of, the action's adverse effects upon an identifiable group." Id. at 677.

This burden of proof, in turn, requires the inquiry into discriminatory intent that the district court's summary judgment ruling preempted. *See* JA3702 (noting that "[n]o inquiry into [] purpose is necessary" for facial classifications). The decision below should be reversed and remanded for the fact-finding that the district court ignored. The correct equal protection inquiry presented by the Plan's coverage exclusion is whether (1) when the Plan originally adopted this exclusion in the 1990s or (2) when the Plan suspended the exclusion for 2017 (and took no action to prevent the automatic reinstatement of the exclusion in 2018), it did so because of the impact on transgender individuals. Such questions of motive are for trial, not summary judgment.

#### III. The district court improperly analyzed the requirement that Plaintiffs must prove they are "similarly situated" for purposes of the Equal Protection Clause.

"To succeed on an equal protection claim, a plaintiff must first demonstrate that he has been <u>treated differently from others with whom</u> <u>he is similarly situated</u> and that the unequal treatment was the result of intentional or purposeful discrimination." *Garraghty*, 239 F.3d at 654 (emphasis added). This is a foundational requirement of equal protection jurisprudence. *See, e.g., City of Cleburne, Tex. v. Cleburne Living Ctr.,* 473 U.S. 432, 439 (1985) (The Equal Protection Clause "is essentially a direction that all persons similarly situated should be treated alike.").

The district court's analysis ignored Plaintiffs' burden of proof on this point. Its critical error was looking only to the desired treatment (surgery or prescription medications) without considering the treatments' connection to the disease or disorder that the procedure or prescription purports to treat. JA3703 n.4 (assuming that treatments at issue are medically necessary). No physician or health benefits plan can determine whether a treatment is "medically necessary" without reference to the specific diagnosis that the physician intends to treat. "[A] function of medical diagnosis is to determine in what ways individuals are <u>not similarly situated</u> so that they can be treated accordingly." *Gann v. Schramm*, 606 F. Supp. 1442, 1447 (D. Del. 1985). Providing different medical treatment for different medical diagnoses is not discriminatory because patients with different medical diagnoses are not similarly situated in the first instance.

This distinction is inherent within the definition of "medically necessary" that the district court adopted, *sua sponte*, from a North Carolina law regulating private insurers. JA3667. That definition links the patient's diagnosis and the prescribed treatment. Under the district court's definition, "medically necessary services or supplies" must be "[p]rovided for" and "[n]ecessary for and appropriate to" the "diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease." JA3667 (quoting N.C. Gen Stat. § 58-3-200(b)).

A similarly situated person for purposes of Plaintiffs' equal protection claim, then, must be a Plan member with the same medical diagnosis. There, the relevant comparator becomes clear. Both a

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cisgender woman and transgender man with cervical cancer are eligible for a hysterectomy, irrespective of their gender identities. Likewise, neither individual is entitled to coverage for this procedure for the purpose of treating gender dysphoria. Both cisgender men and transgender women receive coverage for an orchiectomy to treat testicular cancer, but neither receives coverage for this same procedure to treat gender dysphoria.<sup>9</sup> Cisgender, transgender, gender-fluid, and gender-non-binary individuals all have coverage against the risk of needing breast reduction or mastectomy surgery to treat breast cancer, though none have coverage against the risk of needing this same procedure for gender dysphoria. The State Health Plan's implementation of the coverage exclusion makes this link clear. JA183-196.

By using the term "medically necessary" healthcare without tying it to the diagnosis that makes such a conclusion possible, the district court erroneously concluded that Plaintiffs are similarly situated to other

<sup>&</sup>lt;sup>9</sup> Neither a hysterectomy nor an orchiectomy can be accurately defined or described without "reference to sex" because both procedures are the removal of a sex organ. Even so, a health insurance plan's decision to cover either, or neither, does not violate the Fourteenth Amendment absent proof of purposeful invidious discrimination. *See Dobbs*, 142 S. Ct. at 2245–46.

Plan members (cisgender, transgender, gender-fluid, and gender-nonbinary) seeking treatments for totally different medical conditions.

