IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

CODY FLACK, SARA ANN MAKENZIE, MARIE KELLY, and COURTNEY SHERWIN,

Plaintiffs,

v. Case No. 18-CV-0309

WISCONSIN DEPARTMENT OF HEALTH SERVICES, et al.,

Defendants.

BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Defendants Wisconsin Department of Health Services, and its Secretary Designee Andrea Palm[1], in her official capacity (hereafter the "Department"), ask this Court to deny Plaintiffs' motion for summary judgment and grant summary judgment to them.

First, because Plaintiffs' Affordable Care Act (ACA) claim violates the Constitution's Spending Clause, summary judgment may be entered for the Department. The State of Wisconsin had no clear notice that, when it began to accept federal funding under Title IX, it would be subject to suits from private parties—especially ones for money damages—alleging discrimination on the basis of "transgender status." Title IX, and by incorporation the ACA, expressly prohibits "sex" discrimination. At the time, the State would not have known that Title IX's "sex" discrimination prohibition would expand to include "transgender status," as this Court has recently held.

Second, the submissions reveal that questions remain, based on clinical studies, about the use of gender reassignment surgery and related hormone therapy for transgender persons suffering from gender dysphoria. And, federal courts of appeal have recognized that there is no consensus within the medical

[1] Linda Seemeyer is no longer the Secretary of the Wisconsin Department of Health Services. Andrea Palm is now the Secretary Designee. As a result of Plaintiffs naming Seemeyer in her official capacity only, this Court may substitute Palm for Seemeyer, as a defendant. *See* Fed. R. Civ. P. 25(d).

community as to effectiveness. It therefore is lawful that the Department's regulation excludes "transsexual surgery" and related hormone therapy (hereafter the "Challenged Exclusion") from "medically necessary" services deserving Medicaid coverage. Based on the broad discretion given to the states to determine Medicaid-covered services, Plaintiffs' Medicaid Act claims fail, and summary judgment for the Department is proper.

Finally, as to their equal protection claim, Plaintiffs' request for summary judgment also should be rejected. The submissions reveal economic reasons for the different treatment, as well as medical uncertainty about the efficacy of the procedures. These justifications support summary judgment in favor of the Department. Alternatively, the evidence is sufficient to create genuine disputes of material fact as to the Department's justification for the Challenged Exclusion.

LEGAL STANDARD

To succeed on a motion for summary judgment, the moving party must show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Rule 56 "imposes an initial burden of production on the party moving for summary judgment to inform the district court why a trial is not necessary." *Modrowski v. Pigatto*, 712 F.3d 1166, 1168 (7th Cir. 2013). The trial court must review the evidence in the light

reasonably most favorable to the non-moving party, giving him the benefit of reasonable inferences from the evidence. *White v. City of Chi.*, 829 F.3d 837, 841 (7th Cir. 2016), *cert. denied sub nom. White v. City of Chi.*, 137 S. Ct. 526 (2016). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Where a claim fails as a matter of law, this Court may grant summary judgment to the non-moving party. *See Goldstein v. Fid. & Guar. Ins. Underwriters, Inc.*, 86 F.3d 749, 750 (7th Cir. 1996) (holding district court may enter summary judgment in favor of a party even if no motion for relief of that sort has been filed).

DEFENDANTS' RESPONSE TO PLAINTIFFS' "SUMMARY OF UNDISPUTED FACTS"

The vast majority of the proposed findings of fact that Plaintiffs put forth are not disputed by the Department for the purpose of their summary judgment motion. As a result, the Department will not restate the undisputed facts here but rather direct the Court to their Responses to Plaintiffs' Proposed Findings of Fact. To the extent the Department disagrees with Plaintiffs' discussion of evidence, those disagreements are explained in the Argument section of this brief.

ARGUMENT

I. Summary judgment should be granted to the Department because the Spending Clause requires dismissal of Plaintiffs' Section 1557 Affordable Care Act claim as a matter of law.

Plaintiffs' Section 1557 Affordable Care Act claim must be dismissed and summary judgment entered for the Department based on a violation of the United States Constitution's Spending Clause.

The Constitution provides that "Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the Debts and provide for the common defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. This Spending Clause permits Congress to "further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives." *South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (quoting *Fullilove v. Klutznick*, 448 U.S. 448, 474 (1980)).

Congress' spending power is far from unlimited and "subject to several general restrictions." *Id.* at 207. For example, while "Congress may fix the terms on which it shall disburse federal money to the States," it must prescribe those terms "unambiguously." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). In *Pennhurst*, the Court first explained that legislation enacted under the Spending Clause "is much in the nature of a contract." *Id.* "[I]n return for federal funds, the States agree to comply with federally

imposed conditions." *Id.* Congress' authority "thus rests on whether the State voluntarily and knowingly accepts the terms of the 'contract.'" *Id.* It is impossible for a state to "voluntarily and knowingly" accept any limitations "if a State is unaware of the conditions or is unable to ascertain what is expected of it." *Id.* Thus, if Congress intends to impose a condition on the recipient of federal funds, it must "speak with a clear voice." *Id.*

In *Arlington Central School District Board of Education v. Murphy*, 548 U.S. 291 (2006), the Supreme Court applied these principles in the context of a provision in the Individual with Disabilities Education Act ("IDEA") allowing prevailing litigants to recover attorneys' fees. At issue was whether the cost of experts' services was covered by that fee-shifting provision. *See id.* Relying on a "clear notice" rule, the Court held that expert fees were not recoverable under the IDEA. The Court maintained that the clear notice analysis must be done not from Congress' point of view, but "from the perspective of a state official who is engaged in the process of deciding whether the State should accept" the conditioned funds. *Id.* at 296. The question for a court is "whether such a state official would clearly understand" the IDEA's conditions. *Id.* Under that test, because the IDEA's text did not clearly notify states that they would face liability for the cost of expert fees, the Spending Clause did not permit prevailing parents to recover such fees. *Id.* at 296–98.

