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 and
LINDA SEEMEYER, in her official
capacity as Secretary of the Wisconsin
Department of Health Services,

Defendants.

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR MODIFICATION OF THE PRELIMINARY INJUNCTION

INTRODUCTION

Plaintiffs seek to preliminarily enjoin Defendants Wisconsin Department of Health Services and its Secretary (collectively the "Department") from applying a coverage exclusion for surgical gender dysphoria treatments that remain of unproven value, not only to themselves, but also to an entire putative class consisting of all Wisconsin Medicaid beneficiaries who might be qualified to seek such treatments. This Court should decline to expand the injunction.

First, Plaintiffs remain unlikely to succeed on the merits of their claims under the Affordable Care Act (ACA), the Equal Protection Clause, and the Medicaid Act. At bottom, each claim will fail because inadequate evidence shows that surgical procedures can safely and adequately treat gender dysphoria. This means that the Department is not discriminating on the basis of sex (or transgender status); it is declining to cover procedures that are not medically necessary. For the same reason, Plaintiffs cannot show that they face irreparable harm if the Department continues to enforce the coverage exclusion as this litigation proceeds. Given the lack of reliable scientific evidence regarding surgical gender dysphoria treatments, it is unlikely that getting such surgeries now will result in an improvement in Plaintiffs' (and the putative class's) gender dysphoria. Given these problems in their case, the concrete financial cost to the State of covering these procedures—anywhere from $300,000 a year to $1.2 million a year, using the assumptions of Plaintiffs' own expert—outweighs the distant likelihood of harms to Plaintiffs and the putative class. Moreover, Plaintiffs lack any evidence from putative class members' treating physicians, which means even less basis exists to conclude that those individuals face irreparable harm absent a preliminary injunction.

Plaintiffs' motion to expand the preliminary injunction's scope should be denied.

SUPPLEMENTAL FACTUAL BACKGROUND

Defendants maintain that, for the reasons described in their original opposition to Plaintiffs' motion for a preliminary injunction, surgical treatments have not been demonstrated to be safe and effective treatments for gender dysphoria. (Dkt. 53:7–10.) Further, Defendants rely on the previously-submitted report of David Williams estimating that removing the Exclusion for all Wisconsin Medicaid beneficiaries will cost around $300,000 per year. In response to Plaintiffs' proposed supplemental facts in support of their new motion to modify the injunction, Defendants offer two new declarations, filed separately: one from Dr. Daniel Sutphin, a plastic surgeon, regarding the medical necessity of surgical gender dysphoria treatments, and another from David Williams responding to critiques of his cost estimate from Plaintiffs' expert Jaclyn Hughto. Their declarations are summarized next.

Dr. Daniel Sutphin's opinions

Dr. Sutphin is a practicing plastic surgeon who completed his plastic surgery residency at the University of Tennessee and a fellowship in reconstructive microsurgery at the University of California, San Francisco. He is a Fellow of the American College of Surgeons and a member of the American Society of Plastic Surgeons. (Sutphin Decl. ¶ 2.)

He describes a number of risks associated with removing a person's biologically native genitals and replacing them with a facsimile of those of the

desired sex. Generic surgical risks include infection, bleeding, pain and numbness. Risks unique to the genital surgeries at issue here include diversion of urinary stream, loss of erogenous sensation, and failure to achieve the natural and desired appearance of the external genitals (which may perpetuate a cycle of revisional surgery and scarring). More dramatic and life altering sex reassignment risks of "bottom" surgery include but are not limited to infertility, urinary incontinence, inadvertent bowel injury requiring a diverting intestinal ostomy (the intestine may be drawn out of the abdominal wall and diverted into a collecting bag), urethral stricture with associated increased risk of chronic urinary tract infection, and colovaginal fistula (or communication between the residual colon and the "neovagina" allowing stool to issue from both). (Sutphin Decl. ¶ 13.)

In his opinion, weighed against these risks, the efficacy of gender reassignment surgery, particularly with regard to complication rate and cost, remains unverified in terms of durable objective benefit. (Sutphin Decl. ¶ 36.) Sex reassignment surgery has not achieved the level of de facto safety and wide familiarity such as suggested by the declarations of Plaintiffs' medical providers. (Sutphin Decl. ¶ 32.) Valid patient-reported outcome measures for the transgender patients that are sensitive enough to assess gender confirmation surgery without the influence of other gender–related interventions remain lacking. (Sutphin Decl. ¶ 41.) In addition, the high

number of unreliable instruments used in current literature not only yields uncertain results, but also precludes dependable comparison between different studies. (Sutphin Decl. ¶ 41.) For example, a 2011 study examined nearly every psychiatric admission in Sweden since 1973 and found that, despite surgical sex reassignment, rates of mortality, suicidal behavior and psychiatric morbidity remain elevated in the transsexual population monitored over a 30-year period. (Sutphin Decl. ¶¶ 37, 42.)

Neither the American Board of Surgery nor the American Board of Plastic Surgery has, to date, declared any defined standards of care for treating gender dysphoria, "widely accepted" or otherwise. (Sutphin Decl. ¶ 44.) Even the American Psychiatric Association notes in its 2012 task force report on treatment of gender identity disorder that "[t]he quality of evidence pertaining to most aspects of treatment in all subgroups was determined to be low" and "subjective improvement" is relied upon as "the primary outcome measure." (Sutphin Decl. ¶ 40.) A similar study conducted on female to male genital reconstruction options notes that:

> the vast majority of existing information on outcomes in female-to-male genital reconstruction is considered low-quality evidence. Existing studies on patient satisfaction are limited by a general lack of validated, standardized methods, a paucity of controlled studies, little prospective data collection, and poor response rates in long-term follow-up studies. In addition, there is enormous variation in follow-up periods. Emphasis is placed on the need to develop 'standardized methods to assess the outcomes of surgery' in terms of quality of life before and after surgery, and long-term data collection on preoperative versus postoperative sexual function/ satisfaction.

(Sutphin Decl. ¶ 46.)

Further, Dr. Sutphin explains that in gender reassignment surgery, organs uniquely characteristic of the male and female sex are removed and/or reasonable anatomic facsimiles fashioned in an effort to ameliorate the discordance between what the patient feels regarding their gender and the reality of their natal sex. It is Dr. Sutphin's opinion that such a procedure, unique in all of medicine, in which an otherwise physiologic organ is removed based on the seminal impetus of patient desire and perception, should be supported by a correspondingly exceptional quality of data. (Sutphin Decl. ¶ 54.) But it is not. (Sutphin Decl. ¶¶ 35–48.) Similar, he opines that whatever the perceived subjective benefits of gender reassignment surgery may be, application of these approximately 43 different such surgeries involves "more", not "less" in the sense of technical complexity, invasiveness, irreversibility, cost, resource allocation, and operative patient risk. (Sutphin Decl. ¶ 55.)

David Williams' supplemental opinions

Jaclyn White Hughto, one of Plaintiffs' experts, asserts that the increased availability of gender-confirming care has resulted in cost savings from reductions in negative health outcomes associated with untreated gender dysphoria, including depression, suicidality, drug abuse, HIV infection,

mortality, and costs related to physical and sexual assault. (Dkt. 96 ¶¶ 10–20.) She also critiques the analysis of the Department's cost expert, David Williams, for failing to take into account these purported savings when calculating the cost to the Department of removing the Exclusion. (Dkt. 96 ¶¶ 8, 23.)

