IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al., *Plaintiffs*, v. DALE FOLWELL, et al., *Defendants*.	No. 1:19-cv-00272-LCB-LPA

REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

ARGUMENT[1]

I. There Are No Material Facts Genuinely in Dispute.

Plan Defendants argue the Court "may not resolve [Plaintiffs'] claims" because "[t]he parties fundamentally disagree on critical facts." ECF 197 at 4. But Defendants fail to identify *genuinely* disputed *material* facts.

The party opposing summary judgment "must demonstrate specific, material facts exist that give rise to a genuine issue." *Wai Man Tom v. Hosp. Ventures LLC*, 980 F.3d 1027, 1037 (4th Cir. 2020). "[D]isputed facts must be material to an issue necessary for the proper resolution of the case, and the quality and quantity of the evidence offered to create a question of fact must be adequate to support a jury verdict." *Thompson Everett, Inc. v. Nat'l Cable Advert., L.P.*, 57 F.3d 1317, 1323 (4th Cir. 1995). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Wai Man Tom*, 980 F.3d at 1037 (cleaned up).

A. The law of this circuit recognizes gender-affirming care as medically necessary and effective, and all major medical organizations agree.

Plan Defendants' dispute about the efficacy of medical treatments for gender dysphoria is neither genuine, nor material.

[1] References to "Reply Ex." refer to exhibits to the Third Supplemental Declaration of Amy Richardson filed herewith. References to "Ex." refer to exhibits to the Declaration of Amy Richardson (Docs. 180-81).

Binding circuit precedent recognizes that the "WPATH Standards of Care … represent the consensus approach of the medical and mental health community," *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied*, 141 S.Ct. 2878 (2021), and that medical treatments for gender dysphoria "are safe, effective, and often medically necessary." *Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422, 428 (4th Cir. 2021), *as amended* (Dec. 2, 2021), *cert. denied sub nom. NC Health Plan v. Kadel*, 2022 WL 145183 (U.S. Jan. 18, 2022). And Defendants cannot dispute that all major medical organizations in the United States agree that gender-affirming care is medically necessary and effective. ECF 131-2; Ex. 29. Plaintiffs have presented a bevy of evidence to support this fact. ECF 179 at 14-17, 23-27.[2]

That Defendants proffered as "experts" some individuals who hold contrary and aberrant views does not negate this "consensus approach of the medical and mental health community." *Grimm*, 972 F.3d at 595. Indeed, the Court should disregard the opinions of these "experts" because they are so outside the mainstream, as well as unsupported by science, as set forth in Plaintiffs' concurrently-filed motions to exclude their testimony. And even if this so-called "expert" testimony met the *Daubert* admissibility standard (it does not), "the question remains whether the evidence creates a genuine issue of material

[2] Plan Defendants argue the Court should not consider Plaintiffs' evidence because of Plaintiffs' purported "extensive reliance" upon the WPATH Standards of Care and Endocrine Society's Guidelines. ECF 197 at 12-13. If Defendants intend to make a *Daubert* motion, they must do so separately. LR 7.3(a). Regardless, WPATH is not providing testimony in this case and the Fourth Circuit has recognized the "WPATH Standards of Care … as the authoritative standards of care." *Grimm*, 972 F.3d at 595.

fact." *Miller v. Mandrin Homes, Ltd*., 305 F.App'x 976, 979 (4th Cir. 2009). Defendants' disagreement with the Fourth Circuit and the overwhelming consensus among all major medical organizations does not create a genuine dispute of material fact. *See*, *e.g.*, *Alevromagiros v. Hechinger Co.*, 993 F.2d 417, 421 (4th Cir. 1993) (expert's subjective opinion does not preclude summary judgment because "we are unprepared to agree that it is so if an expert says it is so").

Finally, Defendants' purported concern about the efficacy of this care is an impermissible post-hoc rationale under heightened scrutiny, *see United States v. Virginia*, 518 U.S. 515, 516 (1996), particularly when the Plan covered this care in 2017 as medically necessary. ECF 179 at 9-13. And any justification for the Exclusion is irrelevant to Plaintiffs' statutory claims. *See Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991) ("Whether an employment practice involves disparate treatment through explicit facial discrimination does not depend on why the employer discriminates but rather on the explicit terms of the discrimination.").

B. The Exclusion facially and purposefully discriminates based on sex and transgender status.

Plan Defendants argue they are not obligated to provide coverage for gender-affirming care for gender dysphoria because "health plans are permitted to cover some illnesses and not others" and that Plaintiffs have purportedly "never defined or otherwise provided a concrete list of the procedures that comprise" gender-affirming care. ECF 197 at 14. The Court should disregard Defendants' feigned ignorance.

Defendants cannot credibly claim to be confused about the Exclusion, how to eliminate it, or how to cover this care. To the contrary, they know how to manage coverage without the Exclusion. ECF 179 at 9-13. Their third-party administrator, Blue Cross Blue Shield of North Carolina ("BCBSNC"), maintains a policy for such coverage, which was the policy the Plan used in 2017. Ex. 12, 41:25-42:15; Ex. 40, PLANDEF0012816; Ex. 43. And in 2016, Defendants instructed CVS/Caremark to provide coverage for Lupron (a puberty blocker) as treatment for gender dysphoria. Reply Ex. R1.

Plaintiffs do not seek an "order[] to provide undefined 'gender-confirming care,'" as Defendants claim. ECF 197 at 14. Plaintiffs only seek an order that enjoins the enforcement of a categorical exclusion prohibiting coverage of such care.[3] This Court can easily fashion the necessary injunctive relief.