This remains true even when different diagnoses might have the same prescribed treatment. "A diagnosis of degenerative disc disease with chronic low back pain is different in fact from a diagnosis of cancer," even though both patients can benefit from the same pain medicine. Flaming v. Univ. of Texas Med. Branch, 2016 WL 727941, at \*9 (S.D. Tex. Feb. 24, 2016). An individual with testicular cancer may need testosterone injections, but that person is not "similarly situated" to with See *McMain* someone gender dysphoria. v. Peters, 2018 WL 3732660, at \*3-4 (D. Or. Aug. 2, 2018), aff'd, 2019 WL 3321883 (9th Cir. July 24, 2019) (no violation of Equal Protection Clause for inmate seeking testosterone injections even though inmates with similar symptoms and a diagnosis of Klinefelter Syndrome receive injections).

The district court exacerbated its analytical error by failing to observe the burden of proof at summary judgment. The district court acknowledged that Defendants provided expert evidence that "no reliable studies show that [surgical and hormone] treatments reduce the likelihood" of negative mental outcomes for individuals with gender dysphoria. JA6398 n.3. On summary judgment, this statement alone creates a material issue of fact about whether Plaintiffs' desired treatments are ever "[n]ecessary for and appropriate to" the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease. JA3667 (quoting definition of "medically necessary" at N.C. Gen Stat. § 58-3-200(b)).<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> The district court concludes that one of Defendants' experts, Dr. Stephen Levine, supports the medical necessity of surgery and hormone treatment for gender dysphoria under some circumstances. JA3695-3697.

This misunderstands Dr. Levine's views. Dr. Levine does not support "denying all medical interventions to people with gender dysphoria." JA3685. The question whether State officials should prohibit hormone treatment and surgery for gender dysphoria is, however, a "separate question" from the question whether insurance should cover the procedures as medically necessary. JA3685-3686.

Medical necessity requires more than a willingness to make a procedure available to patients. The treatment must be "[n]ecessary for and appropriate to" the "diagnosis, treatment, cure, or relief" of gender dysphoria. N.C. Gen. Stat. § 58-3-200(b).

Dr. Levine does not "recommend" hormones or surgery as cures for gender dysphoria because he cannot say whether they work. JA2986. This is because there are no long-term, peer-reviewed, reliable research studies that allow physicians to know "the percentage of patients receiving gender transition procedures who <u>are helped</u> by such procedures, using objective criteria" or the "percentage of patients receiving gender transition procedures who

The district court's incorrect substantive analysis allowed it to assume away Plaintiffs' burden of proof at summary judgment, holding that "it is sufficient at this stage that those affected and unaffected by the exclusion are all members of the plan who seek similar or identical treatments." JA3707-3708. However, Plaintiffs are simply not "similarly situated" to other Plan participants who seek treatment for <u>different</u> <u>medical diagnoses</u>. Accordingly, the district court's equal protection analysis should be reversed on the ground that Plaintiffs have failed to establish discrimination relative to "similarly situated" Plan members.

#### IV. The district court's injunction violates Fed. R. Civ. P. 65 because it is impermissibly vague.

The Federal Rules of Civil Procedure require all injunctions to specifically state the reasons for an injunction, specifically state the terms of the injunction, and "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65(d). *See, e.g., Scott v. Clarke*, 355 F. Supp.3d 472, 477 (W.D. Va. 2019) (holding that because the "detailed

<sup>&</sup>lt;u>are harmed</u> by such procedures, measured with objective criteria." JA3253.

settlement agreement" approved by district court was not itself reproduced in court's order, settlement agreement was not enforceable by contempt). The district court's failure to comply with Rule 65 is an error of law, and it is subject to *de novo* review.

Injunctions must not be "founded upon a decree too vague to be understood." *Gunn v. Univ. Comm. to End War in Viet Nam*, 399 U.S. 383, 389 (1970). "Congress [has] responded to that danger by requiring that a federal court frame its orders so that those who must obey them will know what the court intends to require and what it means to forbid." *Id.* "[B]asic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed." *Schmidt v. Lessard*, 414 U.S. 473, 476 (1974).

"The specificity provisions of Rule 65(d) are no mere technical requirements." *CPC Int'l, Inc. v. Skippy Inc.*, 214 F.3d 456, 459 (4th Cir. 2000) (quoting *Schmidt*, 414 U.S. at 476) (internal punctuation omitted). "Compliance is mandatory and [the requirements] must be observed in every instance." *Id.* Without such specificity, "appellate review of an injunctive order is greatly complicated, if not made impossible," and parties face "the possible founding of a contempt citation on a decree too vague to be understood." *Id.* "[A]n order challenged on appeal should be set aside if it fails to comply with the rule." Charles A. Wright *et al.*, 11A FEDERAL PRACTICE AND PROCEDURE § 2955 (3d ed. 2005).