Thus, *Pennhurst* forbids the use of ambiguous conditions on funding. 451 U.S. at 17. And *Arlington Central* requires every condition to carry a "clear notice." 548 U.S. at 296. The wrong alleged here is disparate treatment on the basis of gender identity; however, Section 1557 of the ACA does not contain its own non-discrimination provision. Rather, as relevant here, it prevents discrimination on the grounds already prohibited under Title IX. 20 U.S.C. § 1681(a). Thus, the "clear notice" question is whether the language of Title IX (as incorporated by Section 1557) unambiguously prohibited disparate treatment on the basis of gender identity at the time of Title IX's enactment. It did not.

Here, the State of Wisconsin could not have understood that Title IX would impose on it a new anti-discrimination requirement when this federal law passed. Title IX says that "[n]o person in the United States shall, *on the basis of sex*, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance . . . ." 28 U.S.C. § 1681 (emphasis added). The statute expressly prohibits exclusions "on the basis of sex," not "on the basis of sex or transgender status." Dictionaries contemporaneous with Title IX's passage define "sex" in physiological terms—the biological differences between men and women. *See Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 688 & n.24 (N.D. Tex. Wichita Falls Div. 2016) (quoting three dictionaries);

see also Yates v. United States, 135 S. Ct. 1074, 1082 (2015) ("Ordinarily, a word's usage accords with its dictionary definition."). The Seventh Circuit's decision in *Ulane v. Eastern Airlines, Inc.*, confirms this view, at least as to Title VII. 742 F.2d 1081, 1084–85 (7th Cir. 1984) ("[The district court] concluded that it is reasonable to hold that the statutory word 'sex' literally and scientifically applies to transsexuals even if it does not apply to homosexuals or transvestites. We must disagree."). *See also Wittmer v. Phillips 66 Co.*, 915 F.3d 328, 334–35 (5th Cir. 2019) (Ho, J., concurring), ("No one seriously contends that, at the time of enactment, the public meaning and understanding of Title VII included sexual orientation or transgender discrimination. To the contrary, there is judicial consensus that the public meaning of Title VII in 1964 did not include sexual orientation or transgender discrimination." (citing *Hively v. Ivy Tech Cmty. Coll. Of Ind.,* 853 F.3d 339 (7th Cir. 2017) (en banc) majority, concurring, and dissenting opinions).

Plaintiffs cannot show that, when Title IX was enacted, states unambiguously knew that they would someday be subject to transgender-based discrimination claims. Only much later did federal courts begin to hold that the term "sex" could encompass gender identity. *See, e.g.*, *Smith v. City of Salem*, 378 F.3d 566 (6th Cir. 2004) (Title VII). And the Seventh Circuit did not hold that sexual orientation and transgender status discrimination were covered under Title VII and Title IX, respectively, until decades after the

enactment of Title IX. *See Hively,* 853 F.3d 339 (discrimination on the basis of sexual orientation is "sex" discrimination under Title VII); *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1050 (7th Cir. 2017) (discrimination on the basis of transgender status is "sex" discrimination under Title IX). Thus, Wisconsin was not on "clear notice" that "sex" encompassed transgender status under Title IX upon its enactment in 1972.[2]

Thus, Section 1557 of the ACA, which incorporates Title IX, cannot be used to invalidate the Challenged Exclusion[3] or to obtain money damages from

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[2] The Department acknowledges that binding precedent, *Whitaker*, holds that Title IX's prohibition of "sex" discrimination includes discrimination on the basis of transgender status. 858 F.3d at 1049–50. Further, because the ACA incorporates by reference Title IX, this Court ruled in favor of two transgender plaintiffs who brought sex discrimination claims under the ACA. *Boyden v. Colin*, 341 F. Supp. 3d 979, 995–97 (W.D. Wis. 2018) (citing *Whitaker*). And in this case, this Court has already held that Plaintiffs have a likelihood of success as to their ACA sex discrimination claims. (Dkt. 70:25–29) Accordingly, the Department does not repeat on summary judgment its previously-rejected argument that "sex" discrimination does not encompass "transgender status" discrimination under the ACA. But the Department understands that the U.S. Supreme Court has granted certiorari in three cases, now consolidated, to determine whether "sex" in Title VII, which uses almost identical language as Title IX, includes "transgender status" and "sexual orientation." *R.G. & G.R. Harris Funeral Homes Inc. v. EEOC*, No. 18-107 (U.S. April 22, 2019) (transgender status); *Bostock v. Clayton Cty,, Ga.*, No. 17-1618 (U.S. April 22, 2019) (sexual orientation); *Altitude Express, Inc. v. Zarda*, No. 15-3775 (U.S. April 22, 2019) (sexual orientation). If the Court finds that the statutory term "sex" does not include "transgender status" and "sexual orientation," its holdings may be applied to this case. *See Harper v. Va. Dep't of Taxation,* 509 U.S. 86, 97 (1993) ("When this Court applies a rule of federal law to the parties before it, that rule . . . must be given full retroactive effect in all cases still open on direct review . . . .").

[3] The Department objects to Plaintiffs' new characterization of the Challenged Exclusion. (Defs.' Resp. to PFOF's ¶¶ 2, 118.)

the State of Wisconsin's treasury. Plaintiffs' ACA claim must therefore be dismissed with prejudice and judgment entered in the Department's favor.

II. Plaintiffs are not entitled to summary judgment as to their Medicaid Act claims.

Plaintiffs bring two Medicaid Act claims against the Department—an Availability Provision claim and a Comparability Provision claim—and move for summary judgment on both. Plaintiffs' motion fails. Significant deference is granted to states in determining the services warranting Medicaid coverage. Because there is evidence supporting the Department's decision that "transsexual surgery" and related hormone therapy is not proven treatment for transgender persons suffering from gender dysphoria, Plaintiffs have failed to prove the Challenged Exclusion is unreasonable as a matter of law. Further, even if the Court chooses not to award summary judgment to the Department, the evidence nevertheless raises a genuine dispute of material fact that requires a trial. Either way, Plaintiffs' summary judgment motion as to their Medicaid Act claims must be denied.

