NO. 22-1721

In The

United States Court Of Appeals

For The Fourth Circuit

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

Plaintiffs – Appellees,

v.

DALE FOLWELL, in his official capacity as State Treasurer of N.C.; DEE JONES, in her official capacity as executive Administrator of the N.C. State Health Plan for Teachers and State Employees,

Defendants – Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA AT GREENSBORO

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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

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.

Dated: February 2, 2022

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

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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.

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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

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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

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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

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CVS caremark

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

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

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.

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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

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

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.

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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.

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

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.

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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.

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

V. REFERENCES

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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.
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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.
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Reference number(s)
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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.
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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.

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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

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MOTION TO
EXCLUDE EXPERT TESTIMONY OF DR. PETER ROBIE

Pursuant to Federal Rules of Civil Procedure 26 and Federal Rules of Evidence 104, 403, and 702, and for the reasons set forth in the accompanying Memorandum of Law, Plaintiffs respectfully move this Court to exclude the testimony of Dr. Peter Robie, a disclosed expert of Defendants Dale Folwell, Dee Jones, and the North Carolina State Health Plan for Teachers and State Employees.

Dated: February 2, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby 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

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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, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PETER ROBIE

TABLE OF CONTENTS

Now come Plaintiffs, by and through their counsel, and respectfully submit this Memorandum of Law in support of their Motion to Exclude the expert testimony of Dr. Peter Robie.

I. NATURE OF THE CASE AND FACTUAL BACKGROUND

Plaintiffs are current or former participants in the North Carolina State Health Plan for Teachers and State Employees ("State Health Plan"). As part of compensation for employment, the State of North Carolina ("State") provides health coverage to employees and their dependents through the State Health Plan. Some employees and their dependents, however, receive less compensation than others: those denied coverage for the gender-affirming care that transgender people require. The State Health Plan contains sweeping exclusions of such care, while covering the same kinds of treatments for cisgender employees who require them for other reasons. Defendants thus deny equal treatment to employees who are transgender or have transgender dependents, and harm transgender family members who depend on employees for health care coverage.

II. PROCEDURAL BACKGROUND

Pursuant to the Parties' Rule 26(f) Joint Report, adopted by this Court on August 13, 2020, Plaintiffs identified and disclosed expert reports for Dr. George R. Brown and Dr. Loren S. Schechter. On May 1, 2021, Defendants Dale Folwell, Dee Jones, and the State Health Plan (collectively, "Health Plan Defendants") identified and disclosed reports from the following experts: Dr. Paul R. McHugh, Dr. Paul W. Hruz, Dr. Stephen B. Levine, and Dr. Patrick W. Lappert. In addition, the Health Plan Defendants identified Defendant

Folwell, Defendant Jones, and Dr. Peter W. Robie as experts, but, as permitted by Rule 26(a)(2), they did not disclose any reports.[1] Subsequently, Plaintiffs identified and disclosed expert rebuttal reports for Dr. Randi Ettner, Dr. Dan Karasic, and Dr. Johanna Olson-Kennedy.

The Health Plan Defendants identified Dr. Robie to provide expert testimony on the following issues: (1) "the Board[] [of Trustees'] consideration of requests that the Plan eliminate the current coverage exclusion for gender transition surgery and related hormone treatment"; (2) "the medical knowledge he has shared with other Board members"; and (3) Dr. Robie's opinion that, "in order to provide diagnostic and medical treatment that meets a professional standard of care, primary care physicians must know the chromosomal sex of patients."[2] Disclosure of Expert Witnesses Who Do Not Provide a Written Report Pursuant to Fed. R. Civ. P. 26(a)(2) by Defs. Dale Folwell, Dee Jones, and the North Carolina State Health Plan for Teachers and State Employees 6, May 1, 2021.

Plaintiffs now move to exclude Dr. Robie's opinions and testimony under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny, because Dr. Robie is not qualified to opine about gender dysphoria or its treatment, and his opinions and

[1] Defendant North Carolina Department of Public Safety also identified and disclosed an expert report, but those disclosures are not subject to Plaintiffs' Motion.

[2] A true and accurate copy of the May 1, 2021 Disclosure of Expert Witnesses Who Do Not Provide a Written Report Pursuant to Fed. R. Civ. P. 26(A)(2) by Defendants Dale Folwell, Dee Jones, and the North Carolina State Health Plan for Teachers and State Employees ("State Health Plan Disclosures") is attached as Exhibit A to the Declaration of Deepika Ravi.

testimony are neither relevant nor reliable. His opinions and testimony are likewise inadmissible because any probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. Fed. R. Evid. 403.

III. STATEMENT OF THE QUESTION PRESENTED

Whether the testimony of Defendants' expert Dr. Peter Robie should be excluded because it is irrelevant, unreliable, and he is unqualified to offer it in accordance with *Daubert* and the applicable Federal Rules of Evidence.

IV. SUMMARY OF THE ARGUMENT

This Court should disqualify Dr. Robie as an expert for a number of reasons.

First, Dr. Robie is not qualified to provide the opinions identified in his disclosure and deposition. Dr. Robie, who practices internal medicine, admits he is not an expert in the diagnosis or treatment of gender dysphoria and has no other relevant experience with diagnosis or treatment of gender dysphoria. Further, although Dr. Robie testified during his deposition regarding the alleged cost of providing gender-confirming care, Dr. Robie admits he is not an expert in the cost of treatment for gender dysphoria. Dr. Robie testified regarding his friendship with Defendant Folwell, yet Dr. Robie's personal relationship with Defendant Folwell does not make him an expert on any matter at issue in this lawsuit. Robie Dep. 18:18–19:7 (testifying that Dr. Robie and Defendant Folwell have "been friends since the 1980s," since Defendant Folwell became Dr. Robie's patient).

Second, his opinions are not relevant to the issues to be addressed by this Court. Although Dr. Robie has been designated to testify to the medical knowledge he has shared with other members of the Board of Trustees (the "Board") for the State Health Plan, Dr. Robie testified that the medical knowledge he has shared with the Board pertains to issues wholly unrelated to those before the Court—for example, coverage of continuous glucose monitors for diabetic patients and biological agents for cancer treatment.

Third, even if he were deemed a qualified expert with relevant opinions—and Dr. Robie is not—his opinions are not based on scientific, technical, or other specialized knowledge. Instead, they are based on his own *ipse dixit* and amount to no more than Dr. Robie's pure speculation. Dr. Robie admits that he has never taught on the subject of gender dysphoria and has never conducted research or been published on this subject. And, despite his forty-five years as a medical practitioner, Dr. Robie testified that only four of his patients—all adults—have identified as transgender, to his knowledge.

As Dr. Robie is not qualified to render the proffered opinions, they are neither relevant nor reliable pursuant to the standards set forth in *Daubert* and its progeny. When viewed in the context of Federal Rule of Evidence 403, any probative value of the opinions is substantially outweighed by the danger of unfair prejudice, confusion of issues, waste of time, undue delay, and needless presentation of cumulative evidence and this Court should exclude them.

V. ARGUMENT

Dr. Robie's purported expert testimony should be excluded because it does not meet any of the indicia for admissibility under Daubert and the Federal Rules of Evidence.

A. Legal Standard

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "*relevant* to the task at hand" and "rests on a *reliable* foundation." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (quoting *Nease v. Ford Motor Co.*, 848 F.3d 219, 229–30 (4th Cir. 2017)); *Daubert*, 509 U.S. at 597; *see* Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments) (amendment "affirms the trial court's role as gatekeeper," and that "all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful"). The party offering the expert—here, the Health Plan Defendants—carries the burden of establishing the admissibility of an expert's testimony by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The trial court's initial step is to determine whether the proposed expert is qualified to render the proffered opinion. In doing so, a trial court considers an expert's professional qualifications and the expert's "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009)). If the purported expert lacks the

knowledge, skill, experience, training, or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g.*, *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony, as it is "a precondition to admissibility." *Sardis*, 10 F.4th at 282 (quoting *Daubert*, 509 U.S. at 592). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Sardis*, 10 F.4th at 281 (quoting *Belville v. Ford Motor Co.*, 919 F.3d 224, 232 (4th Cir. 2019)) ("Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.").

Finally, if deemed relevant, the trial court will inquire if the opinion is based on a reliable foundation, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281 (first quoting *Daubert*, 509 U.S. at 594–95; and then quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). When evaluating whether an expert's methodology is reliable, a court considers, among other things:

> (1) whether the expert's theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error inherent in the expert's theory or technique; and (4) whether the expert's methodology is generally accepted in his field of expertise.

Sardis, 10 F.4th at 281 (quotation marks omitted) (quoting *Nease*, 848 F.3d at 229); *see also Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 149–150 (1999); *Daubert*, 509 U.S. at

593–94. While trial courts have "broad latitude" to determine reliability, *Sardis*, 10 F.4th at 281 (quoting *Nease*, 848 F.3d at 299), they still must engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-examination is not a substitute for this Court's gatekeeping role. *See Nease*, 848 F.3d at 231.

In certain situations, when an expert relies upon his experience and training, and not a specific methodology, a modified analysis applies. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). When addressing an expert whose methodology is grounded in experience, courts use three factors: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015) (citing *SMD Software v. EMove, Inc.*, 945 F. Supp. 2d 628, 644 (E.D.N.C. 2013)); *see also Nat'l Ass'n for Rational Sexual Offense L. v. Stein*, No. 1:17-CV-53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021).

Finally, because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it . . . the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises *more* control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595 (emphasis added) (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)). As such, "the importance of [the] gatekeeping function cannot be

overstated." *Sardis*, 10 F.4th at 283 (alteration in original) (quoting *United States v. Barton*, 909 F.3d 1323, 1331 (11th Cir. 2018)).

B. Dr. Robie Is Not Qualified To Offer an Expert Opinion on Any Issue in This Case.

In order to render expert testimony, the witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993) (quoting Fed. R. Evid. 702); *Wright v. United States*, 280 F. Supp. 2d 472, 478 (M.D.N.C. 2003) ("A witness may testify as to his specialized knowledge so long as he is qualified as an expert based on any combination of knowledge, skill, experience, training, or education."). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 5:13-CV-210-BO, 2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014).

Dr. Robie lacks the knowledge, skill, experience, training, or education necessary to qualify him as an expert. Dr. Robie practices internal medicine and has no other board certifications, specializations, or areas of practice. Robie Dep. 9:21–10:2; 11:6–11.[3] Dr. Robie acknowledged in his testimony that he is not an expert in the diagnosis or treatment of gender dysphoria, nor has he *ever* treated a patient for gender dysphoria. Robie Dep. 11:12–23. Moreover, Dr. Robie testified that he is not familiar with the Endocrine Society's Clinical Practice Guidelines on Treatment of Gender Dysphoria or Gender Incongruent Persons. Robie Dep. 33:23–34:1. Nor does Dr. Robie have a position on the

[3] A true and accurate copy of transcript excerpts of the deposition of Dr. Robie ("Robie Dep.") is attached as Exhibit B to the Declaration of Deepika Ravi.

validity of the World Professional Association for Transgender Health Standards of Care for Treatment of Gender Identification Disorder ("WPATH Standards of Care"), Robie Dep. 33:3–10, which are authoritative standards of care for treatment of gender dysphoria. *See, e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020), *as amended* (Aug. 28, 2020) (the WPATH Standards of Care "have been recognized by various courts, including this one, as the authoritative standards of care"). And, when asked if he is "familiar with the DSM 5, the diagnostic and statistical manual of mental disorders definitions," Dr. Robie simply responded, "No." Robie Dep. 33:19–22.

Dr. Robie's lack of experience with diagnosis and treatment of gender dysphoria renders him unfit to offer an expert opinion in this matter. *See, e.g.*, *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 539 (M.D.N.C. 2019) (affirming the district court's exclusion of an expert because the expert lacked experience relevant to the matters at issue).

Beyond his lack of practical experience, Dr. Robie testified that he has never taught on the subject of gender dysphoria, Robie Dep. 12:21–25; and he has never conducted research on the treatment of gender dysphoria, Robie Dep. 13:4–6, been published in the area of gender dysphoria, Robie Dep. 13:1–3, or peer reviewed any literature on this subject, Robie Dep. 14:8–10. And while Dr. Robie stated he has read medical literature regarding gender dysphoria, he testified that his review was limited to the six months preceding his deposition, and he could not recall the authors of any literature he reviewed. Robie Dep. 13:7–14:7. Dr. Robie's lack of any teaching, research, or peer review

experience with the medical care denied to Plaintiffs in this lawsuit disqualifies him from offering an expert opinion in this matter. *See, e.g.*, *Lebron v. Sec'y of Fla. Dep't of Child. and Fams.*, 772 F.3d 1352, 1369 (11th Cir. 2014) (disqualifying purported expert who did not "propos[e] to testify about matters growing naturally and directly out of research [he had] conducted independent of the litigation" (alteration in original) (quoting Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments))).

Defendants also designated Dr. Robie to provide expert testimony about "the Board[] [of Trustees'] consideration of requests that the Plan eliminate the current coverage exclusion for gender transition surgery and related hormone treatment." State Health Plan Disclosures at 6. But this is not a subject on which Dr. Robie can be designated as an "expert" because Dr. Robie's testimony on this subject amounts to nothing more than a recitation of his recollection of an October 2018 Board meeting during which such requests were received. Robie Dep. 19:19–23:10; 81:22–83:14. Dr. Robie's mere presence at the meeting cannot qualify him to provide expert testimony about the meeting. And, when asked what testimony he could provide about the Board's consideration of requests that the State Health Plan eliminate the exclusion, Dr. Robie responded, "[t]he cost of the gender transition surgery and related hormone treatment." Robie Dep. 20:7–11. Yet Dr. Robie admits he is not an expert in the cost of treatment for gender dysphoria, Robie Dep. 11:24–12:1, and as discussed in more detail below, he is not qualified to provide reliable expert testimony on this issue.

C. Dr. Robie's Opinions and Testimony Have No Relevance to This Case.

This case revolves around whether the Health Plan Defendants' exclusion of coverage for gender-confirming healthcare treatment violates Plaintiffs' equal protection rights and discriminates against them on the basis of their sex in violation of Title VII and the Affordable Care Act. Dr. Robie's opinions are not relevant as they will not help the "trier of fact to understand the evidence or to determine a fact in issue." *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 591). Simply put, Dr. Robie's opinion does not "fit" with the facts at issue. *Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004); *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F. Supp. 3d 837, 846 (W.D.N.C. 2016) ("The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." (quotation marks omitted) (quoting *Daubert*, 509 U.S. at 591)).

For example, although Dr. Robie has been designated to opine about the medical knowledge he has shared with other Board members, Dr. Robie testified that the medical knowledge he has shared pertains to coverage of continuous glucose monitors for diabetic patients and biological agents for cancer treatment, and COVID management, care, and status. Robie Dep. 23:11–25:12; 31:19–32:14. These issues bear no relation to the treatment of gender dysphoria involved in this case, and Dr. Robie could not recall any other medical knowledge he has shared with the Board. Robie Dep. at 24:20–25; 31:19–32:14.

Dr. Robie also provides testimony that, while internally inconsistent, simply does not contravene the relief Plaintiffs seek here. When asked whether surgical care for gender dysphoria can be medically necessary, Dr. Robie characterized it as "elective," but defines "elective" simply to mean "it could be scheduled at an opportune time for the patient and surgeon." Robie Dep. at 68:9–69:13. When asked, "is it correct that some elective care can be medically necessary as determined by the doctor/patient," Dr. Robie acknowledged, "If that's determined, the answer is yes." Robie Dep. 86:5–8. Dr. Robie gave inconsistent testimony on this question: earlier in his deposition, when asked whether if there is ever "a circumstance where a provider and patient together could determine that gender confirming care is medically necessary," Dr. Robie answered, "I don't know." Robie Dep. at 36:22–37:2. Regardless, he does not dispute that treatment for gender dysphoria can be medically necessary. His opinions thus are irrelevant since Plaintiffs simply seek the same opportunity to make individualized showings of medical necessity afforded to all other State Health Plan participants.

D. Dr. Robie's Opinions and Testimony Are Unreliable.

Expert testimony should only be admitted if it is sufficiently reliable. Dr. Robie's opinions are unreliable because they are not grounded in any practical experience, research, or methodology.

While not an exhaustive list, when evaluating whether an expert's methodology is reliable, a trial court will examine:

> (1) whether the expert's theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and

> publication; (3) the known or potential rate of error inherent in the expert's theory or technique; and (4) whether the expert's methodology is generally accepted in his field of expertise.

Sardis, 10 F.4th at 281 (quotation marks omitted) (citing *Nease*, 848 F.3d at 229).

Dr. Robie fails to meet any of these factors. Again, Dr. Robie testified that he has never taught on the subject of gender dysphoria, Robie Dep. 12:21–25, and he has never conducted research on the treatment of gender dysphoria, been published in the area of gender dysphoria, Robie Dep. 13:1–6, or peer reviewed literature on this subject, Robie Dep. 14:8–10. It is not surprising that Dr. Robie wholly fails to meet any of the threshold criteria to qualify him as an expert because Dr. Robie freely admits that he is *not* an expert on diagnosis or treatment of gender dysphoria. Robie Dep. 11:12–23.

Even putting the *Daubert* factors aside, although Dr. Robie claims his experience is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied here. *See SAS Inst., Inc.*, 125 F. Supp. 3d at 589; *see also Nat'l Ass'n for Rational Sexual Offense L.*, 2021 WL 736375, at *3.