[3] Defendants' "confusion" about what constitutes gender-affirming care is disingenuous and irrelevant. Gender-affirming care refers to care prescribed for the treatment of a person's gender dysphoria. *See* ECF 75 at ¶ 2; Ex. 23(a) at ¶ 34; Ex. 24(a) at ¶¶ 3, 22, 25-26; Ex. 25(a) at ¶¶ 38-48; Ex. 26(a) at ¶¶ 49-46. Defendants' "experts" understand this. Docs. 197-2 at ¶ 36 (speaking of "affirmation therapy model"); 197-3 at ¶ 52 (speaking of "affirming" approach); 197-5 at ¶ 11 (speaking of "affirmation treatments"). And BCBSNC's "Corporate Medical Policy," upon which Defendants have relied, ECF 179 at 12, notes "Gender affirmation surgery and hormone therapy may be considered medically necessary," Ex. 50. Defendants' confusion is also irrelevant because Plaintiffs do not need to establish a complete list of treatments for gender dysphoria when what they seek is to enjoin enforcement of categorical prohibitions of coverage for such care. "The Plan evaluates whether the billed medical procedure corresponds to a covered diagnosis." ECF 197 at 20. Defendants know how to do this regarding gender dysphoria.

C. Defendants cannot dispute Plaintiffs' gender dysphoria diagnoses.

Plan Defendants argue that Plaintiffs have not submitted any evidence to prove they have gender dysphoria. ECF 197 at 15. Not true. Plaintiffs have provided their own (unrebutted) testimony as to their gender dysphoria diagnoses, as well as submitted (unrebutted) expert testimony from Dr. Brown corroborating their gender dysphoria diagnoses. Docs. 179-1 ¶ 6; 179-2 ¶¶ 5,7; 179-4 ¶ 4; 179-5 ¶ 14; 179-6 ¶ 14; 179-7 ¶¶ 7,8; 179-9 ¶¶ 19,20; 185-1 (Brown Rep. ¶¶ 50−68; Supp. Brown Rep. ¶¶ 9-14); *see also* Fed. R. Evid. 803(4). Defendants have not provided even a scintilla of evidence to contradict these diagnoses. Their "conclusory allegations or denials, without more, are insufficient to preclude granting the summary judgment motion." *Wai Man Tom*, 980 F.3d at 1037.

Defendants argue that because Dr. Brown testified that he was not engaging in the provision of medical care (i.e., the practice of medicine) or establishing a doctor-patient relationship with Plaintiffs, he cannot testify as to his review of their medical records or his independent assessment of them to corroborate their gender dysphoria diagnoses. Defendants cite to no authority in support of this bizarre proposition. The fact that Dr. Brown did not provide medical treatment to Plaintiffs is no different than what any independent medical examiner or forensic medical expert does, and none of this creates a dispute of fact, let alone a material one.

II. Plaintiffs Are Entitled to Summary Judgment on Their Equal Protection Claim.[4]

A. Plaintiffs are similarly situated to cisgender plan enrollees.

"The similarly situated inquiry focuses on whether the plaintiffs are similarly situated to another group for purposes of the challenged government action." *Klinger v. Dep't of Corr.*, 31 F.3d 727, 731 (8th Cir. 1994); *see also Khaliq v. Angelone*, 72 F.App'x 895, 899 (4th Cir. 2003). Thus, it "depends on what government action the plaintiffs are challenging." *Klinger*, 31 F.3d at 731. It does not require plaintiffs to show that cisgender enrollees and transgender enrollees are "similar in all but the protected ways." *Young v. United Parcel Serv., Inc.*, 135 S.Ct. 1338, 1354 (2015).

Here, "Plaintiffs are being distinguished by governmental action from those whose gender identities are congruent with their assigned sex." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 285 (W.D. Pa. 2017). Cisgender enrollees can obtain coverage for their medically necessary care because the care is consistent with stereotypical notions surrounding their birth-assigned sex. Whereas transgender enrollees are denied coverage for their medically necessary care because the care diverges from stereotypical notions surrounding their birth-assigned sex (i.e., *because of their identity as transgender persons*).

In doing so, Defendants impermissibly "insist[] that [enrollees' anatomy] match[] the stereotype associated with their" birth-assigned sex, *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989), and impose stereotypical notions of how physical attributes and

[4] Defendants' arguments about cost are unfounded. *See* ECF 179 at 22-23.

gender identity ought to align. *See Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1030 (D. Alaska 2020); *Flack v. Wisconsin Dep't of Health Servs.*, 328 F.Supp.3d 931, 948 (W.D. Wis. 2018). Thus, coverage for medically necessary care is available if it is *consistent* with one's birth-assigned sex and is denied if it *diverges* from that birth-assigned sex. *See Bostock v. Clayton Cnty.*, 140 S.Ct. 1731, 1741-42 (2020).