However, except for figures associated with decreases in suicidality, Hughto offers no reliable basis to calculate any cost savings to Wisconsin's Medicaid program from covering gender-confirmation surgeries. (Williams Supp. Decl. ¶¶ 6–7, 18–24.) With that one exception, Hughto does not provide quantified cost reductions, quantified reduction in benefit usage, or other measures useful in quantifying the purported cost savings to the Wisconsin Medicaid program. (Williams Supp. Decl. ¶¶ 18–24.) As for decreases in suicidality, assuming the studies on which Hughto relies are accurate, covering gender reassignment surgery would only lower the estimated costs to Wisconsin by around $2,600 per year. (Williams Supp. Decl. ¶¶ 8–17.)

Moreover, Hughto provides a basis to conclude that the Department may incur costs much higher than $300,000 a year. Specifically, she estimates that "at least 5,000 Wisconsin Medicaid recipients are transgender adults who may be affected by the surgical exclusion at some point in their lives." (Dkt. 96:9 ¶ 21.) That is, she estimates that almost all transgender Medicaid beneficiaries will utilize surgical gender reassignment services. (Dkt. 96:9 ¶ 22.) These

figures represent a much higher utilization rate for these surgical services than the one used in Williams' report; combining Hughto's higher utilization rate with Williams' per-patient cost estimates yields a significantly higher estimated yearly cost to the Department. Assuming Hughto's figures are accurate, and that those 5,000 recipients will receive gender reassignment surgery over the next ten years, Wisconsin's Medicaid program would incur $12 million in costs over that period, or around $1.2 million per year. (Williams Supp. Decl. ¶¶ 28, 30.)

ARGUMENT

I. Plaintiffs cannot show a likelihood of success on the merits of either their equal protection, Affordable Care Act, or Medicaid Act claims.

To be "medically necessary" under Wisconsin Medicaid, the medical assistance service the beneficiary seeks coverage for must meet nine standards. Wis. Admin. Code § DHS 101.03(96m)(b)1.–9. As relevant here, the Department considers a procedure not to be "medically necessary" if the procedure is not "[r]equired" to "treat a recipient's illness," does not have "proven medical value and usefulness," is "experimental in nature," is "solely for the convenience of the recipient," or "can[not] safely and effectively be provided." Wis. Admin. Code § DHS 101.03(96m)(a), (b)(5), (b)(7), (b)(9). Because the gender reassignment surgeries covered by the Exclusion do not meet at least these one of these required standards, they do not meet the

definition of "medically necessary." As a consequence, DHS may lawfully exclude them from Medicaid coverage through the Exclusion, and in turn Plaintiffs' equal protection, ACA, and Medicaid Act claims necessarily fail.

A. The Exclusion falls within the State's broad discretion to exclude unproven treatments.

1. State have broad discretion under the Medicaid Act to determine medical necessity.

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); *Miller v. Whitburn*, 10 F.3d 1315, 1316 (7th Cir. 1993); *Alexander v. Choate*, 469 U.S. 287, 303 (1985). State plans must cover a few broad categories of services, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1)–(5), (17), (21), (28); *see Miller*, 10 F.3d at 1316, but States have "considerable leeway" to work out the details, including the freedom to "place appropriate limits on a service based on such criteria as medical necessity," *Bontrager v. Indiana 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 (quoting 42 U.S.C. § 1396a(a)(17)) (emphasis added); *Preterm, Inc. v. Dukakis*, 591 F.2d 121, 125 (1st Cir. 1979).

One "established" application of this principle is "that 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)). It is "a valid exercise of [a State's] discretion" to conclude that "experimental procedures . . . are 'medically *un* necessary'" and exclude them from coverage. *Id.* (quoting *Rush*, 625 F.2d at 1156). Indeed, "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 by Ellis v. Patterson*, 859 F.2d 52, 55 (8th Cir. 1988).

Importantly, a State's medical necessity determinations are not subordinate to a treating physician's view of whether a particular procedure is necessary. *See Rush*, 625 F.2d at 1155; *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1255 (11th Cir. 2011); *see also Smith v. Rasmussen*, 249 F.3d 755, 759 (8th Cir. 2001). "[A] state may . . . place[ ] limits on a physician's discretion." *Moore*, 637 F.3d at 1252, 1255 (emphasis omitted) (quoting Rush, 625 F.2d at 1154). In other words, "the private physician is [not] the sole arbiter of medical necessity." *Rush*, 637 F.3d at 1155. The State's role is to decide which "kinds of medical assistance are . . . sufficiently necessary to come under the coverage of its plan." *Preterm, Inc.*, 591 F.2d at 125.

Given that States have "significant discretion to decide which treatments to cover," a court's review of a State's coverage determination "is not plenary." *Miller*, 10 F.3d at 1320–21. Instead, this Court may consider "*only* whether the [State's] determination that [a] procedure is experimental," for example—"is

reasonable." *Id*. (emphasis added) (citing *Rush*, 625 F.2d at 1157); *see also Beal*, 432 U.S. at 444; *Preterm, Inc.*, 591 F.2d at 125. To gauge the reasonableness of a medical necessity determination, courts may consider, among other things, "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" and whether there is "'authoritative evidence' . . . that attests to a procedure's safety and effectiveness." *Miller,* 10 F.3d at 1320.

Two federal courts of appeals have already endorsed exclusions of gender reassignment surgery from Medicaid coverage. One of the two, *Rush v. Parnum*, 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 Fifth Circuit rejected the idea that "a state has no role in determining whether a particular service is medically necessary." Rush, 625 F.2d at 1155–58. Rather, the "broad discretion" conferred on States to "determin[e] the extent of coverage" allowed Georgia to "exclude experimental treatment." *Id*. at 1155–56. The court remanded to the district court to consider whether Georgia's "determination that transsexual surgery is experimental [was] reasonable." *Id*. at 1157.

In *Smith*, 249 F.3d 755 at 761, the Eight Circuit upheld Iowa's exclusion of gender reassignment surgery for similar reasons. Prior to issuing its exclusion, Iowa had contracted with "the Iowa Foundation for Medical Care,"

a "federally designated medical peer review organization," to conduct "a review of the medical literature." *Id.* at 760. The Foundation reported a "lack of consensus in the medical community" over "the efficacy of and the necessity for sex reassignment surgery." *Id.* at 760–61. The Foundation noted that 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 most recent federal court of appeals to thoroughly review the medical evidence for gender reassignment surgery (the First Circuit, en banc) found that there continues to be "significant" "conflicting" views "within the medical community" over the "acceptable treatments for [gender dysphoria]" and "the necessity of [gender 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 based on the prison's denial of his request for gender reassignment surgery. At trial, an expert for the prison 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). Another expert testified that "[t]here are many people in the country who disagree with [the World Professional Association for Transgender Health (WPATH) guidelines (which advocate for gender reassignment surgery as an appropriate treatment)] who are involved in the [gender dysphoria] field." *Id.* at 76. The court appointed its own expert, who also acknowledged disagreement within the medical community. *Id.* at 77–79. He 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 (emphasis added). The court ultimately rejected the Eighth Amendment claim because "the evidence was conflicting as to the medical need for [gender reassignment surgery]." *Id.* at 92 n.14; *see also Lamb v. Norwood*, 899 F.3d 1159, 1161 (10th Cir. 2018) (rejecting a similar claim).