A. Courts have held that similar rules are reasonable as a matter of law under the Medicaid Act.

The Medicaid Act "confers broad discretion on the States" to determine "which medical services to cover under their Medicaid plans." *Beal v. Doe*, 432 U.S. 438, 444 (1977); *Alexander v. Choate*, 469 U.S. 287, 303 (1985); *Miller v. Whitburn*, 10 F.3d 1315, 1316 (7th Cir. 1993). Outside of a few broad

categories of services that plans must cover, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1)–(5), (17), (21), (28); *see Miller*, 10 F.3d at 1316, states have "considerable leeway" to set coverage standards, including the freedom to "place appropriate limits on a service based on such criteria as medical necessity," *Bontrager v. Ind. Family & Soc. Servs. Admin.*, 697 F.3d 604, 608 (7th Cir. 2012) (quoting 42 C.F.R. § 440.230(d)). Federal law "requir[es] *only* that such standards be 'reasonable' and 'consistent with the objectives' of the Act." *Beal*, 432 U.S. at 444 (emphasis added) (quoting 42 U.S.C. § 1396a(a)(17)); *Preterm, Inc. v. Dukakis*, 591 F.2d 121, 125 (1st Cir. 1979).

Here, the Department, through its past promulgation of the Challenged Exclusion, set the Medicaid coverage standards for the treatments at issue. The question is whether these existing rules are unreasonable as a matter of law.

To determine reasonableness, a court asks, among other things, not only "whether the service has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used" but whether there is "*authoritative evidence* . . . that attests to a procedure's safety and effectiveness." *Miller*, 10 F.3d at 1320 (emphasis added). This standard reflects that "Medicaid was not designed to fund risky, unproven procedures, but to provide the largest number of necessary medical services to the greatest number of needy people." *Ellis v.*

Patterson, 859 F.2d 52, 55 (8th Cir. 1988). Thus, as the Seventh Circuit has held, "a Medicaid-participating state is under no obligation to pay for experimental procedures." *Miller*, 10 F.3d at 1318 (citing *Rush v. Parham*, 625 F.2d 1150, 1154–55 (5th Cir. 1980)).

A state's medical necessity determinations do not become unreasonable simply because a Medicaid beneficiary's treating physician disagrees with it. *See Rush*, 625 F.2d at 1155; *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1255 (11th Cir. 2011). Far from being "the sole arbiter of medical necessity," "the physician is required to operate within such reasonable limitations as the state may impose." *Rush*, 625 F.2d at 1156. Indeed, "a state may . . . place[ ] limits on a physician's discretion." *Moore*, 637 F.3d at 1252, 1255. In other words, it is the state that first must decide which "kinds of medical assistance are . . . sufficiently necessary to come under the coverage of its plan." *Preterm, Inc.*, 591 F.2d at 125. Only then is it left to the treating physician to decide whether "the condition of his patient warrants . . . a type of medical assistance *which that plan makes available*." *Preterm, Inc.*, 591 F.2d at 125 (emphasis added).

In short, federal law allows states to "place appropriate limits on a service based on such criteria as medical necessity." 42 C.F.R. § 440.230(d); *Bontrager*, 697 F.3d at 608. And the Seventh Circuit has held that states may "validly" exclude "experimental" or unproven procedures as "medically *un* necessary" in their Medicaid plans. *Miller*, 10 F.3d at 1318.

Applying these standards, two federal courts of appeals have already addressed exclusions of gender reassignment surgery from Medicaid coverage.

In 2001, the Eighth Circuit upheld Iowa's Medicaid exclusion of gender reassignment surgery. *Smith v. Rasmussen*, 249 F.3d 755, 761 (8th Cir. 2001). Before issuing its exclusion, Iowa contracted with a "federally designated medical peer review organization" to review the medical literature. *Id*. at 760. The organization reported a "lack of consensus in the medical community" over "the efficacy of and the necessity for sex reassignment surgery." *Id.* at 760–61. Some research "indicated that hormone treatments, psychotherapy, and situational treatment may be more appropriate, and at times more effective, than sex reassignment surgery." *Id*. at 760. Given the "evolving nature of the diagnosis and treatment of gender [dysphoria]" and the "disagreement" over surgery, the court held that Iowa's "prohibition on funding of sex reassignment surgery is both reasonable and consistent with the Medicaid Act." *Id*. at 761.

The Fifth Circuit similarly addressed an exclusion of gender reassignment surgery in *Rush v. Parnum*, 625 F.2d 1150 (5th Cir. 1980). That is the very case that the Seventh Circuit cited approvingly for the "established doctrine" that state Medicaid plans need not cover "experimental procedures." *Miller*, 10 F.3d at 1318. The district court in *Rush* held on summary judgment that Georgia could not "categorically deny funding for" gender reassignment surgery and had "to pay for any services a physician determines to be medically

necessary." 625 F.2d at 1154. The Fifth Circuit reversed and remanded, rejecting the idea that "a state has no role in determining whether a particular service is medically necessary." *Id*. Rather, the "broad discretion" conferred on states to "determin[e] the extent of coverage" allowed Georgia to "exclude experimental treatment." *Id*. at 1155–56 (quoting *Beal*, 432 U.S. at 444). The court remanded to the district court to consider whether Georgia's "determination that transsexual surgery is experimental [was] reasonable." *Id*. at 1157. On remand, after a trial with competing expert testimony, the district court concluded that Georgia could reasonably determine that gender reassignment surgery was experimental. *Rush v. Johnson*, 565 F. Supp. 856, 868 (N.D. Ga. 1983).

B. The Department's regulations regarding gender reassignment surgeries and related hormone therapy are legal under the applicable standards and precedent.

As reflected in the foregoing, federal courts have applied the applicable legal standard to uphold exclusions like the one here. The same result should follow in this case. What was true in those cases continues to be true: there is evidence of conflicting views about the efficacy of treatment, including evidence from clinical studies and other official sources. (Defs.' Resp. to PFOF's ¶¶ 5, 8, 59–60, 65–66, 69–70, 72, 99, 122.) In particular, doubts have been raised by the federal government's Centers for Medicare and Medicaid

Services, the Hayes group that evaluates efficacy of procedures, and more generally in the federal circuits when reviewing medical views.

Given this, the Challenged Exclusion's determination that "transsexual surgery" and related hormone therapy is not medically necessary treatment, for purposes of the Medicaid Act, is "reasonable" as a matter of law. *Miller*, 10 F. 3d at 1321. Accordingly, Plaintiff's Medicaid Act claims fail.