The district court's injunction does not comply with Rule 65(d). The injunction consists of one prohibitive command and one mandatory command. Defendants are (1) permanently enjoined from enforcing *one* of the Plan's coverage exclusions, and (2) ordered to reinstate coverage for "medically necessary services for the treatment of gender dysphoria." JA3734. Both aspects of this order are impermissibly vague, but the second requirement is particularly problematic.

#### A. The district court's injunction regarding the gender dysphoria exclusion improperly refers to a document outside of the injunction itself.

The first part of the injunction does not "specifically" identify the coverage exclusion that Defendants cannot enforce. Fed. R. Civ. P. 65(d). *See* JA3734-3735. Regardless of whether Defendants can infer the district court's intention, the injunction's failure to comply with the "mandatory" obligations of Rule 65(d) renders it invalid and reversible on appeal. *CPC Int'l*, 214 F.3d at 459.

The district court's second command also runs afoul of Rule 65. The quotation marks around the phrase "medically necessary services for the treatment of gender dysphoria" indicate that the district court is referring to another document. This is impermissible even when the quoted language has a clear citation. Fed. R. Civ. P. 65(d)(1)(C).

## B. The district court's injunction fails to adequately define its dispositive terms.

More troubling, however, is the uncertainty as to the precise definition of the phrase "medically necessary services for the treatment of gender dysphoria" in the second portion of the injunction. In *Pashby v. Delia*, this Court rejected a similar injunction on this ground. 709 F.3d 307 (4th Cir. 2013). The *Pashby* district court enjoined the North Carolina Department of Health and Human Services from imposing stricter eligibility requirements on in-home personal care services for disabled Medicaid recipients than for other recipients. *Id.* at 313. The injunction prohibited the State from "implementing IHCA Policy 3E" (the challenged policy). *Id.* at 331. When the State undid the entire policy, the district court modified its injunction "to clarify that the injunction simply required the DHHS to continue offering in-home [personal care services] to the plaintiffs who qualified for it before IHCA Policy 3E took effect." *Id*.

This Court rejected the injunction under Rule 65(d), holding that the broad terms provided no guidance about whether the injunction also prohibited the State from following other provisions in "ICHA Policy 3E" that had nothing to do with the challenged financial requirements. *Id.* Further, the district court failed to specify what policy requirements would apply to future Medicaid beneficiaries. *Id.*<sup>11</sup>

The second portion of the injunction here is impermissibly vague for the reasons identified in *Pashby*. The injunction requires Defendants to provide "medically necessary services for the treatment of gender dysphoria" without any definition of this potentially boundless phrase. Because the injunction offers no instructions on the precise extent and scope of this critical term, it creates multiple unanswered questions. The injunction provides no guidance as to which of hundreds of possible

<sup>&</sup>lt;sup>11</sup> Pashby makes clear that the district court cannot simply command that the State Health Plan follow the policy it adopted in 2017. The 2017 policy was a good-faith attempt to comply with a federal regulation that never actually went into effect. The Plan has no way of knowing, with the certainty required by Rule 65, whether its earlier policy was sufficient to comply with that federal regulation.

gender-affirming treatments Defendants must now cover under the threat of contempt. Defendants could possibly defer to the judgment of their current third-party administrator, but that is simply not what the district court has mandated that they do.

### C. Reference to the "last uncontested status between the parties" is inadequate to comply with Rule 65.

The district court's discussion of the rationale for its injunction highlights its disregard of Rule 65(d). In its order, the district court dismissed the hardship of its injunction on Defendants, "particularly given that Defendants and their third-party administrators were able to identify and cover medically necessary care in 2017." JA3728.