The Department's exclusion of gender reassignment surgeries and related hormones, Wis. Admin. Code § DHS 107.03(23)–(24), falls well within its "broad discretion" to determine "which medical services to cover under [its] Medicaid plan[ ]." *Beal*, 432 U.S. at 444; *Miller*, 10 F.3d at 1316. The Exclusion is based on the Department's determination that gender reassignment surgery is "not medically necessary" (Dkt. 21-12:3), and federal regulations explicitly authorize 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. As relevant here, the Department considers a procedure not to be "medically necessary" if the procedure 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)(5), (b)(9). States may "validly" exclude or unproven procedures as "medically *un* necessary." *Miller*, 10 F.3d at 1318 (quoting Rush, 625 F.2d at 1156).

2. The Department reasonably concluded that gender reassignment surgeries are not medically necessary.

The Department's medical necessity determination as to transsexual surgery was reasonable and should survive this Court's limited review. *See Miller*, 10 F.3d at 1320–21; *Beal*, 432 U.S. at 444; *Preterm, Inc.*, 591 F.2d at 125.

To begin, there is simply no "authoritative evidence" at this point that "attests to [the] procedure's [ ] effectiveness." *Miller*, 10 F.3d at 1320. At least three recent comprehensive reviews of the medical literature—including one by the federal Center for Medicaid and Medicare Services (CMS)—have concluded that there is no conclusive evidence that gender reassignment is beneficial. (Dkt. 55-1:8–9; Dkt. 55-2:1, 61–65). The Department's expert in this case (who conducted one of those reviews) concludes that "[m]edical and

surgical treatments have not been demonstrated to be [ ] effective for gender dysphoria." (Dkt. 55-1:4.) These reviews all explain that the studies to date have had significant "methodological flaws" (Dkt. 55-2:61), including "small sample sizes," a lack of "control or comparator group[s]," and of "lack [ ] objective and validated outcome measures." (Dkt. 55-4:6–7.) Importantly, "the four best designed and conducted studies"—according to CMS's review—"did not demonstrate clinically significant changes or differences in psychometric test results after sex reassignment surgery." (Dkt. 55-2:62; Sutphin Decl. ¶ 22.) *See also Kosilek*, 774 F.3d at 89, 91–92 & n.12, 14 (1st Cir. 2014) (noting "significant" "conflicting" views "within the medical community" over the "acceptable treatments for [gender dysphoria]" and "the necessity of [sex-reassignment surgery]"); *Smith*, 249 F.3d at 760–61.

Not only is there little reliable evidence that gender reassignment surgery is effective, there are also reasons to believe it may be harming patients, rather than helping them. After all, the one guaranteed effect of full bottom-surgery is lifelong infertility. And a full surgical transition risks a number of significant complications, including urinary problems and death of the tissue used to create the new genitals. (Sutphin Decl. ¶ 13.) Furthermore, as surgery has become more common, so too have stories of deep regret. The most "robust" long-term studies suggest that these harmful effects (regrets and suicides) take many years to surface, and therefore are not yet fully known.

(*See* Dkt. 55-2:62; Dkt. 55-1:183–84.) A Swedish study reports that sex-reassigned individuals were 19.1 times more likely to die from suicide than the general population and found that these increased mortality rates did not come apparent until after 10 years. (Dkt. 55-2:62.)[1] If these timeframes are accurate, shorter-term studies (which covers most of them) do not show the full picture.

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. (Dkt. 19:32; Dkt. 25:11; Dkt. 26:9). But that ignores the significant evidence on which the Department relies, which demonstrates the lack of adequate evidence that surgical procedures can effectively treat gender dysphoria. Likewise, it ignores the First Circuit's recent finding that "medical providers"

[1] A follow-up study based on this same population found that "the median time lag until [seeking] a *reversal* [of sex-reassignment surgery] was 8 years." Cecilia Dhejne et al., *An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960–2010: Prevalence, Incidence, and Regrets*, Archives of Sexual Behav. 1535 (2014), https://www.researchgate.net/publication/262734734_An_Analysis_of_All_Applications_for_Sex_Reassignment_Surgery_in_Sweden_19602010_Prevalence_Incidence_and_Regrets. Anecdotal evidence supports this timeframe; one recent article recounted various personal testimonies of "regret kick[ing] in at around the six- to eight-year mark." Daisy Dumas, *The in-betweeners*, Sydney Morning Herald (July 31, 2015), https://www.smh.com.au/lifestyle/the-inbetweeners-20150730-ginojq.html.

continue to hold "non-uniform opinions regarding the necessity of [sex-reassignment surgery]." *Kosilek*, 774 F.3d at 91.

Plaintiffs cite the WPATH guidelines as evidence of the "consensus" that sex-reassignment surgery is safe and effective, yet the court-appointed expert in *Kosilek* explained that WPATH "aspires to be both a scientific organization and an advocacy group" and as a result, does "not well tolerate[ ]" "[s]kepticism and strong alternate views." 774 F.3d at 78. (*See also* Sutphin Decl. ¶¶ 23–24.) And another of the Department's experts points out that neither the American Board of Surgery nor the American Board of Plastic Surgery has to date declared any defined standards of care for treating gender dysphoria as "widely accepted" or otherwise. (Sutphin Decl. ¶ 44.)

Setting aside the purported "consensus," Plaintiffs' experts cite to a few studies, but these all have significant "methodological flaws," as CMS and others have recognized. (Dkt. 55-2:61; Dkt. 55-4:6.) First, one form of study frequently invoked as showing the "positive outcomes from gender confirmation surgery" involves little more than polling patients about their

satisfaction with the procedure. (*See*, Dkt. 24:10[2]; Dkt. 27:11 n.10[3].) This type of study has multiple flaws, including a strong potential for selection bias. Most of these studies are conducted by sending questionnaires to a group of post-operative individuals and computing satisfaction rates from *those who respond*—often nowhere near 100 percent. (*See*, Dkt. 55-2:21 (46.9% response rate for Hess study)); (37% participation rate for 2018 van de Grift study)). In one study that Plaintiffs' experts cite, 20 to 30 percent *of those who participated* refused to answer the questions about whether they were satisfied with the procedure. van de Grift 2018 at 143. This study candidly acknowledged that "disappointment may be . . . difficult to admit" for "highly motivated people [who] choose to undergo a procedure with a high risk of complications," and that the study "probably suffered from a selection bias," including because "less satisfied individuals may have been underrepresented." van de Grift 2018 at 146.

Second, many of these studies survey their participants relatively soon after surgery. *See* Hess 2014 (mean of 5.05 years after surgery); van de Grift

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[2] Citing Tim C. van de Grift, et al., *Surgical Satisfaction, Quality of Life, and Their Association After Gender-Affirming Surgery: A Follow-up Study*, 44 J. Sex & Marital Therapy. 138 (2018), https://www.tandfonline.com/doi/pdf/10.1080/0092623X.2017.1326190 (last visited Nov. 15, 2018).

[3] Citing Jochen Hess, et al., *Satisfaction With Male-to-Female Gender Reassignment Surgery*, 111 Dtsch Arztebl Int 795 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4261554/pdf/Dtsch_Arztebl_Int-111-0795.pdf (last visited Nov. 15, 2018).

2018 (4 to 6 years after surgery). Yet the best long-term studies suggest that regrets tend to take much longer to surface, and anecdotal evidence supports this timeframe. (*See* Dkt. 55-2:62; Dkt. 55-1:183–84.)