For example, Dr. Robie has been designated to testify that "in order to provide diagnostic and medical treatment that meets a professional standard of care, primary care physicians must know the chromosomal sex of patients." State Health Plan Disclosures at 6. Defendants point to Dr. Robie's testimony for the principle that "competent medical care requires every diagnosing physician to know and to consider the patient's biological sex." Defs.' Resp. in Opp'n to Pls.' Mot. for Summ. J. 26, ECF No. 197. Yet, Dr. Robie

testified that in his own practice, he does not confirm the chromosomal makeup of his patients, Robie Dep. 29:14–16; 88:1–4, and that he will ask patients about their chromosomal makeup "[o]nly if the nurse says I need to. I can't recall recently where I've been asked to do that." Robie Dep. 87:11–15. Dr. Robie also testified that, despite having been in practice for forty-five years, he formed this opinion only when the present case was filed, around 2019. Robie Dep. 30:3–8. Dr. Robie's recently formed opinion is wholly disconnected from his own experience and does not qualify as an expert opinion. *See, e.g.*, *Nat'l Ass'n for Rational Sexual Offense L.*, 2021 WL 736375, at *3 (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts"); *Lebron*, 772 F.3d at 1369 (disqualifying expert who did not propose "to testify about matters growing naturally and directly out of research [he had] conducted *independent of the litigation*" (alteration in original) (emphasis added) (quoting Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments))).

Nor does Dr. Robie have substantial experience on which to draw. By his own testimony, in his forty-five years as a practicing physician, Robie Dep. 78:3–5, to his knowledge, he has treated only *four* patients who identify as transgender, Robie Dep. 88:15–22, and has never treated a patient *for gender dysphoria*, Robie Dep. 11:12–23. Dr. Robie has *never* treated a transgender adolescent or a transgender child. Robie Dep. 88:15–89:5.

Dr. Robie testified to his opinion as to gender-confirming surgery for adolescents, Robie Dep. 78:25–79:14, but then supported his opinion with testimony about his "personal experience" with this issue based on his friendship with the parents of a transgender child who underwent "transgender surgery" but who was not Dr. Robie's patient. Robie Dep. 79:15–23. Such anecdotal experience is insufficient to qualify Dr. Robie, an internal medicine practitioner with no specialization in treatment or diagnosis of transgender individuals, as an expert in this area. *See, e.g.*, *Hartke v. McKelway*, 526 F. Supp. 97, 100–01 (D.D.C. 1981) (family practitioner unqualified to establish the standard of care for surgical procedure, where the practitioner "ha[d] never performed the operation in question," "had no training or experience with that procedure," and a "major reason for her conclusion that there was negligence was that the result was unfavorable"); *Cooper*, 259 F.3d at 200 (affirming the exclusion of an expert who "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method").

Although Dr. Robie testified during his deposition regarding the alleged cost of providing gender-confirming care, Dr. Robie admits he is not an expert in the cost of treatment for gender dysphoria. Robie Dep. 11:21–12:1. Dr. Robie's own testimony bears out his limited knowledge of the cost of gender-confirming care.

Defendants cite Dr. Robie's testimony regarding his goal to "cut the cost of healthcare for our state workers" to support their claim that limiting health care costs is a "legitimate purpose." Defs.' Resp. in Opp'n to Pls.' Mot. for Summ. J. 33–34, ECF No.

197 (citations omitted). Yet Dr. Robie testified that he was not aware of the total cost that the State Health Plan incurred for covering gender-confirming care in 2017. Robie Dep. 37:9–12. Attempting to offer an opinion about cost without gathering the centrally relevant data on this point—i.e., information about the State Health Plan's actual cost of this care in 2017—cannot be supported.

Nor can Dr. Robie's failure to consider the data actually relevant here be rehabilitated by his Internet research. When Dr. Robie testified that he "looked at the cost" of "transgender surgeries," he acknowledged that his research was limited to an Internet browser search in 2008, a review of only "[f]ive or six" websites around August 2018 and October 2018, and another Internet search the week and the day prior to his deposition. Robie Dep. 38:1-39:15; 50:8–51:12; 56:11–21; 78:6–11, Ex. 4. Dr. Robie testified that he spent approximately 2.5 hours total on this Internet research. Robie Dep. 78:6–11. Dr. Robie could not recall many of the sources he reviewed, Robie Dep. 49:4–17; 50:25–51:2, 55:10–56:4, could not recall any of the dates of the website content, and testified that apart from his limited Internet research, he had never otherwise researched the cost of gender-confirming surgery. Robie Dep. 38:7–43:18; 45:19–46:4, 51:18–53:5. Nor has Dr. Robie ever consulted with other medical providers on how much surgery to treat gender dysphoria might cost. Robie Dep. 43:19–25.

When Dr. Robie testified to the "average cost" of gender-confirming surgery, he could not recall which website presented that figure. Robie Dep. 41:3–11. Dr. Robie further testified that the figure he came up with amalgamated the costs for multiple

different procedures, even though he admitted not every patient may need or want each procedure because care is "very patient specific." Robie Dep. 65:7-23.

As to his own experience, Dr. Robie testified to a single anecdote, which he "guess[ed]" was in approximately 2008, *see* Robie Dep. 48:11–12, with a transgender individual that he helped look into the cost of gender-confirming surgery. Robie Dep. 47:14-48:1. However, even that anecdote is internally inconsistent, referring to the individual as having "no insurance" and then speaking of the cost for the individual "with that insurance." *Id.*

Such limited research and a single anecdotal experience do not qualify Dr. Robie as an expert in this area, especially given his own admission that he is *not* an expert in the cost of treatment for gender dysphoria. *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

E. Dr. Robie's Opinions and Testimony Lack Probative Value and Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Robie offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Thus, consideration of Dr. Robie's testimony would waste time and create confusion. Accordingly, Dr. Robie's testimony

also fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

VI. CONCLUSION

WHEREFORE, based on the foregoing, Plaintiffs respectfully request that this Court grant the instant motion and exclude Dr. Robie's purported expert testimony because it does not meet any of the indicia for admissibility under *Daubert* and the Federal Rules of Evidence. Accordingly, this Court should exclude Dr. Robie's opinions and testimony in full.

Dated: February 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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I hereby 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.

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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, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

DECLARATION OF DEEPIKA H. RAVI

I, Deepika H. Ravi, 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 an attorney at Harris, Wiltshire & Grannis LLP and counsel for Plaintiffs in the above-captioned matter.

3. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Dr. Peter Robie.

4. Attached as **Exhibit A** is a true and correct copy of the May 1, 2021 Disclosure of Expert Witnesses Who Do Not Provide a Written Report Pursuant to Fed. R. Civ. P. 26(A)(2) by Defendants Dale Folwell, Dee Jones, and the North Carolina State Health Plan for Teachers and State Employees.

5. Attached as **Exhibit B** is a true and correct copy of excerpts of the transcript of and exhibits to the deposition of Dr. Peter Robie on September 22, 2021, taken in relation to the above-captioned matter.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 2nd day of February, 2022.

/s/ Deepika H. Ravi
Deepika H. Ravi

Exhibit A

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

MAXWELL KADEL; JASON FLECK; CONNOR THONEN-FLECK; JULIA MCKEOWN; MICHAEL D. BUNTING, JR.; C.B., by his next friends and parents, MICHAEL D. BUNTING, JR. and SHELLEY K. BUNTING; SAM SILVAINE; and DANA CARAWAY,	)
Plaintiffs,	)
v.	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina; DEE JONES, in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees; UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL; NORTH CAROLINA STATE UNIVERSITY; UNIVERSITY OF NORTH CAROLINA AT GREENSBORO; and NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES,	)
Defendants.	)

DISCLOSURE OF EXPERT WITNESSES WHO DO NOT PROVIDE A WRITTEN REPORT PURSUANT TO FED. R. CIV. P. 26(A)(2) BY DEFENDANTS DALE FOLWELL, DEE JONES, AND THE NORTH CAROLINA STATE HEALTH PLAN FOR TREACHERS AND STATE EMPLOYEES

The Rules of Civil Procedure require the Defendants to disclose witnesses who are qualified to provide expert testimony, and are expected to do so, but who are also not retained or specially employed to do so. Fed. R. Civ. P. 26(a)(2). Pursuant to the rule, the Plan Defendants disclosure that the following three individuals will present testimony within their areas of learning and expertise:

(1) Treasurer Dale R. Folwell, CPA:

Treasurer Folwell is the State Treasurer of North Carolina. Prior to his election to this office in 2016, he served as the Assistant Secretary for Employment Security of the North Carolina Department of Commerce from 2013 through 2015. From 2004 through 2011, Treasurer Folwell served in the North Carolina General Assembly. Treasurer Folwell has also earned a Bachelor's degree and a Master's degree in Accounting, and he is a Certified Public Accountant.

In his current role, Treasurer Folwell serves as Chair of the Board of Trustees for the State Health Plan. He has overall supervision of the employees who work for the Plan. In addition to testimony about his actions as Treasurer and his decisions involving the State Health Plan, Treasurer Folwell will present expert opinion testimony about the fiscal issues facing the State Health Plan.

Treasurer Folwell will testify about the role of the State Health Plan in North Carolina. The Plan provides health benefit coverage to more than 740,000 individuals and is one of the largest purchasers of health care in the State. Treasurer Folwell will testify that concerns about the fiscal sustainability of the State Health Plan have existed for

decades. Currently, Treasurer Folwell estimates that the Plan has a $28 billion unfunded liability.

Treasurer Folwell will testify about policies (both those adopted and those not yet adopted) to address this unfunded liability. These measures include premium adjustments, changes in eligibility for future retirees, and ongoing efforts to increase the transparency of health care costs. The Treasurer will contrast the lack of transparency and benchmarks for the State Health Plan with the structure of North Carolina's unemployment insurance program, which he supervised when he was an Assistant Secretary for the North Carolina Department of Commerce. The Treasurer will also testify to the inflation in health care costs resulting from the consolidation of hospital systems in North Carolina.

Finally, the Treasurer will testify to the adverse effect of the current premium structure for the Plan, which imposes significant unsubsidized costs for coverage of dependents. These costs have, for some time, discouraged younger, healthier employees from enrolling their families in the State Health Plan. Further, these costs – when combined with the rising healthcare costs experienced by North Carolina residents – have increased the economic uncertainty for all residents of North Carolina.

(2) Dee Jones, Executive Director of the State Health Plan

Dee Jones is the Executive Administrator of the State Health Plan, a position in which she has served for four years. Ms. Jones previously served as the Chief Operating Officer for North Carolina's Medicaid program. She has expertise in the administration of health benefits programs as well as operational and financial strategy and customer service within other industries. Ms. Jones has earned a Bachelor's degree in accounting and

business management from North Carolina State University and a Master's degree in Accounting and Business Management from the University of Phoenix.

Ms. Jones will testify about the operation of the State Health Plan. She is the Administrator of the Plan, responsible for implementation of policy and management of the State Health Plan, its employees, its contractors, and its vendors. She is also the individual designated by the Plan to testify on its behalf. Fed. R. Civ. P. 30(b)(6). Her testimony will include factual detail about Plan design and operation, including the coverage Exclusion challenged by the Plaintiffs.

The Defendants have also designated Ms. Jones as an expert witness to ensure that her knowledge and experience about how to operate an actuarially sound health plan are within the scope of her allowed testimony.

A portion of Ms. Jones's testimony will include opinion testimony related to the operation of the Plan. Ms. Jones will testify to the rate of increase for appropriations from the North Carolina General Assembly, the Plan's medical costs, and the Plan's pharmaceutical costs.

Ms. Jones will also testify about the cash reserves of the Plan, both the statutorily required reserves as well as the reserves necessary to ensure that the Plan can make timely payment for healthcare. She will testify as to the Plan's tracking of utilization by beneficiaries, and the analysis underlying the Plan's conclusion that a $1 billion reserve is necessary to ensure the Plan's financial soundness.

Ms. Jones will testify about the loss ratio for different age cohorts of Plan beneficiaries. She will also testify that a small portion (approximately 15% of the Plan

participants) incur 85% of the costs of medical treatment. She will testify that the maximum premium for the Plan is set by state law on a two-year cycle, limiting the ability of the Plan to adjust to changing health care costs. Further, Ms. Jones will testify that the statutory structure of the Plan – with caps on premiums for state employees and state employers and unsubsidized premiums for dependents – has skewed the Plan's population to become more elderly and more costly. This heightened cost has led to further diminution of younger participants, which negatively affects the Plan's overall loss ratio.

To ensure long-term sustainability, the State Health Plan's primary goal under her management has been to reduce the individual unit cost of healthcare. For example, the Plan has held family premiums constant even as medical costs have risen. Ms. Jones will testify to the actuarial analysis supporting the need for this policy as well as the feasibility of rejected alternatives, such as reliance on increased appropriations.

Ms. Jones will testify about the analysis performed when beneficiaries request new or augmented benefits from the Plan. Ms. Jones will testify that the Board's fiduciary obligation to the Plan beneficiaries, and concerns about overall Plan soundness, require the Board to review additional coverage benefits within the context of the effect of this additional benefit on the overall health of the Plan population. She will testify that overall cost of the new benefit is considered but that the cost of a new benefit cannot, consistent with prudential financial management, be considered in isolation. Ms. Jones will also testify about the analyses performed over the past five years, including requests that the Plan provide new or increased benefits, including coverage of gender transition costs, acupuncture, hearing aids, Colo-guard, and special dietary supplements.

(3) Peter W. Robie, M.D., FACP

Dr. Robie has served on the Board of Trustees for the State Health Plan since 2017. He also serves on the Pharmacy and Therapeutics Committee for the Plan. Dr. Robie will testify about the Board's consideration of requests that the Plan eliminate the current coverage exclusion for gender transition surgery and related hormone treatment.

Dr. Robie is not a specialist in the treatment of gender dysphoria, and the Defendants do not seek to qualify him as such. Dr. Robie is, however, a primary care physician with more than forty-seven years of experience. As a member of the Board of Trustees, and a physician, Dr. Robie has contributed his medical knowledge to Board deliberations. Dr. Robie will testify to the medical knowledge he has shared with other Board members. He will also testify that, in order to provide diagnostic and medical treatment that meets a professional standard of care, primary care physicians must know the chromosomal sex of patients.

Dr. Robie has served as a primary care physician for more than forty-seven years. He has treated patients as a physician in a small group/solo practice and as a member of a large primary care practice group affiliated with Wake Forest Medical Center. Dr. Robie earned his M.D. with honors from the Baylor College of Medicine in 1976. He has served as an Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine for the Wake Forest School of Medicine since 1981.

Dated this 1st day of May, 2021.

Respectfully submitted by,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that this document was served upon the following individuals through electronic mail on the 1st day of May, 2021.

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/s/ John G. Knepper

Exhibit B

VERITEXT
LEGAL SOLUTIONS

Deposition of:

Peter Robie , M.D.

September 22, 2021

In the Matter of:

Kadel, et al vs. Folwell

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Q. Did you attend college before you attended medical school?
A. Yes. Rice University in Houston, Texas.
Q. What did you study at Rice?
A. Baccalaureate of arts, English, biology. Double major.
Q. When did you graduate?
A. 1972.
Q. Did attend the Baylor College of Medicine right after that?
A. Yes.
Q. What were you studying there?
A. Doctor of medicine.
Q. When did you graduate?
A. 1976.
Q. Did you attend any other school after that?
A. No.
Q. Do you have any other degrees?
A. No.
Q. Do you have any certifications?
A. Yes.
Q. What are your certifications?
A. American Board of Internal Medicine 1979.

Q. Anything else?

A. No.

Q. Where did you work after graduating from Baylor?

A. 1979 to 1981 I was on the faculty of the department of internal medicine at Baylor College of Medicine, Houston. From 1981 to 1991 I was on the faculty, department of internal medicine, Wake Forest University Baptist Medical School. 1991 to 1997 I was in private practice at Forsyth Hospital in Winston-Salem. 1997 to 2016 I returned to Wake Forest and was a general internist in an academic group practice in Winston-Salem. I retired in 2016. Since then I've done five activities. One, I'm one of the medical directors with the community care center. We're the largest and highest rated center for the uninsured and poor in the State of North Carolina. I also attend at the urgent care centers and minor emergency rooms in Winston-Salem as needed. I'm on the county board of health for Forsyth County. And I'm also executive director for a foundation -- Sister Mary Foundation that works in the countries of Benin, the Democratic Republic of Congo to rescue war orphans from their circumstances.

Q. When you retired in 2016, did you stop practicing medicine at that time?
A. For six months.
Q. Are you currently practicing medicine?
A. Yes.
Q. What is your area of practice?
A. Internal medicine.
Q. Do you have any other specializations?
A. No.
Q. Any other areas of practice?
A. No.
Q. Are you an expert in the diagnosis of gender dysphoria?
A. No.
Q. Have you ever diagnosed a patient with gender dysphoria?
A. No.
Q. Are you an expert in the treatment of gender dysphoria?
A. No.
Q. Have you ever treated a patient for gender dysphoria?
A. No.
Q. Are you an expert in the cost of treatment for gender dysphoria?

A. No.
Q. Have you ever submitted a request for pre-authorization for insurance coverage for gender concerning care?
A. No.
Q. Have you ever communicated with an insurer regarding a denial of coverage for gender confirming care?
A. No.
Q. Have you ever taught medicine?
A. Yes.
Q. Where did you teach?
A. Baylor College of Medicine, Wake Forest Baptist Medical Center.
Q. At Baylor what were you teaching?
A. General internal medicine.
Q. Did you teach anything else at Baylor?
A. No.
Q. What about at Wake Forest?
A. General internal medicine.
Q. Either at Baylor or at Wake Forest did you teach on the subject of gender dysphoria?
A. No.
Q. Have you ever taught on that subject?
A. No.