The instruction to "reinstate coverage" implies that the court is simply restoring the "last uncontested status between the parties [that] existed in 2017." JA3729. But Plaintiffs' own experts have testified that "medically necessary services for treatment of gender dysphoria" are not limited to only those procedures that the Plan briefly covered in 2017 (under threat of a now-rescinded federal regulation). JA45 (Doc. No. 257 at 14–15). This is not feigned ignorance. One of Plaintiffs' experts states that medically necessary surgeries "include, but are not limited to": "facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), and hair reconstruction" as well as "pectoral implants" and "various aesthetic procedures." JA4255-4256 ¶¶ 25-26. None of these allegedly "medically necessary" treatments were covered in 2017. See JA4711. (BCBS policy that "[c]osmetic services that may be used for gender confirmation" are not medically necessary). The district court's opinion refers to denial of "vocal therapy," JA3666, but there is no evidence the Plan has ever paid for vocal therapy for treatment of gender dysphoria.

Rule 65 specifically forbids the Court from ordering the Plan to "go figure it out yourself" by delegating to Defendants the obligation to "identify and cover medically necessary care." This was "one of the principal abuses of the pre-federal rules practice," when courts imposed "injunctions that were so vague that [a] defendant was at a loss to determine what he had been restrained from doing." 11A FEDERAL PRACTICE AND PROCEDURE § 2955. Under the district court's injunction, however, this is precisely what has happened. The district court, not Defendants, must precisely identify the "medically necessary" treatments for which coverage <u>must</u> be provided. "Medically necessary" can be subjective, and Defendants should not have to risk a contempt hearing if they get it wrong.<sup>12</sup>

#### D. The district court provides inadequate directions as to how its injunction interacts with the Plan's other coverage exclusions.

Finally, and perhaps most significantly, <u>other</u> facially neutral Plan exclusions affect coverage for the treatment of gender dysphoria. Defendants informed the district court about these overlapping exclusions, yet the injunction fails to even acknowledge them. JA117; JA178-181. Critically, the Plan excludes coverage for cosmetic surgery, which is defined to include "surgery for psychological or emotional reasons." JA117. This coverage exclusion makes no reference to biological sex, gender, or gender dysphoria, but it still wholly eliminates coverage for surgical procedures to treat psychological diagnoses, which would include gender dysphoria. The Plan also excludes "any medication or device not approved by the Food and Drug Administration (FDA) for the

<sup>&</sup>lt;sup>12</sup> The district court suggests that its injunction is a prohibitory one, not a mandatory one. JA3729. This is incorrect. The coverage exclusions at issue have been in effect since the early 1990s, with the exception of the 2017 Plan year. The status quo position is that the Plan does not cover Plaintiffs' desired treatments for gender dysphoria.

applicable diagnosis or treatment," unless the medication is for cancer treatment and has been FDA-approved to treat a different type of cancer. JA123 n.3. This exclusion also makes no reference to biological sex, gender, or gender dysphoria, but wholly eliminates insurance coverage for Plaintiffs' desired gender dysphoria prescriptions. *See* JA3385-3387 (no prescription drugs are FDA-approved for treatment of gender dysphoria).<sup>13</sup>

Although the district court's injunction does not expressly prohibit the Plan from enforcing these facially neutral exclusions, it does create a dilemma by mandating that Defendants provide coverage for "medically necessary services for the treatment of gender dysphoria."<sup>14</sup> Defendants should not be forced to interpret such ambiguity and inconsistency. Defendants are without "explicit notice

<sup>&</sup>lt;sup>13</sup> One can easily determine which treatments are excluded by these coverage limitations "without comparing the member's biological sex before the treatment to how it might be impacted by the treatment." JA3704.

<sup>&</sup>lt;sup>14</sup> Given that the district court made no findings of disparate impact or discriminatory intent, it is unclear whether it would have had the authority to order Defendants to eliminate these facially neutral exclusions even if its injunction unambiguously communicated an intent to do so.

of precisely what conduct is outlawed." *Schmidt*, 414 U.S. at 476. The district court's failure to provide the required detail in its injunction is reversible error.

#### V. The district court's summary judgment analysis improperly admitted, and explicitly relied upon, facts outside of the record.

The district court's grant of summary judgment is also improper because the Court explicitly relied upon factual assertions—scientific and medical assertions made in an *amicus curiae* brief—outside of the discovery process.

As the First Circuit has noted, "by the nature of things an *amicus* is not normally impartial," and "an *amicus* who argues facts should rarely be welcomed." *Students for Fair Admissions v. President & Fellows of Harvard Coll.*, 2018 WL 9963511, at \*1 (D. Mass. Oct. 3, 2018) (quoting *Strasser v. Doorley*, 432 F.2d 567, 569 (1st Cir. 1970)) (internal punctuation omitted). "Only a named party or an intervening real party in interest is entitled to litigate on the merits, and a district court should usually stop short of vesting *amici* with the 'equal litigating rights of a named party/real party in interest, thereby subverting the right of the [parties] to effectively control the future course of the proceedings." *Id.* 

(quoting United States v. Michigan., 940 F.2d 143, 166 (6th Cir. 1991)) (punctuation omitted).