Finally, measuring a transgender patient's *subjective* satisfaction with surgery is not the same as measuring the *objective effects* on the dysphoria. A person who receives a surgery that they strongly desired will of course feel some relief—at the very least from the previously unfulfilled desire—even if the procedure's objective benefits are purely cosmetic and do nothing to affect the underlying dysphoria. (Dkt. 55-3:12 at 42:6–14.) Studies that use more objective assessments of mental health often show little to no benefit from surgery. The CMS reviewers noted that the four best studies they could find, which used "validated [ ] psychometric studies" to measure mental health outcomes, "did not demonstrate clinically significant changes or differences in psychometric test results after [sex-reassignment surgery]." (Dkt. 55-2:62.)

One of Plaintiffs' experts cites two "systematic reviews" of research studies (one of which she authored) as "overwhelmingly find[ing] a positive relationship between hormone therapy and surgery and improvements in gender dysphoria." (Dkt. 26:9–10 (citing Mohammad Hassan Murad, et al., *Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes*, 72 Clinical Endocrinology 214 (2010); Jaclyn M. White Hughto & Sari L. Reisner, *A*

Systematic Review of the Effects of Hormone Therapy on Psychological Functioning and Quality of Life in Transgender Individuals, 1.1 Transgender Health 22 (2016).) Yet neither of these studies actually reviewed the evidence for *surgery*; both considered the effects of *hormone therapy*. And even for hormone therapy, Murad's review concluded that the evidence was "very low quality." (Dkt. 55-1:185.)

In sum, courts and medical reviews recognize that that the effectiveness of surgery to treat gender dysphoria is unproven. The Department acted within its authority and broad discretion under the Medicaid Act to determine that, because these treatments are unproven, they are not medically necessary and thus should not be covered.

B. Plaintiffs will not succeed on their Equal Protection Clause and ACA claims.

Both the Equal Protection Clause and Title IX (which the Affordable Care Act incorporates, 42 U.S.C. § 18116) prohibit sex discrimination. *Craig v. Boren*, 429 U.S. 190 (1976); *United States v. Virginia*, 518 U.S. 515, 531–34 (1996); 20 U.S.C. § 1681. While there are significant differences in the scope of coverage, *see Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246 (2009), the substance of the discrimination analysis is essentially the same when both apply. *See*, *Hayden ex rel. A.H. v. Greensburg Cmty. Sch. Corp.*, 743 F.3d 569, 583 (7th Cir. 2014) (finding both Title IX and equal protection violations "for

the same reasons"); *Waid v. Merrill Area Pub. Sch.*, 91 F.3d 857, 861 (7th Cir. 1996) (calling the rights "essentially identical"), *abrogated on other grounds by Fitzgerald*, 555 U.S. 246 (2009); *Women Prisoners of D.C. Dep't of Corr. v. District of Columbia*, 93 F.3d 910, 924 (D.C. Cir. 1996); *see Fitzgerald*, 555 U.S. at 257 (2009) (noting that the standards for liability under Title IX and the Equal Protection Clause "may not be *wholly* congruent," but identifying only one minor difference not relevant here). These prohibitions on discrimination are "essentially a direction that all persons similarly situated should be treated alike" regardless of sex. *City of Cleburne, Tex. v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985).

1. The Exclusion does not discriminate on the basis of sex.

A plaintiff generally shows sex discrimination in one of two ways. First, and more traditionally, a claimant could attempt to show that a given law disparately treats "women *because* they are women" or "men *because* they are men." *Ulane v. E. Airlines, Inc.*, 742 F.2d 1081, 1085 (7th Cir. 1984) (emphasis added). Or, under *Hively*'s more expansive "comparative method," a plaintiff might "attempt to isolate the significance of the [her] sex" to the government's action: "has she described a situation in which, holding all other things constant and changing only her sex, she would have been treated the same way?" *Hively v. Ivy Tech Cmty. Coll. of Ind.,* 853 F.3d 339, 345 (7th Cir. 2017).

In *Hively* itself, the majority concluded that an employer had failed this test, since, if the plaintiff there had not been a female attracted to females but rather, counterfactually, a *male* attracted to females, the defendant "would not have refused to promote her and would not have fired her." *Id.* at 345. Citing *Hively*, the Seventh Circuit has also held that a plaintiff can show "sex" discrimination by showing gender-identity discrimination that is rooted in sex stereotyping. *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d, 1048 (7th Cir. 2017).

Regardless of the means of proving sex discrimination, however, the "threshold inquiry" is the same. In any discrimination claim—whether under the Equal Protection Clause or Title IX—a plaintiff must identify some actual classification or disparate treatment. *See*, *Women Prisoners*, 93 F.3d at 924; *Tagami v. City of Chicago*, 875 F.3d 375, 379 (7th Cir. 2017); *Graham v. Broglin*, 922 F.2d 379, 382 (7th Cir. 1991).

When a plaintiff challenges a regulation as discriminatory, courts start by examining the rule "on its face" to determine whether it draws an explicit classification or is "facially neutral." *See*, *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991). For Medicaid regulations in particular, the Supreme Court has held that a coverage limitation is "neutral on its face" if all "classes of users [are] subject to the same . . . limitation" and have "access to . . . the [same]

package of [health care] services [that the State] has chosen to provide." *Alexander v. Choate*, 469 U.S. 287, 302–03, 309 (1985) (rejecting a disability discrimination claim); *see also Harris v. McRae*, 448 U.S. 297, 323 & n.26 (1980) (rejecting an age discrimination claim).

Because even facially neutral policies can be applied in a discriminatory manner, plaintiffs may also allege "disparate treatment," in other words, that "similarly situated" individuals were treated differently. *City of Cleburne*, 473 U.S. at 439. The "threshold inquiry" for this type of claim is showing that the groups allegedly treated differently were in fact "similarly situated." *Women Prisoners*, 93 F.3d at 924; *Desris v. City of Kenosha*, 687 F.2d 1117, 1119 (7th Cir. 1982). This type of claim "fails at the threshold" if the two groups were "in fact . . . treated identically." *Graham*, 922 F.2d at 382.

Plaintiffs' discrimination claims "fail[ ] at the threshold" because they cannot show any "actual[ ] classif[ication]" or disparate treatment on the basis of sex. *Graham*, 922 F.2d at 382; *Tagami*, 875 F.3d at 379; *Women Prisoners*, 93 F.3d at 924.

To begin, the Exclusion itself does not draw any explicit sex-based (or even transgender-based) classifications. Indeed, the Exclusion does not even draw lines between different types of people—it excludes coverage for particular procedures (transsexual surgeries and related hormone therapy), only given to persons with a particular condition (gender dysphoria). The

Exclusion applies equally to all Medicaid beneficiaries: male or female, transgender or not, no person may obtain coverage for surgery to change sex. As with the coverage limitation that the Supreme Court considered in *Alexander*, Wisconsin's Medicaid plan provides the same "package of health care services" for all people, and neither men nor women are "den[ied] . . . access to or exclude[d] . . . from the particular package of Medicaid services [Wisconsin] has chosen to provide." 469 U.S. at 302–03, 309. The Exclusion is therefore "neutral on its face." *Id. at 309*; *Harris*, 448 U.S. at 323 & n.26.