Q. Have you ever been published in the area of gender dysphoria?
A. No.
Q. Have you ever conducted research on the treatment of gender dysphoria?
A. No.
Q. Have you ever read medical literature on the subject?
A. Yes.
Q. What literature have you reviewed?
A. Psychology article journals, I can't remember the names of them, but many related to the provision of psychological support for people with gender dysphoria. I've also read recommended guidelines of the American Medical Association, similar other organizations I can't recall, on the management of gender dysphoria.
Q. When did you review this literature?
A. In the last six months.
Q. Do you recall the authors of the literature you reviewed?
A. No.
Q. Do you recall the dates any of it was published?
A. I think the psychology one I read was in

December of 2020.

Q. Do you recall the title of that article?

A. No.

Q. Do you recall any other medical literature that you have reviewed on the subject of gender dysphoria?

A. No.

Q. Have you ever peer reviewed any literature on the subject of gender dysphoria?

A. No.

Q. Are you currently serving on the board of trustees for the North Carolina State Plan Insurance for Teachers and State Employees?

A. Yes.

Q. If I refer to that as the plan today, will you know what I'm talking about?

A. I'm sorry, I didn't hear your question.

Q. If I refer to the North Carolina State Health Plan for Teachers and State Employees as the plan today, will you know what I'm talking about?

A. Yes.

Q. How long have you served on the plan board of trustees?

A. Since February 2018.

Q. What are your responsibilities as a

or modifications?

A. Yes.

Q. Do you see that language on the page there, about two-thirds of the way down?

A. Yes, I see it.

Q. I will ask you to turn to the page marked PLAN DEF2699.

A. We're on that page.

Q. Are you aware that in the 2016 plan year the plan excluded from coverage psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation?

A. Yes.

Q. If I refer to these exclusions from coverage as exclusions today, will you know what I'm talking about?

A. Yes.

Q. Do you know Treasurer Dale Folwell?

A. Yes.

Q. How do you know Treasurer Folwell?

A. We've been friends since the 1980s, and I know him in his capacity as the treasurer of the State of North Carolina and director of the State Health Plan along with Dee Jones as assistant.

Q. You said you've been friends since the

1990s. How long have you known Dale Folwell?

MR. WILLIAMS: Objection to the form.

A. Since the 1980s. 40 years.

Q. Where did you first meet?

A. He came in as a patient. He's been a patient of mine.

Q. I will ask you to take a look at what's been marked as Exhibit 2.

(Exhibit 2, Disclosure of Expert Witnesses, marked for identification, as of this date.)

Q. Have you seen this document before, Dr. Robie?

A. Yes.

Q. Would you turn to page 6 of this document.

A. Okay.

Q. The document states, "Dr. Robie will testify about the board's consideration of request that the plan eliminate the current coverage exclusion for gender transition surgery and related hormone development." Is that correct?

A. Yes.

Q. What testimony can you provide on this

topic?

A. I'm sorry, I didn't hear you.

Q. What testimony can you provide on this topic?

A. Can you be more specific in your question?

Q. What testimony can you provide about the board's consideration of request that the plan eliminate the current exclusion?

A. The cost of the gender transition surgery and related hormone treatment.

Q. What request did the plan receive for eliminating the current exclusion?

A. I don't know.

Q. Do you know what the plan considered in terms of whether to eliminate the exclusion or not?

A. Are you referring to discussions that occurred in 2016?

Q. Are you aware of discussions that occurred in 2016?

A. No.

Q. What about in 2017?

A. No.

Q. In 2018?

A. I think by then the plan excluded the

gender dysphoria treatment so I don't think we had any discussions about eliminating it, it was already not part of the plan package.

Q. Were there any discussions about eliminating the exclusion in 2018?

A. No.

Q. In 2018, did the plan receive any requests to lift the exclusion?

A. Yes.

Q. From whom?

A. Mr. Kadel and some other people in our board meeting, I believe it was October, November, December of 2018 when the public part of our board meeting made a presentation requesting we cover treatment for gender dysphoria.

Q. When was that presentation?

A. I believe October 2018.

Q. Who was giving that presentation?

A. There was a group. There was an attorney present. I do recall Mr. Kadel. I don't recall the other individuals, but there were about four or five others.

Q. In 2018, do you recall any other requests that the plan received to lift the exclusion?

MR. WILLIAMS: Objection to the form of the question. You can answer.

A. No.

Q. What was the board's consideration of the request it did consider?

A. Really, at that time there was no discussion other than hearing what Mr. Kadel and the other people had to say. The board didn't have any more discussion.

Q. Was there any internal deliberation following that meeting in October 2018?

A. At that time or any time since then?

Q. Let's start with at that time.

A. No.

Q. What about since then?

A. I recall two episodes. Ms. Kim Hargett who was a board member bringing up --

MR. WILLIAMS: Dr. Robie, let me caution you. To the extent that these discussions occurred outside the presence of counsel in open session, I think it's perfectly fine and appropriate for you to testify to. To the extent that any discussions occurred in closed session within the presence of counsel, I'm going to instruct

you not to answer those questions.

A. Okay. Well, those were closed sessions so I will not answer.

Q. To clarify, those were closed sessions you're referring to after October 2018?

A. Yes.

Q. Is there any other testimony you can offer about the board's consideration or request that the plan eliminate the exclusion?

A. No.

Q. Turning back to page 6 of the document, it states, "As a member of the board of trustees and as a physician, Dr. Robie has contributed his medical knowledge to board deliberations. Dr. Robie will testify to the medical knowledge he has shared with other board members."

Is that correct?

A. Yes.

Q. What medical knowledge have you shared with other board members?

A. Most recently, the coverage of continuous glucose monitors for diabetic patients.

Q. Anything else?

A. Some discussion of the biological agents for cancer treatment.

Q. Any other medical knowledge you've shared since joining the board?
A. Not that I recall.
Q. How did you share this information with other board members? Was it at a board meeting?
A. Yes.
Q. Which board meeting was it at?
A. Continuous glucose monitors has been over the last three or four board meetings as an agenda item.
Q. What about the information regarding cancer treatment?
A. Those were agenda items for board approval to cover the medicines.
Q. Were there any other board meetings where you shared this information?
A. No.
Q. What about outside of board meetings?
A. No.
Q. Apart from the information regarding diabetic treatment and cancer treatment, is there any other medical knowledge that you have shared with the board since joining the board of trustees?
A. I'm sure there has been, I just can't recall the specifics today.

Q. If anything else comes to mind today, will you let me know?

A. Yes.

Q. With which board members did you share this information?

A. All the board members in attendance at the meetings that I talked.

Q. With regard to the medical knowledge you have shared with other board members, is there any other testimony that you could provide on this topic?

A. No.

Q. Staying on page 6 of the document, it states that you will testify, "In order to provide diagnostic and medical treatment that meets a professional standard of care, primary care physicians must know the chromosomal sex of patients." Is that right?

A. Yes, I see it.

Q. What expert testimony can you provide on this topic?

A. Situations where it would be important for the treating provider to know the chromosomal sex of a patient.

Q. When is it important for a treating

the patient for the three conditions you mentioned here?

A. I would be more concerned about ovarian, uterine cancers in a chromosomal female. Chromosomal male would be testicular cancer. The potential workup and treatment with each condition is very different.

Q. How would that affect the care you give to the patient?

A. Delay in diagnosis.

Q. Is there anything else that affects the care you give the patient?

A. No.

Q. In your practice, do you confirm the chromosomal makeup of your patients?

A. No.

Q. When did you first form the opinion that primary care physicians must know the chromosomal makeup of their patients?

A. When this case was brought up. When I say case, I mean the legal action that you are a part of.

Q. Do you recall the year?

A. Of this individual that I saw?

Q. I'm sorry, I didn't catch that.

A. Would you ask the question a little more specifically, I'm sorry.

Q. You said that you formed the opinion that physicians must know the chromosomal makeup of their patient when this case was brought up. Do you recall the year that you formed that opinion?

A. It was the year the case was filed. So I'm going to guess 2019.

Q. Apart from what you mentioned in terms of delayed diagnosis, are there any other harms that you believe stem from primary care physicians not knowing their patients' chromosomes?

A. No.

Q. We've been going for about a half-hour now. Let's take a quick five-minute break and return in five minutes.

A. Okay.

MS. RAVI: Off the record.

(Recess taken.)

MS. RAVI: Before we proceed, will counsel for the defendant stipulate that the board intends to maintain its attorney/client privilege as to the closed sessions that occurred at board meetings in October 2018 and thereafter?

MR. WILLIAMS: Yes.

Q. Dr. Robie, turning back to page 6 of Exhibit 2, do you still have that in front of you?

MR. WILLIAMS: Let me log back in.

A. Okay, I have it.

Q. With regard to the statement that, "Dr. Robie will testify about the board's consideration of request that the plan eliminate the current coverage exclusion for gender transition surgery and related hormone development," other than what we've discussed today, is there any other testimony that you intend to offer on this topic?

MR. WILLIAMS: Objection to the form of the question.

A. The cost of the procedures.

Q. Anything else?

MR. WILLIAMS: Same objection.

A. No.

Q. Moving down, the document states, "Dr. Robie has contributed his medical knowledge to board deliberations. Dr. Robie will testify to the medical knowledge he has shared with other board members."

Other than what we discussed today regarding your discussions on treatment for patients

with diabetes and cancer treatment, is there any other testimony you intend to offer on this subject?

MR. WILLIAMS: Objection to the form.

A. COVID management, plan for COVID care, the status of COVID in the country, state. I mentioned earlier, I'm on the Forsyth County Board of Health so I'm in the loop, if you will, with boards of health, CDC and other agencies such as the State Department of Health and Human Services. So that was another topic I've spoken on to the board.

Q. Anything else?

A. No.

Q. With regard to your testimony that in order to provide diagnostic and medical treatment that meets the professional standard of care, primary care physicians must know the chromosomal sex of patients, with regard to that issue, apart from the examples you mentioned regarding treatment of patients with hemophilia, contacting patients' families and your own experience with a patient in the mid '90s, is there any other testimony that you intend to offer on this topic?

MR. WILLIAMS: Objection to the

form.

A. No.

Q. Dr. Robie, are you familiar with the World Professional Association for Transgender Health Standards of Care for Treatment of Gender Identification Disorder?

A. Yes.

Q. Do you have a position on the validity of those standards of care?

A. No.

Q. Are you familiar with the American Medical Association's Resolution 122 issued in 2008?

A. May I see it?

Q. Are you familiar with it?

A. I believe, yes.

Q. What is your understanding of that resolution?

A. I can't recall.

Q. Are you familiar with the DSM 5, the diagnostic and statistical manual of mental disorders definitions?

A. No.

Q. Are you familiar with the Endocrine Society Clinical Practice Guidelines on Treatment of Gender Dysphoria Or Gender Incongruent Persons?

A. No.
Q. If you could please take a look at what's been marked as Exhibit 3.
(Exhibit 3, PLAN DEF0028665, marked for identification, as of this date.)
MR. WILLIAMS: Okay.
Q. Have you seen this document before?
A. Yes.
Q. What is this document?
A. It's a statement from Treasurer Folwell, coverage of sex change operations.
Q. Did you discuss the statement with Treasurer Folwell?
MR. WILLIAMS: Objection to the form.
A. Before its release or after its release?
Q. Let's start with before its release.
A. No.
Q. Did you discuss this statement with Treasurer Folwell after its release?
A. The only discussion that I recall that the board with me being on the board was that any further discussion with people not on the board would come through Treasurer Folwell's office, not from us as individuals.

Q. Apart from the statement itself, did you discuss any of the content of the statement with Treasurer Folwell?

MR. WILLIAMS: Objection to the form.

A. No.

Q. Have you ever had a conversation with Treasurer Folwell regarding the medical necessity of gender confirming care?

A. No.

Q. Can gender confirming care ever be medically necessary for a patient?

A. That decision is made by the provider, patient's physician, and the patient together. The medical necessity is determined really at that level. To me, when the guidelines are issued by organizations such as the American Medical Association and the Society and so on, they are guidelines. The medical necessity is not determined by the guidelines, it's determined by the provider and the patient.

Q. Is there ever a circumstance where a provider and patient together could determine that gender confirming care is medically necessary?

MR. WILLIAMS: Objection to the

form.

A. I don't know.

Q. Going back to Exhibit 3, other than Treasurer Folwell, did you discuss the contents of this statement with anyone else?

A. No.

Q. Are you familiar with the Segal Company?

A. No.

Q. Are you aware of the total cost that the plan incurred for covering gender confirming care in 2017?

A. No.

Q. I will ask you to take a look at what's been marked as Exhibit 4.

(Exhibit 4, PLAN DEF0038905, marked for identification, as of this date.)

A. Okay.

Q. Are you familiar with this document, Dr. Robie?

A. Yes.

Q. What is this document?

A. It's an e-mail on our last board meeting sharing my thoughts about several e-mails that plan members had sent to the board since their last meeting.

Q. This e-mail was sent by you on August 26, 2018; is that correct?
A. Yes.
Q. It was sent to Treasurer Folwell and to Dee Jones?
A. Yes.
Q. Your e-mail states you looked into the cost of covering transgender surgery by the State Health Plan; is that correct?
A. Yes.
Q. What did you look into?
A. I looked at the cost using my browser search engine on the potential cost of transgender surgeries and potentially how much that cost would be to the plan.
Q. What sources did you review?
A. I'm sorry, what websites?
Q. Yes. Let's start with websites. What websites did you review on this issue?
A. I don't recall.
Q. Do you recall how many websites you looked at?
A. Five or six.
Q. Do you recall any of the authors of the contents you looked at?

A. No.
Q. Do you recall any of the dates that content was made available?
A. After our board meeting -- really before our board meeting, in October 2018, and I looked at it after Treasurer Folwell released the in statement Exhibit 3, and then I reviewed it last week.
Q. Is it correct that as of the date of your e-mail, August 26, 2018, you had already looked at those five to six websites?
A. Yes.
Q. Do you recall anything else about the websites you looked at?
A. No.
Q. Other than websites, did you look into any other sources regarding the cost of covering transgender surgery by the State Health Plan?
A. I looked at what the city of San Francisco plan was for covering transgender surgery at that time.
Q. You said that was the San Francisco plan?
A. The city of San Francisco, yes.
Q. How did you get that information?

A. Just search on my browser.
Q. Was that one of the five or six websites you looked at?
A. Yes.
Q. What did you learn about the San Francisco plan?
A. That up until, I believe, 2012 San Francisco was giving plan members requiring gender dysphoria treatment care a plan amount of money per year and capped it at that amount of money. I don't remember what the amount was. But the follow-up study that I did showed that they dropped that and now provide full coverage.
Q. I'm sorry, I didn't catch that last sentence.
A. A follow-up study of the plan showed that they had dropped that plan amount and now provided full coverage for gender dysphoria.
Q. Did you review that follow-up study?
A. It wasn't a study, it was just a public release by the city health plan.
Q. With regard to your own searches into the cost of covering this treatment, other than the five to six websites you looked at, were there any other sources that you looked at to learn this

information?

A. No.

Q. Your e-mail states that you were told the average cost of this surgery was on the average of $142,000; is that correct?

A. Yes.

Q. Who told you that?

A. The websites.

Q. Do you recall which website had that figure?

A. No.

Q. Does this $142,000 refer to surgery for a transgender male or transgender female?

A. I believe it was not differentiated that I recall.

Q. What surgical procedures would be included in this $142,000 amount?

A. I believe I counted 20. I'm trying to remember what they were. Scalp surgery, eye surgery, eyebrow surgery, forehead surgery, ear surgery, two nose procedures, one on the bridge of the nose, one on the nose itself, lip surgery, chin surgery, cheek surgery, Adam's apple surgery, breast augmentation or breast removal surgery, genital surgery, surgery on the buttocks and on the

hips, one's going male to female to get the hour glass shape to the top of the body. Those are the surgeries. There are also websites included in the cost. Speech therapy to speak more like the opposite sex. Walking therapy. And then, of course, psychological therapy and medication coverage.

Q. Those are the surgical procedures that would be included within this $142,000 average cost?

A. Yes.

Q. Are there any other surgical procedures that you --

A. There may be, I don't know if there are any more but there may be.

Q. You stated that you were told there is an additional cost of 71,000 for breast augmentation for male to female transgender surgery; is that correct?

A. I think that was -- the answer is yes, I was for people that just wanted that surgery. From what I gathered reading websites, not all transgender individuals want all 20 operations. They want certain operations and not others. So if they're getting just that, that's the cost I saw quoted.

Q. So to clarify, you mentioned earlier that the $142,000 figure could include breast augmentation surgery. Is that cost included within the 142,000 or is that a separate $71,000 cost --

A. That's included in the cost of the 142,000.

Q. Are there any other surgeries that you are aware of that would go into this cost that you were referencing in October 2001?

A. The electrolysis for hair removal.

Q. Anything else?

A. No.

Q. With regard to the cost of breast augmentation surgery, other than the information that you learned from these websites that you looked at, have you ever otherwise researched the cost of the surgery yourself?

A. No.

Q. Have you ever consulted with other medical providers on how much that particular surgery might cost?

A. For gender dysphoria or any other conditions?

Q. Let's start with just gender dysphoria.

A. No.

Q. What about for other conditions?
A. It's really determined by the insurance coverage.
Q. How is the cost of the surgery determined by the insurance coverage?
A. I don't know.
Q. So there's a particular cost of surgery for the surgery and that surgery is determined by a process that includes consideration of insurance coverage?
A. Yes.
Q. But you're not aware of how the insurance coverage plays into the determination of the cost?
A. Yes.
Q. I will ask you to please take a look at what's been marked as Exhibit 5.
(Exhibit 5, PLAN DEF0033668, marked for identification, as of this date.)
A. Okay, I have it.
Q. Are you familiar with this document?
A. Yes.
Q. Is this an e-mail exchange between you, Treasurer Folwell and Dee Jones on October 25, 2018?
A. Yes.