Here, Defendants presented expert testimony that no reliable medical studies show that Plaintiffs' desired treatments—cross-sex hormones and surgery to change one's appearance—improve the health and wellbeing of patients with gender dysphoria over time. JA3698 n.3.

The district court, however, relied upon the *amicus* brief to reach contrary conclusions. JA3669-3670 (quoting JA3539-3559) (Gender dysphoria is "treated both through counseling and medical and surgical treatments to bring the patient's physiology in line with their gender identity."). *See generally* JA3665; JA3669-3671 ("Scientific background").

The district court cited the *amicus* brief for its conclusion that "[t]reatments [for gender dysphoria] may include therapy, medications, or surgery to align the patient's physiology with their identity and 'allow[] the individual to transition from his or her birth assigned sex to the sex associated with his or her gender identity." JA3665 (quoting JA3549). Defendants' evidence is that the effectiveness of these treatment has not been sufficiently proven. JA3224 (summarizing analysis that no scientific evidence indicates that hormonal treatment or surgery affects patient morbidity). The district court set forth its justification for relying on these extra-record facts in one sentence: "While an amicus brief <u>itself</u> may not be considered as evidence on summary judgment if it would not be admissible at trial, it appears that evidence supplied by amici may be considered, so long as it would be admissible at trial and does not exceed the scope of the arguments properly raised by parties to the suit." JA3535-3538. As support for this radical conclusion, the district court cited a passing comment in *Hirschfeld v. Bureau of Alcohol, Firearms, Tobacco & Explosives*, 5 F.4th 407, 441 (4th Cir. 2021), that stated it was "unclear" whether this Court could rely on evidence submitted by amici when the evidence was "neither adopted nor relied on" by the parties below.

The judicial system relies upon on an assurance that evidence is presented to a neutral decisionmaker through the adversarial process. Judges, no less than jurors, cannot conduct independent factual research. Indeed, when jurors engage in such conduct, this Court recognizes a presumption that the defendant's due process rights have been violated. *United States v. Lawson*, 677 F.3d 629, 645–46 (4th Cir. 2012) (presumption of reversal when juror consulted dictionary during criminal trial). If the district court wanted to consider facts outside of the discovery process and beyond the parties' expert witnesses, it was required to follow the only available path: "judicial notice" of adjudicative facts. *See* Fed. R. Evid. 201. Before doing so, however, the rules require the court to conclude the adjudicative facts are "not subject to reasonable dispute" because they are "generally known" within the Court's territorial jurisdiction or that the facts "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

Plaintiffs had every opportunity to identify the trade organizations who filed the *amicus* brief as witnesses with relevant evidence and to provide Defendants with the opportunity to test these factual claims through the standard discovery process. These interested organizations had the right to seek to intervene. None of this occurred. Instead, the district court considered evidence at summary judgment that was brought forward by an unaccountable *amicus* brief, without any opportunity for Defendants to rebut or cross-examine the unsworn opinions therein.

The district court improperly treated summary judgment, the stage of litigation when all factual disputes must be resolved in favor of the

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non-movant (Defendants), as though it was the less constricted factfinding that often takes place at the preliminary injunction stage. Rule 56 does not permit this. The court's decision is limited to "materials in the record." Fed. R. Civ. P. 56(c). The grant of summary judgment is improper and should be reversed.

#### VI. The district court improperly excluded testimony from Drs. Hruz, Robie, and Lappert.

Review of the district court's evidentiary rulings is subject to review for abuse of discretion. In this case, the district court applied the wrong standard for excluding portions of Defendants' expert testimony.

#### A. The district court misapplied Rule 702.

Rule 702 of the Federal Rules of Evidence provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. The Supreme Court has held that this requires the district court to determine that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms.*, *Inc.*, 509 U.S. 579, 589 (1993); *see Benedi v. McNeil-P.P.C.*, Inc., 66 F.3d 1378, 1383 (4th Cir. 1995) (holding that *Daubert* and Fed.
R. Evid. 702 superseded *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)).