Nor can Plaintiffs show any disparate treatment, at least without calling into the question the Department's medically necessity determination. The Exclusion is simply one application of a uniform rule of coverage (medical necessity) that does not take into account either sex or transgender status. *See* Wis. Admin. Code §§ DHS 107.01(1) (general scope of coverage); 101.03(96m) (definition of "medical[ ] necess[ity]"). The Department has many exclusions for a variety of procedures, including "[a]rtificial insemination," "[i]nfertility testing," "[r]eversal[s] of vasectomies," "[i]mpotence devices and services," "[t]esticular prosthesis," "[t]attoo removal," and "[e]ar lobe repair." Wis. Admin. Code § DHS 107.03. As with these other procedures, the Department determined that gender reassignment surgery "[is] not medically necessary." (Dkt. 21-12:3).

Although the Department occasionally covers phalloplasties, vaginoplasties, and the like when they are medically necessary to treat *other conditions*, but does not cover them to treat gender dysphoria because the Department has determined such procedures are not medically necessary to treat *that condition*. If the Department's medical necessity determination is upheld as reasonable, then there is no disparate treatment because the Department's coverage determinations are entirely consistent with a uniform rule (medical necessity) that does not consider sex or transgender status. In other words, unless Plaintiffs first establish that the Department's medical necessity determination is baseless, they cannot show that they are "similarly situated" to the examples they provide. *City of Cleburne*, 473 U.S. at 439.

This explains why the Department's policy does not violate *Hively*, which instructs courts to "hold[ ] all other things constant and chang[e] only [the person's] sex" when using the "comparative" method to identify discrimination. 853 F.3d at 345. The examples Plaintiffs provide for comparison change not only the sex or transgender status of the hypothetical patient, but also the medical condition and the goal of the surgery. When the medical condition is a "car accident" or "congenital defect," the goal of plastic surgery is to restore body parts that were damaged or lost; when the medical condition is gender dysphoria, the goal is to replace body parts with another kind entirely in the hope that this will mitigate psychological distress. To apply *Hively*'s

comparative method properly, one would need to keep the medical condition (gender dysphoria) constant and change only the sex to determine whether sex was the basis for the exclusion. For Flack, the proper question is: if Flack (a biological woman, transgender man) were instead a biological man seeking gender reassignment surgery to treat gender dysphoria, would the procedures be covered? And for Mackenzie, Kelly, and Sherwin, the proper question is, if they (biological men, transgender women) were instead biological women seeking gender reassignment surgery to treat gender dysphoria, would the procedures be covered? In this case, the analysis is not even hypothetical, because Flack and the other plaintiffs are each other's counterfactuals. Under Wisconsin's Medicaid plan, neither biological men (Mackenzie, Kelly, Sherwin) nor biological women (Flack) can obtain coverage for gender reassignment surgery to treat gender dysphoria.

Moreover, the fact that Plaintiffs' physicians have recommended gender reassignment surgery for them is not determinative, since "medical necessity" is not a purely patient-specific determination. Rather, the concept incorporates a number of considerations that have nothing to do with a patient's individual circumstances. *See Miller*, 10 F.3d at 1318. Under the Department's definition of medical necessity, these considerations include whether the procedure is "of proven medical value or usefulness," "experimental," "generally accepted" in the medical community, and "safe[ ] and effective[ ]." Wis. Admin. Code § DHS

101.03(96m)(a), (b)(3), (b)(5), (b)(9). The Department's determination that gender reassignment surgery is "medically *un*necessary" (Dkt. 21-12:3), is justified by the lack of quality evidence showing that surgery is beneficial for treating gender dysphoria, as well concern that the procedure may actually be more harmful than helpful. Those concerns do not change on a case-by-case basis. And the Seventh Circuit has held that these are "valid" considerations in a medical necessity determination. *Miller*, 10 F.3d at 1318.

More importantly, however, a treating physician is not "the sole arbiter of medical necessity." *Rush*, 637 F.3d at 1155; *Moore*, 637 F.3d at 1252, 1255. The federal Medicaid Act confers "*on the States*"—not private physicians—"substantial discretion" to determine "which medical services to cover under their Medicaid plans." *Beal*, 432 U.S. at 444 (emphasis added); *Alexander*, 469 U.S. at 303; *Miller*, 10 F.3d at 1316. While individual physicians may disagree with how the Department resolved some of the factors that go into a medical necessity determination, they do not have the power to overrule a State's decision. *Rush*, 637 F.3d at 1155; *Moore*, 637 F.3d at 1252, 1255.

Finally, courts may only consider whether a medical necessity determination is "reasonable." *Miller*, 10 F.3d at 1320–21; *see also Beal*, 432 U.S. at 444. The Department's determination does not become unreasonable merely because Plaintiffs have experts and doctors who disagree. And the fact that Plaintiffs have raised discrimination claims should not

change this standard of review. As now thoroughly explained, Plaintiffs cannot get past the "threshold inquiry" of showing some "actual[ ] classif[ication]" or disparate treatment without *first* showing that gender reassignment surgery is, in fact, medically necessary. If this Court were to raise the standard of review on this preliminary issue before Plaintiffs even get through the door, it would be loading the dice in their favor.

Given that Plaintiffs' discrimination claims "fail[ ] at the threshold" of showing an "actual classification" or some disparate treatment, *Tagami*, 875 F.3d at 379; *Graham*, 922 F.2d at 382, neither *Hively* nor *Whitaker* are relevant. Both cases involved issues well past that threshold inquiry. The sole issue in *Hively* was whether "[employment] discrimination on the basis of sexual orientation is a form of sex discrimination." 853 F.3d at 341. The procedural posture required the court to assume that the defendants had "refused to promote Professor Hively because she is homosexual." *Id.* at 358 (Flaum, J., concurring). Thus, there was no "threshold inquiry" about disparate treatment; disparate treatment was assumed. Likewise, *Whitaker* involved a school's bathroom policy that required students to use the bathroom corresponding to their biological sex. 858 F.3d at 1039. The court concluded that the policy on its face was "based upon a sex-classification," *Id.* at 1051, and also that the policy subjected "transgender student[s] to different rules . . . and treatment than non-transgender students." *Id.* at 1049–50. The main

dispute was over whether "transgender status is . . . a protected class" and whether the policy survived whatever level of scrutiny applied. *Id*. at 1039. So again, there was no "threshold" issue. Here, on the other hand, Plaintiffs cannot show any facial classification or disparate treatment without first establishing that the Department's medical necessity determination was unreasonable.

2. The Exclusion does not discriminate on the basis of transgender status, and even if it does, transgender status is not protected by the ACA or the Equal Protection Clause.

Plaintiffs' alternate theory that the Exclusion discriminates on the basis of transgender status by "singling out" services that "only transgender people need" (Dkt. 19:33), also fails at the threshold for the same reason. Plaintiffs cannot show an actual classification or disparate treatment without first showing that the Department's medical necessity determination was unreasonable.

As with sex, the Exclusion does not draw any facial classifications based on transgender status. It "does not deny [transgender individuals] access to [Medicaid coverage] or exclude them from the particular package of Medicaid services [Wisconsin] has chosen to provide." *Alexander*, 469 U.S. at 309. Nor does it exclude all forms of treatment for gender dysphoria—in fact, Plaintiffs have received previous treatments for gender dysphoria covered by Wisconsin

Medicaid, including hormone therapy. Instead, the Exclusion precludes coverage for *one particular class of procedures*, based on the determination that *those particular procedures have* not been shown to safely and effectively treat gender dysphoria. Thus, the Department's basis for denying coverage for surgery and related hormone therapy is *not* a Medicaid beneficiary's transgender status but instead a determination about the efficacy of the treatment.