Defendants note there are diagnoses beyond gender dysphoria for which care is also denied. But that is irrelevant where those exclusions do not discriminate based on sex and transgender status (and therefore are not subject to heightened scrutiny). Instructive here is *Boyden v. Conlin*, 341 F.Supp.3d 979 (W.D. Wis. 2018), in which the court rejected the same argument: "The fact that not all medically necessary procedures are covered, therefore, does not relieve defendants of their duty to ensure that the insurance coverage offered to state employees does not discriminate on the basis of sex or some other protected status." *Id.* at 1000 n.15.[5]

[5] The cases Defendants cite for the proposition that "[p]roviding different medical treatments for different medical diagnoses does not violate equal protection," Defs' Resp. 17, ECF No. 197, are inapposite. In *Gann v. Schramm*, "the Plaintiffs [] made no showing that Gann was a member of any 'identifiable group' singled out for different treatment under the laws." 606 F.Supp. 1442, 1447 (D. Del. 1985). Here, Plaintiffs are being singled out because of their sex and transgender status. And *McMain v. Peters*, 2018 WL 3732660 (D. Or. Aug. 2, 2018), and *Flaming v. Univ. of Texas Med. Branch*, 2016 WL 727941 (S.D. Tex. Feb. 24, 2016), both involve challenges by *pro se* incarcerated plaintiffs who alleged that they were being denied the same treatment as those diagnosed with a different condition. In both cases, the plaintiffs presented no evidence to support their bare assertions and the courts conducted a cursory analysis as to why the plaintiffs were not similarly situated. By contrast, this case involves the differential treatment of transgender enrollees vis-à-vis cisgender enrollees and Plaintiffs have presented a fulsome record.

Defendants' argument that "[t]he Plan's benefits, and limits on coverage, apply equally," ECF 197 at 28, also fails. This is reminiscent of the discredited argument that marriage bans for same-sex couples did not discriminate because gays and lesbians could still marry someone of a different sex. *See*, *e.g.*, *Perry v. Schwarzenegger*, 704 F.Supp.2d 921, 969 (N.D. Cal. 2010); *Varnum v. Brien*, 763 N.W.2d 862, 885 (Iowa 2009). Indeed, "[t]he proper focus … is the group for whom the law is a restriction, not the group for whom the law is irrelevant." *City of Los Angeles v. Patel*, 135 S.Ct. 2443, 2451 (2015) (citation omitted). Here, only transgender enrollees are being denied coverage for treatments otherwise covered when medically necessary, as only transgender people would ever seek gender-affirming care.

Defendants argue that Plaintiffs qualify for hormone suppressing drugs "on the exact same basis as every other Plan participant." ECF 197 at 21. Not true. CVS/Caremark guidelines show that but for the Exclusion, puberty blocking or hormone suppressing medications would be covered as treatment for gender dysphoria. *See*, *e.g.*, Reply Exs. R3 (Triptodur); R4 (Supprelin); R5 (Eligard); R6 (Trelstar); R7 (Vantas). Indeed, Defendants intervened to stop coverage that otherwise would be provided specifically because it is for the treatment of gender dysphoria and relates to gender transition. Reply Ex. R2 (instructing CVS/Caremark to deny coverage for Lupron (a puberty blocker) as treatment for gender dysphoria).

Finally, Defendants' argument that Plaintiffs cannot be similarly situated because gender-affirming care, like all medical care, is tailored to the needs of a particular patient

holds no water. That is true of *all* medical care and does not affect the similarly situated analysis. ECF 197 at 18-19. Here, cisgender enrollees can make individualized showings that their care is medically necessary, and be covered by the Plan, but transgender enrollees are categorically precluded from doing so because the Exclusion targets them for differential treatment.[6]

B. The Exclusion facially discriminates based on sex and transgender status.

Relying primarily on *Geduldig v. Aiello*, 417 U.S. 484 (1974), Defendants contend the Exclusion does not facially discriminate. This is wrong.

First, unlike the policy in *Geduldig*, the Exclusion explicitly classifies based on sex as it prohibits coverage for "*gender* transformation" and "*sex* changes." Exs. 8-9; *see Fletcher*, 443 F.Supp.3d at 1027, 1030; *see also Whitaker v. Kenosha Unified Sch. Dist. No.1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017). Every person to whom the Exclusion applies—i.e., those seeking coverage for "gender transformation" or "sex changes"—is therefore discriminated against because of sex.

Second, *Geduldig* only held that an exclusion of pregnancy from a disability benefits program with no showing of "pretext" is not per se "invidious discrimination against the members of one sex." 417 U.S. at 496 n.20. But "[s]ome activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in

[6] The Court should disregard Defendants' deflection toward billing practices and away from the Exclusion that controls those billing and coding practices. *See* Part I.B, *supra*.

exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Thus, even under *Geduldig*, "the pregnancy line" may be a sex-discrimination line even if not all women are affected so long as "discrimination has occurred." *deLaurier v. San Diego Unified Sch. Dist.*, 588 F.2d 674, 677 (9th Cir. 1978).[7] Here, the Exclusion was specifically designed to categorically exclude gender-affirming care from coverage—care "which is only sought by transgender individuals." *Brandt v. Rutledge*, 2021 WL 3292057, at *2 (E.D. Ark. Aug. 2, 2021); *see also* ECF 197-16. That is precisely what *Geduldig* and *Bray* prohibit: a pretextual classification designed to effectuate discrimination.[8]

Third, the centrality of gender transition to transgender identity distinguishes this case from *Geduldig*. Unlike the pregnancy exclusion in *Geduldig*, the Exclusion here is based on a characteristic that defines membership in the excluded group. Pregnancy is not the defining characteristic of a woman. Living in accord with one's gender identity rather

[7] *Geduldig* predates the Supreme Court's modern equal protection jurisprudence and has not been cited by a majority opinion in an equal protection case since the mid-70s. *See* Reva B. Siegel, *The Pregnant Citizen, from Suffrage to the Present*, 19th Amend. Ed. Geo. L.J. 167, 208 n.229 (2020).