Q. You stated that you were asked by a reporter for an interview about the board's attitude about coverage for transgender surgery; is that correct?

A. Yes.

Q. You responded that in the interview you had focused on the cost of the surgery and how we are trying to control cost; is that right?

A. That's what I said. The interview did not take place.

Q. When you referred to, "We are trying to control cost," who were you referring to there?

A. The State Health Plan.

Q. At this time in October 2018, what was your understanding of the cost of surgery for gender confirming care?

A. The numbers that we just discussed, 142,000.

Q. And those numbers were based on research you did prior to your August 2018 e-mail exchange that we just looked at?

A. Yes.

Q. Was there any other time when you researched the cost of gender confirming care?

A. No.

Q. Have there been any other sources that you have consulted regarding the cost of gender confirming care?

A. No.

Q. I will ask you to take a look at what has been marked as Exhibit 6 please.

(Exhibit 6, PLAN DEF0079132, marked for identification, as of this date.)

A. Okay.

Q. Have you seen this document before?

A. No.

Q. Does this appear to be a compilation of articles mentioning or relevant to the North Carolina State Department of the Treasurer circulated on October 25, 2018?

A. Yes.

Q. Around October 22, 2018, did you attend a board of trustees meeting?

A. I don't remember.

Q. You mentioned earlier regarding the board's consideration of request to lift the exclusion that there was some testimony at a meeting around October 2018. Do you recall that?

A. Yes.

Q. Was that a board of trustees meeting?

A. It was an open public session of the board of trustees meeting, for the public to make presentations.

Q. Do you recall speaking at that meeting?

A. Yes.

Q. Did you speak about your own experience with the cost of surgery for gender confirming care?

A. Yes.

Q. Did you speak on any other subject at that meeting?

A. At the open public session?

Q. Yes.

A. Not that I recall.

Q. What did you say about your own experience with the cost of surgery for gender confirming care?

A. Several years before I had a transgender male that had no insurance, was at an age where if he was going to have the transgender surgery he figured that would be the time to do it, the issue was approaching so we looked into the cost, what we thought would be the cost for him with that insurance to have the surgery. At that time, I came up with that figure of 140,000 roughly. And when he heard that, he decided not to proceed

further.

Q. What was the year in which you were having that conversation with the individual thinking about surgery?

A. I don't recall.

Q. It was sometime prior to 2018?

A. Yes.

Q. Do you recall approximately how long prior to 2018 you had that discussion with a patient?

A. It would be a guess, but I would guess 10 years.

Q. If you could turn to the page marked PLAN DEF 79138.

A. Yes. I have it.

Q. The first two paragraphs under "De Minimus," is that an accurate representation of your statements at that October 2018 meeting?

A. To my memory, yes.

Q. Your statement that the cost for uninsured patients for counseling, medication, surgery and follow up was $140,000, how did you come to an understanding of those costs?

A. We did a browser search, and I believe I checked with the Duke Medical Center Transgender

Center which I believe was operational at that time for uninsured patients, those were the numbers I recall being quoted.

Q. Was this browser search separate from the search we discussed prior to your August 2018 e-mail?

A. Yes.

Q. When did you do this browser search?

A. 2008.

Q. 2008?

A. Yes.

Q. What websites did you review in your search in 2008?

A. I don't remember.

Q. Were there any other sources you reviewed in 2008?

A. No.

Q. With regard to your outreach to -- you said it was the Duke Medical Center?

A. To my memory, yes.

Q. Was that also in 2008?

A. Yes.

Q. Who did you talk to there?

A. I didn't. I looked at their website.

Q. What did their website say about the

cost for counseling, medication, surgery and followup?

A. For uninsured patients, that was the number that was provided to my memory.

Q. Were there any other sources that you consulted to get to this estimate of $140,000?

A. No.

Q. Other than the search you conducted in 2008, and the search we discussed that you conducted prior to your e-mail in August 2018, was there any other time that you researched the cost of gender confirming care?

A. Yes.

Q. When was that?

A. Yesterday.

Q. What did you look at yesterday?

A. Websites.

Q. Which websites did you look at yesterday?

A. I looked at several. The one that comes to mind was the Philadelphia Center for Gender Translational Surgery -- that may not be a totally accurate rendition, but it was Philadelphia based transgender surgical site.

Q. Any other websites that you looked at

yesterday?

A. I did, but I don't recall their names.

Q. Do you remember how many websites you looked at yesterday?

A. Three.

Q. One was the Philadelphia center and two others?

A. Yes.

Q. Other than in 2008, around August of 2018, and yesterday, any other time you looked into the cost of gender confirming care?

A. No.

Q. Let's go back to PLAN DEF 7913. Do you still have that in front of you?

MR. WILLIAMS: 79138?

MS. RAVI: That's right.

MR. WILLIAMS: Yes.

Q. At the October 2018 meeting, did you also state that the cost for male to female transgender breast augmentation was $60,000?

A. Yes.

Q. How did you come to the understanding of that cost?

A. My memory is that that was the cost quoted at one of the websites for uninsured

patients.

Q. Was that one of the websites you looked at in 2008?

A. No.

Q. When did you look at that website?

A. The one we're talking about that I just mentioned in this document?

Q. That's right.

A. In October 2018.

Q. In October 2018, were you researching the cost of gender confirming care?

A. Yes.

Q. Was this separate from what you had looked at in August of 2018?

A. I believe it was the same browser search, clicking on websites, it may have been different websites.

Q. Do you remember which website had this information?

A. No.

Q. Other than the websites we've discussed, is there any other source that you have consulted with regarding the cost of gender confirming care?

A. No.

MR. WILLIAMS: Objection to the

form of the question.
A. No.
Q. Have you spoken with anyone about this cost?
A. No.
Q. Regarding the statement that the cost for an insured patients for counseling, medication and surgery and followup was $140,000, what is the counseling referred to in your statement?
A. Pre-surgical counseling for a year and counseling after the surgery.
Q. How much does that counseling cost?
A. I don't remember.
Q. Are you aware of whether the plan currently covers counseling for treatment of gender dysphoria?
A. I believe they do not.
Q. With regard to the medication referred to in your statement, what medication is being referred to there?
A. Hormone therapy.
Q. Any other medication?
A. Psychiatric medication, antidepressants.
Q. Anything else?
A. Not that I can think of.

A. I don't remember.
Q. Do you remember when you received that information?
A. No.
Q. In your statement you refer to followup. What is that followup you're referring to?
A. Surgical followup for potential complications from the surgery plus psychological followup.
Q. Are you aware of the prevalence of individuals in North Carolina who identify as transgender?
A. Last night when I was reading one of the websites for cost, I think I saw the figure estimated of 45,000 individuals in the State of North Carolina that are transgender.
Q. Which website was that?
A. I don't remember.
Q. When did you look at that website?
A. Yesterday.
Q. So this was one of the three websites you reviewed yesterday?
A. Yes.
Q. Do you remember the author of the material you looked at?

A. No.
Q. How long did you spend reviewing that website?
A. I don't remember.
Q. Are you familiar with the number of North Carolina State Health Plan members who are expected to use coverage for gender dysphoria?
MR. WILLIAMS: Objection to the form of the question.
A. No.
Q. Yesterday when you were looking at the three websites you mentioned, how long did you spend looking at them?
A. Half an hour.
Q. You mentioned that you also looked into this issue in around August of 2018. Do you recall how long you spent looking into the issue at that time?
A. No.
Q. What about in 2008?
A. I don't remember.
MS. RAVI: Off the record.
(Discussion off the record.)
Q. Dr. Robie, are you aware of whether the plan negotiates rates with medical providers?

the hospital, total cost for each procedure.

Q. What were the procedures listed on the Philadelphia website?

A. Pretty much the ones that I mentioned earlier. Do you want me to go through them again?

Q. Yes, please.

A. Scalp surgery, eye surgery, eyelid surgery, forehead surgery, eyebrow surgery. Two nose operations, bridge of the nose and the nose itself. Teeth surgery, chin surgery. Ear surgery. Adam's apple surgery. Breast augmentation or removal surgery. Genital surgery. Surgery on the buttocks and hip to get the hour glass figure for female. And I forgot -- electrolysis for hair removal.

Q. Are you aware whether these procedures were covered in 2017 by the plan?

A. No. I don't know.

Q. Are you aware of whether any of the procedures you just mentioned were not covered by the plan in 2017?

A. I don't know.

Q. With regard to your estimate of $140,000, does that cover all of the procedures that you just mentioned?

MR. WILLIAMS: Objection to the form.

A. It covers the procedures, I don't recall if it also covers the counseling and the hormone therapy. I think it did not. These were surgical procedures.

Q. Are you aware of whether a person seeking gender confirming care would receive all of the procedures that you just listed?

MR. WILLIAMS: Objection to the form.

A. From what I saw on the websites, some choose a few procedures, it's very patient specific.

Q. So is it the case that a person seeking gender confirming care might not choose all of these procedures?

A. Yes.

Q. But the cost of them, your understanding based on the websites you reviewed is that the cost of all these procedures together totals $140,000?

A. The one in Philadelphia yesterday was 184,000. One would assume that if the plan covered transgender surgery, we would have a mix of patients wanting a few procedures, moderate number

firm Bell Davis & Pitt and I'm one of the attorneys for Mr. Folwell, Ms. Jones and the State Health Plan.

With apologies to everybody, I will bounce around a little bit to clean up some areas.

EXAMINATION BY

MR. WILLIAMS:

Q. Dr. Robie, I will start by asking you this question. We looked at some -- an e-mail earlier where Treasurer Folwell used the word elective. We talked a little bit about medical necessity. And I wonder if you can just provide some context as to what that means to you as an internist and someone who has been practicing in the medical field for over 40 years?

A. Well, it's an issue I deal with everyday. I mentioned earlier, I'm one of the medical directors of the community care center plus I work in the urgent care centers and minor emergency rooms in Winston-Salem. I've been working several days this month and will work everyday at the end of the month. We have people come in with COVID, with low oxygen levels, that's an emergency, that's not an elective problem,

that's something that needs to be addressed right then and there, and we do that. As opposed to somebody coming in with, relevant to what we're talking about, need for plastic surgery procedure, that's not something that needs to be done to save your life that day. That's something that is elective which means it could be scheduled at an opportune time for the patient and surgeon. As you probably know, many medical centers have actually had to hold off on elective surgery because of the COVID crisis. Transgender surgery would fall in that category, elective, wait until the COVID crisis calms down before they will proceed.

The only thing about elective surgery, we're talking plastic surgical procedures in transgender surgery, and you're cutting across normal tissue, really you're treating a psychological issue, major psychological issue, by cutting on normal tissues. So you're having an elective procedure where you're cutting on normal tissues to treat a psychological condition that could be very significant, but I just want the surgical procedure to be viewed in that mindset.

You know, I've been the head of -- one of the medical directors for the community care

the same kind of numbers. That's what's surprising to me, that the cost is, to me, very high.

Q. Dr. Robie, remind us how long have you been a practicing physician?

A. Since 1976. 45 years.

Q. I believe your testimony was that in 2008 you probably spent about an hour doing this internet research, same thing for 2018, maybe about an hour doing this research, and then yesterday you spent maybe 30 minutes; is that correct?

A. Right.

Q. So based on your 45, 46 years of experience as a physician, combined with the research -- internet research that you did, did you -- were you able to reasonably conclude that those figures that you were using were pretty close?

A. Yes.

Q. Did you determine that the websites that you were visiting and information that you were gathering were both reasonable and reliable to lead you to conclude that those cost approximations were reasonable and accurate?

A. Yes. What struck me is how the numbers haven't changed. Over 13 years.

Q. One thing we haven't touched on today

is, as a physician, your concerns potentially about adolescents receiving transgender treatments. Can you speak a little bit to that?

A. Well, yes. The human brain in an adolescent is not fully developed. I think the current thinking is that in young women, the brain is fully developed by age 21, and the young male or young man would be 25 before the brain is fully developed. So looking at an adolescence brain, it changes dramatically from year to year. To have an adolescent undergo irreversible drug treatment or surgery for gender dysphoria to me is really not ethically appropriate because who you're talking to at age 16 may be different at age 18.

I have a little personal experience with that. I was friends, not the doctor, but I was friends with a couple who had a child at age 16 undergo transgender surgery, graduated high school, went off to college. After a year, had to be treated for severe depression, at age 19 had to hospitalized. One of the issues that caused the depression was that the transgender may have been a mistake. That's got to happen. I don't know that the -- I guess publicized, but it's common sense is going to tell you when you deal with an age group

for counseling as a measure of success goes up after transgender surgery, and if you're doing operations mainly for psychological benefits and then your counseling needs to increase after the surgery, are you really succeeding. I think that's what he is quoting about some uncertainty.

Q. Do you recall having a specific conversation with Treasurer Folwell about this concept of medical uncertainty has never been greater in or around October 2019?

A. I may have, but I don't recall it as I sit here at the moment.

Q. So you don't recall a specific conversation but it's certainly possible?

A. It's possible. But my emphasis is the cost of the procedure, trying to have a fiduciary duty of prudence to the plan members, to spend that much money on a small group of individuals versus spending that money on a large group of individuals before proving benefit is my concern.

Q. Last topic I think.

I want to take you back, teleport you back to October 2018 and the board meeting where Mr. Kadel and others made presentations during the public session to the board meeting.

A. Yes.

Q. The best you can recall, I would like for you to recount for the group what that presentation, what you recall from that presentation and what you recall saying to these folks who were presenting and to the rest of the board in the open session of the board meeting.

A. I do recall there was a group, I think there was about five of them, they had an attorney. I believe the attorney made an opening statement requesting that the board of trustees approve covering for transgender surgery. Mr. Kadel then came and talked. My memory is that he spoke very eloquently. I think he was a music major at UNC. That's my memory. But he was very eloquent in what he was saying. In that mix was a mother and father talking on behalf their teenage child to have transgender surgery. I believe the mother was a nurse, if my memory serves, or in the medical healthcare field I think, was a little more upset that it was not covered.

After the board meeting was over with, that group had a press conference, some people of the press there, I was not party to what they were saying, they did talk to the press afterwards, I

think the attorney was the main one I recall talking to the press, and they had the group picture taken. That's what I recall.

Q. Do you remember addressing the group of presenters during open session?

A. Yes. About the fact the person I had in 2008 searching for the cost for an uninsured person to have transgender surgery, female to male, that's where I got those numbers originally. They took one look at that and said it's too much money, I don't have it.

Q. That's the testimony that you gave earlier about the cost?

A. Right.

Q. Dr. Robie, I'm going to refer you to Exhibit 5.

A. Okay.

Q. I want to refer you to two e-mails in this chain. There's an original e-mail from you, this is at the bottom of the page, that e-mail is from you to Treasurer Folwell with a copy to -- we can't see but presumably it's a copy to Dee Jones, and Mr. Folwell responds to you and we can see the response is copied to Dee Jones; correct?

A. Right.

Q. Your e-mail is October 25, 2018 at 9:40 a.m. This is when you had been approached by North Carolina Policy Watch for an interview that you testified earlier never happened; is that correct?

A. Correct.

Q. My only question with respect to this e-mail is the very last part, the last sentence, it says, "Let me know if you were okay with this PR." What does PR mean in that e-mail?

A. Those are my initials, Pete Robie. It doesn't mean public relations, it means PR, Pete Robie. Those are my initials.

MR. WILLIAMS: Off the record.

(Recess taken.)

Q. Dr. Robie, thank you for your time today and we have no further questions.

MS. RAVI: Off the record.

(Recess taken.)

FURTHER EXAMINATION

BY MS. RAVI:

Q. Dr. Robie, I have just a few follow up questions for you. You were discussing earlier elective treatment and you gave an example of life saving treatment that was not elective. Is it the case that elective surgery is something you consider

doctor, provider and the patient, medical necessity. So the answer is it depends on doctor/patient relationship to make that relationship.

Q. So is it correct that some elective care can be medically necessary as determined by the doctor/patient --

A. If that's determined, the answer is yes.

Q. You also testified earlier regarding knowledge of chromosomal makeup of patients.

A. Correct.

Q. In your practice, do you ask your patients about their gender identity?

A. They are now asked as a standard screen on intake, every patient. We use the Epic electronic medical record and they do have a section on just that question. What do you consider your identity. Cis male, cis female, trans male, trans female. There are so many variations I forget what the others they ask. Not sure. But that question is standard. So the answer is yes, all of them are asked.

Q. When did you start asking your patients that question?

MR. WILLIAMS: Objection to the

form of the question.

A. It was not up to me to make that decision, it was up to the Wake Forest Baptist Medical Center and the Novant Health System -- Epic updated their software to include those questions when that happened. I don't recall. But I know it's been asked for several months now.

Q. I'm sorry, did you say several months now?

A. Yes.

Q. Do you ask your patients in your practice about their chromosomal makeup?

A. Only if the nurse says I need to. I can't recall recently where I've been asked to do that.

Q. When does a nurse tell you that you need to?

A. If the patient's not comfortable expressing that they're trans male or trans female to the nurse. You know, a lot of human communication is non-visual. So the patient may say I'm a cis male but the way they say it to the nurse that there's some uncertainty about this, so, Dr. Robie, would you follow-up on that and try and establish what's going on.

Q. Separate from asking patients about their gender identity, do you ask patients about their chromosomal makeup?

A. No.

Q. Are you aware of whether emergency rooms perform chromosomal testing before providing care?

A. Well, the chromosomal testing is not a quick test. I think it's 24, 48 hours. If they order it, it won't be any help if they have an immediate emergency, life threatening emergency.

