UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

WISCONSIN DEPARTMENT OF HEALTH SERVICES and
LINDA SEEMEYER, in her official capacity as Secretary of the Wisconsin Department of Health Services,

Defendants.

Case No. 3:18-cv-00309
Judge William Conley

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION TO MODIFY PRELIMINARY INJUNCTION

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INTRODUCTION

This Court only needs to answer two questions to resolve Plaintiffs' present motion. First, will members of the Proposed Class[1] be irreparably harmed by denied access to health care because of Defendants' ongoing enforcement of the Challenged Exclusion? And, if so, does the serious risk of harm to class members resulting from the categorical coverage ban on gender-confirming care outweigh the infinitesimal cost to the Wisconsin Department of Health Services ("DHS" or the "State") of covering gender-confirming care for all Wisconsin Medicaid beneficiaries who need it during the remainder of this litigation? Because Plaintiffs have provided this Court with substantial evidence demonstrating the necessity and effectiveness of surgeries to treat gender dysphoria in many transgender people—and the common, predictable, and avoidable harms to transgender individuals unable to access that care—the answer to each question is "yes."

The Court already found that Plaintiffs have shown a reasonable likelihood of success on their Section 1557 and Equal Protection Clause claims. Op. & Order 1-2, 25-35 [Dkt. No. 70] ("PI Op."). Because the Court found that the Challenged Exclusion treats transgender people as a group differently than others, PI Op. 29, the Court's analysis of these claims applies with equal force to the class-wide claims now. The Court should reject Defendants' invitation to reconsider these already-decided issues. Moreover, the Court's findings (and the State's admissions) that Wisconsin Medicaid covers chest and genital reconstructive surgeries to treat conditions other than gender dysphoria, PI Op. 25-26; Defs.' Opp. Br. 25 [Dkt. No. 116] ("Opp. Br."), warrant an

[1] Although the Court has not yet ruled on Plaintiffs' pending class certification motion [Dkt. No. 89], Defendants do not oppose certification [Dkt. No. 115]. The Proposed Class is defined as "[a]ll transgender individuals who are or will be enrolled in Wisconsin Medicaid, have or will have a diagnosis of gender dysphoria, and who are seeking or will seek surgical or medical treatments or services to treat gender dysphoria." Pls.' Mot. for Class Cert. 1 [Dkt. No. 89].

express ruling that Plaintiffs' likelihood of success on their Medicaid Act claims separately justifies the entry of a class-wide preliminary injunction.

Defendants once again treat so-called "transsexual surgery" as a single "service," which, they claim, is an unproven "procedure" that they have the right to categorically exclude. Opp. Br. 13-14. As Plaintiffs have shown—and the Court has recognized—there is no single service or procedure called "transsexual surgery." Rather, there are a range of surgeries and related services that are generally accepted, widely-used treatments for gender dysphoria in transgender people. PI Op. 4.[2] The State freely admits that Wisconsin Medicaid covers identical services to treat other conditions in cisgender people. Opp. Br. 25. At no point has the State put forward *any* evidence that it was motivated by—or even considered—peer-reviewed medical research on the treatment of gender dysphoria (or its predecessor conditions in earlier versions of the DSM) when it adopted the Challenged Exclusion and labeled all "transsexual surgery" unnecessary. Nor have they offered evidence that the State considered, at any time since then, the evolving medical consensus and standards of care on treating gender dysphoria in continuing to enforce the exclusion.

In response to this lawsuit, Defendants have come forward with reports from Lawrence Mayer, Chester Schmidt, and now Daniel Sutphin—none of whom have demonstrable expertise

[2] Although Plaintiffs recognize that Wisconsin Medicaid covers gender-confirming hormones at least some of the time, they dispute whether Wisconsin Medicaid applies the Challenged Exclusion to deny coverage for medically necessary hormone treatments for some beneficiaries. Indeed, Plaintiff Courtney Sherwin must pay out-of-pocket for her hormones. Decl. of Courtney Sherwin ¶ 13 [Dkt. No. 95] ("Sherwin Decl."). The Court need not resolve the question now of whether Wisconsin Medicaid or any of its participating HMOs have applied the exclusion to deny coverage for non-surgical transition-related services. The modified injunction, if granted, will eliminate any uncertainty and inconsistent application of the exclusion by Wisconsin Medicaid or specific HMOs to deny hormones or other services to transgender Medicaid beneficiaries.

on transgender health care, but who all have been hired by various defendants as experts in multiple transgender rights case around the country. The Court previously found Mayer's opinion in this case (and in *Boyden*) to be unpersuasive, PI Op. 21, *Boyden v. Conlin*, No. 17-cv-264-wmc, 2018 WL 4473347, at *18 n.17 (W.D. Wis. Sept. 18, 2018), and also found Schmidt's opinion largely irrelevant. PI Op. 22. Taking another bite at the apple, the State now offers a report from Sutphin—a plastic surgeon with no experience or expertise in treating gender dysphoria—to question the efficacy of gender-confirming surgeries. As explained below, his opinions are based on flawed factual predicates, and, in any event, represent a fringe view far outside the mainstream medical consensus. The Court should give little weight to his opinion.

For the reasons further explained in Plaintiff's opening brief and below, an expansion of the preliminary injunction to fully enjoin the State's enforcement of the Challenged Exclusion will protect many transgender Wisconsin Medicaid beneficiaries from unnecessary suffering and stigma, at little cost to the State. The equities tip in favor of the Proposed Class and the Court should grant Plaintiffs' motion.

ARGUMENT

I. THE COURT SHOULD REJECT THE STATE'S ATTEMPT TO RELITIGATE THE COURT'S FINDING THAT PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR SECTION 1557 AND EQUAL PROTECTION CLAUSE CLAIMS.

The Court's conclusion that Plaintiffs Cody Flack and Sara Ann Makenzie are reasonably likely to succeed on their Section 1557 and Equal Protection Clause claims applies with equal force to the claims of the entire Proposed Class. The Court does not need to revisit those conclusions to resolve Plaintiffs' motion to expand the existing injunction. While Defendants maintain that the Challenged Exclusion does not discriminate against transgender Wisconsin Medicaid beneficiaries on the basis of sex or transgender status, the Court has already rejected

that position in both this case and in *Boyden*. PI Op. 25-31; *Boyden*, 2018 WL 4473347, at *12-14. Moreover, with respect to Plaintiffs' equal protection claim, the Court made a preliminary finding that heightened scrutiny would likely apply (whether the claim was based on sex or transgender status). Subsequently, in *Boyden*, the Court ruled conclusively that heightened scrutiny is indeed the correct standard. 2018 WL 4473347, at *16. Defendants' purported justifications for the Challenged Exclusion cannot survive such scrutiny.

A. The Court has already found the Challenged Exclusion to be facially discriminatory against transgender Wisconsin Medicaid beneficiaries, not just as applied to Cody Flack and Sara Ann Makenzie.

In granting the current injunction, the Court concluded that "plaintiffs have made a persuasive evidentiary showing, albeit a preliminary one, that the Challenged Exclusion prevents them from getting medically necessary treatments on the basis of both their natal sex *and* transgender status, which surely amounts to discrimination on the basis of sex." PI Op. 31. The Court reached this conclusion several ways, all of which are as applicable to members of the Proposed Class as they are to Cody Flack and Sara Ann Makenzie.

Noting that the Challenged Exclusion facially excludes coverage for "transsexual surgery," the Court observed that "'sex' would seem to encompass 'trans*sex*ual.'" *Id.* at 25. Without resolving that question, the Court found that "[e]ven accepting defendants' definition of sex, . . . the Challenged Exclusion certainly denies coverage for medically necessary surgical procedures based on a patient's *natal* sex," as Wisconsin Medicaid would cover the same surgeries for any individual whose "natally assigned sexes had *matched* their gender identities." *Id.* at 25-26. In addition, the Challenged Exclusion "creates a different rule governing the medical treatment of transgender people" by "directly singl[ing] out a Medicaid claimant's transgender status as the basis for denying medical treatment." *Id.* at 29. Since, "[b]y definition, a

transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth," *id.* at 27 (quoting *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1048 (7th Cir. 2017)), singling out transgender people as a group for different treatment is based on impermissible sex stereotypes. The Court specifically found that "the Challenged Exclusion feeds into sex stereotypes by requiring all transgender individuals receiving Wisconsin Medicaid to keep genitalia and other prominent sex characteristics consistent with their natal sex no matter how painful and disorienting it may prove for some." *Id.* at 31 (citing *EEOC v. Harris Funeral Homes, Inc.*, 884 F.3d 560, 576-77 (6th Cir. 2018)). Moreover, the Court found that "discriminating on the basis that an individual was going to, had, or was in the process of changing their sex – or the most pronounced physical characteristics of their sex – is *still* discrimination based on sex." *Id.* at 27.

Defendants now try to claim that the Challenged Exclusion is "facially neutral" because "the Exclusion itself does not draw any explicit sex-based (or even transgender-based) classifications" and that "the Exclusion does not even draw lines between different types of people." Opp. Br. 23. Nonsense. Even if the Court had not already found otherwise, it defies reason that a policy that expressly excludes "*transsexual* surgery," without defining the term, treats transgender and cisgender Wisconsin Medicaid beneficiaries equally. The Court rejected this argument both here and in *Boyden*. PI Op. 25-26; *Boyden*, 2018 WL 4473347, at *12-13. As with the exclusion at issue in *Boyden*, the Challenged Exclusion "on its face treats transgender individuals differently on the basis of sex." *Boyden*, 2018 WL 4473347, at *14.

The Court has also rejected Defendants other arguments—including its citation to the Supreme Court's 44-year-old decision in *Geduldig v. Aiello*, 417 U.S. 484, 497 (1974), for the proposition that heightened scrutiny was inappropriate for a policy that singularly affects

transgender people. Opp. Br. 30. The Court noted that Defendants' reliance on *Geduldig* was misplaced because the Court had found the exclusion at issue in *Boyden* to discriminate on the basis of sex. *Boyden*, 2018 WL4473347, at *16. So too here. In any event, Plaintiffs do not rely on the fact that the Challenged Exclusion, as applied, affects only transgender people. For the reasons stated above and already endorsed by this Court, the policy facially discriminates against transgender people as a group.

B. The State has offered no evidence that it ever studied the safety or efficacy of surgical treatments for gender dysphoria when the Challenged Exclusion was adopted or at any time before this lawsuit.

To survive heightened scrutiny, "[t]he State must show at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives." *Boyden*, 2018 WL 4473347, at *16 (quoting *United States v. Virginia*, 518 U.S. 515, 533 (1996)). "[I]n proffering a justification, the State must proffer reasons that are 'genuine, not hypothesized or invented *post hoc* in response to litigation.'" *Id.* (quoting same). "[T]he burden coming forward with such a reason 'rests entirely on the State.'" *Id.* (quoting same).

As in this case, the Defendants in *Boyden* submitted expert testimony to raise concerns about the efficacy of gender-confirming surgery. *Id.* at *17. The Court found that "without any evidence to support a finding that defendants were *actually* concerned about efficacy in reinstating the Exclusion," Defendants failed to meet their burden of showing the concerns raised by their experts were anything more than *post hoc* rationalizations. *Id.* at *17-18. Defendants attempt to distinguish the Court's equal protection finding in *Boyden* by claiming that their medical necessity defense is not a *post hoc* justification for the Challenged Exclusion. But, as in *Boyden*, Defendants have proffered *no* evidence that the State, either at the time of the policy's

implementation or in its enforcement over the years, has ever been motivated by genuine concerns of medical necessity. Simply labeling "transsexual surgery" as medically unnecessary on the face of the exclusion, without any regulatory record justifying that label, is insufficient to meet Defendants' burden that this was a legitimate interest motivating the policy. Significantly, all the evidence Defendants have submitted regarding the purported concerns with the safety, effectiveness, or medical necessity of gender confirming procedures for the treatment of gender dysphoria have been reports from purported experts hired specifically for the purposes of litigation. Moreover, the evidence put forward by those purported experts post-dates Defendants' adoption of the Challenged Exclusion. The State has offered no evidence whatsoever in the record that it ever studied or reviewed the medical necessity, safety, or efficacy of such treatments for gender dysphoria prior to adopting the exclusion at issue, or at any point prior to the initiation of this lawsuit.

Even if the State was legitimately interested in protecting transgender Medicaid beneficiaries from "unproven" treatments, for the reasons this Court has already found, a categorical prohibition on coverage for gender-confirming surgeries is not substantially related to that interest because gender-confirming surgeries are safe, effective, generally accepted treatments for gender dysphoria.

C. The State's purported justifications for the Challenged Exclusion have been rejected by this Court and the mainstream medical community.

As this Court has already found, gender-confirming services are medically necessary, effective treatments for many transgender people with gender dysphoria. PI Op. 16-22; *see also Boyden*, 2018 WL 4473347, at *4-5. This Court has already determined that for many transgender people with gender dysphoria, gender-confirming surgeries, including chest and genital reconstructions, "meet the prevailing standard of care" and constitute "medically

necessary treatment." PI Op. 16. And the Court has already recognized that gender-confirming surgeries are "commonly offered and performed across the country to ease the suffering of those with gender dysphoria." *Id.* at 26 n.22.

The State has failed to demonstrate that this Court's conclusions were erroneous, or that gender-confirming treatments are unproven, unnecessary, or ineffective treatments for gender dysphoria. To the contrary, Plaintiffs have firmly established that gender-confirming surgical care is "generally accepted by the professional medical community as an effective and proven treatment" for gender dysphoria. *See* Decl. of Loren Schechter, MD ¶¶ 35-39 [Dkt. No. 27] ("Schechter Decl."); Supp. Decl. of Loren Schechter, MD ¶¶ 4-6, 11-14 ("Schechter Supp. Decl."); Decl. of Daniel Shumer, MD, MPH ¶ 31 [Dkt. No. 25] ("Shumer Decl."). And this Court has found as much. PI Op. 26 n. 22; *Boyden*, 2018 WL 4473347, at *5. As the Court noted in *Boyden*, "[w]hen individuals diagnosed with gender dysphoria do not obtain competent and necessary treatment, serious and debilitating psychological distress often occurs," and that mainstream medical organizations "recognize the medical necessity of transition-related care for transgender people with gender dysphoria." 2018 WL 4473347, at *5.