[8] Defendants make much of testimony by some of Plaintiffs' experts that not every transgender person has gender dysphoria, as diagnosed under the DSM-5. ECF 197 at 27. But Defendants ignore the context for this testimony (*see* Reply Ex. R8) and misrepresent its relevance. The undisputed evidence is that gender dysphoria, and therefore the treatment for it, are exclusive to transgender people. ECF 197-16. In any event, there is no rule that a discriminatory policy must affect every member of a particular group in order for it to be facially discriminatory and to trigger heightened scrutiny. *See Rice v. Cayetano*, 528 U.S. 495, 516-17 (2000); *Nyquist v. Mauclet*, 432 U.S. 1, 8 (1977).

than birth-assigned sex is the defining characteristic of a transgender person. *See*, *e.g.*, *Glenn v. Brumby*, 663 F.3d 1312, 1316 (11th Cir. 2011). Thus, when a "defendant discriminates against individuals on the basis of criteria that are almost exclusively indicators of membership in the disfavored group," the discrimination is treated as a facial classification. *Pac. Shores Props., LLC v. City of Newport Beach*, 730 F.3d 1142, 1160 n.23 (9th Cir. 2013).

Accordingly, multiple courts have found exclusions from coverage of gender-affirming care to facially discriminate based on sex and transgender status. That is because the Exclusion "singles out transgender individuals for different treatment" because "transgender individuals are the only people who would ever seek gender reassignment surgery." *Toomey v. Arizona*, No. 19-cv-00035, 2019 WL 7172144, at *6 (D. Ariz. Dec. 23, 2019); *see also Bear Creek Bible Church v. Equal Emp. Opportunity Comm'n*, 2021 WL 5449038, at *35 (N.D. Tex. Nov. 22, 2021) ("The employers' prohibition of surgery and hormone treatment would apply only to individuals with gender dysphoria, so on their face, the policies explicitly target transgender individuals."); *Fletcher*, 443 F.Supp.3d at 1027, 1030 (holding that exclusion prohibiting treatment "related to changing sex or sexual characteristic" is "facially discriminatory"); *Flack*, 328 F.Supp.3d at 950.[9]

[9] The Supreme Court has "declined to distinguish between status and conduct in this context." *Christian Legal Soc'y Chapter of the Univ. of California, Hastings Coll. of the Law v. Martinez*, 561 U.S. 661, 689 (2010); *Lawrence v. Texas*, 539 U.S. 558, 583 (2003) (O'Connor, J., concurring).

C. The Exclusion intentionally and purposely discriminates against transgender people.

Furthermore, the Equal Protection Clause prohibits classifying for "the purpose of disadvantaging the group burdened by the law." *Romer v. Evans*, 517 U.S. 620, 633 (1996). And while the Supreme Court has sometimes described this impermissible purpose as "animus" or a "bare … desire to harm a politically unpopular group," *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973), an impermissible motive does not require "malicious ill will." *Bd. of Trs. of Univ. of Alabama v. Garrett*, 531 U.S. 356, 374-75 (2001) (Kennedy, J., concurring). It can also take the form of "negative attitudes," "fear," "irrational prejudice," *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448, 450 (1985), or "some instinctive mechanism to guard against people who appear to be different in some respects from ourselves." *Garrett*, 531 U.S. at 374. That is exactly what the Exclusion does, which was reinstated with full knowledge and awareness that it only harmed transgender people.[10]

III. Plaintiffs Are Entitled to Summary Judgment on Their Statutory Claims Under Section 1557 and Title VII.

A. The Exclusion is a form sex discrimination prohibited by Section 1557.

For the reasons articulated in Plaintiffs' opening brief (ECF 179) and herein, the Exclusion discriminates based on sex in violation of Section 1557.

[10] In reinstating the Exclusion, Defendant Folwell explicitly referred to "sex change operations." Ex. 49.

Defendants rely on the preamble of a 2020 Rule by HHS[11] to argue that the Exclusion is necessary to prevent inappropriate interference with the ethical and medical judgment of health professionals. ECF 197 at 36. Nonsense. As Defendants admit, "[t]he Plan is not a doctor." *Id.* at 32. Yet, by enforcing the Exclusion, Defendants actively interfere with Plaintiffs' ability to obtain care that their providers have deemed medically necessary, in their ethical and medical judgment—care that, but for the Exclusion, would be covered. Section 1557 does not mandate the provision of particular care or coverage, nor is that at issue in this case; rather, Section 1557 instructs that when care or coverage is provided, it be done without discriminating based on sex. Section 1557 thus prohibits categorical exclusions that eliminate considered, patient-centric decision-making about whether a treatment is medically necessary for a particular patient. It is the Exclusion that interferes with medical judgment.

Defendants also cite the Rule's preamble in support of their contention that gender-affirming care is not effective. But none of the sources HHS cited therein refute that gender-affirming care generally is accepted within the medical community as medically necessary and effective to treat gender dysphoria. *See* 85 Fed. Reg. at 37,187 & nn.157, 159, 160. To the contrary, the Centers for Medicare & Medicaid Services have made clear there is "a consensus among researchers and mainstream medical organizations that transsexual

[11] The preamble's parts upon which Defendants rely pertain to the gender identity aspects of the Rule that have been enjoined by two courts. *See Walker v. Azar,* 480 F.Supp.3d 417, 430 (E.D.N.Y. 2020); *Whitman-Walker Clinic, Inc. v. HHS*, 485 F.Supp.3d 1, 64 (D.D.C. 2020).

surgery is an effective, safe and medically necessary treatment for transsexualism." *Decision - NCD 140.3, Transsexual Surgery*, Docket No. A-13-87, Decision No. 2576, at 20 (May 30, 2014), https://perma.cc/W6T9-WYEB.