1. Centers for Medicare and Medicaid Services (CMS)

To begin, the federal government has stated that there is no "authoritative evidence" that attests to the surgical procedures' and related hormone therapy's "effectiveness." *Id.* at 1320.

In 2016, the federal Centers for Medicare and Medicaid Services (CMS) decided *not* to issue a National Coverage Determination—approving Medicare coverage across the U.S.—of gender reassignment surgery for treatment of gender dysphoria, because there was "inconclusive" clinical evidence regarding the medical efficacy of such surgery for the Medicare population. (Dkt. 55-2:1 (*Decision Memo for Gender Dysphoria and Gender Reassignment Surgery*, dated August 30, 2016).) CMS evaluated "relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury." (Dkt. 55-2:7.) CMS could not conclude in the affirmative. Instead, it concluded: "Based on an extensive assessment of the

clinical evidence . . . there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these [surgeries] can be identified prospectively." (Dkt. 55-2:65.) In not agreeing to national coverage, CMS encouraged "robust clinical studies [to] fill the evidence gaps that help inform which patients are more likely to achieve improved health outcomes with gender reassignment surgery, [and] which types of surgery are most appropriate . . . to ensure that patients achieve improved health outcomes." (Dkt. 55-2:3.)

2. Hayes, Inc.

The federal government is not alone in its conclusion. Like CMS, Hayes, Inc., a company that evaluates the effectiveness of various medical treatments for health care providers across the county, also found very poor evidence regarding the effectiveness of both gender reassignment surgery and ancillary procedures in four reports.[4]

a. Standard gender reassignment surgeries.

Hayes reviewed a total of 36 studies that met the inclusion criteria to assess the effectiveness of gender reassignment surgery (i.e., genital and

[4] The Hayes reports—two from 2014 and two from 2018—are proprietary and, thus, are filed under seal, subject to this Court's protective order.

chest/breast). (Ostrander Decl. Ex. B:3.)[5] The effectiveness was primarily assessed on the following outcomes: symptoms of gender dysphoria, quality of life, sexual function, patient satisfaction with aesthetic results of surgery, body image satisfaction, and psychological outcomes. For most of these outcome measures, there was only a single study available. (Ostrander Decl. Ex. B:9.)

In fact, the majority of the studies published to date in the peer-reviewed literature are either (1) cross-sectional studies that do not provide information on whether outcome measures are actually different from what they were before initiation of hormone therapy or (2) pretest-posttest studies that can show change but do not have a control group. (Ostrander Decl. Ex. B:112.) Hayes acknowledges the reporting of some positive evidence, but stresses that there are serious limitations in the evidence of both effectiveness and safety. (Ostrander Decl. Ex. B:21.)

More specifically, Hayes determined that, while the body of evidence concerning gender reassignment surgery for treating gender dysphoria is large, it is nonetheless very low quality due to the limitations of individual studies. (Ostrander Decl. Ex. B:9, 41.) The inconsistency of the results from studies comparing gender reassignment surgery with stand-alone hormone

[5] The Hayes reports are exhibits to Dr. Ostrander's Declaration and are cited in many of Defendants' Responses to PFOF's, such as ¶¶ 5–6, 8, 58–61, 65–66, 69–70, 72, 76–77, 99, and 122–23.

treatment, coupled with the overall very low quality of supporting evidence, does not allow for definitive conclusions regarding the comparative effectiveness of gender reassignment surgery and hormone therapy for treating gender dysphoria. (Ostrander Decl. Ex. B:9.)

The Hayes report also found that few studies were available that compare outcomes in patients who received different components of gender reassignment surgery. The results of these studies suggest that more extensive gender reassignment surgery (e.g., genital *and* chest surgery) may improve outcomes to a greater extent than less extensive gender reassignment surgery (e.g., genital *or* chest surgery). However, for most outcome measures, there was only a single study available. The evidence is thus insufficient to provide definitive conclusions about the comparative effectiveness of different components of gender reassignment surgery for treating gender dysphoria. (Ostrander Decl. Ex. B:10–11.)

In addition to the lack of clarity on medical efficacy, the evidence of safety was very low quality, also due to limitations of the individual studies. Not all studies reported all outcomes, meaning that complications may be underrepresented. (Ostrander Decl. Ex. B:41.)

The conclusion of Hayes supports the reasonable determination that the services falling under the Challenged Exclusion are not medically necessary because they are unproven treatments. For purposes of the legal question

posed here, the body of evidence lacks the kind of clear conclusions that might render the Challenged Exclusion unreasonable as a matter of law.

b. Ancillary procedures.

In 2014, Hayes also reviewed literature regarding gender reassignment ancillary procedures and services for the treatment of gender dysphoria. The result was no better.

The 2014 report concerned an evidence-based assessment of ancillary procedures for alleviation of symptoms associated with gender dysphoria and improvement of recipients' well-being. (Ostrander Decl. Ex. D:4.) Hayes reviewed thirteen case series studies of ancillary procedures and chart reviews. (Ostrander Decl. Ex. D:4.) Those ancillary procedures were for vocal cords, voice training, rhinoplasty, facial feminization surgery, and permanent hair removal. (Ostrander Decl. Ex. D:4–5.) Like the evidence for the non-ancillary gender reassignment procedures, the individual study quality was generally very poor. The quality of the evidence was very low because of study limitations, including small sample size and few studies evaluating each procedure category, lack of a control or comparator group, variable follow-up duration, inconsistent availability of results for all outcome measures, lack of baseline data for self-rated outcome measures, and lack of statistical analysis of results. (Ostrander Decl. Ex. D:5, 28.) Further, outcome measures were

focused on technical success and patient satisfaction; only one study evaluated an overall measure of well-being. (Ostrander Decl. Ex. D:5.)

Hayes concluded that while there is some evidence that transgender patients are satisfied with the results of rhinoplasty and facial feminization surgery, patient satisfaction with vocal cord surgery and voice training was mixed. The evidence has serious limitations, and the effect of these procedures on overall individual well-being is unknown. (Ostrander Decl. Ex. D:5–6.)