Notwithstanding this medical consensus and the Court's findings, Defendants imply now that the Challenged Exclusion is permissible because gender-confirming surgeries are "experimental." *See* Opp. Br. 9-14. First, the record has established that gender-confirming surgeries are not experimental, but are generally-accepted, commonly used, and safe and effective treatments for gender dysphoria. *See* PI Op. at 21; *see also infra* 16-18. Indeed, Defendants previously conceded that gender-confirming surgeries are *not* experimental. PI Op. 26 n.22 (noting Defendants "acknowledged this type of surgery was not experimental in nature" at oral argument); Jul. 19, 2018 Hr'g on Mot. for Prelim. Inj. Tr. 33:10-13 [Dkt. No. 69]. Thus,

the Court should disregard the State's self-serving attempt to argue otherwise now. *See McCaskill v. SCI Mgmt. Corp.*, 298 F.3d 677, 680 (7th Cir. 2002) ("The verbal admission by [] counsel at oral argument is a binding judicial admission, the same as any other formal concession made during the course of proceedings.")

D. The opinions of Dr. Daniel Sutphin, who has no demonstrated expertise on the treatment of gender dysphoria, are factually flawed, unsupported by reliable research, and fall well outside the medical consensus that gender-confirming surgeries are safe and effective treatments for gender dysphoria.

Having failed to persuade the court with the unreliable opinion of their initial expert, Dr. Lawrence Mayer,[3] Defendants now turn to Dr. Daniel Sutphin to try to convince the court to disregard the substantial evidence that gender-confirming surgeries, when performed consistent with the WPATH Standards of Care, are safe and effective treatments for gender dysphoria for many transgender individuals. They fare little better this time around.

As an initial matter, Dr. Sutphin's qualifications to opine on the effectiveness of gender-confirming surgeries are doubtful, at best. As he testified in another case, he has never treated patients for gender dysphoria or performed or assisted with any gender-confirming surgery. Dep. of Daniel Sutphin, *Bruce v. State of South Dakota*, No. 17-5080 (D.S.D. July 17, 2018) 21:3-10, 25:18-25 ("Sutphin Dep.") (excerpts attached as Exhibit A). Nor has he conducted any research (let alone peer-reviewed research) relating to surgical treatments for gender dysphoria. Sutphin Dep 27:13-28:9. His qualifications falls short of what would be required to provide expert testimony on the gender-confirming surgical care under the requirements of *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

[3] This Court previously noted in *Boyden* its "serious concerns with the reliability of Dr. Mayer's opinion that no credible studies demonstrate that gender confirming surgery and hormone therapy are effective treatments for gender dysphoria." *Boyden*, 2018 WL 4473347, at *18 n.17.

Furthermore, even if Dr. Sutphin were qualified to offer expert testimony on this subject, the opinions he offers here are based on flawed factual premises and do not withstand even cursory examination. Gender-confirming surgeries are not, as Dr. Sutphin claims, "unique in all of medicine." Even if they were, any number of conditions have "unique" treatments that are nevertheless medically necessary. Dr. Sutphin contends that gender-confirming surgeries are unique because "an otherwise physiologic organ is removed based on the seminal impetus of patient desire and perception" and are solely intended to alleviate psychological symptoms. Decl. of Daniel Sutphin ¶ 54 ("Sutphin Decl.") [Dkt. No 118]. First, this statement miscasts transgender individuals' medical need for gender dysphoria treatment as a subject "desire." Schechter Supp. Decl. ¶ 10 ("[G]ender-confirming surgery is performed to treat a recognized medical condition, and is more properly characterized as a health need, not a 'want.'"). Nor are gender-conforming surgeries "unique" because they are conducted on physiologically healthy tissue, as Dr. Sutphin claims. Surgical procedures may be conducted on physiologically healthy tissue for a number of reasons—for example, where a cisgender woman who carries a predisposition to breast and/or ovarian cancer obtains a prophylactic mastectomy or oophorectomy, although the tissue at issue is not cancerous. *Id.*

Moreover, gender-confirming surgeries are not unique in having, as one of their aims, the alleviation of psychological symptoms. Other medically-necessary surgeries are also performed in part for psychological benefits. *Id*. For example, a cisgender woman who has had a mastectomy due to breast cancer may choose to have reconstructive surgery to alleviate psychological distress associated with the absence of breasts. *Id.* Indeed, Dr. Sutphin himself recognizes that some surgical treatments provided to cisgender individuals are performed, all or in part, to alleviate psychological symptoms and social stigma. For example, he acknowledges

that cisgender men with persistent gynecomastia, a condition that causes them to develop female-appearing breasts, may seek surgical treatment, in some cases purely to alleviate the resulting psychological distress and social stigma. Sutphin Dep. 181:8-182:12. And despite his professed concerns with such surgery when performed for the purposes of treating gender dysphoria, he has no such concerns when performed to help cisgender individuals—he considers bringing a cisgender man's physical body into alignment with the typical male phenotype an "entirely appropriate medical consideration," and would not hesitate to perform such surgery himself. *Id.* 179:22-25, 181:8-182:12.

A large percentage of Dr. Sutphin's declaration is devoted to detailing the implications and limitations of gender-confirming surgical treatments for gender dysphoria, and the types of complications that can arise from such treatments. Sutphin Decl. ¶¶ 8-21. Yet complication rates are no higher when these procedures are performed as treatment for gender dysphoria than when performed on cisgender people for other reasons, Schechter Supp. Decl. ¶¶ 14-15, as even Dr. Sutphin acknowledges. Sutphin Dep. 22:8-21. In fact, the medical literature indicates that complication rates for some procedures are in fact *lower* for gender-confirming surgery than they are for the same or similar procedures performed on cisgender individuals. Schechter Supp. Decl. ¶ 14. There is, therefore, no basis for concluding that the risk of complications poses any greater concern or barrier to coverage for gender-confirming surgeries than it would for any other surgical treatment—as this Court has recognized. *Boyden*, 2018 WL 4473347, at *7 (noting that "[s]tudies show overall complication rates for surgical procedures to treat gender dysphoria are similar to the rates for similar surgical procedures for treating other medical conditions.").

Dr. Sutphin's conclusions regarding the safety and effectiveness of these treatments are predicated on the same Dhejne and Meyer studies the Court found to have "serious flaws" when

they were relied on by Dr. Mayer in *Boyden*. *Boyden*, 2018 WL 4473347, at *18 n.17. *See also* Schechter Supp. Decl. ¶¶ 17-18 (discussing flaws inherent in these studies); Second Supp. Decl. of Stephanie Budge, PhD, LP ¶¶ 8-11 ("Budge Second Supp. Decl."). Dr. Sutphin's declaration therefore provides no basis for disputing the clear medical consensus that gender-confirming surgeries are safe and effective treatments for gender dysphoria. Schechter Decl. ¶¶ 35-39; Schechter Supp. Decl. ¶¶ 11, 17-23. Indeed, even Dr. Sutphin agrees that it is not unreasonable to permit individual doctors to determine that surgery for gender dysphoria is medically necessary for a given patient, and presumes that it can be executed safely and effectively in the hands of an experienced surgeon. Sutphin Dep. 193:3-9; 216:21-217:2.

Dr. Sutphin suggests that transgender people experience elevated rates of suicidal behavior and other risk factors after gender-confirming surgery. Sutphin Decl. ¶ 42. This is, at best, misleading. First, the study cited by Dr. Sutphin compares the suicide rates of transgender individuals who obtained gender-confirming surgeries to the rates in the *general population*, not to similarly-situated transgender individuals who did not obtain treatment for surgery. Although, for a variety of reasons including lack of equitable access to health care, widespread discrimination and stigma, and other factors, there is no dispute that transgender people as a group face higher rates of suicidality than the general population. The relevant question is whether appropriate treatments for gender dysphoria can help *reduce* these risks, not eliminate them altogether. Research shows that it does. For example, a 2015 study found a 62 percent relative risk reduction post-surgery for transgender people. Budge Second Supp. Decl. ¶ 11. Another 2015 study found that transgender women who underwent chest reconstruction surgery reported lower rates of suicidal ideation than transgender women who had no had not received gender-confirming treatments. *Id.* As Dr. Budge has concluded based on her professional clinical

experience and review of the peer-reviewed research, transgender individuals "are *less* likely to experience suicidal ideation or attempt/complete suicide after receiving medically necessary surgical care for gender dysphoria." *Id.* ¶ 12. Dr. Sutphin's opposite conclusion is not supported by the research and is simply incorrect. *Id.*

Finally, Dr. Sutphin offers no support for his claim that the possibility that individuals who receive gender-confirming treatments may "regret" them later suggests that these treatments are not effective. Nor does he provide support that anecdotal stories of "regret" are a basis to categorically foreclose Medicaid coverage for gender-confirming surgeries performed in accordance with the WPATH Standards of Care. Dr. Sutphin offers general concerns that some patients may regret undergoing a medical transition. However, he provides nothing beyond citations to three articles in the popular press and a vague reference to a sole scholarly article from a surgeon, Dr. Miroslav Djordjevic. Sutphin Decl. ¶¶ 27-28. He does not offer more detail, and for good reason—his sources simply do not support his assertion that there is any significant regret experienced by transgender individuals diagnosed with gender dysphoria who receive appropriate transition-related treatments under the supervision of their doctors. According to Dr. Djordejevic's article, the patients who reported regret (a total of seven people) had all been *misdiagnosed* with gender identity disorder prior to their original surgical treatment, and did not receive surgery consistent with the WPATH Standards of Care. Budge Second Supp. Decl. ¶ 4; Schechter Supp. Decl. ¶ 24. Unlike these seven people, all members of the Proposed Class have (or will have) a gender dysphoria diagnosis under the diagnostic criteria in the DSM-5 before seeking gender-confirming treatment consistent with the WPATH Standards of Care. In short, this study is irrelevant to this case. As Dr. Budge points out, Dr. Sutphin also appears to misunderstand the opinion of another expert, Dr. Charles L. Ihlenfeld, who he suggests opposes

gender-confirming surgeries. Budge Second Supp. Decl. ¶ 9. To the contrary, Dr. Ihlenfeld supports such surgeries when medically necessary. *Id.*

In fact, the weight of the research shows that the number of patients who express any degree of regret after undergoing gender-confirming surgery is extremely low. *Id.* ¶¶ 5-6. The vast majority of transgender individuals who have obtained surgical treatments for gender dysphoria have experienced significant improvements in their gender dysphoria, overall health and well-being, and life outcome. *Id.* ¶¶ 14-15. The lived experience of one of the Plaintiffs, Cody Flack, is further evidence of these benefits. Mr. Flack, who experienced severe gender dysphoria, depression, social anxiety, and other distress prior to obtaining chest reconstruction surgery in September, reported immediate and marked improvements in his overall well-being, his comfort going out in public, and his future after his surgery. Supp. Decl. of Cody Flack ¶ 3-4 [Dkt. No. 91].

Based on his deposition testimony in the *Bruce* case, Dr. Sutphin's opinions on gender-confirming surgeries appear to be influenced at least as much by his personal religious views as by scientific evidence. Dr. Sutphin agrees with the position statement of the Christian Medical & Dental Associations ("CMDA") on gender-confirming care, including CMDA's statement that "attempts to alter gender surgically or hormonally for psychological indications . . . are medically inappropriate, as they repudiate nature, are unsupported by the witness of Scripture, and are inconsistent with Christian thinking on gender in every prior age." Sutphin Dep. 37:6-16 (referencing CMDA, Transgender Identification, https://cmda.org/article/transgender-identification/). Consistent with this statement, Dr. Sutphin believes that gender-confirming procedures "repudiate nature" and are contrary to "what is natural." *Id.* 38:15-16, 39:17-19. Because he believes "that God does not make mistakes," he accords his practice with Biblical

principles and refuses to perform any surgeries he believes are "cosmetic." *Id.* 38:21, 41:2-17. While Dr. Sutphin is entitled to his personal religious views and to limit his own surgical practice accordingly, the *Bruce* deposition testimony makes clear that those beliefs color his purported scientific conclusions and render his opinions here unreliable.

In sum, Dr. Sutphin's opinions provide no basis for concluding that the gender-confirming surgeries the Plaintiff Class seeks access to can never be medically necessary.

II. BECAUSE THE STATE CANNOT CATEGORICALLY EXCLUDE TREATMENTS FOR GENDER DYSPHORIA THAT IT ADMITTEDLY COVERS FOR OTHER DIAGNOSES, PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR MEDICAID ACT CLAIMS.

A. DHS's reliance on the Medicaid Act and its own Medicaid regulations to justify the blanket exclusion is misplaced.

Defendants are wrong that the Challenged Exclusion constitutes an appropriate exercise of the State's discretion to exclude medically unnecessary services from its Medicaid program. While Defendants may exclude unnecessary services from Medicaid coverage, the categorical exclusion at issue here exceeds their discretion under the law and therefore violates the Medicaid Act. The categorical exclusion on "transsexual surgeries" is *per se* unreasonable, since it makes a broad range of medically necessary services that treat gender dysphoria completely unavailable to transgender Medicaid beneficiaries despite substantial evidence that these services are safe and effective treatments for gender dysphoria for many people.

There is no dispute that the Medicaid Act gives states the discretion 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)). The parties agree that the test for whether a service is medically necessary is "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 v. Whitburn*, 10 F.3d 1315, 1320 (7th Cir. 1993). As Defendants acknowledge, Opp. Br. 9, a state may only restrict access to a service based on standards that are "'reasonable' and 'consistent with the objectives' of the Act." *Beal v. Doe*, 432 U.S. 438, 444 (1977) (quoting 42 U.S.C. § 1396a(a)(17)); *Preterm, Inc. v. Dukakis*, 591 F.2d 121, 125 (1st Cir. 1979). Consistent with the Medicaid Act, the Wisconsin Medicaid regulations mandate that in determining whether a service is medically necessary, the Department must consider "whether the procedure is 'of proven medical value or usefulness,' 'experimental,' 'generally accepted' in the medical community, and 'safe[ ] and effective[ ].'" Opp. Br. 26-27 (quoting Wis. Admin. Code § DHS 101.03(96m)(a), (b)(3), (b)(5), (b)(9)). As stated above, the State has not put forward any evidence that it has ever undertaken this type of review for any gender-confirming surgical treatment for gender dysphoria. In the absence of such evidence, they are not entitled to any deference.