The fact that the Exclusion applies to procedures that "only transgender people" want does not automatically establish a classification on the basis of transgender status. The Supreme Court has consistently rejected similar reasoning. For example, "while it is true that only women can become pregnant it does not follow that every legislative classification concerning pregnancy is a sex-based classification." *Geduldig v. Aiello*, 417 U.S. 484, 497 (1974). Discriminatory intent can occasionally be presumed if some activity is "an irrational object of disfavor" and "happen[s] to be engaged in exclusively . . . by a particular class of people"—for example, "[a] tax on wearing yarmulkes is a tax on Jews." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). But the Exclusion here has a rational justification (medical necessity) that has nothing to do with transgender status. If medical necessity were irrelevant, then the Department's exclusions for "reversals of vasectomies" and "testicular prosthesis" would also automatically constitute sex discrimination.

Thus, as with their sex discrimination theory, Plaintiffs must *assume* that gender reassignment surgery is in fact medically necessary to get past the "threshold inquiry" of showing disparate treatment. *Women Prisoners*, 93 F.3d at 924. But if the Department is correct that gender reassignment surgery is not medically necessary, then the Exclusion does not create a different rule governing the medical treatment of transgender people. The Department used a single, uniform rule of medical necessity and applied it consistently by denying coverage.

And even assuming the Exclusion does discriminate on the basis of transgender status, it would not violate the ACA or the Equal Protection Clause. As explained in the Department's first preliminary injunction opposition brief, Title IX (and thus the ACA) does not cover transgender status claims, and transgender claims are only entitled to rational basis review under the Equal Protection Clause. (Dkt. 53:39–45.)

C. Plaintiffs will not succeed on their Medicaid Act claims.

Plaintiffs' Medicaid Act claims will fail for the same reasons as their ACA and equal protection claims. Assuming Plaintiffs are correct that the Medicaid Act's Availability Provision, 42 U.S.C. § 1396a(a)(10)(A) and 42 C.F.R. § 440.230(b), requires the Department to cover medically necessary treatments

(Dkt. 108:30–31 (collecting cases)),[4] the claim will fail given the lack of adequate evidence that gender reassignment surgeries are medically necessary.

As for Plaintiffs' Medicaid Act claim based on the Comparability Provision, 42 U.S.C. § 1396a(a)(10)(B) and 42 C.F.R. §§ 440.240(b), 440.230(c), that claim mimics their ACA and equal protection discrimination claims. But the State may "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d). When analyzing a Medicaid Act claim based on the Comparability Provision, the court in *Davis v. Shah* agreed, explaining that "[the Comparability Provision] prohibits discrimination among individuals *with the same medical needs* stemming from different medical conditions." 821 F.3d 231, 258 (2d Cir. 2016) (emphasis added). Determining whether individuals have the "same medical needs" requires examining whether the treatments are medically necessary for the different medical conditions. *See Cruz v. Zucker*, 195 F. Supp. 3d 554, 577 (S.D.N.Y. 2016) ("[T]he Comparability Provision incorporates a medical necessity requirement."). And, critically, "[w]here a state purports to have made a medical determination that a particular service

[4] Under Wisconsin Medicaid, "[p]hysician services" are a type of services the State has chosen to cover. *See* Wis. Admin. Code § DHS 107.06(1). Physician services must be "medically necessary diagnostic, preventative, therapeutic, rehabilitative or palliative services." *Id.*

is not a necessary or appropriate treatment for a particular condition, [court] review of that judgment would presumably be highly deferential." *Davis*, 821 F.3d at 258.

The Department has made just such a medical determination here—that gender reassignment surgeries are not medically necessary to treat gender dysphoria. Therefore, just because the Department covers certain reconstructive surgeries when medically necessary to treat other conditions–such as cancer, traumatic injuries, or congenital defects–that decision does not automatically require it to cover those surgeries for gender reassignment purposes. Patients seeking coverage for gender reassignment do not have an equivalent medical need for the surgeries as those receiving similar surgeries for cancer, traumatic injuries, congenital defects, and the like.

D. Plaintiffs' requests for procedures such as electrolysis, voice therapy, and hair growth stimulants fall outside the scope of Plaintiffs' motion to modify the preliminary injunction because they are not prohibited by the Exclusion.

In their materials submitted in support of their motion to modify the preliminary injunction, Plaintiffs Kelly and Sherwin describe their efforts to obtain electrolysis, voice therapy, and finasteride (a hair growth stimulant) to treat their gender dysphoria. (*See,* Dkt. 93 ¶¶ 17–18; Dkt. 95 ¶¶ 13, 23–32.) Presumably, they seek to include coverage for these treatments under Wisconsin Medicaid as part of the preliminary injunction order for both

themselves and other class members. There is no basis in law for fact to support this request.

In their motion to modify the preliminary injunction, Plaintiffs' request is that the Court enter an order that "fully enjoins Defendants' enforcement of the Challenged Exclusion." (Dkt. 107:1.) The Exclusion is identified in both the amended complaint and Plaintiff's motion to modify the preliminary injunction as "Wis. Admin. Code § DHS 107.03(23)–(24)." (Dkt. 85:1; Dkt. 107:1.) The administrative code provisions that comprise the Exclusion prohibit Wisconsin Medicaid coverage for "[t]ranssexual surgery" and "[d]rugs, including hormone therapy, associated with transsexual surgery or medically unnecessary alteration of sexual anatomy or characteristics." Wis. Admin. Code § DHS 107.03(23)–(24). The Exclusion, and Defendants' enforcement of the Exclusion, is the basis for all four causes of action outlined in the amended complaint. (*See* Dkt. 85:38–41.) Plaintiffs do not challenge the application of any other provisions in Wisconsin's Medicaid program.

By its terms, the Exclusion does not apply to procedures such as electrolysis or voice therapy, since these are neither surgery nor drugs. Electrolysis is not surgery. Indeed, a person only needs a cosmetology license to perform this procedure in Wisconsin. *See* Wis. Admin. Code § COS 4.09 ("Electrolysis"). Moreover, under Wis. Admin. Code § DHS 107.06(5)(i), electrolysis is a non-covered service for *all* Wisconsin Medicaid recipients,

regardless of sex or transgender status.[5] As a result, all of Kelly's claims on this basis fail. Equal protection "keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992). Here, because DHS is not treating Kelly differently than other Medicaid beneficiaries in denying her electrolysis, she is not being denied coverage for medically necessary care that anyone else is receiving.

Similarly, Sherwin's request for voice therapy was not denied under the Exclusion. It was denied because an initial evaluation completed by a speech and language pathologist was not submitted to support Sherwin's diagnosis of dysphonia and to determine medical necessity of services. (Triller Decl. ¶ 4 Ex. A.) And like electrolysis, voice therapy is neither surgery nor a drug, so the Exclusion would be inapplicable to such a request. (Wiggins Decl. ¶ 4.)

Finally, though finasteride is a drug, Sherwin's request for this medication "to promote hair growth" also falls outside the provisions of the Exclusion, since it is not "associated with transsexual surgery" or "alteration of sexual anatomy or characteristics." Wis. Admin. Code § DHS 107.03(23).

[5] In addition, no evidence supports Plaintiffs' proposed fact that Kelly's medical provider has even recommended that she obtain electrolysis for facial hear removal to treat her gender dysphoria. (*See* Dkt. 94.)While Kelly claims that her provider, Linda Wesp, recommended it, Wesp's declaration only mentions a recommendation for *surgeries*. (Dkt. 94 ¶ 12).