3. Several appellate decisions reflect a lack of medical consensus that gender reassignment surgery is effective treatment for gender dysphoria.

Consistent with the CMS and Hayes reports, cases describe that medical views lack consensus on the medical efficacy and safety of gender reassignment surgery and related hormone therapy.

To show that the Department's medical necessity determination was "[un]reasonable," *Miller*, 10 F.3d at 1318, Plaintiffs and their experts assert that there is now a "prevailing medical consensus" that gender reassignment surgery is an effective and necessary treatment for gender dysphoria. (Pls.' Br. 39.) They are incorrect. Plaintiffs' position ignores the significant evidence to the contrary, which is discussed above and in several federal circuit courts. Those courts concluded there is no medical consensus that gender reassignment surgery is an accepted medical treatment for transgender persons suffering from gender dysphoria.

The First Circuit stated just a few years ago that there are "significant" "conflicting" views "within the medical community" over the "acceptable treatments for [gender dysphoria]" and "the necessity of [sex-reassignment surgery]." *Kosilek v. Spencer*, 774 F.3d 63, 89, 91–92 & n.12, 14 (1st Cir. 2014) (en banc). In that case, a prisoner brought an Eighth Amendment deliberate indifference claim challenging a prison's denial of his request for gender reassignment surgery. An expert explained that there is a "lack of 'professional consensus' regarding the 'medical necessity' of [gender reassignment surgery]" and a "'dearth of empirical research upon which to base treatment decisions' for [gender dysphoria]." *Id.* at 73 (citation omitted). One expert for the prison testified that there are many experts in the gender dysphoria field "who disagree with" the WPATH guidelines, which advocate for gender reassignment surgery as an appropriate treatment. *Id.* at 76. The court's appointed expert, also acknowledging disagreement within the medical community, explained "that 'large gaps' exist in the medical community's knowledge regarding the long-term effects of [gender reassignment surgery] and other [gender dysphoria] treatments in relation to its positive or negative correlation to suicidal ideation." *Id.* at 78. The court ultimately rejected the prisoner's Eighth Amendment claim because "the evidence was conflicting as to the medical need for [gender reassignment surgery]." *Id.* at 92 n.14. The Eighth Circuit reached the same conclusion in *Smith*, 249 F.3d at 760–61.

Moreover, just recently, the Fifth Circuit in *Gibson v. Collier*, 920 F.3d 212 (5th Cir. Mar. 29, 2019), rejected a transgender inmate's Eighth Amendment claim for gender reassignment surgery. The court found it "indisputable" that there is "significant disagreement within the medical community" over the "necessity and efficacy of sex reassignment surgery." *Id*. at 216. "[A] genuine debate exists within the medical community about the necessity or efficacy of that care." *Id*. at 220. Like Plaintiffs do here, the *Gibson* plaintiff cited the WPATH guidelines as evidence of a consensus that surgery effectively treats gender dysphoria, but the court "agree[d] with the First Circuit" that the WPATH guidelines "do not reflect medical consensus," but "merely one side in a sharply contested medical debate over sex reassignment surgery." *Id*. at 221–23.

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The Challenged Exclusion rests upon the determination that gender reassignment surgery and related hormone therapy is "not medically necessary" treatment, as that term is defined in Wis. Admin. Code § DHS 101.03(96m).[6] As allowed under the Medicaid Act's broad grant of discretion, a procedure is not "medically necessary" if "experimental in

[6] The Department's expert, Dr. Ostrander, takes no position on the question of medical necessity as to any particular medical procedure or service for any particular patient, including the named plaintiffs. (Ostrander Decl. ¶ 12.)

nature," does not have "proven medical value and usefulness," is not "generally accepted," is not "required" to "treat a recipient's illness," or "can[not] safely and effectively be provided." Wis. Admin. Code § DHS 101.03(96m)(a), (b)3., (b)5., (b)9. Although the Department does not contend that all gender reassignment surgery is "experimental" as that term is used in the Wisconsin Administrative Code, the reasoning of *Miller*, *Rush*, and *Smith* applies nonetheless—a state is not required to cover unproven treatment. That means Plaintiffs' Medicaid Act claims fail.

C. Plaintiffs' arguments that the Medicaid Act is violated should be rejected.

As explained, under the applicable standards and given the state of the medical consensus, the Challenged Exclusion does not violate the Medicaid Act. Nothing the Plaintiffs argue changes that.

1. Plaintiffs' Availability Provision claim fails.

Plaintiffs assert that the Department violates the Medicaid Act's Availability Provision by failing to make mandatory medical services available in sufficient amount, duration, and scope. (Pls.' Br. 22–23.) Generally speaking, the Availability Provision requires states to "make[ ] medical assistance available" to all individual who qualify. 42 U.S.C. § 1396a(a)(10)(A). Plaintiffs contend that the Availability Provision requires the Department to

cover the treatment precluded by the Challenged Exclusion. Plaintiffs' argument is not persuasive.

The Department agrees that the Medicaid program must cover services when they fall into a category of mandatory medical services that it has elected to provide (e.g., physician and inpatient hospital services) and that are medically necessary. (Pls.' Br. 24.) But the Department is not required to provide Medicaid coverage for "transsexual surgery" and related hormone therapy when its regulations contain a legally "reasonable" determination that such treatment is not "medically necessary" because it is unproven. Given that, no duty arises.

Plaintiffs claim that the Challenged Exclusion's premise—that "gender-confirming care for adults" is not medically necessary—is "false and unsupported." (Pls.' Br. 24.) This claim ignores the evidence showing that there are only poor quality studies alleging that gender reassignment surgery and ancillary procedures are medically efficacious and safe treatment for gender dysphoria. Contrary to Plaintiffs' contention, the premise that the treatment is unproven is supported, which is all that matters under the Medicaid Act's "reasonableness" standard.