Defendants fail to establish, however, that the State's categorical exclusion of *all* gender-confirming surgical treatments for gender dysphoria is an appropriate limit based on medical necessity, or that it is reasonable and consistent with the objectives of the Medicaid Act or its own regulations defining medical necessity. Nor can they do so. This Court has already recognized that gender-confirming surgeries are "commonly offered and performed across the country to ease the suffering of those with gender dysphoria." PI Op. 26 n.22; *see also* Schechter Decl. ¶¶ 23-28; Shumer Decl. ¶¶ 29-31. The Court has also recognized that "surgeons used many of the same procedures to treat other medical conditions," which "would also appear to support a finding that the procedures are safe." *Boyden*, 2018 WL 4473347, at *7 & n.5. Indeed, the treatments sought by Plaintiffs are medically necessary according to all the criteria set forth in Defendants' regulation: they have proven medical value or usefulness, they are not experimental,

they are generally accepted in the medical community, and they are safe and effective. In fact, the Court determined that the gender-confirming chest and genital reconstruction surgeries "meet the prevailing standard of care" and constitute "medically necessary treatment" when recommended by treating providers consistent with the WPATH Standards of Care. PI Op. 2, 16. Defendants' claim that "the effectiveness of surgery to treat gender dysphoria is unproven," Opp. Br. 20, is simply incorrect and unsupported by the record before the Court.

Defendants' assertion that the Challenged Exclusion is "justified by the lack of quality evidence," Opp. Br. 27, is insufficient to overcome Plaintiffs' showing that gender-confirming surgeries are safe, effective treatments for gender dysphoria for many transgender individuals, and are recognized as such by the mainstream medical community.[4] The quality of the evidence supporting gender-confirming surgeries is comparable to that supporting other surgical procedures, and plastic surgery in particular. Schechter Supp. Decl. ¶ 19. As Dr. Schechter explains, "while randomized, double-blind, placebo-controlled studies are the gold standard for scientific studies, they cannot always be used to test clinical procedures" because of practical and ethical limitations on conducting such research. *Id.* In particular, "it is not possible to perform a double-blind study of surgeries that modify body parts, nor is there a placebo that can mimic such a surgery." *Id.* Nevertheless, the medical literature definitively establishes that gender-confirming surgeries are safe and effective treatments for gender dysphoria in many transgender individuals. *See id.* ¶¶ 4-6, 11-14.

[4] Unlike Dr. Sutphin, who has no personal experience providing gender-confirming care, and appears to possess only a passing familiarity with the literature, Dr. Schechter has performed hundreds of gender-confirming surgeries, has authored the surgical chapter of the WPATH Standards of Care as well as several peer-reviewed articles about gender-affirming surgeries, and trains other surgeons to perform these surgeries. Schechter Decl. ¶¶ 7-13.

Defendants have not put forth any reliable evidence to contradict Plaintiffs' preliminary evidentiary showing that gender-confirming surgeries are safe, effective, and medically necessary treatments for gender dysphoria. Nor have their experts adduced any evidence to support Defendants' claim that "the procedure [sic] may actually be more harmful than helpful." Opp. Br. 27. As discussed above, the rates of complication and regret among individuals who have received gender-affirming surgeries is comparable to, if not lower than, the rates of those who receive the same surgeries to treat other conditions. Schechter Supp. Decl. ¶¶ 14-15, 24-25; Budge Second Supp. Decl. ¶¶ 4-12. Defendants have simply been unable to rebut Plaintiffs' evidence showing that both the medical community and the clinical literature agree that gender-confirming surgery is a safe and effective treatment for gender dysphoria. *See* Schechter Supp. Decl. ¶¶ 4-16, 11-14; Schechter Decl. ¶¶ 34-39; Shumer Decl. ¶¶ 29-31.

Without factual support for their contention that surgical treatments for gender dysphoria are unproven, Defendants rely instead on decades-old cases, *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980) and *Smith v. Rasmussen*, 249 F.3d 755 (8th Cir. 2001), that found that certain gender-affirming treatments could be excluded from Medicaid because they are experimental or not generally accepted in the medical community. Even assuming *arguendo* that those cases were correct when decided, both the scientific literature and clinical practice have developed significantly in the intervening decades since those decisions. Schechter Decl. ¶¶ 25, 35-37. *Cf.* PI Op. 20 n.15 (distinguishing a Tenth Circuit case that refused to consider scientific advances in

the treatment of gender dysphoria since a prior decision in 1986).[5] Indeed, the policy at issue in *Smith*—Iowa's categorical exclusion on Medicaid coverage for gender-confirming health care—was recently found by an Iowa court to be unlawful under Iowa law and inconsistent with current medical standards. *See Good v. Iowa Dep't of Human Servs.*, CVCV054956., slip op. 20, 28 (Iowa Dist. Ct. June 6, 2018) [Dkt. No. 62-1]; *see also* Pls.' Reply Br. in Supp. of Mot. for Prelim. Inj. 3 n.3 [Dkt. No. 62].

B. Plaintiffs are likely to succeed on their Medicaid Act claims.

For the reasons stated in Plaintiffs' opening brief, Plaintiffs are also likely to succeed on their Medicaid Act claims. Nothing in Defendants' response rebuts Plaintiffs' arguments.

First, since Plaintiffs have established that gender-affirming care is medically necessary for many transgender individuals with gender dysphoria, it must be covered in Medicaid under the Medicaid Act's Availability Provision. 42 U.S.C. § 1396a(a)(10)(A); 42 C.F.R. § 440.230(b). The Medicaid Act requires states to make mandatory medical services (as well as optional

[5] Moreover, while Defendants cite a more recent case from the First Circuit, that case did not hold that gender-affirming surgeries are unproven treatments, or not generally accepted. Rather, that case considered under the Eighth Amendment whether gender-confirming surgery was a "medically necessary component of [a particular individual's] care, such that any course of treatment not including surgery is constitutionally inadequate." *Kosilek v. Spencer*, 774 F.3d 63, 86 (1st Cir. 2014) (en banc). Notably, the standard for determining whether a prison's denial of care is so inadequate that it constitutes unconstitutional cruel and unusual punishment under the Eighth Amendment sets a much higher bar than Medicaid's "medical necessity" standard. *See id.* (noting that even "simple medical malpractice does not rise to the level of cruel and unusual punishment") (quoting *Watson v. Caton*, 984 F.2d 537, 540 (1st Cir. 1993)). The fact that medical experts in that case disagreed as to whether surgery was the only adequate treatment option for a particular individual with gender dysphoria given her specific circumstances does not establish that all gender-affirming care is experimental or not generally accepted in the medical community. *See id.* at 90-91. Moreover, there was a dispute among the experts in *Kosilek* about whether the plaintiff could, while in prison, meet the requirements for "real-life experience" then required as a precondition of surgery under an earlier version of the WPATH Standards of Care. *See id.* at 88-89. That question, while arguably material to the decision in an Eighth Amendment case, has no bearing on a case outside the prison context.

medical services that a state has decided to cover) available in a sufficient amount, duration, and scope. 42 U.S.C. § 1396a(a)(10)(A); 42 C.F.R. § 440.230(b). Defendants do not dispute that the gender-affirming treatments at issue here are coverable services under the Medicaid Act, only that they are not medically necessary for transgender beneficiaries with gender dysphoria. *See* Opp. Br. 9-10. Because, as described in detail above, Plaintiffs have established that these services are medically necessary for many individuals, Defendants are obligated to cover them in an amount, duration, and scope that is sufficient. Because Defendants completely exclude all gender-affirming surgical treatments from coverage, they have violated the Medicaid Act. *See Bontrager*, 697 F.3d at 608 (holding that state may not "den[y] coverage for medically necessary" services outright); *see also Collins v. Hamilton*, 349 F.3d 371, 376 (7th Cir. 2003). As an Indiana court found last month, this extends to categorical exclusions on gender-confirming surgeries. *S.K.J. v. Walthall*, No. 49D03-1709-MI-034611, slip op. Conc. of Law ¶¶ 21-25 (Super. Ct. of Marion Cty., Ind., Nov. 9, 2018) (attached as Exhibit B).

Second, since Defendants cover the treatments sought by Plaintiffs to treat conditions other than gender dysphoria, their failure to provide them to treat gender dysphoria violates the Medicaid Act's Comparability Provision. *See* 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. §§ 440.230(c), 440.240(a). That provision requires that services available to any individual enrolled in Medicaid "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). Here, Defendants have conceded that they provide the same treatments sought by Plaintiffs to treat conditions other than gender dysphoria. Opp. Br. 25. Thus, they *must* provide them to treat gender dysphoria when medically necessary. *See, e.g.*, *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016); *Cruz v. Zucker*, 195 F. Supp. 3d 554, 576 (S.D.N.Y. 2016), *reconsideration granted on other grounds*,

218 F. Supp. 3d 246 (S.D.N.Y. 2016). Because gender-confirming surgical procedures are often medically necessary to treat gender dysphoria, as established above, Defendants may not categorically exclude them from their Medicaid program. *See S.K.J.*, No. 49D03-1709-MI-034611, Concl. of Law ¶ 21-25.

III. THE RISK OF IRREPARABLE HARM TO MEMBERS OF THE PROPOSED CLASS IS CONTRARY TO THE PUBLIC INTEREST AND FAR OUTWEIGHS THE IMMATERIAL COST IMPACT TO THE STATE OF COVERING GENDER-CONFIRMING TREATMENTS UNDER A PRELIMINARY INJUNCTION.

A. All members of the Proposed Class face the risk of irreparable harm from delayed or denied treatment for gender dysphoria.

As explained in Plaintiffs' opening brief, all members of the Proposed Class face the common, serious risk of irreparable harm from untreated or inadequately treated gender dysphoria, including psychological distress, physical health harms, and stigma, if the Challenged Exclusion is not fully enjoined. Pls.' Mem. in Supp. of Mot. to Modify Prelim. Inj. 16-18 [Dkt. No. 108] ("Pls.' Br."). These harms are not speculative. As Plaintiffs' experts have explained, denied or improperly treated gender dysphoria predictably results in adverse effects on transgender individuals' health and well-being. Decl. of Stephanie L. Budge, PhD, LP ¶¶ 72-73 [Dkt. No. 24] ("Budge Decl."); Decl. of Jaclyn White Hughto, PhD, MPH ¶¶ 41-46, 50 [Dkt. No. 26] ("Hughto Decl."). Although not every class member will experience identical injuries, delayed or denied health care to *all* members of the proposed class, and the attendant health risks, are sufficient to justify a class-wide injunction. Pls.' Br. 17-18. Defendants do not dispute that delayed or denied medical care is an irreparable harm warranting preliminary injunctive relief, as many courts have found. Rather, they resort to their assertion that these treatments are unproven. As explained above, the Court has already rejected these arguments as contrary to the weight of the scientific and medical evidence.

Defendants mistakenly claim that "Plaintiffs have made no showing of irreparable harm for potential Medicaid beneficiaries in the putative class," falsely asserting that Plaintiffs "have not presented evidence from treating doctors that gender reassignment surgeries are necessary treatments for anyone but themselves." Opp. Br. 45. First, Defendants wholly ignore that the expert testimony from Dr. Budge, Dr. Schechter, Dr. Shumer, and Dr. Hughto of the harms to transgender Medicaid beneficiaries that will predictably result from the Challenged Exclusion is evidence of irreparable harm. As Dr. Budge has opined, the "*failure* to provide transition-related medical care can lead to significant harm." Budge Decl. ¶¶ 34, 36. Dr. Schechter similarly opined that denial of gender-confirming treatments to individuals in need "is likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes, and even suicide." Schechter Decl. ¶¶ 41-42. Dr. Shumer concluded that the Challenged Exclusion "is at complete odds with the prevailing standards of care" and "puts the lives of individuals living with gender dysphoria at risk." Shumer Decl. ¶ 43. Dr. Hughto similarly noted that "Wisconsin's categorical policy barring access to gender-affirming care has harmful health implications for those [transgender Wisconsin Medicaid beneficiaries] who currently require such care as well as those who will require this care in the future." Hughto Decl. ¶ 49.

Defendants also ignore the declarations of two primary care providers in Wisconsin—Kathy Oriel, MD, MS, and Linda Wesp, MSN, RN, APNP, FNP-C, AAHIV-S—who recounted the harms to their patients who have been denied coverage for gender-confirming care. Decl. of Kathy Oriel, MD, MS ¶¶ 9-10, 13 [Dkt. No. 109] ("Oriel Decl."); Decl. of Linda Wesp, MSN, RN, APNP, FNP-C, AAHIV-S ¶ 15 [Dkt. No. 94] ("Wesp. Decl."). Dr. Oriel shared stories of patients denied gender-confirming care who experienced adverse health effects, self-harm, and

suicidality, and wrote that the Challenged Exclusion "limits my ability to provide my patients with treatments I know would alleviate their gender dysphoria and suffering." Oriel Decl. ¶¶ 9-14.[6] Ms. Wesp similarly wrote that the Challenged Exclusion "has categorically eliminated [her] ability to provide [her] patients with the care they need," resulting in inadequate treatments for gender dysphoria. Wesp Decl. ¶ 16.