Since Plaintiffs have failed to submit any evidence to support their claim that they were denied electrolysis, voice therapy, or finasteride under the Exclusion, their requests for electrolysis, voice therapy, and hair growth stimulants are outside the scope of their amended complaint and request for preliminary injunctive relief. Plaintiffs should not be allowed to bootstrap all aspects of their gender transitions to the Exclusion in hopes obtaining coverage that was denied under other provisions of the Wisconsin Medicaid program that are not at issue in this case.

* * *

Plaintiffs are unlikely to ultimately succeed on the merits of their claims. As a result, this Court should not modify the current preliminary injunction.

II. Plaintiffs Kelly and Sherwin and the Proposed Class cannot show they will suffer irreparable harm without a preliminary injunction.

Plaintiffs primarily argue that they face irreparable harm because the Exclusion will cause them to be denied necessary medical care while this case proceeds. (Dkt. 108:22–24.) This argument fails for largely the same reason that their claims will fail on the merits—inadequate evidence exists to conclude that the surgical procedures at issue can safely and efficaciously treat gender dysphoria. Dr. Daniel Sutphin, Dr. Lawrence Mayer (Dkt. 55-1), and the Center for Medicare and Medicaid Services (Dkt. 55-2) all share this view of the available evidence. So, Plaintiffs and the putative class fail to show that

obtaining the surgeries they seek will effectively treat their gender dysphoria, and thus they face no irreparable harm.

Nor are Plaintiffs entitled to an injunction purely due to a likelihood of success on their constitutional equal protection claim. (Dkt. 108:24–26.) As explained above, Plaintiffs are not likely to succeed on that claim. They point out this Court's recent decision in *Boyden v. Conlin*, No. 17-CV-264-wmc, 2018 WL 4473347, at *18 (W.D. Wis. Sept. 18, 2018), but that case will not control here. The equal protection portion of that decision largely rested on this Court's finding that the defendants in that case generated their state interests *post hoc* during litigation, and thus that the state's asserted interest in medical necessity could not be considered. *Id.* at 17–18. Here, however, evidence shows that the Department originally created the Exclusion because it did not view surgical gender dysphoria treatments as medically necessary. (*E.g.*, Dkt. 21-12.) Therefore, this Court will need to consider the Department's medical necessity defense on its merits, and the evidence discussed above shows that the Department will prevail here, unlike the defendants in *Boyden*.

III. The balancing of harms favors no modification of the injunction.

Expanding the preliminary injunction to apply to all potential transgender Medicaid beneficiaries suffering from gender dysphoria and seeking coverage for gender reassignment surgeries would tip the balance of harms in Defendants' favor. This analysis examines whether "the balance of

harms favors [Plaintiffs] or whether the harm to other parties or the public is sufficiently weighty that the injunction should be denied." *Jones v. Markiewicz-Qualkinbush*, 842 F.3d 1053, 1058 (7th Cir. 2016). Moreover, generally speaking, the "purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Benisek v. Lamone*, 138 S. Ct. 1942, 1945 (2018).

1. The monetary cost to the Department.

Based on the preliminary analysis of David Williams, a professional health care benefits consultant, enjoining the Department from applying the Exclusion to any Medicaid beneficiaries may impose a potentially unrecoverable cost of around $300,000 per year. (Dkt. 74-1:6.) That cost estimate accounts for both the different prevalence rate of gender dysphoria in the Medicaid population (compared to the general population) and the different reimbursement rates that apply to Medicaid claims (compared to commercial claims). Specifically, the prevalence rate is likely to be higher in the Medicaid population than the general population, but Medicaid reimbursement rates are substantially lower than commercial rates. And taking figures presented by Hughto, Plaintiffs' expert, at face value (Dkt. 96:10 ¶ 22), Wisconsin's Medicaid program would incur around $1.2 million per year in additional costs. (Williams Supp. Decl. ¶¶ 28, 30); (Dkt. 108:14, 30.)

Trial in this case is set for September 16, 2019, so assuming a preliminary injunction would be put in place on December, 1, 2018, the Department would operate under the preliminary injunction for nearly four-fifths of a year. That would result in total coverage costs over that period ranging from $240,000 (using Williams' original cost estimate) to $960,000 (using Williams' updated estimate based on Hughto's higher utilization rate).

2. Plaintiffs' claim that elimination of the Exclusion will result in cost savings is based on speculation and should be disregarded.

Hughto's opinion that eliminating the Exclusion will save money should be disregarded because it is not based on any data or evidence, and she does not employ any recognized cost-savings methodology in reaching this conclusion. An expert may not base her opinion on speculation or conjecture. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997). A district court is required to rule out an expert's subjective belief or unsupported speculation by considering whether the testimony has been subjected to the scientific method. *Id.*; *Clark v. Takata Corp.*, 192 F.3d 750, 757 (7th Cir. 1999). An expert must "substantiate his opinion; providing only an ultimate conclusion with no analysis is meaningless." *Huey v. United Parcel Serv., Inc.*, 165 F.3d 1084, 1087 (7th Cir. 1999) (citation omitted).

Hughto's supplemental report relies on several vague and unsupported hypotheses. First, she opines that because transgender individuals who receive

surgery and/or hormone therapy have lower levels of substance abuse, "covering gender-confirming surgeries under Medicaid would likely result in the Wisconsin Medicaid program spending less on costs related to substance use." (Dkt. 96:6.) She also states that "the physical and mental health costs of violent harassment, hate crimes, and related health systems costs are likely to decrease" without the Exclusion, as are "the enormous costs associated with the HIV epidemic." (Dkt. 96:7–8.) Further, Hughto asserts that elimination of the Exclusion will result in "reductions in unemployment, sex work, and related criminal justice and health system costs," which will lead to "fewer transgender individuals needing Wisconsin Medicaid coverage." (Dkt. 96:9.)

Providing insurance coverage for surgical gender reassignment procedures is not a proven panacea for such a wide array of societal harms. Except for figures associated with decreases in suicidality, Hughto offers no reliable basis to calculate any cost savings to Wisconsin's Medicaid program by covering gender-confirmation surgeries. (Williams Supp. Decl. ¶¶ 6–7, 18–24.) She does not provide quantified cost reductions, quantified reduction in benefit usage, or other measures useful in quantifying the purported cost savings. (Williams Supp. Decl. ¶¶ 18–24.)

Instead, she makes assumptions based entirely upon a general premise. For example, she notes that studies demonstrate lower levels of substance use among transgender individuals receiving hormones and/or surgery. Therefore,

she assumes that when these transitional treatments are made available, costs associated with substance use will decrease. (Dkt. 96:6.) Similarly, Hughto explains that hormones and surgery can reduce gender dysphoria, improve body image, and provide a greater self-esteem. (Dkt. 96:6–7.) Therefore, these treatments will make transgender individuals less likely to enter into an abusive relationship or be a victim of violence, which will reduce the costs for treating these types of assault. (Dkt. 96:7.) She employs the same type of conclusory analysis to her opinions regarding how eliminating the Exclusion will save on costs associated with treating HIV, unemployment, and the criminal justice system. (Dkt. 96:7–9.) None of this analysis relies on evidence of cost savings; rather, it rests on (at best) logical inferences about the possible relationship between providing insurance coverage and reductions in other social and medical ills.