Plaintiffs further argue that the Department's own actions suggest this treatment is medically necessary because it may approve gender reassignment surgery for the under 21 population. (Pls.' Br. 25–26.) However, that

population is subject to a separate Medicaid law, and has no bearing on the 21 and over population. The Early and Periodic Screening, Diagnostic and Treatment benefit (EPSDT) under federal Medicaid law, expressly requires *individualized* determinations of medical necessity to the under 21 population. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B). Thus, as a matter of law, the Challenged Exclusion—a categorical exclusion based, in part, on lack of an *overall* consensus on medical necessity—has no application to this age group. (Defs.' Resp. to PFOF's ¶ 7.) Just because there are instances when gender reassignment surgery can be medically necessary in an *individual* case, that does not change the big-picture lack of consensus that drives the Challenged Exclusion at issue here.

Next, Plaintiffs point out that the Department approved Cody Flack's prior authorization request for gender confirmation surgery after the Court issued the original preliminary injunction. However, this proves nothing relevant here. *A court order* prevented the Department from applying the Challenged Exclusion to Flack. Thus, even though Dr. Sager found gender reassignment surgery to be medically necessary for Flack, that individualized approval is not the same as "transsexual surgery" being medically necessary in general. (Defs.' Resp. to PFOF's ¶¶ 6, 96–97.) *See Smith*, 249 F.3d at 761.

2. Plaintiffs' Comparability Provision claim fails.

Plaintiffs' Comparability Provision claim suffers the same fate as the Availability Provision claim.

Under the Comparability Provision, the services made available by the Department to a Medicaid beneficiary "shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); *see also* 42 C.F.R. § 440.240(b). And "[t]he Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

The Comparability Provision, however, does not require the Department to cover surgical procedures to treat gender dysphoria simply because it covers the same surgical procedures to treat other medical diagnoses and conditions. The reason, again, is medical necessity. A threshold issue in a Comparability Claim is whether the service is medically necessary. *See Cruz v. Zucker*, 195 F. Supp. 3d 554, 577 (S.D.N.Y. 2016) ("[T]he Comparability Provision incorporates a medical necessity requirement."). As explained above, there has been a permissible determination that gender reassignment surgery and related hormone therapy are not medically necessary to treat gender dysphoria. Whether a surgical procedure may be medically necessary to treat

a diagnose or condition *other than* gender dysphoria does not matter. (Defs.' Resp. to PFOF ¶¶ 4, 93.)

Plaintiffs' citation to federal case law is unhelpful. They first discuss *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977). In *White*, the Third Circuit merely held that the State of Pennsylvania could not limit Medicaid coverage of eyeglasses by denying this medically necessary service on the basis of etiology alone, without regard to medical necessity. *Id.* at 1148, 1152. Pennsylvania agreed that the coverage of eyeglasses was medically necessary in all instances. Here, in contrast, the Challenged Exclusion is all about the medical necessity determination as applied to the relevant condition, gender dysphoria. (Defs.' Resp. to PFOF ¶ 93.)

The Second Circuit's *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016), decision is of no help to Plaintiffs, either. In *Davis*, the court held that New York violated the Medicaid Act's Comparability Provision by refusing to cover orthopedic footwear and compression stockings for Medicaid beneficiaries based on the nature their medical conditions. *Davis* is distinguishable, however, because New York conceded that all Medicaid beneficiaries had the "exact same medical needs" for the coverage of the footwear and stockings. *Id.* at 256. Here, that is not the case. Again, the Challenged Exclusion is based on gender reassignment surgical procedures not being proven as medically necessary for transgender persons suffering from gender dysphoria. Under

that regulation, Plaintiffs here do not have the "same levels of medical need" as other Medicaid beneficiaries who receive coverage for surgical procedures unrelated to gender reassignment. *Davis*, 821 F.3d at 257.

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In summary, Plaintiffs are not entitled to summary judgment on their Medicaid Act claims. The dearth of quality clinical evidence that gender reassignment surgery and related hormone therapy is efficacious and safe for persons suffering from gender dysphoria means the Challenged Exclusion is "reasonable" as a matter of law. This entitles the Department to summary judgment. Alternative, the Department is entitled to trial because the evidence creates a genuine dispute of material fact as to the Challenged Exclusion's reasonableness.

III. Plaintiffs' equal protection claim fails because the evidence supports judgment for the Department; at a minimum, genuine disputes of material fact exist.

The Equal Protection Clause prohibits a state from "deny[ing] to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. "The guarantee of equal protection . . . [is] a right to be free from invidious discrimination in statutory classifications and other governmental activity." *Harris v. McRae*, 448 U.S. 297, 322 (1980). "[It] does not forbid classifications. It simply keeps governmental decisionmakers from

treating differently persons who are in all relevant respects alike." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992).

A. Summary judgment for Plaintiffs would be improper under any potentially-applicable level of review.

When reviewing a claim that state action violates equal protection, a court must first determine the applicable level of scrutiny. *See Dunn v. Blumstein*, 405 U.S. 330, 335 (1972). In this case, it does not matter which level is applied because, even under heightened scrutiny, the Challenged Exclusion would survive.

To prevail under rational basis review, Plaintiffs must show that "(1) the state actor intentionally treated plaintiffs differently from others similarly situated; (2) this difference in treatment was caused by the plaintiffs' membership in the class to which they belong; and (3) this different treatment was not rationally related to a legitimate state interest." *Srail v. Vill. of Lisle*, 588 F.3d 940, 943 (7th Cir. 2009).[7]

[7] The Seventh Circuit, in *Whitaker*, applied heightened scrutiny to a high school's bathroom policy for a transgender student because the policy could not be stated without referencing sex. 858 F.3d at 1051–52. This Court applied heightened scrutiny to the plaintiffs' equal protection claim in *Boyden*, concerning a health insurance coverage exclusion for surgical procedures to treat gender dysphoria, similar to the Medicaid exclusion here. 341 F. Supp. 3d at 995–97. And this Court has already applied heightened scrutiny to Plaintiffs' equal protection claim in its decision granting a preliminary injunction. (Dkt. 70:34–35.) In light of *Whitaker* and this Court's previous decisions, and in the furtherance of efficiency, the Department does not repeat its arguments for rational basis review here. However, because a decision in the consolidate case the Supreme Court recently accepted for review, see supra n.2,

To succeed under intermediate scrutiny, the State "must establish an 'exceedingly persuasive justification' for the classification" and "must show 'at least that the classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.'" *U.S. v. Virginia*, 518 U.S. 515, 524 (1996) (citations omitted). The asserted state interests must be "genuine, not hypothesized or invented post hoc in response to litigation," and "must not rely on overbroad generalizations about the different talents, capacities, or preferences" of the classification at issue. *Id.* at 533. And Supreme Court decisions "simply require that the proffered purpose for the challenged gender classification be the actual purpose, although not necessarily recorded." *Id.* at 563 n.* (Rehnquist, J., concurring). And unlike strict scrutiny which is often strict in theory but fatal in fact, intermediate scrutiny recognizes that sex "has never been rejected as an impermissible classification in all instances." *Tagami v. City of Chi.*, 875 F.3d 375, 380 (7th Cir. 2017) (citation omitted).