And, finally, Defendants ignore the declarations of newly-named Plaintiffs Courtney Sherwin and Marie Kelly, as well as those of several members of the Proposed Class who describe the multiple adverse effects to their health and well-being, and their experiences feeling stigmatized, from being unable to access gender-confirming care. *See* Decl. of Marie Kelly ¶¶ 14-17 [Dkt. No. 93]; Sherwin Decl. ¶¶ 10, 12, 19-21, 23-25, 30-31; Decl. of Tori Vancil ¶¶ 10-14 [Dkt. No. 97]; Decl. of Emma Grunenwald-Ries ¶¶ 14-18 [Dkt. No. 98]; Decl. of Lexie Vordermann ¶¶ 7, 12-13 [Dkt. No. 99].[7]

Even without all this evidence, the deprivation of class members' Constitutional right to equal protection is, on its own, a cognizable irreparable harm. *See* Pls.' Br. in Supp. of Mot. for Prelim. Inj. 20 [Dkt. No. 19]. Given Plaintiffs' likelihood of success on the merits of their Equal Protection Clause claim, PI Op. at 2, this alone would justify modifying the injunction to provide class-wide relief. *Id.*

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[6] In addition, Dr. Oriel is the treating provider for two of the class member declarants, Tori Vancil and Emma Grunenwald-Ries, and has recommended gender-confirming surgeries for each of them. Decl. of Tori Vancil Decl. ¶ 13 [Dkt. No. 97]; Decl. of Emmar Grunenwald-Ries Decl. ¶ 17 [Dkt. No. 98].

[7] While Defendants dismiss the class member declarants' treating physicians' recommendations as "hearsay," statements made for medical diagnosis or treatments are not hearsay. Fed. R. Evid. 803(4). Even if those recommendations were hearsay, the Court can consider evidence at the preliminary injunction stage that might be inadmissible at trial. *Dexia Crédit Local v. Rogan*, 602 F.3d 879, 885 (7th Cir. 2010).

In sum, Plaintiffs have provided ample evidence that members of the Proposed Class are experiencing and will continue to face irreparable harm as long as the Challenged Exclusion remains in effect. And the State's purported interests in categorically denying health care pale in comparison to these harms.

B. The monetary impact to the State of eliminating the Challenged Exclusion is insignificant and immaterial.

Defendants continue to urge the Court to deny the motion to modify the injunction because of the potential cost impact to the State of covering Wisconsin Medicaid beneficiaries' gender-confirming treatments during the pendency of this case. As a threshold matter, the Seventh Circuit recognized in *Bontrager* that, in a case involving Medicaid coverage, the cost to a state Medicaid agency of covering medically necessary care in a nondiscriminatory manner is not a cognizable harm to that agency. *See Bontrager*, 697 F.3d at 611-12.

But even if the cost impact has some bearing on the Court's equities analysis, the estimated costs to the State from a preliminary injunction are insignificant and immaterial. Defendants have offered various projections of the cost to the State of a class-wide preliminary injunction. In their response, they now project a cost impact ranging from $240,000 to $960,000. Opp. Br. 39 (based on their assumption that the preliminary injunction will be in place, at most, for approximately nine months until the trial set for September 2019). Although the precise impact is unknown, the cost to the State under *any* of these estimates would represent nothing more than a rounding error in the State's annual Medicaid spending. In *Boyden*, the Court concluded that the estimated cost impact to the State of covering gender-confirming care for state employees—representing 0.1 to 0.2 percent of overall health insurance spending—was "minuscule" and "immaterial." *Boyden*, 2018 WL 4473347, at *17. Here, even the State's

highest projected cost impact is, by orders of magnitude, a significantly tinier portion of Wisconsin Medicaid's annual spending.

The State's actuarial expert originally estimated that the annual cost impact of a class-wide injunction would be only about $300,000. Report of David Williams 3 [Dkt. No. 74-1] ("Williams Report") (adjusted to $240,000 for a nine-month period); Opp. Br. 39. A $240,000 cost impact represents only about 0.006 percent (six thousandths of one percent) of the State's $3.9 billion share of the $9.7 billion annual Wisconsin Medicaid spending. This is 16 to 33 times smaller than the 0.1 to 0.2 percent cost impact this Court deemed "immaterial" in *Boyden*.

Williams now speculates that the actual annual cost impact from an injunction could be closer to $1.2 million (or $960,000 over the nine-month life of the injunction estimated by the State). Supp. Decl. of David Williams ¶¶ 25-28 [Dkt. No. 119] ("Williams Supp. Decl."). In reaching this higher estimate, Williams relies on the estimated size of the Proposed Class calculated by Plaintiffs' expert, Jaclyn White Hughto. *Id.* Based on Hughto's estimate 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*," Hughto Decl. ¶ 49 (emphasis added); Supp. Decl. of Jaclyn White Hughto ¶ 21 [Dkt. No. 96] ("Hughto Supp. Decl."), Williams inexplicably assumes that all 5,000 individuals would obtain surgery in the next ten years. Williams Supp. Decl. ¶¶ 25-28. He thus assumes that Wisconsin Medicaid would need to cover 500 surgeries over the next year. *Id.* Williams concedes his estimate is based on "broad and simplified assumptions," *id*., and, in fact, there is no support at all for his assumption that Hughto's estimate that class members may seek gender-confirming surgeries during their *lifetime* translates into all class members obtaining surgery over the next *decade*. As such, Williams' higher cost estimate based on this faulty assumption should be given no weight. Regardless, even if the higher

estimate were accurate, it would still be immaterial. $960,000 represents only about 0.03 percent of Defendants' share of the annual Wisconsin Medicaid budget—still a fraction of the cost impact projected in *Boyden*.

Despite the State's contention otherwise, Dr. Hughto, a public health expert, did not purport to quantify the total cost savings for Wisconsin Medicaid. Instead, she merely pointed out that the already minimal additional costs to the State from covering gender-confirming care are likely to be mitigated further by the cost savings to the State associated with properly treated gender dysphoria. Hughto Supp. Decl. ¶¶ 8-20. Although Defendants describe Dr. Hughto's conclusions as "unreliable," Dr. Hughto has provided thorough analysis based on her professional experience as an epidemiologist and her review of peer-reviewed scientific (and testable) studies, showing that providing the full range of transition-related medical care is likely to result in improved outcomes for transgender Wisconsin Medicaid beneficiaries with gender dysphoria, and therefore, reduced expenses to the State and other public health benefits. *Id*.

Simply put, the actuarial cost estimate put forth by the State was an incomplete analysis because it did not include the broader public health and policy benefits associated with lifting the Challenged Exclusion. Williams admits as much. Williams Supp. Decl. ¶¶ 5-7. As Plaintiffs' experts have shown, covering the full range of transition-related medical care is likely to result in improved psychosocial, socioeconomic, and health outcomes for transgender Medicaid recipients. Budge Decl. ¶¶ 35-37; Hughto Supp. Decl. ¶¶ 8-20. As the Court has recognized, these improved outcomes are in the public interest. PI Op. at 37. Further, these improved outcomes can, in turn, be expected to reduce the costs to Wisconsin Medicaid, and to the State generally, of providing medical services related to suicide attempts, substance abuse, assault, and other risk factors. Hughto Supp. Decl. ¶¶ 8-20. It is worth noting that while the State concedes

that some cost savings may accrue from lower suicide rates following gender-confirming surgery, Opp. Br. 7 (citing Williams Supp. Decl. ¶¶ 8-17), the State does not acknowledge that the public interest in saving human lives is infinitely more valuable than mere cost savings—and a necessary consideration in this analysis.

Ultimately, the Parties agree on the essential point: the cost impact to the State of a class-wide preliminary injunction will be low. That suffices to show both that Defendants will suffer no irreparable harm from the entry of a class-wide preliminary injunction and will be unable to justify the Challenged Exclusion based on marginal cost savings.

CONCLUSION

For the reasons stated herein and in Plaintiffs' opening brief, the Court should modify the preliminary injunction to enjoin Defendants from denying any member of the Proposed Class coverage for gender-confirming care during the pendency of this lawsuit.

Dated: December 10, 2018

Respectfully submitted,

/s/ Joseph J. Wardenski

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EXHIBIT

A

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF SOUTH DAKOTA

TERRI BRUCE,)
Plaintiff,)
vs.) No. 17-5080
STATE OF SOUTH DAKOTA and)
LAURIE GILL, in her official)
capacity as Commissioner of)
of the South Dakota Bureau)
of Human Resources,)
Defendants.)

DEPOSITION OF DR. DANIEL SUTPHIN, M.D., FACS
TAKEN ON BEHALF OF THE PLAINTIFF
JULY 17, 2018

(Starting time of the deposition: 8:50 a.m.)

INDEX

EXHIBITS

(Original exhibits retained by the court reporter to be copied and attached to the transcript.)

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF SOUTH DAKOTA

TERRI BRUCE,)
Plaintiff,)
vs.) No. 17-5080
STATE OF SOUTH DAKOTA and)
LAURIE GILL, in her official)
capacity as Commissioner of)
of the South Dakota Bureau)
of Human Resources,)
Defendants.)

Deposition of DR. DANIEL SUTPHIN, M.D., FACS, produced, sworn and examined on the 17th Day of July, 2018 between the hours of 9:00 a.m. and 5:00 p.m. at the offices of Alaris Litigation Services, 711 N. 11th Street, in the City of St. Louis, State of Missouri, before Rebecca Brewer, Registered Professional Reporter, Certified Realtime Reporter, Missouri Certified Shorthand Reporter, and Notary Public within and for the State of Missouri.

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but he doesn't seem well. Something's amiss for him. That could be a myriad number of possibilities. He may have just been up all night with American Airlines flying all over the country or he may really -- he may have an alcohol problem. It could be any number of things, but just even unprofessional observation will lead you to assume that something's not exactly typical for a surgeon, at least.

Q So, just going back to our boring list. For the third residency, in the department of plastic surgery and reconstructive surgery at University of Tennessee, during that residency, did you have any training in treating gender dysphoria?

A No, sir.

Q Did you have any training in psychology or psychiatry?

A No, sir.

Q Okay. And so, finally, the fellowship at UCSF, during that fellowship, did you have any training in treating gender dysphoria?

A At that point, I did have some exposure to gender dysphoric patients and that was really the first occasion that professionally I'd encountered with a patient in that condition. Even at that

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stage, just a few relatively short years ago, there was no formal, well-organized program as UC. And as is submitted in my declarations, I think that's an area of need that's been recognized nationwide and Dr. Delgado at Miami, who I don't know personally, suggests that we really need dedicated fellowships, that the current state of training in the United States in plastic surgery, this is something that is lacking. Given the location in San Francisco, by default, I think, really, we were even sensing a need at that point to be able to address those patients other than, okay, well, yeah, we know some procedures, we can execute procedures, but we still don't really understand what's bringing to the table here. And so that's kind of where I found myself taking care of patients, not on a regular basis, but occasionally we would see somebody at San Francisco General would come in -- or I remember on one occasion, at St. Mary's Hospital, taking care of a patient who had undergone a metoidioplasty and was having some complications with that. But it wasn't a formalized component. Of course, at that juncture, I was doing a dedicated fellowship in microsurgery. And so, the curriculum was not structured specific to transgender surgery and I

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think, obviously, even as Dr. Schecter is testimony of, I think he's working on developing a fellowship for people within the discipline of microsurgery to tend specifically to transgender patients. Just wasn't that formal presence at that point.

Q So, do the procedures that are involved in sex reassignment surgery follow within the rubric of microsurgery?

A Some, yes, sir.

Q Which ones?

A Phalloplasty is probably the predominant technique that would be best executed, utilizing my microsurgical technique.

Q Does vaginoplasty?

A Depending on whether intestinal transposition is utilized.

Q So, if no intestinal transposition, then it doesn't fall within microsurgery?

A No, it does not. And even in most cases, for intestinal transposition, there's not a need for microsurgical technique unless, perhaps, there's a vascular complication that requires utilizing -- disrupting the native blood supply to the intestine.

Q And mastectomy doesn't fall within microsurgery, does it?

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A No, sir.

Q During this fellowship, did you have any training in psychiatry or psychology?

A No.

Q You also said this was around the time when you started doing your own reading on SRS, is that right?

A Yes, sir.

Q And so, what sources did you begin to read?

A The only sources that I could find at the time were basically limited to our plastics literature, occasionally urology literature.

Q Did you read only in medical journals or did you read beyond that as well?

A Such as? Forgive me, I don't understand the question.

Q Sorry. Were there other writings, from a philosophical perspective or from a non-medical perspective, on SRS that you read at that time?

A Only perhaps what was in the lay press.

Q So, going to the next section of your CV, on work history, you know, maybe we can make this a little bit -- go a little bit quicker by, you know, asking you if, you know, during any of these

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professional work history stints you ever treated someone for gender dysphoria.

A I don't know if I treated them, if that would be the primary diagnosis. I treated gender dysphoric patients, yes, sir.

Q So, give me an example of what treatment you gave for gender dysphoric patients.

A Male to female patients that had complications with their breast implants or infection.

Q Any other context?

A No. I did not treat a patient specifically with gender dysphoria, but a spouse of a patient. A lady came to see me about her consult for her breast implants and, to my recollection, she had a technique which is not commonly accepted within well-credentialed plastic surgery. She had a number of implants stacked in her breast to make them inordinately large, basically. Her spouse was a transgender female.

Q I'm sorry, by transgender female, do you mean someone whose sex assigned at birth was female or someone whose sex assigned at birth was male?

A Male. So I didn't treat that individual specifically and, in fact, the patients or the

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patient who was coming to me for counsel, I think ultimately decided to seek care elsewhere. I expressed concern to her that, given the stretching of her breast envelope, what she wanted to accomplish wasn't going to be safely doable. She had been multiply operated previous times, including some surgeries outside the country, so --

Q The complications that you did see and treat for breast implants, were those complications different from the type of complications that a cisgender female would experience having breast implants?

A No more related to the complication of the implant itself; common complications like device failure or infection around the device.

Q So the fact that the implant was -- as part of -- was provided as part of gender transition didn't make it more likely to result in a complication than if it had been provided to a cisgender woman?

A I don't know any reason why, per se, no.

Q Going back for one second to your fellowship at UCSF. When you were there, about how many gender dysphoric patients do you estimate you interacted with?

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A Oh, it was probably no more than 25 total.

Q And what sort of treatment did you provide them?