B. The Exclusion violates Title VII.

1. NCSHP violates Title VII.

Plan Defendants assert that Sgt. Caraway "misunderstands the application of Title VII to fringe benefits." ECF 197 at 37. Their argument that employee health benefits are not "compensation" for purposes of a state statute is incorrect under binding Supreme Court precedent that, under Title VII, "[h]ealth insurance and other fringe benefits are 'compensation, terms, conditions, or privileges of employment.'" *Newport News Shipbuilding & Dry Dock Co. v. E.E.O.C.*, 462 U.S. 669, 682 (1983). And their argument analogizing to a litigant's position in *City of Los Angeles, Dep't of Water & Power v. Manhart*, 435 U.S. 702 (1978), is equally unavailing because, as discussed above, Plaintiffs are not arguing that the Plan needs to "pay for all of [their] treatments," but rather that it may not deny coverage because of their sex and transgender status. As in *Manhart*, the Exclusion "does not pass the simple test of whether the evidence shows 'treatment of a person in a manner which but for that person's sex would be different.'" 435 U.S. at 711; *see* 42 U.S.C. § 2000e-2(a)(1); ECF 179 at 29-30.

The claim that Sgt. Caraway's "health care payments 'are ultimately determined by' her *actual medical needs*; [and] 'any differential in benefits paid … in the aggregate is thus based on a factor other than sex,'" ECF 179 at 38-39, is brazenly false. As Defendants

admit, health care "payments [are] based on diagnosis and procedure code" and "[t]he Plan excludes coverage for specific procedures if they are prescribed for treatment of the psychiatric diagnosis of gender dysphoria." ECF 197 at 21, 25. In other words, the categorical Exclusion does not consider Sgt. Caraway's *actual* medical needs, *i.e.*, treatment for gender dysphoria, but instead prohibits all coverage regardless of medical need because she is transgender. *See Bostock*, 140 S.Ct. at 1754.

Plan Defendants do not directly address NCSHP's liability under Title VII as either an agent of or joint employer with DPS. As to agency, this Court already rejected Defendants' arguments as a matter of law when it permitted Plaintiffs to amend their Complaint. *See Kadel v. Folwell*, 2021 WL 848203, at *8 (M.D.N.C. Mar. 5, 2021). It should do so again. Likewise, state law delegates control over employee health coverage to the Plan, N.C. Gen. Stat. § 135-48.2(a), and the undisputed facts make clear the NCSHP functions as a joint employer for purposes of health coverage.

2. DPS violates Title VII.

DPS argues it does not discriminate under Title VII because it lacks the option to provide nondiscriminatory health coverage to its employees. ECF 196 at 2-4. However, the plain text of Title VII does not provide for the defense DPS seeks to assert, and the Supreme Court has rejected such an argument before. *See Arizona Governing Comm. for Tax Deferred Annuity & Deferred Comp. Plans v. Norris*, 463 U.S. 1073, 1089, 1090-91 (1983). Nor does Title VII provide for any defense to liability because an employer characterizes its actions in offering and providing discriminatory benefits as "ministerial."

DPS attempts to rely on *Lange v. Houston County*, 499 F.Supp.3d 1258, 1272 (M.D. Ga. 2020), and *Boyden v. Conlin*, 2018 WL 2191733 (W.D. Wis. May 11, 2018). But *Lange* and *Boyden* stand for the proposition that a government's creation of a separate agency to administer its employee benefit programs does not absolve it from its obligations under Title VII. 499 F.Supp.3d at 1272; 2018 WL 2191733 at *2. And unlike in *Boyden*, where the dismissed employer defendant allegedly had "no role" in the employee health plan, 2018 WL 2191733 at * 4, DPS concedes it plays a "necessary" role here. ECF 196 at 3. Although DPS characterizes its necessary role as "incidental" and "ancillary," such a defense, as with its "ministerial" one, finds no basis in Title VII's text. DPS does not, and indeed cannot, dispute that it is Sgt. Caraway's employer, that it provides her with health insurance under the Plan, or that the insurance is discriminatory. That is sufficient to establish DPS's liability.

Finally, DPS argues that it is not the principal in a principal-agency relationship with NCSHP. But DPS' liability is not dependent on whether it is a principal, but rather on whether it is an "employer," 42 U.S.C. 2000e-2(a), and DPS does not dispute that it is. Further, DPS does not contest that it is jointly and severally liable with NCSHP for their discrimination against Sgt. Caraway, because as "joint employers" they "share or co-determine … the essential terms and conditions of employment," *Butler v. Drive Auto. Indus. of Am., Inc.*, 793 F.3d 404, 408 (4th Cir. 2015); *see also Schultz v. Cap. Int'l Sec., Inc.*, 466 F.3d 298, 301, 310 (4th Cir. 2006). But DPS is also liable for NCSHP's actions

in administering the Plan as DPS's agent. *See*, *e.g.*, *Norris*, 463 U.S. at 1086-91; *Manhart*, 435 U.S. 702, n.33.