Q. So is it the case then that an emergency room would not provide that test before providing emergency care?

A. Yes.

Q. You've been practicing as a primary care physician for 45 years; is that correct?

A. Yes.

Q. In that time, how many transgender patients have you treated?

A. That I've knowingly treated. Four come to mind. But I'm sure there were others that I was not aware were transgender.

Q. Of those four, how many were adults?

A. All four.

Q. Have you ever treated a transgender

adolescent?

A. No.

Q. Have you ever treated a transgender child?

A. No.

Q. Thank you very much. I have no further questions.

MR. WILLIAMS: Nothing further from me.

MR. MCINNES: No questions on behalf of the North Carolina Department of Public Safety.

THE REPORTER: Would you like a copy of the transcript, Ms. Ravi?

MS. RAVI: Yes, please.

THE REPORTER: Would you like a copy of the transcript, Mr. Williams?

MR. WILLIAMS: Just however they have been sent before, yes.

THE REPORTER: Would you like a copy of the transcript, Mr. McInnes?

MR. MCINNES: Yes, e-Tran please.

(Deposition concluded at 1:07 p.m.)

(Signature reserved)

Exhibit 04

From: Peter Robie <pwrobie@gmail.com>
Sent: Sun, 26 Aug 2018 10:55:01 -0400
To: Dee Jones <dee.jones@nctreasurer.com>
CC: Dale.Folwell@nctreasurer.com
Subject: Emails since our last board meeting

I'd like to share some thoughts on several emails members have sent to the board since the last meeting, in preparation for the meeting this Thursday. An early email was limiting the cost of an insulin pump for juvenile diabetics. The writer implied that juvenile diabetics were not at fault for their diabetic state as opposed to adult onset diabetics. I think if a deductible change is made for insulin pump diabetics it should apply to all diabetics not just juvenile onset diabetics. I suspect this would be cost prohibitive and not an option the board should pursue. On a similar line there was a request to cover transgender surgery by the state health plan, claiming not doing so was discriminatory. I looked into the cost of such surgery and was told it was on average $142,000, with an additional cost of $71,000 for breast augmentation for male-to-female transgender surgery I don't think the plan can absorb such costs and I think we should decline coverage because of this. I got the impression there may be legal action taken against the state health plan if we don't cover transgender surgery but on a cost basis alone I don't think we can afford it. Another member decried the cost of taking his son to the ER late at night and having to pay a four figure charge for the visit after the state health plan discount was applied. This problem is not a state health plan issue but just the effects of unavailable urgent care coverage at night. One member decried the limitation on pain med limitations-I reviewed the NC medical board's position paper on opioid prescribing and the BCBS coverage is entirely in keeping with current opioid prescribing practices-perhaps that member should be directed to a pain clinic to explore nonopioid options for chronic pain. Finally a member requested that the plan cover CPAP supplies more generously. I agree with her that we should look into that, perhaps at a board meeting if you think the board should make a decision. The other emails I think were handled fine by your excellent staff. See you Thursday! Pete Robie MD

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MOTION TO EXCLUDE
EXPERT TESTIMONY OF DR. PAUL W. HRUZ

Now come, Plaintiffs, by and through their counsel, and respectfully move this Court to exclude the expert report, opinions, and testimony of State Health Plan Defendants[1] proposed expert, Dr. Paul W. Hruz, pursuant to Federal Rules of Civil Procedure 26 and 37, and Federal Rules of Evidence 104, 403, and 702. Dr. Hruz is not a qualified expert on gender dysphoria or its treatment, and his opinions and testimony are neither relevant nor reliable, under Federal Rule of Evidence 702 and the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions and testimony are likewise inadmissible because any probative value they may have (and they have none) is substantially outweighed by the danger of unfair prejudice,

[1] The State Health Plan Defendants are the North Carolina State Health Plan for Teachers and State Employees ("NCSHP"); Dale Folwell, in his official capacity as State Treasurer; and Dee Jones, in her official capacity as Executive Administrator of the NCSHP.

confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. *See* Fed. R. Evid. 403.

A memorandum of law is filed contemporaneously herewith.

Dated this 2nd day of February, 2022.

Respectfully submitted,

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

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

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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, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PAUL W. HRUZ

TABLE OF CONTENTS

Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Paul W. Hruz.[1]

STATEMENT OF THE CASE AND FACTS

Plaintiffs are current or former participants in the North Carolina State Health Plan for Teachers and State Employees (the "Health Plan"). North Carolina provides health coverage to its employees and their dependents through the Health Plan. The Plan denies coverage for the gender-affirming care that transgender people require because it contains sweeping exclusions of such care but covers the same kinds of treatments for cisgender employees who require them for other reasons. Defendants thus deny equal treatment to Plaintiffs because they are transgender.

INTRODUCTION

Plan Defendants identified and disclosed an expert report from Dr. Hruz to support their contention that they need not provide coverage for gender-affirming care, including hormones and surgery, as treatment for gender dysphoria. But Dr. Hruz has no experience treating or diagnosing gender dysphoria, has never done any original research on the issue, has never published any peer-reviewed literature on the matter, and holds opinions that are purely speculative and far afield from the mainstream of the medical and scientific communities.

[1] Unless otherwise specified, all exhibits cited herein are attached to the contemporaneously filed Declaration of Omar Gonzalez-Pagan.

Dr. Hruz is thus unqualified to serve as an expert in this case and his opinions should be excluded as irrelevant and/or unreliable under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions are also inadmissible under Rule 403 because any probative value they may have (and they have none) is substantially outweighed by the danger of unfair prejudice and confusion of the issues they would cause.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court, *Nease v. Ford Motor Co.*, 848 F.3d 219, 230 (4th Cir. 2017), to ensure that an expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). And "the importance of the gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

"Where the admissibility of expert testimony is specifically questioned, Rule 702 and *Daubert* require that the district court make explicit findings, whether by written opinion or orally on the record, as to the challenged preconditions to admissibility." *Id.* "The proponent of the testimony must establish its admissibility by a preponderance of proof." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F.Supp.3d 529, 537 (M.D.N.C. 2019) (quotation omitted), *aff'd*, 842 F. App'x 847 (4th Cir. 2021).

First, the court must determine whether the proposed expert is even qualified to render the proffered opinion, which requires examining the expert's professional

qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012). If the purported expert is not qualified, the court should exclude the testimony. *See SMD Software, Inc. v. EMove, Inc.*, 945 F.Supp.2d 628, 639 (E.D.N.C. 2013).

Second, even if the expert is qualified, the court must consider the relevancy of the expert's testimony as it is "a precondition to admissibility." *Sardis*, 10 F.4th at 282. To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281. "[I]f an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.*

Third, the court must inquire if the opinion is based on a reliable foundation, focusing on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* at 281-82. In evaluating reliability, courts consider, among other things, whether: (1) the theory "can be and has been tested"; (2) has been "subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "whether the technique is generally accepted in the scientific community." *Id.* at 281; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149-150 (1999). These factors are "neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199–200 (4th Cir. 2001) (citation omitted).

When an expert relies upon his experience and training, and not a specific methodology, the application of the *Daubert* factors is more limited. *See Freeman v. Case*

Corp., 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). In such cases, courts consider: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F.Supp.3d 579, 589 (E.D.N.C. 2015); *see also Nat'l Ass'n for Rational Sexual Offense Laws v. Stein*, No. 1:17CV53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021).

Finally, the Fourth Circuit has cautioned that although the trial court has "broad latitude" to determine reliability, it must still engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-examination is not a substitute for the court's gatekeeping role. *See Nease*, 848 F.3d at 231.

ARGUMENT

I. Dr. Hruz is not qualified to offer an expert opinion on the diagnosis and treatment of gender dysphoria, or any issue in this case.

An expert witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *Wright v. United States*, 280 F.Supp.2d 472, 478 (M.D.N.C. 2003). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 5:13-CV-210-BO, 2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014).

However, "qualifications alone do not suffice." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *see also Patel ex rel. Patel v. Menard, Inc.*, No. 1:09-CV-0360-TWP-DML, 2011 WL 4738339, at *1 (S.D. Ind. Oct. 6, 2011). Even "[a] supremely

qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under … *Daubert*." *Clark*, 192 F.3d at 759 n.5.

Moreover, "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp.*, No. 04 C 1274, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *see also Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014). "Generalized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362, at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has achieved certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F.Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994); *see also*, *e.g.*, *Hartke v. McKelway*, 526 F.Supp. 97, 100-101 (D.D.C. 1981).

Here, Dr. Hruz is not qualified to render expert opinions on the issues at hand. Dr. Hruz has not treated any transgender patients with gender dysphoria or conducted any original or peer-reviewed research about gender identity, transgender people, or gender dysphoria. He is also not qualified to render opinions on the diagnosis of gender dysphoria, as he is not a psychiatrist, a psychologist, nor mental health care provider of any kind. Indeed, Dr. Hruz has never been qualified by a court as an expert in these matters.

Dr. Hruz has never treated or diagnosed a transgender patient with gender dysphoria. Ex. A at 88:18-89:8, 89:17-25; Ex. C at 24:11-24:14, 25:20-25:23. Dr. Hruz has also not sat in on a meeting with a patient discussing the treatment options for gender dysphoria. *Id.* at 40:6-40:11. Nor has he conducted any original research about transgender people or gender dysphoria. Ex. A at 35:5-36:1; Ex. C at 62:25-63:9; Ex. D at 25:24-28:13. He has not published any scientific, peer-reviewed literature on gender dysphoria or transgender people either. Ex. A at 42:14-49:19; Ex. C at 61:17-64:7, 295:19-295:23.[2]

Dr. Hruz is neither a psychiatrist, a psychologist, nor a mental health care provider of any kind qualified to diagnose gender dysphoria or to opine on the reliability of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5"). Ex. A at 112:9-11, 55:23-56:15; Ex. C at 41:21-42:2, 42:11-42:18. Thus, Dr. Hruz cannot provide any opinion on the diagnosis of gender dysphoria, nor does he have expertise relating to psychiatric diagnoses. *See Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("The *Daubert* test must be applied with due regard for the specialization of modern science. A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science."). Here, Dr. Hruz's opinions regarding the diagnosis of gender dysphoria and reliability of the DSM-5 are

[2] Dr. Hruz's only publication relating to gender dysphoria in a peer-reviewed journal is a letter to the editor not based on any original research or scientific study, and for which it is unclear if letters to the editor are subjected to peer-review. Ex. A at 43:9-45:15.

based on "talking, you know, to those that are engaged more in the field of psychiatry." Ex. A at 110:7-8. As such, Dr. Hruz is not an expert qualified to opine on these matters.

Instead, Dr. Hruz bases his opinions solely on his review of literature and conversations he has had with others. The fact that Dr. Hruz has read about gender dysphoria and transgender people does not qualify him as an expert on these issues, however. That is precisely the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. As with the disqualified expert in *Lebron* who "reached his opinion instead by relying on studies," this is not a sufficient qualification to serve as an expert witness. 772 F.3d at 1369.

Indeed, Dr. Hruz is the definition of a manufactured "expert witness" as his involvement originates from and dates back to a conference by the Alliance Defending Freedom ("ADF")[3] organized specifically to cultivate professional "experts" who would testify against the gender-affirmation of transgender people. Ex. A at 241:10-246:20; Ex. C at 92:21-93:24; Ex. D at 147:11-21; *cf.* Ex. M at 84:3-85:12, 90:13-91:13 (Dr. Lappert testifying that he attended the same ADF conference as Dr. Hruz in 2017 where the "poverty of [experts] who are willing to testify" against gender-confirming policies was

[3] ADF is well-known for pushing anti-LGBT policies across the country and internationally. *See*, *e.g.*, Nico Lang, *A Hate Group Is Reportedly Behind 2021's Dangerous Wave of Anti-Trans Bills*, them. (Feb. 19, 2021), https://bit.ly/3HEqCR9; Julie Compton, *Activists take aim at anti-LGBTQ 'hate group,' Alliance Defending Freedom*, NBC News (Nov. 14, 2018), https://nbcnews.to/3oEe9Es. The Southern Poverty Law Center has designated ADF a hate group. *See* S. Poverty Law Ctr., *Why is Alliance Defending Freedom a Hate Group?* (Apr. 10, 2020), https://bit.ly/3HE6LS1 (accessed Nov. 19, 2021).

discussed and that attendees "were asked whether they would be willing as participate as expert witnesses"). Like the disqualified expert in *Lebron*, Dr. Hruz "developed his opinions expressly for purposes of testifying" in an area that he did not otherwise specialize in. *Lebron*, 772 F.3d at 1369.

In sum, Dr. Hruz is not qualified to serve as an expert on the diagnosis or treatment paradigms for gender dysphoria. He is "not qualified by background, training, or expertise to opine" about any of the factual issues in this case. *Lebron*, 772 F.3d at 1369.

II. Dr. Hruz's opinions and testimony are not relevant to this case.

The "court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). "[I]t is axiomatic that expert testimony which does not relate to any issue in the case is not relevant and non-helpful." *Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F.Supp.3d 837, 846 (S.D. W.Va. 2018). In order to be relevant, an opinion needs to "fit" with the facts at issue. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004). "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F.Supp.3d 837, 846 (W.D.N.C. 2016) (cleaned up).

This case is about whether Defendants' exclusion of coverage for medically necessary gender-affirming health care treatments violates Plaintiffs' rights under the equal protection clause, Title VII, and Section 1557 of the Affordable Care Act. Dr. Hruz's

opinions are not relevant to this inquiry as they will not help the "trier of fact to understand the evidence or to determine a fact in issue." *Nease*, 848 F.3d at 229. His opinions do not "fit" because they are not sufficiently tied to the facts of the case so that they will aid a factfinder.

A. Dr. Hruz's opinions about "desistance" are irrelevant.

Take for example Dr. Hruz's opinions about purported "desistance" rates as a reason to question the provision of gender-confirming care. Dr. Hruz spends considerable time on (and builds most of his testimony questioning the propriety of gender-affirming health care upon) antiquated studies showing that a majority of *prepubertal* children diagnosed with *gender identity disorder*—an outmoded diagnosis *distinct from gender dysphoria* with different diagnostic criteria—"desisted" from their gender nonconformity or cross-gender behavior. *See*, *e.g.*, Ex. B at 4-5, 43-44. Based on this evidence, Dr. Hruz states that, "Desistance (i.e., realignment of expressed gender identity to be concordant with sex) provides the greatest lifelong benefit and is the outcome in the vast majority of patients and should be maintained as a desired goal." *Id.* at 51. But not only are such opinions based on faulty propositions, they simply do not fit within the facts of this case.

For one, as Dr. Hruz admitted, absolutely no gender-affirming medical or surgical care is provided to *prepubertal* children. Ex. A at 125:23-126:5. That is true for each of the treatment paradigms Dr. Hruz discusses (apart from "conversion" or "reparative therapy"), a fact Dr. Hruz did not disclose. *Id.* at 119:22-140:12. And, as Dr. Hruz

acknowledges, "the nature of this case" is about the coverage for medically necessary gender-affirming medical care. *Id.* at 73:21-25.

Similarly, Dr. Hruz admits that the "desistance" studies on which he relies speak only to prepubertal youth who were diagnosed with *gender identity disorder* under the DSM-III or the DSM-IV, and do not pertain to "desistance" in prepubertal youth diagnosed with *gender dysphoria* under the DSM-5. Ex. A at 143:18-146:9.

Lastly, Dr. Hruz further admits that the studies pertain to "desistance" among *prepubertal* children and not adolescents or adults. *Id.* at 146:10-147:9. But again, no hormonal or surgical care is recommended for or provided to *prepubertal* children, nor are any of the plaintiffs prepubertal children.

Dr. Hruz's opinions regarding "desistance" are thus irrelevant to this case.

B. Dr. Hruz's opinions about supposed controversies in other countries are irrelevant.

Likewise, Dr. Hruz's opinions about "controversies" regarding the provision of gender-confirming care in Finland, Sweden, and the United Kingdom are both misleading and wholly irrelevant. Ex. B at 18. Dr. Hruz failed to disclose that each of these countries *provides and covers* gender-confirming hormonal and surgical treatment for gender dysphoria for adolescents and adults, whereas the NCSHP excludes it completely from coverage. *See*, *e.g.*, Ex. A at 183:23-184:4, 185:3-10, 189:14-190:7. Moreover, how care is provided and covered in countries with nationalized health care systems is not relevant

to whether coverage of gender-confirming care should be covered by the NCSHP in North Carolina.[4]

C. Dr. Hruz's musings about the causes of gender dysphoria are irrelevant.

Dr. Hruz opines, without any evidence, that gender dysphoria *may be* caused by social contagion and social pressure. Ex. B at 40-43, 99. But whether gender dysphoria is caused by social contagion is both wholly unsupported, as described below, and irrelevant to the case at hand. It is undisputed that gender dysphoria is a recognized medical condition that necessitates medical treatment. *See*, *e.g.*, Ex. A at 57:24-58:9 ("Q. Would you agree there are transgender people in this world? A. … That's undeniable that … there are individuals that have this experience of discordance between their gender identity and their sex."); *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594-95 (4th Cir. 2020).