A Again, most occasions it was dealing with complications of the surgery. Many of them were, thankfully, non-operative. The lady I alluded to previously who developed bleeding and incisional dehiscence after a metoidioplasty thankfully didn't require surgery. There were other occasions where we would take care of trans female patients who were male at birth and had developed complications with their implants. To that end, the question that you mentioned earlier, is there any reason for failure in that patient population? Not so much an anatomic reason other than the male pectoralis implants are usually more well developed, depending upon the stage at which the patient underwent transformation. And certainly that patient population, I don't ever recall seeing an individual who had undergone transition, pre-pubertal. So, they had a fully male phenotype in terms of skeletal development and muscular development. And if the implant's in a submuscular position, certainly that could lead to increased implant migration. The behavioral pattern in terms of those people, in terms of S&M and

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bondage, I would not say are typical for -- but who can say that sexual proclivities of, I mean, across the country, between male, female, cis, or transgender, that's far beyond my expertise, but that was something that may perhaps lead to increased failure, but that would be a common issue, whether a person's a biological male or female, if you smash the implant repetitively, it's going to rupture, you know, so no matter what your gender or where the thing is located. So pretty elementary, not microsurgical techniques. That may have reflected the knowledge base of the surrounding surgical community, even in an area like San Francisco, which is keen, certainly, to be able to provide this care to people that really reflects the rapid growth, even in the last decade, so --

Q Can you explain more about the rapid growth that's happened in the past decade?

A Well, I can just share with observation in terms of authors like Dr. Schecter, who are working diligently to be able to bring a greater knowledge base to various disciplines, I think he -- I can't speak for him, but he would probably be the first to say, not just plastics, but outside of plastic surgery, disciplines like neurology as well.

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Q Just want to be clear on understanding what you're saying. Is it fair to say that, you know, the medical community's familiarity with treating gender dysphoria has increased dramatically over the past decade?

A I have no objective proof of that, but my subjective impression, at least there's a greater awareness of it. The fact that it's not reflected in any of my training, I don't believe, is geographical. I think it's time specific.

Q And do you think that -- so the fact that -- well, strike that. Before I move on from your professional work history, I just want to make sure that I'm not missing any other context in your education or your professional work history in which you've treated gender dysphoric patients.

A No, sir.

Q And during the fellowship, or in your subsequent work history, were you ever involved in performing or assisting to perform the transition surgery as opposed --

A No, sir. I was not. Really, my knowledge has been self-directed, to try to learn more, how can we better care for these people? They're human just as you or I. And so, that's really been my

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own, self-directed. And I think that's true. I'm not anything special in that regard. Every surgeon, whether this is transgender surgery or whether this is laparoscopic surgery, a neurosurgeon practicing in 1989 or you're a vascular surgeon practicing in the early '90s before endovascular therapy was available, you're going to continually work to critically analyze what's coming down the pipeline of treatment so you can continue to provide good care for people, whatever their background is, whatever their orientation is, whatever their sexuality is.

Q You continue to evaluate new material?

A Yes, sir. Absolutely. That's our duty and obligation. We wouldn't be practicing good medicine if we didn't.

Q And do you think that in deciding what sort of procedures should be covered by insurance, that an insurance company should be, you know, looking at new material and reevaluating decisions in light of new material?

MR. JOHNSON: Lack of foundation.

Q (By Mr. Block) You can go ahead and answer.

A Well, if I could speak for insurance

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companies, I would be in a very different place right now. I have no concept of what insurance companies do, don't do, or why they do what they do. I continue to be amazed. I've had insurance companies deny treatment for patients for many different reasons and, if I understood why, there would be a large plaque on my wall called the Nobel Prize.

Q Has anyone, you know, in your training or your work experience asked you to perform surgery for gender transition?

A No, sir. No, sir.

Q And in your -- going down on your CV, for your research presentations and publications, am I right that none of your research listed on your CV concerns treatment for gender dysphoria?

A Yes, sir.

Q And none of the research on your CV concerns performance of transition-related surgeries?

A Correct.

Q And none of the research on your CV concerns psychological or psychiatric care?

A Correct.

Q And have you conducted any other research,

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presentations, or publications not listed on your CV?

A No, sir. I just received a request to be a potential author, actually, for Merkel cell, management of Merkel cell cancer, but I have not embarked on that. But that would not be original research. That would be a literature review and synopsis of that. That's the only other thing that's not on my CV right now.

Q What's the difference between original research and literature review?

A In the context that I use it, I mean, for instance, if you look at my CV, the research done with botulinum toxins. That is the concept that's nidus and whose caring to fruition began just with a clinical question that I had as opposed to a question where I'm gathering data from -- just to offer my colleagues a synopsis of what exists in the medical literature at the present, you know, what's valid today may not be valid tomorrow, depending on what we learn overnight. It's that kind of thing.

Q So, what do you think qualifies you to provide expert testimony on the -- on transition-related surgery and its medical necessity?

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A Just an evaluation, I guess, as a plastic surgeon, many of the principles and techniques that are being utilized, obviously, are inherently derived from plastic surgery, whether they're local regional flaps, whether they're surgical techniques. And I think that based on my training, which is excellent technical training, offers me the ability to discuss, with clinical acumen within my specialty, what these complications actually mean. And what does it mean to have a 40 percent stricture rate versus 10 percent and how does really affect people's lives? Because whether they're male or female or transgender or cisgender, if you can't void properly, that's a life-altering thing. And certainly, as I'm going to, you know, as a plastic surgeon, looking toward the future, I have to, as I alluded to earlier, I have to critically analyze literature based on what -- what the literature says to know whether it's something I need to get on board with, so to speak, or whether it's something that, really, I need to refrain from. And that's just my own personal opinion, obviously.

Q So, do you think that anyone who has completed plastic surgery fellowship would have similar competence to be an expert on these issues?

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A I think anyone who has completed fellowship training with a microsurgical background would be able to discuss, intelligently, some of the risks and potential benefits of some of these techniques, yes, sir.

Q Is there anything that distinguishes you from anyone else who has completed a fellowship in plastic surgery with a microsurgery background -- I apologize if I didn't use the right term -- is there anything that distinguishes you from anyone else who has that credential in providing expert testimony on this specific issue?

A You probably have to talk to my patients to make that determination. But in an academic sense, no, sir. No, sir.

Q So, without, you know, revealing the substance of any conversations, when were you first retained to be an expert in this case?

A I honestly don't remember the date. It was in the calendar year 2018, to my recollection. Earlier in the calendar year, probably before spring.

Q Okay. So, we'll just refer to that as early 2018. Is that --

A May I ask?

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MR. JOHNSON: No, just --

A I don't recall the specific date, quite honestly.

Q (By Mr. Block) Okay. And before you were retained as an expert in this case, had you spoken to anyone about your concerns with SRS?

A No, sir.

Q Do you --

A Patients? That's a question I don't know that I fully understand.

Q Thanks for asking me to clarify. Had you --

A I mean, I've spoken to colleagues and said, Hey, what do you think? I mean, this is a pretty high complication rate, but --

Q So, in what context did you speak to colleagues about SRS?

A Just observation, phone conversations. Given the practice location, I'm practicing in an underserved area, so I would contact colleagues about microsurgical cases and just chat over whatever, you know, you don't see each other or talk to each other professionally very often and you try to catch up, what's going on.

Q So, if no one has asked you to perform

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SRS, you know, what prompted you to, you know, pick up the phone and have these conversations with colleagues?

A It wasn't a conversation where I called with that being the nidus. It was a conversation where, what's happening, what's going on in your world? I've got this patient who's, you know, an 88-year-old person who, I think, really needs a free flap, what would you do? That sort of thing. It wasn't a lengthy or extensive conversation.

Q Do you -- do you have any knowledge of if -- I'll take that away. Have you spoken to any of your colleagues about being an expert in this case?

A No, sir.

Q Have you -- before you were retained as an expert in this case, had you expressed any interest to colleagues about providing expert testimony regarding SRS?

A In 2016, when I was still in New Mexico, I submitted that there was a call for opinion regarding the -- there was an injunction issued in a federal court, I think out of Texas, and there was a call for opinion, public opinion. And there was a gentleman by the name of Imbody, Jonathan Imbody,

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that I got an e-mail. I don't think it was directed specifically to me, per se, just making a request, as, you know, if anybody who has any background in plastic surgery and is willing to make some comments and provide testimony about your impressions.

Q How do you spell Imbody?

A I-M-B-O-D-Y.

Q And did he -- was he speaking on behalf of any organization?

A I don't know. I don't know.

Q Are you familiar with the Christian Medical and Dental Association?

A I am. Yes, sir.

Q What's the basis of your familiarity?

A I'm actually a member of CMDA.

Q And CMDA was one of the plaintiffs in that case in Texas, is that right?

A I honestly don't know.

Q How long have you been a member of CMDA?

A Probably since 2000 in a student capacity.

Q And what is CMDA?

A Christian Medical Dental Association.

Q And what does it do?

A Well, it's basically an association of, I would say, like-minded physicians and dentists who

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share a Christian faith. I don't fully know all the capacity of CMDA. I know that they facilitate various missions outreach around the world and serving various areas that are underserved throughout the world. I've never -- never participated in that element, but I know it's a strong element of the organization.

Q So, what's the substance of your participation in the organization?

A Well, I'm a Christian and so, medicine is a very demanding specialty. It's not a position that you can just leave at home. And I think -- I think all of us within medicine, having had friends who come from various different world view perspectives; atheist, Jewish, Mormon, Muslim, all of us have to figure out how are we going to deal with the realities that I was just relating earlier. I'm sitting down with somebody and telling them they're probably not going to be here in a few months. And so I think whatever a person's -- whatever their world view is, I think it's important for them to find that fellowship. That's the basis for my membership.

Q Are there annual or semi-annual meetings that you attend?

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A I've never been to one.

(Deposition Exhibit 10 marked.)

Q So, marking this as Exhibit No. 10. This is a printout of the web page for CMDA. It obviously looks different on paper than it does on the computer screen, but does this appear -- have you visited the website of CMDA at all?

A This looks like it would be legitimate. My dad's in internet security, so he taught me you can make anything look any way you want. He showed me websites that are said to be Bank of America and they're based in Russia, so --

Q But there doesn't appear to be anything wrong with this?

A No, sir. This doesn't appear to be a misrepresentation of anything related to CMDA that I'm aware of.

Q Okay. Great. And under "Our mission and vision" at the bottom of the first page.

A Yes, sir.

Q It says, Our mission. And then it says, Christian Medical and Dental Association motivates, educates, and equips Christian healthcare professionals to glorify God by -- and the first bullet point is serving with professional excellence

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as witnesses of Christ's love and compassion to all peoples. And, second bullet point, Advancing biblical principles of healthcare within the church and to our culture?

A Yes, sir.

Q And do you agree with that mission envision? Is that something that you try to adhere to?

A Yes, sir.

Q And what's your understanding of biblical principles of healthcare?

A Compassion, selflessness, and commitment to excellence.

Q Anything else?

A For me as a Christian that ultimately models Christ, love for us as humans. And I don't see anything discordant with that with care of transgender people. In fact, you know, if you read through the New Testament, I think Paul was probably the original guy to blow up binary definitions in the Book of Galatians; with him there is no male nor female, slave nor free man, there's no Jew or Greek. And so I've never had any -- personally, I can't speak for the whole organization, but for me personally, I've never had any -- if you look at the

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life of Christ, he got himself in a lot of trouble tending to people that were not espoused as and worthy of care. And I can find no better example than that.

(Deposition Exhibit 11 marked.)

Q Another document marked as Exhibit 11. This is a PDF from CMDA's website entitled Transgender Identification. Have you seen this CMDA statement before?

A No, sir, I have not.

Q Okay. So I'll give you a minute to read it and familiarize yourself with it.

A Okay.

Q Okay. So, is there anything in this document that you disagree with?

A No, sir.

Q So, if we go to the very first page, the second paragraph.

A Yes, sir. Biological?

Q No. Starting with "CMDA affirms."

A Okay.

Q CMDA affirms the obligation. Is that the second paragraph? Did I say the first? So the second paragraph on the first page; CMDA affirms the obligation of Christian healthcare professionals to

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care for patients struggling with gender identity, with sensitivity and compassion. CMDA holds that attempts to alter gender surgically or hormonally for psychological indications, however, are medically inappropriate, as they repudiate nature, are unsupported by the witness of scripture, and are inconsistent with Christian thinking on gender in every prior age. Accordingly, CMDA opposes medical assistance for gender transition on the following grounds. Now, so, do you agree that attempts to alter gender surgically or hormonally for psychological indications are medically inappropriate?

A I don't know.

Q Do you agree that they repudiate nature?

A Yes, I do.

Q Do you agree that they're inconsistent with Christian thinking?

A Well, Christian thinking is a very broad -- and as much as I believe that we are created beings and that God does not make mistakes, yes.

Q If you go to the third page, under the heading of CMDA recommendations for Christian healthcare professionals, Item 3, it says -- do you

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have it?

A Yes, sir.

Q It says, CMDA believes that Christian physicians should not engage in hormonal and surgical interventions that alter natural sex phenotypes as this contradicts the basic principles of Christian medical ethics which regards medical treatment as intended to heal and not to harm. Do you agree with that statement?

A I think that Christian medical ethics don't have a monopoly on the intent to heal or not to harm. I think that's true for all of us. I think all of us in this room would agree that our goal is to strive to help anyone. I think -- I'm going to have to speak as my own self, not just as CMDA, though I'm a member of CMDA, that's a body. As Daniel Sutphin, I would agree that it is -- in one sense, sex reassignment surgeries are an advocation of what is natural. That is a biological state the person is born into. And so whether I'm Christian or not, I have to stop and say, why would we -- not just why would the person, but why we, as a culture, abandon -- seems a very debased valuation of the body itself, physical human body, as opposed to a body honoring this is -- this is a special

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structure. And as a surgeon, you know that it is. And I often joke with patients, if you don't believe there's a God, try reconstructing the hand. It's really hard to do. It's a very complex structure that whatever -- whatever one's religious beliefs, you open the hood of a car, something intelligent put that together. You open a human hand -- and I don't practice hand surgery -- it's a pretty amazing design. One millimeter off affects the tendon excursion and flexion. So just from a natural sense, I would have natural questions that is this a valid option. And that's why I say I think we have to first turn to -- we have to look at the medical literature and say, What does it say? What facts are there? Because if the fact is that something helps someone, well, then you have to stop and consider how do I need to adjust my thinking? Is my thinking correct? There's only one God. I'm not him. I don't pretend to know everything. I think in scripture, the principle that I do support that CMDA declares is that male and female, he made them. And I'm a Christian as much as I believe that Jesus Christ is who he said he was, who he claimed to be. And he actually declared that himself while he was on earth. So, some people would just say, well,

it's a nice fairytale. I respect that. I can't prove that. I can't at all. The New Testament speaks to the truth of what I've seen in my own life and what I've seen in the lives of those around me. I don't -- I don't see any evidence at the present, factual evidence, that tells me that I, as a plastic surgeon, need to engage in this surgery in an effort to save a person's life. And I feel a strong enough sense of obligation to patients, honestly, even for cisgender women, I don't offer cosmetic breast surgery. I really focus my practice on what I would say, I guess, is surgery that I know that what I'm engaging in can produce a tangible -- a tangible result for someone that will not just make them feel better about themselves, that's very gratifying, but restore what disease or nature has taken away, I guess.