Further, intermediate scrutiny does not require that a regulation perfectly solve the problem it was enacted to solve—the regulation is valid even if it only partially solves the problem. "[T]he validity of the regulation depends

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may have an impact on whether rational basis or heightened scrutiny review applies, its holding may be applied to this case. *See Harper,* 509 U.S. at 97.

on the relation it bears to the overall problem the government seeks to correct, not on the extent to which it furthers the government's interests in an individual case." *Ward v. Rock Against Racism*, 491 U.S. 781, 801 (1989). Thus, a regulation is valid of it could reasonably have been determined that the overall interests sought to be protected would be served less effectively without the regulation.

Notably, courts have recognized that containing health care costs and protecting public health are important government interests. *See IMS Health Inc. v. Sorrell*, 630 F.3d 263, 276 (2d Cir. 2010), *aff'd*, 564 U.S. 552 (2011) ("[W]e agree with the district court that Vermont does have a substantial interest in both lowering health care costs and protecting public health."); *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 55 (1st Cir. 2008), *abrogated on other grounds by Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011) ("[C]ost containment is most assuredly a substantial governmental interest."; the state has a "substantial interest in reducing overall healthcare costs"); *Bonidy v. USPS*, 790 F.3d 1121, 1127 (10th Cir. 2015) ("administrative convenience and economic cost-saving" are "relevant" to intermediate scrutiny analysis); *Stuart v. Camnitz*, 774 F.3d 238, 250–51 (4th Cir. 2014) (government has an important interest in "promoting . . . psychological health" and preventing "psychological harm"). And, as relevant here, the Supreme Court has recognized that conserving scarce resources and the related issues of "economic supply and distributional

fairness" also qualify as important government interests. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 569 (1980). *See also id.* at 576 ("[P]reventing . . . low quality health care [is a] 'substantial,' legitimate, and important state goal[ ]") (Blackmun, J., concurring).

B. Under intermediate scrutiny, the Challenged Exclusion is valid, and Plaintiffs cannot be granted summary judgment.

There are two government interests that matter if intermediate scrutiny were applied here: containing costs and protecting public health in the face of uncertainty. (Defs.' Resp. to PFOF's ¶¶ 5, 78.) Plaintiffs have no specific evidence refuting these reasons, meaning summary judgment is properly entered for the Department. Alternatively, at a minimum, these interests prevent summary judgment being entered in favor of Plaintiffs.

1. The Challenged Exclusion is substantially related to the important government interest of containing Medicaid costs.

The State's containment of Medicaid costs is an important governmental interest that properly may justify denying coverage for surgical procedures and services unproven to be medically efficacious and safe.

As an initial matter, an obvious logical connection exists between the Challenged Exclusion and containing Medicaid costs. Each procedure, service, and supply, comes with a corresponding cost. Indeed, in 1996, the Wisconsin

Legislative Research Bureau concluded that the Challenged Exclusion would "[d]ecrease [c]osts." (Dkt. 21-14:2; Defs. Resp. to PFOF's ¶ 78.)

In addition, the evidence establishes a connection between the important government interest—saving Medicaid costs—and the Challenged Exclusion. The Departments' financial expert, David V. Williams of Milliman Healthcare Consultants, the largest independent actuarial consulting firm in the United States, performed a detailed analysis of data regarding Medicaid claims in 2016 for gender dysphoria treatments. (Dkt. 74-1.) His expert analysis suggests that removing the Challenged Exclusion could cost roughly $739,000 annually due to increased services—surgical benefits for treating Medicaid transgender patients suffering from gender dysphoria. (Dkt. 74-1:6.) Due to Wisconsin receiving federal money to partially fund its Medicaid program, Williams' analysis showed that a reasonable estimate of the potential yearly cost of removing the Challenged Exclusion would come to just over $300,000. (Dkt. 74-1:6.)

Plaintiffs' expert, Dr. Jaclyn White Hughto, criticizes Williams for failing to account for the short- and long-term cost savings associated with covering gender reassignment surgeries under Wisconsin Medicaid. Her analysis mirrors a State of California assessment. (Dkt. 96.) But Williams points out that such economic impact statements are not designed to put a specific price tag on addition coverage for surgical gender dysphoria treatments, like his

report does. (Dkt. 122 ¶ 5.) Also, Williams exposes the holes in Dr. Hughto's expert opinion: she failed to provide a quantified savings amount associated with providing coverage for gender reassignment surgeries or empirical evidence necessary to calculate savings for the categories she discussed, making her cost savings bases wholly unreliable. (Dkt. 122 ¶¶ 6, 18–23.) And Hughto's critique improperly extends unquantified *socioeconomic* and related *criminal justice* costs and purported savings onto *the Medicaid program*. (Dkt. 122 ¶¶ 7, 24; Defs.' Resp. to PFOF's ¶ 77.) As to Hughto's opinion that, if gender reassignment surgeries were covered there would be a savings in mental health costs associated with suicide and suicide attempts, even if accepted as true, the savings to the entire Medicaid program would be only $2,568 per year. (Dkt. 122 ¶¶ 12, 29.) Finally, using Hughto's "broad and simplified assumptions," Williams concluded that if the Challenged Exclusion were removed, the cost to the State's Medicaid program would be about $3 million annually, of which Wisconsin would bear $1.2 million (ignoring inflation). (Dkt. 122 ¶ 28.) This is actually a higher cost than what Williams concluded with his numbers.