D. The totality of Dr. Hruz's opinions are irrelevant because they are based on hypotheticals and speculation.

Finally, and perhaps most crucially, all of Dr. Hruz's opinions are irrelevant because they are not based on fact, let alone "fit" within the facts of case. The entirety of Dr. Hruz's opinions is based on *hypotheses*, meaning they are based on speculation. Ex. A at 154:4-8 ("A. You know, all along here, … I've been stating, and I hope very clearly, that much of my opinion is based upon hypotheses and alternative hypotheses, because there is no definitive answer to this question."); *id.* at 57:1-3 ("A. Because I present many things in

[4] For example, in Sweden standards of care are developed through legislation and thus part of a political process. *See* Socialstyrelsen, *About the National Board of Health and Welfare*, https://www.socialstyrelsen.se/en/about-us/ (accessed Nov. 19, 2021) (noting that standards are based on legislation).

my report as hypotheses. And without making definitive statements."). Indeed, Dr. Hruz purportedly has no view as to what modality of treatment should be provided to transgender people suffering gender dysphoria. *Id.* at 61:21-62:2. In other words, Dr. Hruz lacks knowledge "of facts which enable him to express a reasonably accurate conclusion as opposed to conjecture or speculation." *Jones v. Otis Elevator Co.*, 861 F.2d 655, 662 (11th Cir. 1988). And opinions based on "subjective belief or unsupported speculation" should be rejected. *Daubert*, 509 U.S. at 589-590.

* * *

The opinions expressed by Dr. Hruz are insufficiently tied to the facts of this case so that they will aid a factfinder and should be excluded as irrelevant.

III. Dr. Hruz's opinions and testimony are unreliable.

An expert's testimony should only be admitted if it is sufficiently reliable. And "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018). Here, Dr. Hruz's opinions fail all indicia of reliability. Dr. Hruz's proffered opinions are based on nothing more than rank speculation, "untested" theories, uncorroborated anecdotes, and assumptions that are obsolete, flawed, unethical, and expressed opinions based upon "unsettled science." What is more, some of his opinions are patently false.

A. Dr. Hruz's opinions are unreliable because they are based on untested hypotheses and speculation.

As noted above, ***all of Dr. Hruz's opinions are hypotheses***; hypotheses that he himself has not tested or studied. And "[w]hile hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination." *Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003). "[T]he courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). Indeed, such "speculation is unreliable evidence and is inadmissible." *Dunn*, 275 F.Supp.2d at 684; *see also Sardis*, 10 F.4th at 291; *Small v. WellDyne, Inc.*, 927 F.3d 169, 176-77 (4th Cir. 2019); *Samuel v. Ford Motor Co.*, 112 F.Supp.2d 460, 470 (D. Md. 2000).

B. Dr. Hruz's opinions are unreliable because they are misleading and therefore do not serve to enlighten the trier of fact.

In addition, some of Dr. Hruz's opinions are misleading at best, or flat out false. Take the following examples:

One. Dr. Hruz opines that gender-affirming "treatments – hormones and surgery – for gender dysphoria and 'transitioning' have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy [sic], medicine, psychology, etc.)." Ex. B at 100. Not true. It is the official, consensus, evidence-based position of the National Academies of Science, Engineering, and Medicine that, "[a] major success of these guidelines has been identifying evidence and establishing expert consensus that gender-

affirming care is medically necessary and, further, that withholding this care is not a neutral option." Ex. F at 12-10;[5] Ex. A at 205:20-206:22. Indeed, "[a] number of professional medical organizations have joined WPATH in recognizing that gender affirming care is medically necessary for transgender people." Ex. F at 12-10. This includes, among others, the American Medical Association, American Psychiatric Association, American Psychological Association, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the Endocrine Society. *Id.*; Ex. C at 58:21-61:9. It also includes Dr. Hruz's own employer, Washington University in St. Louis. Ex. A at 85:14-86:11.

Additionally, binding and recent circuit precedent recognizes the provision of gender-affirming care, consistent with the Standards of Care published by the World Professional Association for Transgender Health, to "represent the consensus approach of the medical and mental health community," and to "have been recognized by various courts, including [the Fourth Circuit], as the authoritative standards of care." *Grimm*, 972 F.3d at 595. Indeed, per the Fourth Circuit, "[t]here are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups." *Id.* at 595-596.

[5] Exhibit F, a report of the National Academies, is self-authenticating as a publication issued by a public authority, Fed. R. Evid. 902(5), and is appropriate for judicial notice, *United States v. Doe*, 962 F.3d 139, 147 n.6 (4th Cir. 2020).

Two. Dr. Hruz attacks the reliability of the DSM, in part, by stating that it is "being 'dumped' by the National Institute of Mental Health ["NIMH"] as a key basis for research funding" and then goes on to cite selectively from some news stories. Ex. B at 30. However, not only is Dr. Hruz not a psychiatrist, psychologist, or mental health provider of any kind, but he also failed to disclose that the NIMH considers the DSM, along with the International Classification of Diseases, to "represent[] the best information currently available for clinical diagnosis of mental disorders" and "that the DSM is the key resource for delivering the best available care" as well as "the main contemporary consensus standard for how mental disorders are diagnosed and treated." Ex. A at 115:21-119:21.

Three. In his report, Dr. Hruz presented a number of modalities of treatment for the care of patients with gender dysphoria, including: (1) "conversion" or "reparative therapy"; (2) "watchful waiting"; and (3) the "affirming" approach, as if these did not endorse the provision of gender-affirming medical care for adolescents and adults. Ex. B at 49-50. In doing so, Dr. Hruz opined that the approach advocated by Dr. Kenneth Zucker and the "watchful waiting" model "involve[] no medical treatment and is currently the best scientifically supported intervention." *Id.* at 50-51. Dr. Hruz, however, misrepresented both Dr. Zucker's approach and the "watchful waiting" model, both of which recommend the provision of gender-affirming medical care if a patient's gender dysphoria persists into adolescence. Ex. E; Ex. A at 121:6-12, 125:11-17.

In that same vein Dr. Hruz, presented "reparative therapy" as if it was an accepted modality of treatment. Nothing could be further from the truth, however. The provision

of conversion/reparative therapy represents a fringe view completely contrary to the mainstream medical and scientific community in the United States. As Dr. Hruz acknowledged in his deposition, the American Psychiatric Association and the American Psychological Association oppose "reparative therapy" or gender identity change efforts as unethical and harmful. Ex. A at 164:1-170:8. A position adopted by the National Academies. *Id.* at 176:9-177:24; Ex. F at 12-16. And binding circuit precedent establishes that "mental health practitioners' attempts to convert transgender people's gender identity to conform with their sex assigned at birth did not alleviate dysphoria, but rather caused shame and psychological pain." *Grimm*, 972 F.3d at 595.

Four. Dr. Hruz opines that using puberty blockers to treat gender dysphoria is "unethical" because it "is not FDA-approved" and not conducted in "the setting of a carefully controlled and supervised clinical trial." Ex. B at 60. However, Dr. Hruz is not an expert on clinical controlled trials (Ex. D at 39:12-25; Ex. A at 31:17-34:8), because if he was, he would have known (and presumably disclosed) that clinical controlled trials are actually relatively rare in the pediatric population. Ex. A at 210:14-211:2. Similarly, Dr. Hruz failed to disclose and discuss the Food and Drug Administration's position that, "once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient," Ex. G at 2, and that the American Academy of Pediatrics does not consider the use of "off-label" drugs to "imply an improper, illegal, contraindicated, or investigational use," Ex. H at 1; Ex. A at 208:3-219:3.

The Court "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. Here, Dr. Hruz has misrepresented or omitted information that goes to the heart of his opinions and calls into question the reliability of his opinions. While usually the factual basis of an expert opinion goes to credibility, "it is possible for an experts' omission of articles to render his or her opinion inadmissible on reliability grounds." *Huggins v. Stryker Corp.*, 932 F.Supp.2d 972, 994 (D. Minn. 2013). Such is the case here where Dr. Hruz omits key information, or worse, misrepresents facts that if properly disclosed would contradict his opinions and undermine their foundation. In such circumstances, the "potential to mislead" rather "than to enlighten" is too great. *In re Lipitor*, 892 F.3d at 632.

C. Dr. Hruz's opinions are unreliable because they are not generally accepted in the scientific and medical community.

General acceptance in the relevant scientific community is also relevant to the reliability inquiry. *Nease*, 848 F.3d at 229. Not only is widespread acceptance an important factor in assessing the reliability of an expert's opinions, but the fact that a known technique or theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Here, Dr. Hruz's opinions are outside the mainstream of medical and scientific opinion and have been explicitly rejected by these relevant communities.

The provision of gender-confirming care has been accepted and endorsed, *inter alia*, by the: American Medical Association; American Psychiatric Association; American Psychological Association; Endocrine Society; Pediatric Endocrine Society; American

Academy of Pediatrics; National Academies of Science, Engineering, and Medicine; and Dr. Hruz's own employer. Ex. A at 164:5-11; Ex. C at 70:25-71:22; *id.* 57:11-59:14; Ex. F at 12-10. And the Fourth Circuit has described it as "the consensus approach of the medical and mental health community." *Grimm*, 972 F.3d at 595.

In fact, just this year, another federal district court found as much when it enjoined Arkansas' state law seeking to ban gender-confirming treatment for minors. *See Brandt v. Rutledge*, No. 4:21-CV-00450-JM, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021). In doing so, the *Brandt* court explicitly found that: (a) "Gender-affirming treatment is *supported by medical evidence* that has been *subject to rigorous study*;" and (b) "*Every major expert medical association* recognizes that gender-affirming care for transgender minors may be *medically appropriate and necessary* to improve the physical and mental health of transgender people." *Id.* at *4 (emphasis added). Notably, Dr. Hruz filed an expert declaration in the *Brandt* case that is virtually identical to the report he filed in this case. *Compare* Ex. B *with* Decl. of Paul W. Hruz, M.D., Ph.D., *Brandt v. Rutledge*, No. 4:21-CV-00450-JM (E.D. Ark. filed July 9, 2021) (Dkt. No. 45-3). As such, the *Brandt* court's findings stand as a stark repudiation of Dr. Hruz's opinion that gender-affirming care is "experimental," "not medically necessary," and "not generally accepted by the relevant scientific community." Ex. B. at 17.

Conversely, Dr. Hruz's opinions in support of reparative therapy or gender identity change efforts has also been rejected by the general scientific community, among others. Ex. A at 164:1-170:8; Ex. C. at 118:7-19, 237:1-23. *See also King v. Governor of the State*

of New Jersey, 767 F.3d 216, 221–22 (3d Cir. 2014); *Pickup v. Brown*, 740 F.3d 1208, 1223–24 (9th Cir. 2014). This again shows that Dr. Hruz's opinions are wildly outside the mainstream and unreliable.

D. Dr. Hruz's opinions are unreliable because they have no support and are based on ipse dixit.

As noted herein, Dr. Hruz's opinions are based on untested hypotheses and do not have any factual support. For example, Dr. Hruz opines that gender dysphoria *may be* caused by social contagion and social pressure. Ex. B at 40-43, 99. But he offers no evidence for this hypothesis, which he admits has not been tested. *Id.* at 41. Of course, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). And this is one of those circumstances in which "there is simply too great an analytical gap between the data and the opinion proffered." *Id*. In fact, the only study to have looked at this hypothesis found no support for the hypothesis. Ex. L.

* * *

Given that Dr. Hruz's opinions fail to meet the most basic indicia of reliability, the Court should exclude Dr. Hruz's opinions and testimony as unreliable.

IV. Dr. Hruz's opinions are so tainted by his personal bias as to render his opinions unreliable.

While Plaintiffs are cognizant of the fact that bias in an expert witness's testimony is usually an issue of credibility as opposed to one of admissibility, when an expert's

opinions are based on bias as opposed to scientific or medical knowledge, then the question of bias becomes one of reliability and admissibility. Indeed, reliability is a flexible inquiry wherein "courts must ensure that an expert's opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281. Here, there is ample evidence that Dr. Hruz's testimony is so permeated and tainted by his unscientific views and personal bias as to render it unreliable. *Cf. Sanchez v. Esso Standard Oil de Puerto Rico, Inc.*, No. CIV 08-2151, 2010 WL 3809990, at *4 (D.P.R. Sept. 29, 2010).

More specifically, Dr. Hruz's testimony appears to be motivated by his personal and religious views regarding transgender people. To be clear, Plaintiffs do not seek to impugn or malign whatever moral or religious views Dr. Hruz may hold. However, to the extent Dr. Hruz's moral and religious views have influenced his purported expert opinions—indeed, they seem to be the motivating factor—that is something the Court must be aware of and should consider as it assesses the reliability of his testimony.

In his report, Dr. Hruz discusses meeting with Dr. Norman Spack, a noted pediatric endocrinologist and the co-founder of Boston Children's Hospital Gender Management Service Program, as someone he consulted when he first began to study issues relating to gender dysphoria from a scientific standpoint. But Dr. Spack's account of this encounter is quite different. Ex. B at 3. Dr. Spack asserts that "Dr. Hruz did not discuss or mention that his issues or concerns were based on science." Ex. I at ¶ 13. To the contrary, Dr. Hruz expressed to Dr. Spack that he had "a significant problem with the entire issue" and "whole

idea of transgender," and that for him, it was "a matter of [his] faith." *Id.* at ¶¶ 11-12. When confronted with Dr. Spack's account, Dr. Hruz notably did not deny he made such statements. Ex. A at 247:10-251:4.

Similarly, Dr. Hruz misrepresents the nature of his conversations with parents of children with gender dysphoria as that of seeking "to understand the unique difficulties experienced by this patient population." Ex. B at 3. The account of one of these parents is quite different, however. Dr. Hruz met with Kim Hutton, the mother of a transgender child, in 2013. Ex. C 102:24-103:9, 126:12-129:25. Dr. Hruz says he met with the parent of a transgender child who was affiliated with an organization called TransParent, during a "very early investigative phase" of his study of gender dysphoria. Ex. C. 103:25-104-7, 102:24-103:9.

However, the nature of Dr. Hruz's conversation with Ms. Hutton revealed that his opposition to gender-affirming care, as well as his opposition to a having a Transgender Center at St. Louis Children's Hospital, was already firmly established and rooted in his personal moral and religious views. Indeed, Dr. Hruz told Ms. Hutton, "there will never be a pediatric gender center at St. Louis Children's Hospital. I won't allow it," Ex. J at 30:8-30:11, at a time when he claims he was "very early" in his investigation of gender dysphoria, Ex. C at 103:25-104:7, 102:24-103:9. Dr. Hruz also told Ms. Hutton that her "child was not normal and would never be normal," Ex. J at 28:20-28:23; that "the idea of doing surgeries on transgender people is -- is wrong," *id.* at 21:21-27:24; and that Ms. Hutton should "read Pope John Paul II's writings on gender," *id.* at 29:17-29:20. And in

response to Ms. Hutton's statement that transgender children "are at a 41 percent risk of suicide if they don't have acceptance and -- and care from their parents and -- and if they don't get their medical needs met," Dr. Hruz responded that, "Some children are born in this world to suffer and die." *Id.* at 29:21-30:4. As a result, Ms. Hutton left her conversation with Dr. Hruz—a conversation Dr. Hruz says he "was approaching [] in a purely investigative manner," Ex. C at 126:16-127:3—"perplexed" due to "the religious tone of the conversation," which she "figured [] would at least be based on science." Ex. J at 37:11-37:19.

The bias illuminated by Dr. Spack's and Ms. Hutton's testimony is further confirmed by the nature of Dr. Hruz's publications and presentations on this issue. With one exception, all of Dr. Hruz's publications pertaining to gender dysphoria have been in religiously affiliated, non-scientific publications. Ex. A at 42:10-49:19. Similarly, aside from a handful of grand rounds, Dr. Hruz has not made any presentations about this topic at scientific conferences, *id.* at 90:17-93:3; instead, presenting on this topic to religious organizations. For instance, in November 2017, Dr. Hruz gave a presentation at the Saint John Paul II Bioethics Center at the Holy Apostles College & Seminary, where he referred to being transgender as something that "probably goes back to some of the early heresies in the church," and to pictures of transgender people as "disturbing." Ex. C at 83:5-85:20. When confronted with these statements, Dr. Hruz did not disavow or deny making them. *Id.* And in February 2018, Dr. Hruz presented at an "International Conference on Gender, Sex and Education" that was billed as "the world's first great public objection to totalitarian

LGBTI laws," "a conference to oppose gender ideology," and "against the LGBTI doctrine … taking hold of Western Countries." Ex. K; Ex. A at 93:4-97:10.

The foregoing, coupled with Dr. Hruz's departure with generally accepted medical and scientific standards, demonstrates that Dr. Hruz's purported expert testimony lacks any indicia of reliability. And while the Federal Rules of Evidence state that "[e]vidence of a witness's religious beliefs or opinions is not admissible to attack or support the witness's credibility," Fed. R. Evid. 610, the Advisory Committee Notes to Rule 610 make clear that "an inquiry for the purpose of showing interest or bias because of them is not within the prohibition." Advisory Committee Notes to Rule 610. Indeed, "[w]ithout this critical information," the Court would be "deprived of the necessary facts from which it could appropriately draw inferences about [Dr. Hruz's] reliability." *State v. Heinz*, 485 A.2d 1321, 1328 (Conn. App. 1984). Here, it is evident that Dr. Hruz has not been candid regarding his experiences or the bases for his "opinions." The record evidence demonstrates a clear bias by Dr. Hruz against transgender people generally, which infects his reliability as a purported expert witness in this case.

V. Dr. Hruz's opinions lack probative value and are therefore inadmissible under Federal Rule of Evidence 403.

Finally, the Court should exclude Dr. Hruz's opinions because its introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Dr. Hruz offers no opinions relevant to the issues in this case, and, in any event, the opinions he offers are speculative and unreliable. The testimony would also result in

prejudice, as the testimony seeks to sow confusion about the propriety of gender-confirming care based on speculation, irrelevant, misleading, or biased opinions.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Hruz's report, opinions, and testimony in full.

Dated this 2nd day of February, 2022.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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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.

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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, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

DECLARATION OF OMAR GONZALEZ-PAGAN

Pursuant to 28 U.S.C.§ 1746, I, Omar Gonzalez-Pagan, do hereby declare as follows:

1. I am over 18 years of age.

2. I am a Senior Attorney at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the stated herein, except those stated on information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul W. Hruz.