Q You spoke about how complicated the human hand is.

A Yes, sir.

Q Do you believe in intelligent design?

A As defined how? I've heard a lot of people define that in different ways. I believe there is a creator and I believe, to me, my faith is an active process where I look, you know, I sit down

with Josh Block, I talk with him, and Josh is a smart guy and he's got some good ideas and he arrived at those with good reason, somehow. So, what -- how does what I, as Daniel David, think about, how does that compare and where am I amiss? Or where might Josh be, in my opinion? As it relates to intelligent design, I believe in it as much as I think, yes, it's easier for me as an individual to have faith there is a God when I see structures like this and when you operate on the human eye and you know that when you sit as a human and look at me, you can perceive two milliliters of asymmetry in my upper lids, just in casual observation. When you try to restore or correct that, when you try and put it back together again, you realize this is not -- this is pretty neat stuff, so --

Q Do you believe in Darwin's Theory of Natural Selection?

A As defined as what?

Q Well, how -- do you have a definition of it?

A I don't. I don't. I mean, I don't.

Q Okay.

A I've heard a lot of --

MR. JOHNSON: You've answered it.

Q (By Mr. Block) I mean, do you believe that humans developed through evolution?

A No. I believe we're created beings and that the genome is something that is what our physical manifestations are reflective of, that that's something that allows for -- if that's what you mean by Darwin's Natural Selection, allows manifestations of what we commonly hear as survival of the fittest. You know, if Josh and Daniel live in the desert southwest and they're blue-eyed, fair-skinned white guys, and they don't have any protection, they're going to die pretty quick of melanoma or other related skin cancers over time. They're going to thrive and do better in an overcast Northern European environment.

Q But you don't believe that's how human beings, as a species, developed?

A I don't personally, no, sir.

Q One more question just on this document from CMDA and on the same paragraph that we spoke about last. So Paragraph 3. It says -- just focusing on the first clause of that sentence -- CMDA believes that Christian physicians should not engage in hormonal and surgical interventions that

alter natural sex phenotypes. And just want to confirm, you agree with that statement, is that right?

A Based on what I've read to date, yes, sir.

Q So, going back to your contact with Jonathan Imbody. Do you know if he was -- sent that e-mail on behalf of CMDA?

A I don't. I'd have to -- I'd have to look at the e-mail.

Q And what did you write in response to the e-mail?

A I have no recollection, honestly, other than I would be happy to provide whatever -- in essence, what I said is I'd be happy to provide any insights that I can, based on my technical expertise in the realm of microsurgery and plastic surgery. If I can help, let me know.

Q And so, after that, do you have any subsequent contact with Jonathan Imbody?

A No, sir.

Q Did you have any contact with anyone from Alliance Defending Freedom?

A No, sir.

Q Do you know what Alliance Defending Freedom is?

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the surgery, is that right?
A Correct.
Q But the surgery isn't life saving, is it?
A Not that we're aware of, no, sir.
Q So, do you believe that the benefits of the surgery are -- outweigh the risks to make it medically justified?
A That depend on the case and the severity of the deformity and the patient's symptoms that you're describing.
Q So, could you explain what would make it medically justified?
A If the patient complains of physical pain, and I can appreciate, on examination, a mass in the retroareolar position of the man's chest wall that I don't believe is going to be amenable to observation alone, then if he complains the pain associated with it is sufficient to warrant acceptance of the risks associated with the procedure, then I would consider it reasonable.
Q Isn't -- doesn't the surgery remove organically healthy tissue?
A It's abnormal tissue.
Q But it's organically healthy?
A No, sir. There's no -- if -- I think

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we're thinking the same thing, Josh, but we're coming from different vocabularies. There's no oncologic disease process. There's no infection. But it is abnormal hypertrophied tissue. In some cases, the actual etiology of which cannot be excluded or confirmed as benign until it's under a microscope.
Q Well, but the surgery is performed --
A It's not normal for males to have breasts, biological males.
Q Yeah, no, I'm getting to that. I'm getting to that. But the surgery, you know, can be medically necessary, even when it's known that the tissue is benign, right?
A Yes, sir. It can be appropriate. Even when the tissue is thought to be benign, yes.
Q But it is -- it is not -- but the tissue does not conform to the type of tissue that males usually have in their chest, is that right?
A I don't know that the tissue "conform" is the right word, but it is not typical physiologic phenotype and it does lead to question, though, in the vast majority of cases, it is only benign disease, the only way to exclude that with certainty is to examine the specimen under the microscope, but

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yes, sir, in the vast majority of cases, it's benign tissue. And by no means would I tell a patient, oh, if you came to me and said, Josh, I think you're going to be all right, you know, we can't say that with absolute certainty until it's under microscope, but I think it's going to be okay. But if it's causing you discomfort, it's causing you pain, are you willing to accept the risks of the surgery? Then that -- yes, sir, that would be how I would approach gynecomastia, depending upon the patient's age.
Q And one of the purposes of the surgery is to bring the person's body into align with the typical male phenotype?
A One of the purposes of the surgery would be to alleviate pain and the other purpose would be to verify no physiologic abnormality, and a third benefit, I would think, would be that it would bring the patient's body into alignment with what already exists in his body. Not to create something or disrupt the state of the body otherwise.
Q But that's an entirely appropriate medical consideration; to bring a person's physical body into alignment with his typical male phenotype?
A Yes, sir, what already exists, yes.

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Q Okay. If there's no -- can surgery for gynecomastia be medically necessary, even when there is no physical pain?
A This is one case, at least in my experience, Josh, that there is a lot of variability from insurance companies and policies. Some policies have exclusions that others don't have. Even with pain, some policies require progressive growth that does not subside over time. It can vary.
Q And how about your own personal belief? Do you provide surgery for gynecomastia even if there's not physical pain?
A If I have any objective concern that there may be occult disease, then yes, sir. And even if I don't operate the patient initially, I see them back in followup to verify that my findings at the time I see them initially are consistent over time and/or resolving. And if that behaves in a manner atypical, then irrespective of just the symptoms of physical pain, I would make a recommendation that they undergo at least tissue biopsy and/or imaging studies like ultrasound.
Q If there's no indication, if there's no -- nothing to indicate that the tissue is not benign

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and the patient is not suffering physical discomfort, just has abnormal growth and extreme social discomfort from it, would you provide the surgery in those circumstances?

MR. JOHNSON: You said is not benign?

A Nothing to indicate the tissue is not benign.

Q (By Mr. Block) So there's no concern about performing a biopsy, the only concerns are that this is abnormal growth that does not subside and the person is suffering social distress from it, would you perform the surgery in those circumstances?

A If I may, I'm going to repeat what my brain is picking up. I have a patient who doesn't appear to have any pain. I have very low concern that there's any pathologic mass suspicious for oncologic process, however, the growth is persisted and the only concern at this point is stigma, is that correct?

Q Well, social distress and anxiety.

A Yes, that would be a reasonable thing. His insurance may not cover it, but I would offer that.

Q Because of the stigma?

A Yes. Yes. To the point in terms of a

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patient like Mr. Bruce, what stigma has the patient had by having breasts alone? I don't know. Those begin to become more complex issues. Furthermore, I've never examined Mr. Bruce and I can't comment on the breast size and considerations associated with that, but most gynecomastia patients as, again, as also noted this month and I think very well noted in the article dealing with the same in Clinics about male to female and female to female chest surgery, there are important differences that need to be recognized between the two surgeries and they're not the same surgeries at all.

Q Understood. So, is it fair to say, in your view, a major distinction between performing surgery for gynecomastia to alleviate distress from social stigma and performing surgery to treat gender dysphoria is that when you're performing gynecomastia on a man, you're removing abnormal tissue, but when you're performing transition-related surgery, you are removing tissue that is normal for that person?

A It's physiologic. We would presume, unless there's a disease state that we know of to be present, the fact that those two are technically different procedures is reflected in CPT

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terminology.

Q I just want to confirm that, you know, a distinguishing thing between those two surgeries that's important to you is that for gynecomastia for a man, the tissue is physiologically abnormal, and for mastectomy for a transgender man, the tissue is physiologically normal?

A Yes, sir.

Q And you're more concerned about tissue that is physiologically normal than you would be about removing tissue that is physiologically abnormal?

A Correct. That represents an abnormal developmental state, which gynecomastia does.

Q Do you think that having gender dysphoria is a normal state?

A That's an interesting question, Josh. I think those that I have observed with what I would describe as a real disorder, no, I don't think it's a normal state, but as opposed to one that can be appreciated physically on examination, that I have a high degree of confidence that I can address with a scalpel, it's something that I would be altering the patient's native biological state to achieve something that I don't know that I can address. And

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my colleagues, again, if they have been able to produce evidence that they're highly confident, very good, but I just not -- I have not seen that data reproduced over time.

Q You've spoken a lot about phalloplasty in particular. Are you aware that some insurance companies cover vaginoplasty and chest surgery but do not cover phalloplasty? Are you aware that some insurance companies make that distinction?

A I never cease to be amazed at the distinctions insurance companies make, yes, sir.

Q Phalloplasty is a much more complicated surgery to perform than those other surgeries I mentioned, right?

A I would agree. And if I may submit, my judgment is not how complex it is. If it's something that's going to help the patient and bears a sufficiently minimal level of risk to achieve a result, that's where we get into the, you know, economics of medicine. It may be something that it should not be, in my estimation, excluded based on the complexity alone.

Q And phalloplasty is a much more expensive a surgery than chest surgery or vaginoplasty, right?

A Yes, sir.

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reviewed what they had to work with at the time were not unreasonable.

Q (By Mr. Block) So, was it reasonable for them to say that it is an option? Was it reasonable for CMS to say that surgery for gender dysphoria is an option for individual doctors to pursue based on their determination of medical necessity?

A I don't think it's -- I don't think it's unreasonable.

Q Now, you're aware that Medicare, before 2014, had a rule that prohibited surgery, regardless of the individual views of a treating doctor, right?

MR. JOHNSON: Excuse me, I think you're misstating the studies. There's an '89, 2014, 2016. Maybe I'm misunderstanding your question.

Q (By Mr. Block) Yeah, before 2014, so you're aware that in the past, until the 2014 decision, Medicare had a blanket rule saying it wouldn't cover surgery to treat gender dysphoria under any circumstances, right?

A Yes.

Q And the rule adopted in 2016 is different from a blanket ban on coverage, right?

A Correct.

Q And do you have a preference between CMS's

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current rule and a rule that simply prohibits coverage across the board?

A I think it's in situations from a physician perspective, I think in situations it's more ideal to have a latitude to work with. I think from third party payer perspectives, it's more ideal to have blanket statements one way or the other because it becomes very challenging to sort that group.

Q Is the fact that CMS has -- is the fact that CMS provides -- let me rephrase it again. Do you think that CMS would provide coverage for a condition if it did not meet accepted standards of medicine?

MR. JOHNSON: I'm going to object. Lack of foundation. Speculation.

A I think CMS, in all candor, is an organization that can be very difficult to understand what basis, logical or illogical, exists for their support of one procedure over another, if at all.

Q (By Mr. Block) So, do you think that CMS's decision to provide coverage on an individualized basis is at least evidenced in favor of the conclusion that the procedure meets accepted

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standards?

A Well, I think -- I can't speak for the thought process of those who reviewed the literature, but I think what they're trying to do with candor is really recognize the fact that we don't have the answers that we need quite yet, but we're willing to consider. And that's what all of us, I think, really, must strive to do; is let's consider, let's be candid, let's really look at this and see what can we do to help these people.

Q And would you describe that as the accepted standard right now?

A What's that, Josh?

Q The attitude of there's still more information we need, we don't have all the answers, but we're willing to consider providing the surgery on an individualized basis, would you say that's the prevailing accepted standard right now?

A Within what circle?

Q Within just accepted standards of medicine.

A I mean, I think the American Psychiatric Association has made their declarations, to my opinion, based on subjective sentiment themselves without good objective data, as they candidly note.

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I think in terms of CMS, that's why I'm asking, what body are we talking about? I mean, all of us, I think, I would hope, within medicine, really, are taking that approach of let's look at this, let's see, but I don't think that the statement that -- to raise objections, to raise questions, is illogical and unfounded and, you know, I have it, because I just read it this weekend. I just took it with me. I just got clinics before I came. I mean, we can sit here, all of us, and look at just two of the papers that, you know, came out of clinics in terms of complication rates and say, Yikes. Okay. Well, what -- you know, even if this is fantastic and does alleviate dysphoria, part of our job as surgeons is to think to the next step. What are we going to do now? You know, that's kind of our job and we probably all do that in different ways. But, my statement is --

Q What I'm getting at is just trying to make sure that we're talking about the same thing when we talk about what it means for something to meet accepted standards of medicine. And I hear you to be interpreting that phrase as has it been proven definitively to be effective in a way that outweighs the risks?

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disorder that we can alleviate by surgery, general consensus, that's unprecedented and may well be the case. But if it is so, and that's my observation, just Daniel Sutphin, in taking care of these people, if there is mental discord and distress there, there is more than just simple dysphoria. And to couch it in terms that we may think are less discriminatory or emotionally harmful to the patient, I don't do the patient a service if I don't call what's happening what it is and I can do that in a respectful manner and in a manner sensitive and that's my obligation as a surgeon to do so, but I don't help them if I ignore the process. And by not calling it as such, I think it creates a lot of confusion in terms of diagnosis.

Q So your view is that some transgender people have a level of dysphoria that is low enough that it's comparable to the displeasure that a cisgender person might have with their physical body?