Where the proffered expert offers nothing more than a "bottom line" conclusion, she does not assist the trier of fact. *Clark*, 192 F.3d at 759. As the Seventh Circuit noted in *Clark,* "[a] supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant . . . ." *Id.* at 759 n.5. None of her conclusions are testable through a recognized scientific method, and so none of them are reliable.

Hughto's analysis is also unreliable because it fails to isolate any cost savings for the provision of surgery, alone. Wisconsin's Medicaid program has provided limited coverage for hormone therapy, which Hughto's own sources have recognized cause the greatest decrease of psychoneurotic distress. (Dkt. 96-3:5, citing a study finding that "[t]he overall psychoneurotic distress scores decreased significantly after hormone therapy," but that "[n]o further decrease is observed after sex reassignment surgery"). Hughto's report fails to provide any analysis regarding a reduction in substance use, violence, HIV, unemployment, sex work, or criminal justice and health care costs after surgery, alone, which is the relevant question in this case, since all the named plaintiffs are already receiving hormone therapy.

3. The balance of harms weighs in favor of the Department.

Expanding the Exclusion would likely impose irreparable harm on the Department. As Plaintiffs have conceded, "[t]he State's potential budgetary concerns are entitled to . . . consideration." (Dkt. 19:48 (citing *Bontrager*, 697 F.3d at 611).) As explained above, the Department could expect to pay between $240,000 (using Williams' original cost estimate) to $960,000 (using Hughto's higher utilization estimate) to cover claims affected by the Exclusion until the end of the this case.

Plaintiffs have argued that this monetary cost cannot constitute irreparable harm (Dkt. 19:47–48), but it is unclear how the Department could ever recoup those costs if they ultimately prevail. By the time a final judgment is entered in this case, claims will already have been paid to providers involved in the affected surgical procedures. No clear legal remedy for recovering those costs from providers exists, once they have been made for the services provided. And this Court indicated its inclination not to require a bond from the indigent plaintiffs, which further exposes the Department to unrecoverable costs while a preliminary injunction remains in place.

Connected to this cost is the harm the Department would suffer from being forced to fund procedures with a meaningful risk of harm (*see* Dkt. 55-6:62–64) that have not been proven to effectively treat gender dysphoria (*see generally* Dkt. 55-1). That further distinguishes this case from *Bontrager*, where no debate existed over appropriateness of the routine dental services at issue. 697 F.3d at 606. The Department's core mission of advancing public health (*see* Wis. Stat. § 250.03(1)) would be compromised by being forced to provide such coverage, a significant irreparable harm.

Lastly, the Department would be irreparably harmed by the mere fact of being prevented from enforcing a valid law. *See Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018) ("[T]he [State's] inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State."); *Maryland v. King*, 567 U.S.

1301 (2012) ("[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.") (Roberts, C.J., in chambers) (citation omitted). This Court has only concluded that Plaintiffs have shown a "reasonable" likelihood of success on the merits of their Affordable Care Act claim, and it did not resolve whether their equal protection claim would likely succeed. (Dkt. 70:1–2.) The Department is likely to prevail on the merits, whether after a final judgment in this Court or on appeal, which means that they would be forbidden from enforcing a valid regulation while the preliminary injunction remains in place—an inherently irreparable harm.

On Plaintiffs' side of the ledger, this Court has only concluded that they have demonstrated irreparable harm with regard to themselves—Flack and Makenzie only. In its preliminary injunction order, this Court rested its irreparable harm finding almost exclusively on the evidence presented by these two plaintiffs' treating doctors. (Dkt. 70:16–19.) Those doctors opined that these plaintiffs' themselves face irreparable harm, not any putative class members. Likewise, the Court rejected the Department's efforts to distinguish *Bontrager* because evidence from the named plaintiffs' treating doctors showed that enforcing the Exclusion "threatens their well-being." (Dkt. 70:19 n.14.) (*See also* Dkt. 70:22 (citing the "informed opinions of plaintiffs' treating physicians").) And the Court noted that "the only question at this point is

whether Cody Flack and Sara Ann Makenzie have a medical need for these surgeries such that denial will be detrimental to their health. On the current record, the answer clearly is yes." (Dkt. 70:21.) Of course, there are two new plaintiffs this time around, but Plaintiffs still lack evidence from putative class members' treating physicians—evidence this Court previously relied on when granting preliminary injunctive relief to the named plaintiffs.

Plaintiffs have made no showing of irreparable harm for potential Medicaid beneficiaries in the putative class. They have not presented evidence from treating doctors that gender reassignment surgeries are necessary treatments for anyone but themselves.[6] There is simply no comparable evidentiary basis on which this Court can find that non-parties will be irreparably harmed by the Exclusion, as it found for Flack and Makenzie before (and may now find for Kelly and Sherwin). This means that there is inadequate evidence of irreparable harm to the putative class members that can outweigh the concrete harms the Department will suffer from providing this coverage. Indeed, this Court identified the very problem Plaintiffs now face, noting that the named plaintiffs "are the only ones who have documented having

[6] While Plaintiffs have submitted declarations from three putative class members describing treatment recommendations from their physicians, those descriptions are inadmissible hearsay. (Dkt. 97:3 ¶ 13, Dkt. 98:3 ¶ 17, Dkt. 99:2 ¶ 8.)

immediate impacts." (Dkt. 52 Tr. 9:2–3.) Plaintiffs still have not developed the record on this crucial point since this Court's observation.

Plaintiffs will likely respond that testimony from their non-treating experts suffices to establish irreparable harm for other potential Medicaid beneficiaries. This argument would fail because it would require this Court to resolve a core disputed issue in this case: whether Plaintiffs or the Department is correct regarding the state of scientific evidence on the efficacy of surgical treatments for gender dysphoria. That is, this Court can only find irreparable harm to non-parties if it rejects the testimony from the Department's experts that such treatments are not generally safe and effective—something it has so far declined to do.

Put simply, Plaintiffs have provided inadequate evidence that other potential Medicaid beneficiaries will face irreparable harm absent an injunction. Since the concrete harms that the Department would face outweigh those speculative harms, the balance of equities tips in the Department's favor and the preliminary injunction should not be expanded.

CONCLUSION

Defendants Wisconsin Department of Health Services and Linda Seemeyer respectfully ask this Court to deny Plaintiffs' motion for a modification of the current preliminary injunction.

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Dated this 16th day of November, 2018.

Respectfully submitted,

BRAD D. SCHIMEL
Attorney General of Wisconsin

s/ Steven C. Kilpatrick
STEVEN C. KILPATRICK
Assistant Attorney General
State Bar #1025452

COLIN T. ROTH
Assistant Attorney General
State Bar #1103985

JODY J. SCHMELZER
Assistant Attorney General
State Bar #1027796

Attorneys for Defendants State of Wisconsin Department of Health Services and Linda Seemeyer

Wisconsin Department of Justice
Post Office Box 7857
Madison, Wisconsin 53707-7857
(608) 266-1792 (Kilpatrick)
(608) 264-6219 (Roth)
(608) 266-3094 (Schmelzer)
(608) 267-2223 (Fax)
rothct@doj.state.wi.us
schmelzerjj@doj.state.wi.us
kilpatricksc@doj.state.wi.us
(608) 264-6219 (CTR)
(608) 267-2223 (Fax)
kilpatricksc@doj.state.wi.us
rothct@doj.state.wi.us