5. Attached as **Exhibit A** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Paul W. Hruz on September 29, 2021 taken in relation to the above-captioned matter.

6. Attached as **Exhibit B** is a true and correct copy of the expert witness report of Dr. Paul W. Hruz, M.D., Ph.D. (including a copy of his curriculum vitae) in the above-captioned matter, which is dated April 30, 2021, was served upon plaintiffs on May 1, 2021, and was entered as Exhibit 1 to Dr. Hruz's deposition in this matter on September 29, 2021.

7. Attached as **Exhibit C** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Paul W. Hruz on November 20, 2017 taken in relation to *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018), and which was entered as Exhibit 2 to Dr. Hruz's deposition in this matter on September 29, 2021.

8. Attached as **Exhibit D** is what I understand, upon information and belief, to be a true and correct copy of the transcript of the deposition of Dr. Paul W. Hruz on July 16, 2018 taken in relation to *Bruce v. South Dakota*, No. 17-cv-05080 (D.S.D), and which was entered as Exhibit 3 to Dr. Hruz's deposition in this matter on September 29, 2021.

9. Attached as **Exhibit E** is a true and correct copy of the article "Gender nonconforming youth: current perspectives," published in the scientific journal *Adolescent Health, Medicine and Therapeutics* on May 25, 2017, and which was entered as Exhibit 8 to Dr. Hruz's deposition in this matter on September 29, 2021.

10. Attached as **Exhibit F** is a true and correct copy of excerpts of *Understanding the Well-Being of LGBTQI+ Populations*, a Consensus Study Report of the

National Academies of Sciences, Engineering, and Medicine published in 2020, and which was entered as Exhibit 12 to Dr. Hruz's deposition in this matter on September 29, 2021.

11. Attached as **Exhibit G** is a true and correct copy of a printout of the webpage "Understanding Unapproved Use of Approved Drugs 'Off Label,'" published by the U.S. Food and Drug Administration, and which was entered as Exhibit 15 to Dr. Hruz's deposition in this matter on September 29, 2021.

12. Attached as **Exhibit H** is a true and correct copy of "Policy Statement: Off-Label Use of Drugs in Children" from the American Academy of Pediatrics, which was published in the scientific journal *Pediatrics* on March 2014 and was entered as Exhibit 17 to Dr. Hruz's deposition in this matter on September 29, 2021.

13. Attached as **Exhibit I** is a true and correct copy of Declaration of Dr. Norman P. Spack, M.D., dated December 5, 2017, which was filed in *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018), and which was entered as Exhibit 19 to Dr. Hruz's deposition in this matter on September 29, 2021.

14. Attached as **Exhibit J** is a true and correct copy of excerpts of the transcript of the deposition of Kim Hutton on December 5, 2017 taken in relation to *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018).

15. Attached as **Exhibit K** is a true and correct copy of a printout of the web-page "I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success,"

published by the Gender and Sex Conference on February 28, 2018, and which was entered as Exhibit 6 to Dr. Hruz's deposition in this matter on September 29, 2021.

16. Attached as **Exhibit L** is a true and correct copy of the article "Do Clinical Data From Transgender Adolescents Support the Phenomenon of 'Rapid-Onset Gender Dysphoria'?," accepted for publication in the scientific journal *The Journal of Pediatrics* on November 10, 2021, and published online on November 15, 2021.

17. Attached as **Exhibit M** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Patrick Lappert on September 30, 2021 taken in relation to the above-captioned matter.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 2nd day of February, 2022.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan

EXHIBIT A

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

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

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF DR. PAUL W. HRUZ
Taken on behalf of the Plaintiffs
September 29, 2021

Sheryl A. Pautler, RPR,
MO-CCR 871, IL-CSR 084-004585

(The proceedings began at 9:31 a.m. Eastern.)

INDEX OF EXHIBITS

INDEX OF EXHIBITS CONTINUED

(Exhibits attached to transcritp.)

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

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF WITNESS, DR. PAUL W. HRUZ, produced, sworn, and examined on the 29th day of September, 2021, between the hours of nine o'clock in the forenoon and eight o'clock in the afternoon of that day, via Veritext Zoom, before SHERYL A. PAUTLER, RPR, Certified Shorthand Reporter within and for the State of Illinois and Certified Court Reporter within and for the State of Missouri, in a certain cause now pending before the United States District Court for the Middle District of North Carolina, wherein MAXWELL KADEL, et al. are the Plaintiffs, and DALE FOLWELL, et al. are the Defendants.

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Q. Okay. What is a wet lab?

A. A wet lab is really designating somebody that does hands-on research usually with either in-vitro or in-vivo studies, as opposed to a dry lab which mostly does literature searches or computer programming or things that do not involve experimentation with -- the reason the term comes, from wet reagents like buffers and solutions and bodily fluids.

Q. Is your research primarily conducted in a wet lab?

A. My -- until recently the vast majority of my research has been conducted in a wet lab. I have participated on a few occasions in clinical trials and have served as an adviser and consultant for colleagues in those types of studies.

Q. On how many occasions have you participated in clinical trials?

A. I never direct -- well, there was one trial at Washington University where I was more directly involved. But all of -- as far as principal investigator, all of my NIH funded research and service as a principal investigator has been done with my basic science research.

Q. Would you agree that clinical trials is

not your area of expertise?

MR. KNEPPER: Objection, form.

A. I would not agree with that statement. I would say that I -- in the course of the last decade that -- as I've been required to investigate the literature surrounding this particular issue of treatment of gender dysphoria, I have developed considerable expertise in clinical trials. And I also have previously served on institutional review boards. I did that while I was a medical student, where I reviewed the ethics of clinical trials and -- and in other ways as well. So I would say that covers my -- is included in my expertise as a physician scientist.

Q. (By Mr. Gonzalez-Pagan) Earlier you stated that the testimony you provided in the Bruce deposition was truthful; is that right?

A. To the best of my knowledge.

Q. In the Bruce deposition, you were asked: So clinical trials is in your area of expertise?

And you answered: That is correct.

MR. KNEPPER: Objection, form.

A. Can you please read that statement again? And it might even be helpful if we went to the area of that deposition so I can see the entire context.

But for now maybe you can just reread that just so I understand what that statement said.

Q. (By Mr. Gonzalez-Pagan) Well, let's -- my computer is not going to survive today. I apologize. It's on Page 39 of Exhibit 3.

A. Is there an easy way to navigate directly to a page without just scrolling down?

Q. Unfortunately I don't believe so. It's limitation of the medium. I apologize for that.

MR. KNEPPER: I will confirm that. Yeah. I haven't found one either.

A. Okay. So which line are you -- I'm on Page 39 right now.

Q. (By Mr. Gonzalez-Pagan) All right. So on line -- beginning on Line 23.

A. Okay.

Q. It says, Question: I see. So clinical trials isn't your area of expertise?

Answer: That is correct.

Did I read that correctly?

A. Well, if you read the preceding lines, it immediately followed a question about my direct participation in clinical trials where I clearly stated that there was only one clinical trial. That was the one I just mentioned to you at Washington

University. And similar to what I had in this deposition, my role in that project was relatively minor.

So in that sense, that does not mean that I do not have knowledge and experience in the context of clinical trials. It only means I have not directly participated in those clinical trials. Context is important.

Q. What is primary research?

A. I'm sorry. Primary research?

Q. Yeah.

A. Oh, so you're -- you're talking about the difference between conducting experimental -- directly conducting experiments versus systematic reviews and literature reviews of that nature. Is that the distinction you're trying to get at?

Q. Is that what you understand the distinction between primary and secondary research to be?

MR. KNEPPER: Objection, form.

A. That would be one definition that I would agree with, yes.

Q. (By Mr. Gonzalez-Pagan) Okay. Would it be okay if I were to adopt that definition, that primary research refers to conducting experiments --

experiments, etc. and not literature review or metanalysis of existing data?

A. For the purposes of this deposition, yes, that is fine.

Q. With that understanding, have you conducted any primary research relating to gender dysphoria?

MR. KNEPPER: Objection, form.

A. So if you're asking whether I have directly participated in clinical trials on gender dysphoria, the answer is no.

Q. (By Mr. Gonzalez-Pagan) Have you participated in cross-sectional studies related to gender dysphoria?

A. Again, I have not -- cross-sectional studies, you're meaning retrospective reviews?

Q. It could be longitudinal observational. It could be cohort studies. I guess my question is -- let me back up. Have you conducted any direct research relating to gender dysphoria that is not based on a literature review?

MR. KNEPPER: Objection, form.

A. It would depend on what your definition of conduct. I have not physically myself done those chart reviews or participated in the clinical

setting. My experience to what you had described as primary research is limited to my role as associate or assistant fellowship program director in supervising my fellows, two of whom are doing what we would -- what you would define as primary research.

I'm not the primary investigator, but I do have a role in directing my fellows in doing that research to make sure it's of the highest quality and standards that we expect of all of our fellows.

Q. (By Mr. Gonzalez-Pagan) When did you resume supervision of the fellowship program?

A. The official designation has happened since the time I filed my initial curriculum vitae. However, I have continually throughout my career been involved in the fellowship program.

One of the reasons I was reappointed as the assistant program director was that it was recognized that the area of scholarly research needed somebody with my background to be able to help the fellows to be able to select projects, select mentors and conduct research in the most rigorous manner. And that was a shortcoming that had developed since I had formally stepped away from

A. Okay.

Q. Well, actually, let me -- let me check. We've been going about an hour. Would you like to take a break right now or I can do this line of questioning? And we can --

A. I'm actually doing quite well. I'd be fine to keep pressing on.

MR. GONZALEZ-PAGAN: Sheryl, is that okay?

THE COURT REPORTER: That's fine.

Q. (By Mr. Gonzalez-Pagan) Okay. So if we go to the list of publications in your CV. Are you with me?

A. I am.

Q. In the category of journal articles, No. 48 is titled Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. Did I read that correctly?

A. Yes. And I do see it here.

Q. Is that one of your publications relating to gender dysphoria?

A. Yes, it is. And it's probably one of the most highly cited of the papers that I provided.

Q. Sure. Is that a publication based on any primary research that you conducted?

MR. KNEPPER: Objection, form.

A. As which have defined it, no. It's a review of the literature and critical appraisal of the evidence.

Q. (By Mr. Gonzalez-Pagan) And that publication is -- that -- sorry. That -- that article was published in the Linacre Quarterly; is that right?

A. That is correct.

Q. Is the Linacre Quarterly a scientific publication?

A. It is an ethics journal. In fact, it's the longest standing continuously published ethics journal in the United States.

Q. Who publishes the Linacre Quarterly?

A. The NCBC.

Q. What does the NCBC stand for?

A. The National Catholic Bioethics Center.

Q. Turn to 50. Is this one of the other publications you have relating to gender dysphoria?

A. It's a letter to the editor.

Q. So it's not -- this is not a publication based on any primary research or scientific study you have conducted?

MR. KNEPPER: Objection, form.

A. As we have defined primary research, it is

merely a presentation of -- of concerns about the literature that has already been published.

Q. (By Mr. Gonzalez-Pagan) And as I understand this letter to the editor is a commentary on another publication, on another article; is that right?

MR. KNEPPER: Objection, form.

A. It includes more information than just the article itself. But, yes.

Q. (By Mr. Gonzalez-Pagan) And just pure curiosity, I don't know the answer to this, but are letters to the editor peer reviewed?

A. This particular one was. I recall when we were submitting this, that we were asked to make changes. And I interpret that as being peer reviewed.

Q. Well, I just want to clarify. There's peer review and then there's editorial review; is that right?

MR. KNEPPER: Objection, form.

A. There are numbers of different types of review; that's correct.

Q. (By Mr. Gonzalez-Pagan) Okay. As I understand peer review to mean, it is a process of objecting and circulating an author's work to the

scrutiny of others who are experts in the same field; is that right?

MR. KNEPPER: Objection.

A. That's how it's generally defined yes.

Q. Are you saying that the letter to the editor was circulated to experts in the field before it was published?

A. I don't know the details of how the letter was handled. I only can say that when we submitted it, we were asked to make revisions. It was reviewed by individuals with understanding of the area that was covered. I don't know any more details. And that's the way generally peer review occurs. One is not usually told who actually reviews the submission.

Q. The next publication, it's -- it's No. 2 under book chapter. It's titled Medical Approaches to Alleviating Gender Dysphoria. And it's a chapter in the book Transgender Issues in Catholic Healthcare; is that right?

A. That is correct.

Q. Who publishes the book, Transgender Issues in Catholic Healthcare?

A. That was also the NCBC.

Q. Is the book a peer-reviewed publication?

A. No.

Q. Going to the next page, there's a list of invited publications; is that right?

A. Yes.

Q. No. 6 is your article titled Growing Pains, Problems With Pubertal Supression in Treating Gender Dysphoria.

Did I read that correctly?

A. Yes, you did read it correctly.

Q. Is this a peer-reviewed publication?

A. It is not peer reviewed. It was editorially reviewed.

Q. The growing pains article was published in the New Atlantis; is that right?

A. That is correct.

Q. Is the New Atlantis a scientific journal?

A. It is not considered a scientific journal in the definition that we normally designate it. It was -- it's a journal that provides more broad readership to be able to distill topics of relevance at an understandable level to the lay public.

Q. At the time of the publication of the article, who published the New Atlantis?

A. Well, the New Atlantis.

Q. Was the new Atlantis a publication of the

ethics and public policy center?

MR. KNEPPER: Objection, form.

A. I believe that may be true. I didn't pay much attention to that.

Q. (By Mr. Gonzalez-Pagan) Let's turn to Exhibit No. 3, Page 44 -- sorry -- Page 46.

A. I went too far.

Q. You know what, it could probably be me. It's a few later. It's Page 49. I do apologize. Page 49.

A. I'm still scrolling, so. Okay. I'm there.

Q. Okay. Beginning on Line 13, it reads; Question: Okay. And the New Atlantis was founded by the Ethics and Public Policy Center; is that right?

Answer: I believe that that is correct.

Question: Okay. And that's a center dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy; is that your understanding?

Answer: I believe that question came up at the last deposition. And I believe that that's an accurate statement.

Did I read that correctly?

A. You did read it correctly, yes.

Q. And you stand by that testimony?

A. Yes. I have no reason -- it's not something that I consider all that important. And I don't usually retain that. I've got so many other pieces of information for me to retain. But, yes.

Q. Going back to your CV, under invited publications.

A. I'm there.

Q. Okay. The next publication is an article titled The Use of Cross-Sex Steroids in Treating Gender Dysphoria; is that right?

A. That is correct.

Q. It was published in the National Catholic Bioethics Quarterly; is that right?

A. That is correct.

Q. Is this article, The Use of Cross-Sex Steroids, a peer-reviewed publication?

A. No, it is not.

Q. Is the National Catholic Bioethics Quarterly a peer-reviewed journal?

A. No.

Q. Is the National Catholic Bioethics Quarterly a scientific journal?

A. No. It is an ethics journal.
Q. All right. And the next publication, 8, under publications in your CV is Experimental Approaches to Alleviating Gender Dysphoria in Children; is that right?
A. Yes.
Q. And this is another one of your publications that relates to gender dysphoria?
A. Yes.
Q. Is this a peer-reviewed article?
A. It is published in the same journal as No. 7. And it is not a peer-reviewed journal.
Q. Okay. Do you have any other publications besides the ones that we just went through that relate to gender dysphoria?
MR. KNEPPER: Objection, form.
A. So there are -- I have no publications that have been added since the time I submitted this CV and it reflects my publications to date.
Q. (By Mr. Gonzalez-Pagan) Do you have any other publications besides the ones that we've discussed today relating to transgender people?
A. Not that I recall.
MR. GONZALEZ-PAGAN: All right. I actually do need to break. So if we can go off

scientific understanding of this condition. To my understanding, the transition from this definition as gender identity disorder to gender dysphoria was not based upon new scientific information.

It was more of a desire to alleviate the discomfort that one has in that label. So how we classify that really rests on the premises that one has about the underlying etiology. And I think that there are -- are more than one valid hypothesis or I should say premises that can be put forward, not necessarily all of equal weight.

Q. (By Mr. Gonzalez-Pagan) Okay. But what is your understanding of the condition of gender incongruent?

MR. KNEPPER: Objection, form, scope.

A. It's a very broad question. Could you narrow it down a little bit?

MR. GONZALEZ-PAGAN: John, what's the objection of the scope? I thought Dr. Hruz is here to testify about gender-affirming treatment for the condition of gender dysphoria and gender incongruent.

MR. KNEPPER: Hold on, Omar. You're free to ask the questions. I think the question I'm trying to understand is: Are you trying to ask

him to testify about -- as a psychiatrist or a psychologist? And it's not clear to me, you know, what the definition of gender incongruence -- are you -- it's not clear to me when you use that term, are you trying to say it's the ICD-11 definition or are you using something else?

I'm happy -- happy to let you continue to pursue this. I'm just as interested as you are. But I want to make sure that as you go through this, we don't end up -- we don't end up down a path where you're trying to say, now, ah-ha, he's coming here pretending to be a psychologist which is outside the scope of what he said he's going to testify to.

MR. GONZALEZ-PAGAN: Well, I mean, we have a 90-page report that I'm happy to go through.

MR. KNEPPER: Please do.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, in your report, you state a number of opinions about the validity of the diagnosis of gender dysphoria contained within the DSM; is that right?

MR. KNEPPER: Objection, form.

A. I would be much more comfortable looking at the specific areas that you're referring to.

Because I present many things in my report as hypotheses. And without making definitive statements. So it would be most helpful if we can look at specific areas that you're referring to.