A Not only me, but it's even observed in this month's Clinics; that, really, that's actually going to be an issue in the future with insurances because there are people who are really not even dysphoric but are seeking these surgeries and now

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what do we do?

Q But you agree that there are at least some transgender people who have dysphoria that is much more severe so that it qualifies, in your view, as rising to the level of a mental disorder, is that right?

A It appears to me to be much more severe than dysphoria.

Q And you agree that that set of people are not comparable to a cisgender person who wants surgery because they're uncomfortable with their body?

A I don't see the degree of distress in that patient population, no, sir.

Q Just want to make sure that the -- I think I understand what you're saying, but you're saying you don't see -- when you said that you don't see that degree of distress in the patient population, you were referring to cisgender women, right?

A Correct. And so, that's part of the illustration in Point 19. That, to me, further underscores, from a state perspective, if what we're talking about is dysphoria, I don't know how we would expect the state to pay for -- or a third party to pay or cover a procedure if what we're

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talking about is a real disorder. That's, perhaps, a valid point, if the other criteria that we discussed about, at least to my opinion, are satisfied. Obviously, based on Point 20, Dr. Schecter does not believe the definition of reconstructive and cosmetic surgery. He does not ascribe to that definition of surgery that I do, that I stated earlier. I made no statement in Point 24, whatsoever, regarding the frequency of regret. My only point is to illustrate it does occur. And I did not raise it as such as a statement, gender reassignment surgery should not be performed because there is a large percentage of regret, it's just for consideration, a candid point for consideration. We discussed the Point No. 25. And I do understand Dr. Schecter's -- and how he would perceive that. That's not my point in illustrating that. It's just a casual observation in the sense that I stated earlier. And Point 26, the research, which is research as well as my own clinical expertise, I would say that based on the volume of his practice he does have considerable expertise, show that surgical procedures for gender dysphoria are safe and effective. I would argue that there are so many procedures. Are we talking were trans men, trans

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women, what -- that's a very broad statement. I don't know of any other procedure that I would offer reproducibly knowing that the complication rate of something is 40 percent and call that safe.

Q Well --

A I would say it's a procedure fraught with complications and, in fact, one of -- one of our colleagues notes that. Even going so far as to describe a procedure like phalloplasty is a hydra with multiple tentacles of potential pitfalls, so --

Q Let's confine the statement in this paragraph to vaginoplasty and chest surgery.

MR. JOHNSON: Excuse me, paragraph what?

MR. BLOCK: 26.

MR. JOHNSON: 26?

MR. BLOCK: Yes.

A I think it would be better to say "can be executed safely and effectively." They are not, by default, safe and effective. If they were, we wouldn't be talking about fellowships for them.

Q (By Mr. Block) But they can be executed safely and effectively?

A In the hands of people like Dr. Schecter, yes, sir, I would presume, again, I haven't seen his own personal literature, but I would presume that,

given his practice, that he finds the same to be true. I don't know what he's referencing when he describes the medical community. I'm not sure what he's talking about with these analogous procedures. Presumably any such procedure like mastectomy for a cis woman, to the point that I made earlier, I'm not sure that just because we can execute it safely doesn't mean we necessarily should.

Q Do you agree that the surgical techniques used for these surgeries are adapted from surgical techniques that are performed on cisgender patients?

A Some, not all. For instance, vaginoplasty with penile inversion is truly novel. Very creative, I might add. And just like a plastic surgeon to come up with. I disagree with Dr. Schecter's statement in Point 28, no matter what the ascribed gender of the patient; assigned, perceived, otherwise, there's still the reality of biology and if ignore that we do that to the peril of the patient and to the peril of the medical record. I don't understand Dr. Schecter's use of a subcutaneous mastectomy unless he's performing it for a female patient. That code is, by default, performed for a female patient. The code that was submitted for this case was that for gynecomastia

and, Josh, those are two very different things. Very, very different. And that's something that, no matter what side of this coin a person is on, we all recognize that there's certain principles you have to acknowledge the IMF. You have to acknowledge the blood supply to the nipple. You have to be aware of the fact that the female nipple is going to be wide and effaced in most cases at this point in a women's life, so I don't -- I think candor is vital, whatever we do and decide, I think we've got to be candid about are we doing a mastectomy, which is the code Dr. Schecter would assign, versus the code that was utilized in this case, which was --

Q So the code Dr. Schecter would assign is consistent with your view of what the proper code would be?

A Yes, sir. Yes, sir. And my apologies if I wasn't clear on that. The code that I understand was used in the case was not this code.

Q Understood.

A And it was not -- it was presented as gynecomastia, not as the reality of a natal female breast. Irrespective of where you come down on the argument, the pathologist needs to know that when he or she gets the specimen, because a woman who's

obese at 53 of age, you're going to be much more concerned about an occult breast cancer in that than if you're getting a little bit of gynecomastia. Much, much different scenario.

Q In your practice, have you ever submitted authorization requests for a procedure and used the wrong code by accident?

A I would imagine I have, but I never ascribed a letter that ascribes a condition and, based on my interpretation of the language used in the letter seeking approval. There's a big difference in gynecomastia refractory to weight loss and natal female breasts. I don't perceive Dr. Schecter would make that comment in any of his cases. In Section 29, looking specifically at complication rates from chest surgeries. Two recent studies reveal a complication rate among transgender men between 11 and 12 percent in comparison to the complication rate of 43 percent for cisgender women undergoing breast reduction in a 2005 surgery -- or study, excuse me. To the point that I just made, the female breast is different, is a different construct altogether, the biological female breast. And Dr. Schecter, in his discussion here, doesn't go on to reveal what -- we can say major complications,

moderate complications. I, at this point, have not read this study to know, and No. 5, analysis of breast reduction complications, but it is -- a breast reduction is not the same surgery at all to that of a mastectomy, subcutaneous mastectomy. If I'm understanding the patient population, are we talking about transgender men meaning natal females who are transitioning to men?

Q Yeah, if you look at Footnote 4, female to male transgender chest reconstruction, so these are natal females having chest surgery.

A To answer this more intelligently, I would have to see what is the age. For instance, even in cis women, we notice a -- once a woman gets past the age of 45, her risk of wound healing complications, infection, tends to go up considerably. We think that's likely tied to hormonal-related changes in the breast parenchyma. At that station of life more women may begin to experience menopause. And we, in light fashion, speculate that some of that change is due to change in vascularity of the breast, again, I'd have to look more in depth at that. Those are my comments.

MR. BLOCK: Thank you. Just give me a moment. So we can go off the record.

EXHIBIT

B

STATE OF INDIANA

IN THE MARION SUPERIOR COURT 3

COUNTY OF MARION

CAUSE NO. 49D03-1709-MI-034611

S.K.J. and L.H.,
Petitioners/Plaintiffs,

vs.

JENNIFER WALTHALL et al.,
Respondents/Defendants.

FILED
November 9, 2018
Myla A. Eldridge
CLERK OF THE COURT
MARION COUNTY
ND

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

Comes now, Gary L. Miller, Judge of the Marion Superior Court, Civil Division, Room 3, and having set this matter for a hearing on consolidated cases of two separate actions for judicial review of the denials by the Indiana Family and Social Services Administration ("FSSA") of Petitioners' requests for Medicaid prior authorization for surgery. Arguments were made before the Court on September 26, 2018 where all parties appeared by counsel. The Court, having heard the arguments and reviewed the submissions of counsel now finds as follows:

1. This is a consolidated case of two separate actions for judicial review of the denials by the Indiana Family and Social Services Administration ("FSSA") of Petitioners' respective requests for Medicaid prior authorization for bilateral mastectomy and breast nipple reconstructive surgery for the treatment of their gender dysphoria diagnoses.

2. At all times since June 11, 2015, Petitioner S.K.J. (hereinafter "SKJ") received and continues to receive Medicaid coverage as a disabled adult receiving Supplemental Security Income through the Hoosier Care Connect

managed care health plan administered by FSSA and provided through a managed care organization ("MCO"), Anthem.

3. At all times relevant to these proceedings, SKJ is a "categorically needy" Medicaid recipient as defined by 42 C.F.R. § 435.4.

4. At all times since February 1, 2015, Petitioner L.H. (hereinafter referred to as "LH") received and continues to receive Medicaid coverage as an eligible Medicaid Expansion recipient under 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII) through the Healthy Indiana Plan (HIP) 2.0 managed care plan administered by FSSA and provided through a MCO, Anthem.

5. At all times relevant to these proceedings, LH is a "categorically needy" Medicaid recipient as defined by 42 C.F.R. § 435.4.

6. Jennifer Walthall (hereinafter referred to as "Walthall") is the Secretary of FSSA and is charged with administering the Indiana Medicaid program under 42 U.S.C. § 1396 et seq. pursuant to Indiana Code § 12-15-1-1.

7. Walthall is the ultimate authority for the Indiana Medicaid program pursuant to Indiana Code § 12-8-6.5-6.

8. On September 15, 2016, Dr. Sidhbh Gallagher, (hereinafter referred to as "Gallagher") the treating surgeon for both Petitioners, submitted individual prior authorization requests to Anthem on behalf of both petitioners requesting Medicaid coverage for bilateral mastectomy and breast nipple reconstructive surgery for treatment of the Petitioners' gender dysphoria symptoms, with a requested surgery date of October 1, 2016.

9. Breast Plastic and Reconstructive Surgery is a covered service under the Indiana Medicaid Plan.

10. On September 21 and 22, 2016, Anthem issued identical denials to petitioners, stating the procedures were "Not Medically Necessary" because "[s]urgery (for gender dysphoria) is not a covered benefit."

11. Following Petitioners' requests for review of the denials, Anthem upheld both denials on identical basis that the requested procedures are "not a covered benefit" and that "[s]urgery (for gender dysphoria) is not a covered benefit," making no reference to the medical necessity of the procedures.

12. Petitioners timely requested state fair hearings with FSSA to appeal the prior authorization denials.

13. A State Fair Hearing on SKJ's appeal was conducted by FSSA Administrative Law Judge Renitra Moore-Marion on June 5, 2017. SKJ appeared at the hearing represented by counsel, and representatives for Anthem also appeared. FSSA did not appear.

14. At the hearing, SKJ testified that without treatment of bilateral mastectomy and breast nipple reconstructive surgery, he struggles to meet his daily needs. He struggles to leave the house, he has others grocery shop and run errands for him, he cannot view himself in the mirror, and he continuously lays on his stomach to try and reduce his awareness of his chest. I

15. SKJ has difficulty speaking about or looking at his chest. In attempts to compress his chest, SKJ experiences pain and overheating. Talking about his chest makes SKJ distraught.

16. SKJ avoids discussing the topic with his therapist because past discussion about his chest with his therapist caused an increase in gender dysphoria symptoms. SKJ also testified that bathing is extremely difficult and that he previously went a month without showering because the sight of his chest exacerbates his gender dysphoria symptoms. SKJ has nightmares about his chest and dreams of cutting his breasts off himself. Since receiving the prior authorization denial SKJ's gender dysphoria symptoms currently overwhelm his life, and that he is impaired in performing self-care and activities of daily living like shopping independently and interacting with others.

17. SKJ identified 405 I.A.C. § 5-2-17 as the state Medicaid definition of "medically necessary services" applicable to his prior authorization request that was denied by FSSA.

18. For traditional Medicaid recipients, including Hoosier Care Connect, "medically necessary services" are defined as:

> a covered service (as defined in section 6 of this rule) that is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice. For a service to be reimbursable by the office, it must:
>
> (1) be medically necessary, as determined by the office, which shall, in making that determination, utilize generally accepted standards of medical or professional practice; and
>
> (2) not be listed in this title as a noncovered service, or otherwise excluded from coverage.

19. SKJ identified the Diagnostic Statistics Manual (DSM) and the International Classification of Diseases (ICD) as the generally accepted medical

practice standards for diagnosing medical and mental health conditions, both of which set forth specific diagnostic criteria for gender dysphoria.

20. SKJ identified the World Professional Association for Transgender Health (WPATH) Standards of Care as the generally accepted medical practice standards for treatment of gender dysphoria, which sets for the specific criteria for finding that surgery treatment is medically necessary.

21. The WPATH Standards of Care are recognized as authoritative standards of care by the American Medical Association, the American Psychiatric Association, and the American Psychological Association.

22. At SKJ's hearing, Anthem's representative conceded that Anthem "did not reach medical necessity determination" on SKJ's prior authorization request because the requested services are "not a covered benefit to begin with."

23. In its memorandum submitted following SKJ's hearing, Anthem asserted that its finding that the requested services were not covered services under Indiana Medicaid was "specifically . . . based upon the IHCP Policy Module (version 2.7, effective April 2017), program module Breast Plastic and Reconstructive Surgery, which indicates IHCP reimbursement is not available for breast reconstruction 'for conditions not related to congenital defects, developmental anomalies, trauma, infection, tumors, or disease' which aligns with 405 IAC 5-29-1 Noncovered services, which states that 'The following services are not covered by Medicaid . . . (21) Reconstructive or plastic surgery unless related to disease or trauma deformity.'"

24. The agency record is devoid of any accepted medical standards demonstrating that gender dysphoria is not a condition "related to congenital defects, developmental anomalies, trauma, infection, tumors, or disease" or that gender dysphoria is not a "disease" as that term is used in 405 I.A.C. § 5-29-1.

25. A State Fair Hearing on LH's appeal was conducted by FSSA Administrative Law Judge Jessica Manis on June 21, 2017. LH appeared in person represented by counsel, and representatives for Anthem also appeared. FSSA did not appear.

26. At the hearing, LH testified that his gender dysphoria manifests with heightened depression, anxiety, and high blood pressure. He testified that his gender dysphoria and the presence of his large breasts cause an increase in his depression. As a result of his depression he secludes himself or covers his body in a way that causes overheating when he goes in public. His depression and seclusion negatively impact his relationship with his child, co-workers, and clients. Prior to receiving treatment for gender dysphoria he would cut himself when experiencing depression. Denial of this treatment has caused LH anxiety and high blood pressure, for which he takes medication. To mitigate his gender dysphoria symptoms LH often wears a chest binder to flatten his breasts in order to reduce his gender dysphoria symptoms, despite his awareness of the medical risk of breast binding which include causing physical deformities in one's chest. Additionally, due to the presence of his large breasts, LH fears that he physically appears female and that others will perceive him as transgender, which he perceives to increases his risk of experiencing discrimination or physical assault.