This evidence—from both sides' experts—demonstrates that removing the Challenged Exclusion would impose a meaningful cost upon Wisconsin's Medicaid Program. Preventing increased Medicaid costs is an important governmental objective, and the Challenged Exclusion is substantially related

to the achievement of that objective. Thus, the Challenged Exclusion satisfies intermediate scrutiny. *Bonidy*, 790 F.3d at 1127 (court considered costs as a relevant consideration, in concert with other state interests); *Sorrell*, 630 F.3d at 276; *Ayotte*, 550 F.3d at 55.

Plaintiffs contend that this cost savings to the Medicaid program —even assuming $1.2 million annually—is too small to satisfy heightened scrutiny. (Pls.' Br. 36.) But, again, a regulation is valid under intermediate scrutiny even if it only partially solves the problem at hand. *Ward*, 491 U.S. at 799, 801. "In order to survive intermediate scrutiny . . . a law need not solve the . . . problem, it need only further the interest in preventing [the problem]." *Ass'n of Cmty. Organizations for Reform Now v. Town of E. Greenwich*, 453 F. Supp. 2d 394, 410 (D.R.I. 2006), *aff'd sub nom.* 239 F. App'x 612, 2007 WL 1829374 (1st Cir. 2007) (citation omitted). Although the costs savings are a relatively small portion of Wisconsin's total Medicaid costs, every dollar saved directly contributes to the important interest of cost savings. (Defs.' Resp. to PFOF's ¶ 91.) Plaintiffs' line of reasoning—that savings is minimal—could be used to justify an unlimited expansion of benefits, since *every* benefit, taken individually, is a small part of the whole. Yet, it cannot be true that the Department must offer unlimited benefits. Rather, where to draw the line to control costs is a policy decision. Accordingly, the Challenged Exclusion passes

muster under intermediate scrutiny as a measure designed to contain health insurance costs.

Rather than support judgment for Plaintiffs, this evidence supports judgment for the Department.

2. The Challenged Exclusion is substantially related to the important governmental interest of protecting public health.

In addition to controlling Medicaid costs, the Challenged Exclusion also protects public health, another important governmental interest. *See Sorrell*, 630 F.3d at 276; *Stuart*, 774 F.3d at 250–51. The Department directs this Court to the evidence cited above in section II.B. of this brief showing that there is very poor quality clinical evidence that surgical procedures are medically efficacious and safe for the treatment of gender dysphoria. This provides further support for judgment in favor of the Department here.

In all, then, there are two governmental interests that justify the exclusion and that preclude summary judgment in favor of Plaintiffs: cost savings and doubts about safety and efficacy. Plaintiffs come forward with no evidence squarely refuting the Department's cost estimate or the proposition that the efficacy of treatment is subject to dispute, as detailed above. The Department is therefore are entitled to summary judgment. In the alternative, if this Court believes Plaintiffs' evidence is sufficient to create a material dispute, then there should be a trial.

3. Plaintiffs' counterarguments about governmental interests do not justify summary judgment in their favor.

Plaintiffs argue that the Department's articulated governmental interests—cost savings and public health protection—should not be considered because they are "*post hoc*" justifications in response to litigation. (Pls.' Br. 35–36, 38.) Plaintiffs are mistaken.

As Plaintiffs acknowledge, there is historical documentary evidence proving that the Department *was* considering cost savings and medical efficacy at the time of the implementation of the Challenged Exclusion. (Pls.' Br. 36.) In 1996, the Wisconsin Legislative Reference Bureau concluded that the Challenged Exclusion was part of a set of policies meant to "eliminate coverage of some services that the Department has determined are not medically necessary" and to "[d]ecrease costs." (Dkt. 21-14:2.) And, in 1997, the Department determined "transsexual surgery" and related drugs to be "medically unnecessary." (Dkt. 21-12:3.) These documents prove that the Department considered both cost savings and medical efficacy at the time of the Challenged Exclusion's implementation.[8] As a result, Plaintiffs' arguments

[8] This evidence satisfies this Court's ruling in *Boyden* that there must be evidence that the State was *actually* concerned with efficacy. *Boyden*, 341 F. Supp. 3d at 1001.

that these two governmental objects are simply "*post hoc* rationalization in response to litigation" is simply incorrect. (Pls.' Br. 36.)

Further, in arguing that the Department cannot use expert witness reports in response to their equal protection claim (Pls.' Br. 38), Plaintiffs confuse *evidence* with post hoc *justification*. *Virginia* only precludes a state from raising post hoc justifications for the allegedly discriminatory policy, rule, statute, etc. 518 U.S. at 533. It does not, however, prevent a state from submitting expert evidence that was created after the alleged discriminatory action or in response to the litigation. Indeed, in *Virginia*, the state produced expert witnesses who undoubtedly did not come to their opinion at the creation of the Virginia Military Institute's male-only admission policy in 1839. *Id.* at 540. And this expert evidence was not ignored by the Supreme Court. Thus, Plaintiffs are incorrect in their assertion. States are not bound, as an evidentiary matter, to records from decades in the past.

IV. Plaintiffs are premature in asserting they are entitled to a permanent injunction.

The Department intends to reserve its response to Plaintiffs' argument that they are entitled to a permanent injunction (Pls.' Br. 43–49) unless or until it is necessary. In the event this Court denies Plaintiffs' summary judgment motion and grants judgment to the Department, or this case goes to trial, Plaintiffs' argument is premature. If this Court grants Plaintiffs summary

judgment motion, the Department respectfully requests that it be allowed to file a supplemental response brief on the issue of relief, including but not limited to whether Plaintiffs are entitled to a permanent injunction and, if so, its scope. Indeed, as made clear in its Motion to Stay Proceedings, the Department intends to promulgate emergency and permanent rules that would repeal the Challenged Exclusion. (Dkt. 175.) If successful in removing the Challenge Exclusion through rulemaking, there would be nothing for this Court to enjoin. For these reasons, the Department seeks to respond to Plaintiffs' request for permanent injunction relief only if necessary.

CONCLUSION

The Department respectfully asks this Court to deny Plaintiffs' motion for summary judgment and grant the Department summary judgment or, in the alternative, proceed to trial on the equal protection claim.

Dated this 21st day of May, 2019.

Respectfully submitted,

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