At the outset, the district court must consider the expert's qualifications to offer the testimony, including his or her professional record and "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012). But expert testimony may rest on knowledge, skill, experience, training, <u>or</u> education. "These are disjunctive; an expert can qualify to testify on any one of the grounds." *Cooper v. Laboratory Corp. of America Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998) (citing *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993)).

Under Rule 702, expert testimony is relevant if it has "a valid scientific connection to the pertinent inquiry" and helps "the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591–92. Significantly, the Supreme Court has instructed the district court, "as gatekeeper, [to] conduct[] a flexible inquiry, focusing on the principles and methodology employed by the expert rather than the conclusions reached." *Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F. Supp.2d 684, 690 (W.D.N.C. Apr. 17, 2003) (citing *Daubert*,

509 U.S. at 594–95). After all, a district court's gatekeeping role "is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices* & *Prod. Liab. Litig. (No. II)*, 892 F.3d 624, 631 (4th Cir. 2018).

### B. The district court's approach to expert qualification is not consistent with this Court's precedent.

For several of Defendants' experts, the district court excluded testimony on the ground that the witnesses did not specialize in the treatment of transgender patients. JA3681-3682 (Hruz); JA3690-3691 (Lappert). This analysis reflects the view of a small minority of courts, outside the Fourth Circuit, that "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony." *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362 at \*2 (N.D. Ill. Aug. 30, 2007); *see also O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376 (C.D. Ill. 1992); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352 (11th Cir. 2014).

By concluding that Defendants' experts are not qualified to provide certain opinions because they have not performed certain narrowlydefined medical procedures or published in specific journals, the district court artificially constrained the "technical area" of the substantive issues at hand. Consistent with the inclusive approach mandated by Rule 702, this Court should recognize that a multitude of medical specialties—including, but not limited to, endocrinology and surgery affect the treatment of transgender individuals. Under this view, the challenged experts clearly have an extensive substantive basis to offer their opinions.

Further, such a narrow focus directly contradicts this Court's standards for expert qualification. An expert's research work is straightforwardly not dispositive: "although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert." *United States v. Young*, 916 F.3d 368, 381 (4th Cir. 2019). Here, the excluded experts' knowledge, skill, and education were more than adequate to establish their specialized knowledge.

### C. The district court misconstrued Dr. Hruz's qualifications.

The district court stated that Dr. Paul Hruz has not "conducted any original research about gender dysphoria diagnosis or its causes,"

JA3681, but completely ignores his statement that—as the head of a fellowship program at a teaching hospital—he supervises two fellows who are directly engaged in primary research on this specific subject. While he is not the "primary investigator" (a specialized term related to grant funding), he is "directing [] fellows in that research to make sure it's of the highest quality and standards." JA1236. The district court's statement that Dr. Hruz has never published peer-reviewed literature on gender dysphoria is clearly erroneous. Compare the district court's order with the deposition transcript it cites:

- Q. And as I understand this letter to the editor is a commentary on another publication, on another article; is that right?
- A. It includes more information than just the article itself. But, yes.
- Q. And just pure curiosity, I don't know the answer to this, but are letters to the editor peer reviewed?
- A. <u>This particular one was.</u> I recall when we were submitting this, that we were asked to make changes. And I interpret that as being peer reviewed."

JA1239 (emphasis added).

The district court stated that Dr. Hruz has "never treated a transgender patient," JA3681, even though the Plaintiffs' exhibit

referenced by the court says just the opposite. Dr. Hruz testified at his deposition:

I have not treated with hormones for the purpose of alleviating gender dysphoria. I have however treated patients that have experienced side effects related to that hormonal treatment including obesity, diabetes, dyslipidemia. So in that respect I have treated them, but not to address dysphoria. But, rather, the complications that have occurred in association with that treatment.

JA1255-1256.

The district court's evidentiary decisions are reviewed for an abuse of discretion, but clearly erroneous fact-finding is an abuse of discretion. The district court's assessment of Dr. Hruz's qualifications is flatly wrong, diminishing his credentials with untrue statements, and its exclusion of his testimony about the treatment of gender dysphoria should be reversed.