27. LH's treating surgeon, Dr. Gallagher, testified at L.H.'s state fair hearing. Gallagher testified that she has received extensive training in the surgical treatment of gender dysphoria; she has travelled across the United States, and internationally to Belgium, Australia, and Serbia to train with experts in these treatments. She further testified that the medical necessity of gender confirmation surgeries to treat gender dysphoria is well established, citing to the WPATH Standards of Care, and that gender dysphoria is recognized as a serious medical condition associated with significant suicidality. Gallagher pointed to WPATH's extensive research showing that gender transition, including reconstructive surgery treatment to masculine or feminize the individual patient's body and face, is the only effective treatment for gender dysphoria.

28. Gallagher distinguished between a transgender identity or gender nonconformity, which she stated are not necessarily pathological conditions, and gender dysphoria, which is the clinically significant distress that may be associated with the incongruence between a person's experienced sex and their sex assigned at birth, which "most certainly is a disease." Gallagher described in detail the procedures her practice follows to assure that patients have an accurate diagnosis of gender dysphoria and that gender confirmation surgery is medically necessary for the individual patient.

29. Gallagher gave her professional opinion that LH meets the medical necessity requirements for the requested breast reconstructive surgery procedures pursuant to the WPATH Standards of Care.

30. LH identified 405 I.A.C. § 10-2-1(31) as the state Medicaid definition of "Medically necessary services" applicable to his prior authorization request that was denied by FSSA. Pursuant to that regulation, for HIP 2.0 recipients, "medically necessary service" is defined as:

> a covered service that, in a manner consistent with accepted standards of medical practice, is reasonably expected to:
>
> (A) prevent or diagnose the onset of:
>
> (i) an illness;
>
> (ii) an injury;
>
> (iii) a condition;
>
> (iv) a primary disability; or
>
> (v) a secondary disability;
>
> (B) cure, correct, reduce, or ameliorate the:
>
> (i) physical;
>
> (ii) mental;
>
> (iii) cognitive; or
>
> (iv) developmental;
>
> effects of an illness, an injury, or a disability; or
>
> (C) reduce or ameliorate the pain or suffering caused by:
>
> (i) an illness;
>
> (ii) an injury;
>
> (iii) a condition; or
>
> (iv) a disability.

31. LH and Gallagher identified the DSM and the ICD as the generally accepted medical practice standards for diagnosing medical and mental health conditions, both of which set forth specific diagnostic criteria for gender dysphoria.

32. LH and Gallagher, identified the WPATH Standards of Care as the generally accepted medical practice standards for treatment of gender dysphoria, which sets for the specific criteria for finding surgery treatment medically necessary.

33. At LH's hearing, Anthem's representative conceded Anthem "did not address this from a medical-necessity perspective, because we don't even get to medical necessity if it's not a covered benefit under the state benefit design."

34. In its memorandum submitted following LH's hearing, Anthem asserted that its finding that the requested services were not a covered service under Indiana Medicaid was "based upon the IHCP Policy Manual, program module Breast Plastic and Reconstructive Surgery, which indicates IHCP reimbursement is not available for breast reconstruction 'for conditions not related to congenital defects, developmental anomalies, trauma, infection, tumors, or disease' which aligns with 405 IAC 5-29-1 Noncovered services, which states that 'The following services are not covered by Medicaid . . . (21) Reconstructive or plastic surgery unless related to disease or trauma deformity.'"

35. The LH agency record is devoid of any accepted medical standards demonstrating that gender dysphoria is not a condition "related to congenital defects, developmental anomalies, trauma, infection, tumors, or disease" or that gender dysphoria is not a "disease" as that term is used in 405 I.A.C. § 5-29-1.

36. "Disease" as used in 405 I.A.C. § 5-29-1 is not defined in state law.

37. Under both regulations defining "medically necessary services" applicable to the Petitioners' respective prior authorization requests, consideration of

medical necessity must be consistent with the "accepted standards of medical practice."

38. Gender dysphoria is a medical condition generally recognized by the medical community and for which specific diagnostic criteria are generally accepted by the medical community, described in both the DSM and ICD.

39. The DSM and the ICD are the generally accepted standards for the diagnosis of medical and mental health conditions used by health care professionals in the United States.

40. Both SKJ and LH meet the diagnostic criteria for gender dysphoria as set forth in the DSM-V and the ICD-10.

41. The generally accepted standards of medical treatment for gender dysphoria are those published by the World Professional Association for Transgender Health (WPATH).

42. The WPATH Standards of Care indicate surgery for the treatment of gender dysphoria – including bilateral mastectomy and breast nipple reconstructive surgery for men – is medically necessary for many individuals to alleviate their gender dysphoria symptoms.

43. The current edition of the WPATH Standards of Care indicate that bilateral mastectomy and breast nipple reconstructive surgery for the treatment of gender dysphoria is considered medically necessary when the following criteria are met:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);

4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

44. FSSA and its MCO did not consider whether the services requested by Petitioners are medically necessary as defined by the applicable Indiana Medicaid regulations and accepted standards of medical practice.

45. FSSA and its MCO declined to consider whether the services requested by Petitioners are medically necessary as defined by state law based solely on the condition for which Petitioners seek treatment.

46. The substantial evidence establishes that bilateral mastectomy and breast nipple reconstructive surgery is medically necessary for both SKJ and LH for the treatment of their gender dysphoria, consistent with the generally accepted standards of medical practice for the treatment of gender dysphoria, in accordance with the relevant Indiana Medicaid regulatory definitions of "medically necessary services" applicable to each petitioner.

47. Both LH and SKJ testified that their gender dysphoria symptoms cause them to experience impairments in their activities of daily living due to physical and mental effects of the condition, as well as pain and suffering. The generally accepted standards of medical practice for the treatment of gender dysphoria indicate that bilateral mastectomy and breast nipple reconstructive surgery are medically necessary and appropriate treatments required for the well-being of patients with gender dysphoria for the purpose of reducing or ameliorating their gender dysphoria symptoms. Both petitioners experience persistent gender dysphoria, have attained the age of majority, have the capacity to make fully

informed decisions, and are not experiencing significant medical or mental health concerns beyond their gender dysphoria which are not reasonably controlled.

48. FSSA's interpretation of its regulations and medical policy to exclude reconstructive surgery services for the treatment of gender dysphoria, even in cases when the services are medical necessity in accordance with generally accepted standards of medical practice, reduces the amount, duration, and scope of a required services to Petitioners solely because of the condition for which they seek treatment.

49. By operation of its actions during the agency proceedings, FSSA categorically excluded reconstructive surgery services for the treatment of gender dysphoria.

50. By failing to consider the medical necessity of the services requested by Petitioners, FSSA has unlawfully delayed or withheld agency approval of the Petitioners' prior authorization requests.

CONCLUSIONS OF LAW

1. This court has jurisdiction over the Petitioners' requests for judicial review pursuant to Indiana Code § 4-21.5-5.

2. The court shall grant relief to Petitioners if Petitioners were prejudiced by agency action that is invalid because it is:

(1) Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(2) Contrary to constitutional right, power, privilege, or immunity;

(3) In excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(4) Without observance of procedure required by law; or

(5) Unsupported by substantial evidence.

3. The burden of demonstrating the invalidity of agency action is on the party to the judicial review proceeding asserting the invalidity. Indiana Code § 4-21.5-5-14(a).

4. The court reviews the agency's determinations in the light most favorable to the administrative action and may not reweigh the evidence or attempt to reassess the credibility of the witnesses.

5. While the court must give broad deference to the agency's fact-finding, the court is not bound by the agency's interpretations of law, and the court is free to determine any legal question which arises out of an administrative action.

6. Whether the State Medicaid agency is permitted to exclude a requested treatment from Medicaid coverage is a question of statutory and regulatory interpretation, and therefore a question of law reserved for the court.

7. While an agency's interpretations of the statutes and regulations that it is charged to enforce are given deference by the courts, courts owe no deference to agency interpretations that are inconsistent with the law.

8. Medicaid is a joint program between the federal and state government. The Medicaid program is administered by the state, according to federal requirements. Medicaid was established in Federal law at Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (the "Medicaid Act"). Medicaid is codified in Indiana at Indiana Code § 12-15.

9. The central purpose of the Medicaid Act is to enable each state, as far as practicable under the conditions in such State, to furnish medical assistance to

those whose income and resources are insufficient to meet the costs of necessary medical services.

10. To receive federal funding, the states must comply with the federal Medicaid statutes and regulations.

11. Every Medicaid recipient is guaranteed a minimum set of benefits, known as "mandatory" benefits which the state Medicaid plan must cover.

12. Mandatory benefits which all Medicaid state plans must provide to Medicaid recipients are inpatient hospital services, outpatient hospital services, laboratory and X-ray services, nursing facility services, diagnostic and family planning services, and physician services (including nurse-midwife and nurse practitioner services).

13. Physician services are service performed by a physician as permitted by state law. In the state of Indiana, physician's services for which Medicaid coverage must be provided to all recipients includes the performance of any kind of surgical operation on a human being.

14. Reconstructive surgery services, like those requested by SKJ and LH, are mandatory benefits in the Indiana Medicaid plan and are therefore must be covered services in all cases of medical necessity.

15. The state Medicaid plan is required to cover all medically necessary services in mandatory benefit categories and in optional benefit categories for which the state Medicaid plan opts to offer coverage.

16. Federal Medicaid regulations prohibit a state Medicaid agency from arbitrarily denying or reducing the amount, duration, or scope of a required

service to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.

17. If medically necessary treatments are excluded, the coverage is not sufficient in amount, duration and scope to fulfill the purpose of providing the service.

18. Absent a federal definition of medical necessity, the responsibility for defining medical necessity is left to the states. As long as the definition comports with the purpose of the Medicaid Act and the regulatory requirement that coverage be sufficient in amount, duration and scope, each state is free to define medical necessity as broadly or as narrowly as required to fulfill the state's policy goals; and each state may define medical necessity in a manner that is, to use the statutory language, 'practicable' for that state.

19. The Indiana Court of Appeals laid out a three-part test for challenges to state Medicaid exclusions of services from Medicaid coverage. The individual challenging the exclusion must:

(1) identify the State definition of medical necessity applicable to the challenged exclusion; and

(2) prove that the excluded equipment or treatment is medically necessary as defined by the State" or

(3) "[i]n the alternative, an individual could obtain coverage of excluded equipment or treatment by proving that the State definition of medical necessity is invalid according to State or federal law.

Davis v. Schrader, 687 N.E.2d 370, (Ind. Ct. App. 1997).

20. If the individual proves that the equipment or treatment is medically necessary according to the State definition, the regulatory exclusion is invalid and the State Medicaid program must cover the equipment or treatment.

21. SKJ established that the excluded treatment of bilateral mastectomy and breast nipple reconstructive surgery is medically necessary according to the state definition of "medically necessary services" set forth at 405 I.A.C. § 5-2-17.

22. SKJ also established that the FSSA's categorical exclusion of reconstructive surgery services for the treatment of gender dysphoria is invalid according to federal law, as it violates the Availability and Comparability requirements of the Medicaid Act.

23. LH established that the excluded treatment of bilateral mastectomy and breast nipple reconstructive surgery is medically necessary according to the state definition of "medically necessary services" set forth at 405 I.A.C § 10-2-1(31).

24. LH also established that FSSA's categorical exclusion of reconstructive surgery for the treatment of gender dysphoria is invalid according to federal law, as it violates the Availability and Comparability requirements of the Medicaid Act.

25. SKJ and LH were prejudiced by the agency actions in these cases because:

a. The failure by FSSA and its manage care entity, Anthem, to consider whether the services requested by the Petitioners are medically necessary as defined by state law was an abuse of discretion and a clear procedural error which denied the petitioners their due process rights.

b. FSSA's determination that the requested surgeries are not medically necessary is arbitrary and capricious because those determinations lack a basis by which a reasonable person would reach the

same conclusion and are without consideration and in disregard of the facts and circumstances of the case.

c. Respondents' assertion that FSSA has discretion to deny coverage for services that meet the states medically necessary services definition based solely on the medical condition that will be treated by the services, so long as the Indiana Medicaid plan provides the same services to other Medicaid recipients with other diagnoses, is not in accordance with the law.

d. Respondents' denial of the Petitioners' prior authorization requests was based solely on the condition to be treated in violation of the Medicaid Act's Availability and Comparability requirements.

26. FSSA's failure to consider whether the services requested by Petitioners' prior authorization requests are medically necessary, in violation of 405 I.A.C. § 5-3-11 in regard to SKJ's request and in violation of 405 I.A.C. § 10-2-1(44) in regard to LH's request, unreasonably delayed and unlawfully withheld agency action required by state law. This Court may "set aside an agency action and compel agency action that has been unreasonably delayed or unlawfully withheld." Indiana Code § 4-21.5-5-15.

27. No further development of the record is required to determine whether the services requested by SKJ and LH's prior authorization requests are medically necessary, and remand without instruction would serve no purpose but to allow FSSA to further delay approving the Petitioners' prior authorization requests.

For the foregoing reasons, this Court finds that the agency actions at issue were arbitrary and capricious, an abuse of discretion, contrary to law, without observance of procedures required by law, and unsupported by the substantial evidence produced in the agency proceedings.

This Court further finds that the agency's denials of SKJ and LH's prior authorization requests was for no other purpose than to unlawfully withhold Medicaid treatment from SKJ and LH based solely on the condition for which they sought treatment.

IT IS THEREFORE ORDERED, ADJUDGED, AND DECREED that the decisions by the Indiana Family and Social Services Administration and affirmed by Respondent Walthall are hereby vacated. SKJ and LH's respective judicial review claims are remanded to FSSA with instruction that FSSA review the medical necessity of the requests and approve the requests in accordance with state and federal law based on the agency records as they are currently developed.

All of which is ORDERED on this the 8th day of November, 2018.

Gary L. Miller
Judge

cc: counsel of record