DPS's argument that it has not authorized NCSHP to be its agent is unconvincing. DPS expressly instructs NCSHP to cover its employees. Ex. 12, 118:6-17; *id.* at 88:22-89:3; Ex. 14, 16:7-22; *id.* at 28:3-29:8. And the case on which DPS relies, makes clear an "agent's apparent authority flow[s] from the principal's conduct." *Auvil v. Grafton Homes, Inc.*, 92 F.3d 226, 231 (4th Cir. 1996); *accord* Restatement (Third) of Agency § 1.03.[12] DPS's conduct also includes paying NCSHP $521.96 per month per employee for their participation, Ex. 7, Admis. 2; providing benefits information to employees so they can determine if they would like to join the Plan, Ex. 6, Interrog. 3(a); Ex. 12, 88:22-89:3; serving as employees' "first line of contact" about the Plan, Ex. 14, 24:11-13; and employing "Health Benefit Representatives" who work with the Plan. Ex. 14, 21:20-25. This is more than sufficient to demonstrate that NCSHP administers the Plan with DPS's assent.

C. Plaintiffs expressly reserved the question of damages for trial.

Plan Defendants argue that Plaintiffs have not made a showing for damages and therefore the Court cannot award summary judgment on their claims. ECF 197 at 37. Defendants ignore that Plaintiffs moved for "partial summary judgment on their statutory

[12] DPS' brief, at 6, incorrectly cites the Restatement.

claims, seeking declaratory and permanent injunctive relief," and "reserve[d] issues of damages … for trial." ECF 179 at 1.

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Respectfully submitted,

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* Appearing by special appearance pursuant to L.R. 83.1(d).

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) and the Court's January 27, 2022 Order (ECF 200) because the body of this brief, including headings and footnotes, does not exceed 4,625 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

/s/ Amy Richardson
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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: February 2, 2022

/s/ Amy Richardson
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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al., *Plaintiffs*, v. DALE FOLWELL, et al., *Defendants*.	No. 1:19-cv-00272-LCB-LPA

THIRD SUPPLEMENTAL DECLARATION OF AMY RICHARDSON

I, Amy Richardson, do hereby declare as follows:

1. I am more than 18 years of age, have personal knowledge of the facts set forth herein, and am otherwise competent to testify to the matters set forth herein.

2. I am a partner with Harris, Wiltshire & Grannis LLP, and counsel for Plaintiffs in this matter. I submit this declaration in support of Plaintiffs' Reply in Support of Plaintiffs' Motion for Summary Judgment.

3. Attached to this declaration are true and correct copies of the documents listed in the table below. Entries in the table indicate where documents have been excerpted or have had highlighting applied to indicate the relevant portions of the document.

Exhibit	Description
R1	CVS/Caremark "Specialty Guideline Management – North Carolina State Health Plan: Lupron Depot 3.75mg (leuprolide acetate for depot suspension) Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)," dated 2016, KADEL00130527
R2	CVS/Caremark "Specialty Guideline Management – North Carolina State Health Plan: Lupron Depot 3.75mg (leuprolide acetate for depot suspension) Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)," dated 2017, KADEL00265955
R3	CVS/Caremark "Specialty Guideline Management – Triptodur (triptorelin)," KADEL00290571
R4	CVS/Caremark "Specialty Guideline Management – Supprelin LA (histrelin acetate)," KADEL00294761
R5	CVS/Caremark "Specialty Guideline Management – Eligard (leuprolide acetate)," KADEL00309332
R6	CVS/Caremark "Specialty Guideline Management – Trelstar (triptolerin pamoate)," KADEL00308907
R7	CVS/Caremark "Specialty Guideline Management – Vantas (histrelin acetate)," KADEL00297881
R8	Excerpt of Dep. Tr. of Dan H. Karasic, M.D.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: February 2, 2022

/s/ Amy Richardson
Amy Richardson

CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: February 2, 2022

/s/ Amy E. Richardson

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Exhibit R1

CVS/caremark

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan:
Lupron Depot 3.75mg (leuprolide acetate for depot suspension)
Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)

PROGRAM RATIONALE
Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]
Coverage is provided for:
- Endometriosis
- Uterine Leiomyomata (fibroids)
- Gender Dysphoria

FDA-APPROVED INDICATIONS[2,3]
1. Endometriosis
   - Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment and retreatment should be limited to six months.
2. Uterine Leiomyomata (Fibroids)
   - Lupron Depot 3.75mg and Lupron Depot-3 Month11.25mg, concomitantly with iron therapy, is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with Lupron Depot 3.75 mg and 11.25 mg is up to 3 months. (The 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.)

CRITERIA FOR APPROVAL

1. What is the diagnosis?
   a. Endometriosis → *Approve 6 months*
   b. Uterine Leiomyomata (fibroids) → *Approve 3 months*
   c. Gender Dysphoria→ *Approve 12 months*
   d. Other → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy.
2. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2013.
3. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2013.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 06/2016
Revised:	ST 12/2016 (added gender dysphoria)
Reviewed:	CDPR/LCB 06/2016, ME 02/2017

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS/caremark.

_____ _____
Signature Date

_____
Client Name

Exhibit R2

Reference number(s)
C11969-A

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan:
Lupron Depot 3.75mg (leuprolide acetate for depot suspension)
Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)

PROGRAM RATIONALE
Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]
Coverage is provided for:
- Endometriosis
- Uterine Leiomyomata (fibroids)

FDA-APPROVED INDICATIONS[2,3]
1. Endometriosis
   - Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment and retreatment should be limited to six months.
2. Uterine Leiomyomata (Fibroids)
   - Lupron Depot 3.75mg and Lupron Depot-3 Month11.25mg, concomitantly with iron therapy, is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with Lupron Depot 3.75 mg and 11.25 mg is up to 3 months. (The 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.)