### D. The district court misconstrued the relevance of Dr. Robie's testimony.

Finally, the district court excluded expert testimony from Dr. Peter Robie, M.D., as irrelevant, even though his opinion and expertise demonstrate a core fallacy with the district court's equal protection analysis. Dr. Robie has served as an internal medicine physician for more than forty years, and he currently serves on the Board of Trustees of the State Health Plan. The district court held that his testimony is irrelevant because it only considered facial discrimination, not whether there was intentional discrimination. JA3679. But Dr. Robie's testimony is that, in order to provide diagnostic and medical treatment that meets a professional standard of care, physicians must consider the sex of their patients. JA3500.

Dr. Robie's testimony demonstrates that the district court's understanding of medicine—that medical conditions, such as pregnancy, "can be explained without reference to sex, gender, or transgender status"—is false. JA3669. Dr. Robie's testimony is that there is no such thing as a gender-neutral diagnosis or gender-neutral medicine. Every cell in a patient's body has a specific biological sex coded into it, and all medical diagnoses and treatments are sex-specific, whether the illness is high blood pressure or gender dysphoria. No medical treatment or medical condition, anywhere, can be "stated or effectuated without referencing sex." JA3704. The district court's attempt to discuss medical treatment in a gender-neutral manner is only possible because the court uses abstract or oblique language that does not reflect the actual healthcare system. The district court's exclusion of Dr. Robie's testimony should be reversed.

#### CONCLUSION

Defendants respectfully request that this Court vacate the district

court's injunction and remand for further proceedings.

#### **REQUEST FOR ORAL ARGUMENT**

Defendants respectfully request oral argument on the issues presented herein.

Respectfully submitted this the 31st day of August, 2022.

<u>/s/ John G. Knepper</u> Wyo. Bar. No. 7-4608 LAW OFFICE OF JOHN G. KNEPPER, LLC 1720 Carey Ave. Suite 590 Cheyenne, WY 82001 Telephone: (307) 632-2842 Facsimile: (307) 432-0310 john@knepperllc.com

<u>/s/ Kevin G. Williams</u> N.C. Bar No. 25760

N.C. Dai 110. 20700

<u>/s/ Mark A. Jones</u> N.C. Bar No. 36215 BELL, DAVIS & PITT, P.A. 100 N. Cherry St. Suite 600 Winston-Salem, NC 27101 Telephone: (336) 722-3700 Facsimile: (336) 722-8153 kwilliams@belldavispitt.com mjones@belldavispitt.com

#### **CERTIFICATE OF COMPLIANCE**

The foregoing complies with the type-volume limitation of Federal Rule of Appellate Procedure Rule 32(a)(7)(B) because it contains <u>10,854 words</u>, excluding those parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). The foregoing complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5), (6) because it has been prepared in a proportionately spaced typeface using Microsoft Word in Century Schoolbook 14-point font.

<u>/s/ John G. Knepper</u> Wyo. Bar. No. 7-4608 LAW OFFICE OF JOHN G. KNEPPER, LLC 1720 Carey Ave. Suite 590 Cheyenne, WY 82001 Telephone: (307) 632-2842 Facsimile: (307) 432-0310 john@knepperllc.com

<u>/s/ Kevin G. Williams</u> N.C. Bar No. 25760

/s/ Mark A. Jones N.C. Bar No. 36215 BELL, DAVIS & PITT, P.A. 100 N. Cherry St. Suite 600 Winston-Salem, NC 27101 Telephone: (336) 722-3700 Facsimile: (336) 722-8153 kwilliams@belldavispitt.com mjones@belldavispitt.com

#### **CERTIFICATE OF SERVICE**

I hereby certify that on August 31, 2022, I filed the foregoing document through the Court's CM/ECF system, which will serve an electronic copy on all registered counsel of record.

/s/ John G. Knepper	/s/ Kevin G. Williams
Wyo. Bar. No. 7-4608	N.C. Bar No. 25760
LAW OFFICE OF JOHN G. KNEPPER, LLC	2
1720 Carey Ave. Suite 590	/s/ Mark A. Jones
Cheyenne, WY 82001	N.C. Bar No. 36215
Telephone: (307) 632-2842	Bell, Davis & Pitt, P.A.
Facsimile: (307) 432-0310	100 N. Cherry St. Suite 600
john@knepperllc.com	Winston-Salem, NC 27101
	Telephone: (336) 722-3700
	Facsimile: (336) 722-8153
	kwilliams@belldavispitt.com
	mjones@belldavispitt.com