CRITERIA FOR APPROVAL

1. What is the diagnosis?
   a. Endometriosis → *Approve 6 months*
   b. Uterine Leiomyomata (fibroids) → *Approve 3 months*
   c. Gender Dysphoria→ *Deny*
   d. Other → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy.
2. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; May 2017.
3. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; May 2017.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 06/2016
Revised:	ST 12/2016 (added gender dysphoria), TE 12/2017 (removed gender dysphoria)
Reviewed:	CDPR/LCB 06/2016, ME 02/2017, ME 12/2017

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS/Caremark.

_____ _____
Signature Date

_____
Client Name

Exhibit R3

Reference number(s)
2190-A, 2504-A

SPECIALTY GUIDELINE MANAGEMENT

TRIPTODUR (triptorelin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty.

B. Compendial Use
Gender dysphoria (also known as gender non-conforming or transgender persons)
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.

2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member has reached Tanner stage 2 of puberty

2. Authorization of 12 months may be granted for gender reassignment in an adult member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member will receive Triptodur concomitantly with cross sex hormones

III. CONTINUATION OF THERAPY

A. CPP

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

B. Gender Dysphoria

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; September 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R4

Reference number(s)
1973-A, 2078-A

SPECIALTY GUIDELINE MANAGEMENT

Supprelin LA (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Supprelin LA is indicated for the treatment of children with central precocious puberty.

B. Compendial Use
Gender Dysphoria (also known as gender non-conforming or transgender persons)
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics

2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics

III. CONTINUATION OF THERAPY

A. CPP

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R5

Reference number(s)
1966-A, 2084-A

SPECIALTY GUIDELINE MANAGEMENT

ELIGARD (leuprolide acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
   a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
   b. Initial androgen deprivation therapy (ADT) for:
      i. Intermediate risk group
      ii. High or very high risk group
      iii. Regional disease
      iv. Metastatic disease
   c. Recurrent disease in patients who experience biochemical failure after previous therapy
   d. Progressive castration-naïve disease
2. Gender Dysphoria (also known as gender non-conforming or transgender persons)
   NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage for prostate cancer will not be provided when Eligard is used as neoadjuvant therapy prior to radical prostatectomy.

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Eligard [package insert]. For Collins, CO: Tolmar Pharmaceuticals; January 2017.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 09, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 10, 2016.
4. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2009;94:3152-3154.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R6

Reference number(s)
1968-A, 2085-A

SPECIALTY GUIDELINE MANAGEMENT

TRELSTAR (triptorelin pamoate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
   1. Palliative treatment of advanced prostate cancer

B. Compendial Uses
   1. Prostate cancer
      a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
      b. Initial androgen deprivation therapy (ADT) for:
         i. Intermediate risk group
         ii. High or very high risk group
         iii. Regional disease
         iv. Metastatic disease
      c. Recurrent disease in patients who experience biochemical failure after previous therapy
      d. Progressive castration-naïve disease
   2. Gender dysphoria (also known as gender non-conforming or transgender persons)
      NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage for prostate cancer will not be provided when Trelstar is used as neoadjuvant therapy prior to radical prostatectomy.

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Trelstar [package insert]. Parsippany, NJ: Watson Pharma; August 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 14, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 09, 2016.
4. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94:3152-3154.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R7

Reference number(s)
1969-A, 2086-A

SPECIALTY GUIDELINE MANAGEMENT

VANTAS (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication[1]
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer[2]
2. Gender dysphoria (also known as gender non-conforming or transgender persons)[4-6]
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer[1-3]
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals; June 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 29, 2017.

3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 2.2017. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 29, 2017.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017:102(11):3869–3903.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R8

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

MAXWELL KADEL, et al.,
Plaintiffs,
vs.
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,
Defendants,

DEPOSITION OF DAN H. KARASIC, M.D.
Remote
September 20, 2021
9:00 a.m. Pacific Time

Prepared by:
Vicki L. O'Ceallaigh Champion, CR
Certificate No. 50534

Prepared for:

(Certified copy)

when we are referring to people with gender dysphoria, little-G-little-D, we are also maybe referring people -- to people who might meet a criteria -- might meet the criteria for the DSM diagnosis, but the DSM diagnosis is, you know -- has a specific set of criteria.

And the gender dysphoria, small letters, existed before those seven criteria were laid out, because that -- those criteria did not, you know, exist until 2013.

BY MR. KNEPPER:

Q. Do all transgender people suffer from the diagnosis of gender dysphoria?

MR. HASKEL: Objection to form, foundation.

A. So in the DSM, they put in a post-transition specifier, and specifically -- so the people -- people can get ongoing care post-transition, so -- so I think that that was put in specifically so that if people are being, you know, treated under that diagnosis and their -- their symptoms have alleviated because of treatment, they can continue getting treatment under that diagnosis.

BY MR. KNEPPER:

Q. Are there individuals -- does that mean that all individuals -- are there any other individuals

who are transgender who do not suffer from gender dysphoria other than individuals who are post-transition?

MR. HASKEL: Objection to form, foundation.

A. Are you asking me to make a diagnosis of all transgender people?

BY MR. KNEPPER:

Q. I'm asking you if the set of people who are transgender and the people -- and the set of people who suffer from gender dysphoria, the psychiatric diagnosis, are the same -- are the same. In other words, it's a one-to-one correlation.

Do all people who are transgender suffer from gender dysphoria, the psychiatric diagnosis?

MR. HASKEL: Object to the form, foundation.

A. So the DSM-5 and the APA make a distinction between people who have transgender identity and people who meet the criteria of the diagnosis for gender dysphoria making it, you know -- establishing that you have the diagnosis of gender dysphoria if you meet the criteria for it, but that transgender identity itself is not a mental illness.

BY MR. KNEPPER:

Q. I want to try to see if I can get a specific answer. Is your testimony that not all individuals who express a transgender identity have a diagnosed illness of gender dysphoria?

MR. HASKEL: Same objections, form, foundation.

A. I think I would just leave my testimony as it is.

BY MR. KNEPPER:

Q. I will try to get you to a "yes" or "no" then.

Do all transgender individuals suffer from gender dysphoria within the DSM-5 criteria?

MR. HASKEL: Objection; form, foundation, asked and answered.

A. So, again, I would -- I would say people meet the DSM diagnosis. They meet the criteria for it. If they meet the criteria for it, I can't say whether every person does. I do think one can say that the APA left an open door with the post-transition specifier to continue giving the diagnosis, you know, with that specifier for people even after they have received transition care.

BY MR. KNEPPER:

Q. So is your testimony that you do not know whether all individuals expressing a transgender identity suffer from gender dysphoria?

MR. HASKEL: Objection; form. Objection; foundation, mischaracterizing the witness's testimony.

A. Yeah. I said my testimony, and that's -- that's what it is.

BY MR. KNEPPER:

Q. Sure. Can you answer the following question "yes" -- I'm going to ask you whether you can answer the following question with a "yes" or "no" answer.

Do all individuals -- do all transgender individuals suffer from gender dysphoria as described in the DSM-5?

MR. HASKEL: Objection; form, foundation.

A. So, again, my testimony is what it is. I can't speak for every transgender people, for every transgender person. I think the APA left an open door for that diagnosis. I know, for example, in discussions --

BY MR. KNEPPER:

Q. Doctor -- Doctor -- I'm sorry to --

MR. HASKEL: If you could let the Witness

finish, and then you can ask --

MR. KNEPPER: I asked him a very specific question, Warren. I asked him whether he could answer that question "yes" or "no." And I haven't gotten --

MR. HASKEL: Hold on. Hold on. Let's let the record -- he was answering your question. I think there was testimony. The record is clear. If you want to strike that question and then ask your question again. I objected to form, foundation. I'm still --

MR. KNEPPER: This is going to be a very long day if I can't even get him to answer whether he can answer a "yes" or "no" question. It's very simple. If he can answer it, he can say "yes." If he can't answer it, he can say "no." At that point, if he --

MR. HASKEL: If he --

MR. KNEPPER: -- if he wants to say "no because," that's fine, but that's what I'm asking for.

BY MR. KNEPPER:

Q. Can you answer that question "yes" or "no," Dr. Karasic?

A. Well, I thought I was in the middle of

answering the question.

Q. Okay.

MR. HASKEL: Do you want to ask it again, Counsel, so we have a clear record.

MR. KNEPPER: Vicki -- Vicki, could you read that question back, please.

THE COURT REPORTER: Certainly. Give me just a moment.

(Requested portion of record read.)

MR. HASKEL: Objection; form, foundation.

A. Okay. So I don't need -- I was going to give you an example, but I would say "no."

BY MR. KNEPPER:

Q. Now, I would love to have the example. I wanted to make sure I had that answer on the record.

A. Okay. So when -- I know when we were in discussions about this when -- about the diagnosis of -- so discussions about the diagnosis of gender dysphoria, which is in DSM-5, and gender incongruence, which is in ICD-11 -- an example was given by Peggy Cohen-Kettenis, who was leading the efforts, along with Ken Zucker, for the gender dysphoria diagnosis in DSM-5 and was an essential person in the ICD-11 diagnosis.

And there was discussion about the

differences between gender dysphoria and gender incongruence, and an example given by Peggy Cohen-Kettenis was that there are sometimes -- sometimes children who were started at -- on puberty blockers who were not expressing gender dysphoria that was causing social or occupational dysfunction, because they seemed to be functioning similarly to gender peers, and so that was an example that Peggy Cohen-Kettenis gave.

And so the -- I think they intentionally, with DSM-5, had this post-transition specifier with ICD-11, they did not include a specifier for clinically significant distress or impairment and social and occupational functioning. And I think the intent in ICD-11 was to include all transgender people. Of note, though, ICD-11, the diagnosis was outside of the mental disorder chapter.

Q. Your testimony was that you can't answer "yes" or "no" to the question whether all transgender individuals suffer from gender dysphoria as defined by the DSM-5.

Are there -- are you aware of any --

A. I think there is an objection over there, but --

MR. HASKEL: Well, I don't think there was

actually a question. I think you were characterizing his testimony, which I don't know if that's a question or you were going to ask a question after --

MR. KNEPPER: Hold on. Hold on. I stopped, because I wanted to let Dr. Karasic speak.

MR. HASKEL: Okay.

MR. KNEPPER: I absolutely will finish my question, but I want to give the Witness -- when he raised his finger and said he wanted to say something, I wanted to give him an opportunity to make sure that I was saying something correctly.

BY MR. KNEPPER:

Q. So go ahead, Dr. Karasic.

A. So on that last answer, I was saying in the example I was giving was a "no" to the question of do all transgender people also have a diagnosis of gender dysphoria, and I was giving an example that related to the difference between gender dysphoria and gender incongruence of ICD-11, so just to clarify my answer --

Q. Thank you. That does -- that does clarify for me.

I'm going to ask you the converse question now. Do all individuals -- are all individuals who