Q. (By Mr. Gonzalez-Pagan) Okay. So I guess what I'm curious about is, do you have a particular as a physician scientist, do you have a particular belief as to whether gender dysphoria is a disorder?

A. I have multiple scientific premises that I have and continue to consider. Again not of equal weight or validity. One of those premises is that this condition arises from a disconnect between neuronal biology and the bodily from -- sex -- bodily form of the body.

Another scientific premise is that this condition is due to the number of environmental, social, hormonal and neuronal components. So how we understand this condition is markedly influenced by the premise that we come to address the hypotheses that we're going to need to consider to develop clinical trials to establish safety and efficacy of treatment that provides the greatest benefit to the affected patients.

Q. Would you agree there are transgender people in this world?

A. Again, we have to be very careful about the terminology that we're using, to acknowledge that the condition of sex discordant gender identity, and there are individuals that -- that express an identity that is not in agreement with their biology is a true statement. That's undeniable that these -- there are individuals that have this experience of discordance between their gender identity and their sex.

Q. Do you believe that the experience of discordance between their identity and what you term their biology, is a disorder?

MR. KNEPPER: Objection, form.

A. So, again, it depends on what premise you're operating under. As far as whether this is a normal experience of -- of a human condition or whether it falls outside of -- of the norm for us as sexed beings. And, again, as a physician scientist I'm obligated to be able to consider all possibilities to be able to do the proper science to get at the ultimate question here as to what we can do to alleviate the suffering.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I guess I'm a little confused as to what it is that is your opinion here. Can you briefly summarize for me what

more cautious approach by the recognition that the studies that have been done up to this point in time do not give us an answer as to whether this is the best or the only course of intervention to alleviate that suffering. Is that -- is that what you're looking for?

Q. Thank you. I appreciate that. In your -- as part of your opinions, do you provide -- let me back up.

Do you express an opinion as to which modality of care should be provided to people diagnosed with gender dysphoria?

A. I believe that it's an ongoing scientific question about what the most efficacious approach is to provide the greatest benefit with the least amount of risk. And that is why I'm participating as an expert witness in this case, to bring to light for the benefit of the court that this is something that needs to be very much investigated to be able to get an answer to that question.

Q. Do you express an opinion as to which modality of care should be provided to people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. I would say because it's an unsettled

scientific question, that I don't have a firm opinion as to which is the best approach. Yet as time has gone on, more and more information is being generated that calls into question the affirmation-only approach.

Q. (By Mr. Gonzalez-Pagan) And I don't want -- what I'm trying to do is get clarity here. So would it be fair to say that you do not provide an opinion as to which modality of care should be provided for people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. My opinion is that based upon the lack of evidence for the gender -- gender-affirmation approach, that if we are going to provide interventions for this population that it is best done under a carefully controlled clinical experimental setting.

Q. (By Mr. Gonzalez-Pagan) You express that there are ongoing questions as to the efficacy of the gender-affirmation approach; is that right?

A. That is correct.

Q. Again for clarity's sake, are you -- you're not expressing an opinion with -- with medical certainty as to whether the gender-affirmation approach is effective or not; is

anxiety?

A. I would say that the answer is yes.

Q. So for people who experience gender dysphoria and do not have any other co-morbidity, what would you do to address their gender dysphoria while the clinical trials are being conducted?

MR. KNEPPER: Objection, form.

A. That's a broad question. And it depends upon the individual characteristics of the patient, including their age and including all of the other factors that are associated with that gender dysphoria. Was it a child who is prepubertal? Is it a child who is an adolescent? Is it an adult? Is it a child or an adult that, you know, all of the social situations or circumstances that they're involved in?

Again, without having a formal diagnosis of depression or anxiety or these other co-morbidities, all of that is going to impact how one approaches that particular patient.

Q. (By Mr. Gonzalez-Pagan) I guess here we're talking about this case, you said it's a provision of coverage for treatment for gender dysphoria; is that right?

A. That is the nature of this case, correct.

had a new chairman that came on board from the one that recruited me to that position. We disagreed in more than one area.

There was also my research program had been rapidly expanding and was getting into the area of drug development. I would say that the role of chief of any division is a thankless job. It requires a tremendous amount of time and effort. And so, you know, the decision to -- to step down from that position was actually very advantageous to my further career development. But, you know, it was one of the -- the gender center was one among many disagreements that I had at that time.

Q. Does the Washington University Transgender Center offer pediatric and adolescent gender-affirming care?

A. Yes. In the definition that we're talking about here meaning the GnRH agonist or puberty blockers, cross-sex hormones.

Q. Does the Wash --

A. In addition to --

Q. Does the Washington University Transgender Center offer hormone therapy as treatment for gender dysphoria in adults?

A. Does the pediatric center -- your question

is does the pediatric center provide care for adults?

Q. Well, my -- the transgender center offers both care to pediatric and adult patients; is that right?

A. So in general, the care that's delivered at St. Louis Children's Hospital spans birth to the low -- early 20s. There are individuals that are adults that are cared for by the adult endocrine division. And there's a separate team of doctors that participate in that care.

Q. Are you a member of the Endocrine Society?

A. Yes.

Q. The Endocrine Society publishes clinical practice guidelines regarding the treatment of gender dysphoria; is that right?

A. That's correct. Their initial document came out in 2009 with lead author Hembree and then they had a revision that was done in 2017.

Q. Showing you what's been marked as Exhibit 5.

(Whereupon Exhibit 5 was introduced for identification.)

A. Okay. I see it.

Q. (By Mr. Gonzalez-Pagan) Do you recognize

THE COURT REPORTER: Thank you.

MR. GONZALEZ-PAGAN: Borrowing a word from you, John.

Q. (By Mr. Gonzalez-Pagan) What is WPATH?

A. It's an organization known as the World Association of Professional Transgender Health. It is -- again, this is the organization that came out with their version seven of the guidelines quite a long time ago to provide their perspective on what should be done for people that experience sex discordant gender identity.

Q. Does the Washington University Transgender Center follow the WPATH guidelines?

A. Again, I will say that I'm not directly involved in the gender center. My understanding based on conversations with the director of that center, he claims that they do.

Q. Do you, yourself, provide treatment for gender dysphoria?

A. I will state that I'm a pediatric endocrinologist charged with treating hormonal diseases. And because I have not seen the evidence that supports the proper risk/benefit to that intervention, I do not provide that care, as I don't in any other area where I have not determined

appropriate benefit versus risk.

Q. Have you ever diagnosed a person with gender dysphoria?

MR. KNEPPER: Objection, form.

A. I'm a pediatric endocrinologist and my charge is to treat hormone related diseases. And therefore, I've not been called upon to make that diagnosis.

Q. (By Mr. Gonzalez-Pagan) Would you agree you do not have any clinical experience providing care for people for gender dysphoria?

A. I would not agree with that.

Q. Do you provide treatment for people?

A. I provide -- I provide treatment for hormone-related conditions that includes people with gender dysphoria.

Q. But specifically in treating gender dysphoria, do you have any clinical experience with regards to the treatment of that condition?

A. Since I'm a pediatric endocrinologist, my experience is limited to the treating of hormone-related diseases.

Q. Is that a no?

A. I have not treated with hormones for the purpose of alleviating gender dysphoria. I have

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

Q. Clarify, you said association, yes?

A. That's correct.

Q. Do you have proof -- do you have proof that it was caused by the treatment for gender dysphoria?

A. If I thought I had enough evidence to say cause, I would have said caused. I said association.

Q. Thank you. You've given a number -- Strike that.

Have you given presentations regarding gender dysphoria?

A. Yes.

Q. Have any of these presentations been at medical conference -- conferences or settings?

A. Yes. I've -- well, I've delivered many lectures to major academic centers during medical grand rounds. And I'm happy to detail those for you. It includes University of Tennessee, Texas

Tech, Notre Dame, the University of Montevideo. And there are probably others. I can't remember. So -- and so as being a grand rounds presentation in major medical centers, yes.

Q. Aside from grand rounds, have you provided any presentations regarding gender dysphoria at any medical conferences or sites?

A. Well, I would consider grand rounds a conference.

Q. Grand rounds is when there's an invited lecturer at a particular hospital and everybody is invited to attend; is that right?

A. So you're asking about national meetings, like the Endocrine Society meetings or such?

Q. Well, let me just clarify what grand rounds are for the record. So what are grand rounds?

A. Grand rounds are usually a recurring series of talks given by experts in various fields to the relevant scientific community about topics of interest to those physicians. And generally, it involves the presentation of high quality scientific evidence for the conditions that those physicians in the audience would encounter.

Q. Okay. So you have not conducted any

studies for any gender dysphoria, right?

A. I believe we answered that question earlier when we went through my CV.

Q. Well, I'm just wondering what your presentation of the grand rounds are since you have not conducted any such study?

A. It was providing the same types of evidence that I presented in my expert declaration about the scientific studies that have been done or need to be done in this field. Presenting the various hypotheses for etiology and potential treatment. The various side effects that are known or potentially could occur. So it includes all of -- or very similar information regarding the scientific studies that I presented in my expert declaration.

Q. And now, to continue aside from grand rounds, have you provided any presentations regarding gender dysphoria in any other medical conferences or settings?

A. I would have to -- I'd have to think through my list. It's actually most of the major presentations that I've made are listed within my CV. So I'd have to look back as to what I listed there. But if you're asking about the Endocrine

Society or the pediatric Endocrine Society or those types of organizations, I have not presented at those conferences.

Q. Are you familiar with the gender and sex conference?

A. Yes. And are you referring to the one in Madrid.

Q. That was going to be my question. Did you participate in the gender and sex conference in Madrid in 2018?

A. I don't recall the exact date. But if it was 2018, yes, I did present there.

Q. Did you know that the conference was billed as, quote: A rebellion against the gender ideology and its freedom destroying damaging law, closed quote?

A. I -- I don't recall that language being presented to me when I agreed to present at that conference.

Q. Did you know that the conference was focused on opposing what it termed "gender ideology"?

A. You know, again, I was asked -- and this is true for -- if you're going to go through the list of all of the places that I've spoken at. When

I've been invited to present at any of these conferences, my desire is to provide the most accurate and up-to-date scientific information related to the condition of gender dysphoria.

I am willing to present to any audience that is willing to hear that information. I don't make judgment about what the motives are of the individuals organizing the conference. But merely serve with my area of expertise and my knowledge to be able to further that discussion in a productive manner. And that applies to that sex and gender conference in Madrid.

Q. Who organized the gender and sex conference in Madrid?

A. I do not recall the entity. I'm sure you'll tell me. But again that wasn't who invited me was not as important as whether I was going to be given the opportunity to present the information objectively on this particular condition within my area of expertise.

MR. GONZALEZ-PAGAN: Oh, shoot. John, I just published an exhibit without a label. Do you have any objection to me calling it Exhibit 6?

MR. KNEPPER: Having done that very same

thing, Omar, let me take a look at it. But, no, I -- I cannot imagine I will have an objection. Actually it labeled it as Exhibit 6 automatically, but there's no stamp.

MR. GONZALEZ-PAGAN: There's no stamp, yes.

MR. KNEPPER: Sheryl, you'll have to put the stamp on it. But I'm completely okay with calling that Exhibit 6.

MR. GONZALEZ-PAGAN: Thank you.

(Whereupon Exhibit 6 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I'm showing you what's been marked as Exhibit 6.

A. I can see it.

Q. And I apologize for the formatting. Some pages don't print as well as others. This appears to be a press release following the conclusion of the gender and sex conference which you were talking about; is that right?

A. I've never seen this document before.

Q. Okay. If you go to the second page.

A. Okay. I think I'm there.

Q. It talks about the gender and sex -- in the paragraph beginning eight speakers, sort of --

A. Okay. I'm there. I've got it now.
Q. Okay. It speaks of the gender and sex conference as being organized by HazteOir.org and its international platform, CitizenGo; is that right?
A. That's what it says here, yes.
Q. And does that -- is that in keeping with your recollection about who organized the gender and sex conference?
A. Yes. I seem to recall now that you've jogged my memory. That is correct.
Q. Okay. And then on the third page in the middle, there's a paragraph beginning: The rest of the panel experts and lecturers was made up by Professor Glenn Stanton; Dr. Paul Hruz; the sociologist, Gabriella Kuby; and the former transsexual, Walt Heyer.
Did I read that correctly?
A. I see the paragraph that starts Stanton assured that and, in quotes, the gender theory is unscientific, is that what you're --
Q. Just above.
A. Oh.
Q. I skipped the links in reading those.
A. Ah, okay. I see that, yes.

Q. Okay. So it is your recollection then that you presented at this conference; is that right?

A. Oh, yes. I do recall the conference. I just didn't until you reminded me. I didn't know who organized it.

Q. You used the term "gender ideology" in your report; is that right?

A. I have used that term in the course of my investigation of this condition, yes.

Q. What is gender ideology?

A. I would define ideology is including statements that are made on a non -- a non-scientific basis with premises and goals that are outside of science.

Q. Do you consider any healthcare professional that subscribes to the gender-affirming treatment model to be a gender ideolog?

A. I think you're conflating different terms. You mentioned gender-affirming medical care and ideology; those are two separate --

Q. Well, that's my question. My question is, does somebody that provides or advocates for gender-affirming treatment, is that person a person who subscribes to the gender ideology?

turn to, to be able to define, you know, the condition and the treatment approach. And I --

Q. Isn't that true for many psychiatric conditions?

A. Absolutely. I would -- absolutely. It is not unique to the area of gender dysphoria. In fact, in talking, you know, to those that are engaged more in the field of psychiatry, they will acknowledge that the rudimentary nature of the discipline in comparison to the rest of the medical -- medical enterprise, it is a very known and serious shortcoming. And there is a desire certainly to -- to fill in those gaps.

And there's actually hope that as time moves forward with the advance in tools that one has, to study neurobiology and address some of these questions. But there will be an opportunity to provide clearer answers that are more evidenced based.

Q. Sure. But, I mean, isn't that the nature of science and medicine; we don't know everything, period?

A. We know far less of the psychiatric conditions that are listed in -- or many of the psychiatric conditions -- I wouldn't say all -- that

Q. But your practice is in the field of endocrinology, not psychiatry; is that right?

A. I think we've touched upon this earlier, but I'm happy to expound upon that. Is --

Q. Well, it's a yes or no.

A. I'm a physician scientist. So I'm very qualified to talk about deficiencies in scientific evidence that are present in this particular area.

Q. So you're not a psychiatrist?

A. I covered that earlier. That I'm a pediatric endocrinologist. Yes, that's correct.

Q. Are you aware that the revision of the DSM involves the establishment of a scientific review committee that evaluated and provided guidance on the strength of evidence of any proposed changes?

A. You know, that is how they describe the process. I again have asked for the evidence, scientific evidence for the change between gender identity disorder and gender dysphoria and then even the move to shift toward the ICD code of gender incongruence, that is based upon a scientific evidence, rather than something other than that.

Q. You also make reference in your report with statements by Thomas Insel, the then director of the National Institute of Mental Health, that it

field forward. So I think that's entirely consistent with my interpretation of the whole question.

Q. Were you aware that two weeks after the statement that you reference from Dr. Insel, Dr. Insel issued a joint statement with the American Psychiatric Association stating that, quote: The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders.

Were you aware of that statement?

A. Yes. And that is completely in agreement with my opinion that I put forward here as well.

(Whereupon Exhibit 7 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 7.

A. I have it.

Q. Okay. This is a statement issued by Thomas Insel, the then director of the National Institute of Mental Health, and Jeffrey Lieberman, the then president elect of the American Psychiatric Association; is that right?

A. Yes. I believe -- well, I don't know for sure, but I agree.

Q. Okay. Right below DSM-5 and RDoC, colon, shared interests, it states: The authors of this statement.

Do you see that?

A. I see the two authors, Thomas Insel and Jeffrey Lieberman, correct.

Q. All right. Going to the second paragraph, it reads: Today the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders. Patients, families and insurers can be confident that effective treatments are available, and that the DSM is the key resource for delivering the best available care. The National Institute of Mental Health has not changed its position on DSM-5. As the National Institute of Mental Health research domain criteria project website states, the diagnostic categories represent that in the DSM-IV and the International Classification of Diseases 10, the main contemporary consensus standard for how mental disorders are

diagnosed and treated.

Did I read that correctly?

A. You read it correctly. Yet what follows in the next paragraph is more pertinent to the statement that I made in the declaration acknowledging the fact that the DSM is not sufficient for researchers and the statement was related to the basis for research funding. So, you know, taken in context, this document is completely in line with the statement that I made about the limitations of the DSM.

Q. But the DS -- the DSM -- this is a case about the treatment of gender dysphoria; is that right?

MR. KNEPPER: Objection form.

A. So as we've been talking about all morning, okay, the ability to have effective treatments is based upon quality research. And if the DSM is not sufficient for researchers to be able to conduct their scientific study, because of how the DSM generates their diagnostic codes, I think that that understanding is completely relevant to why one needs to be aware of that.

Q. (By Mr. Gonzalez-Pagan) All right. Going to what is the fifth paragraph, the second to last

sentence. It states: As research findings begin to emerge from the RDoC effort, this finding may be incorporated into future DSM revisions and clinical practice guidelines. But this is a long-term undertaking. It will take years to fulfill the promise that this research effort represents for transforming the diagnosis and treatment of mental disorders.

Did I read that correctly?

A. You did read it correctly.

Q. Is there a reason why you did not include this follow-up statement from Dr. Insel regarding the DSM views and reliability in your report?

A. You know, I could have put the entire document that you have here into the report. The point being made, I think, is one that I fully agree with. I think that as we be able to -- are able to incorporate science into the DSM, it is going to increase in its validity and its usefulness. But in its current state there is acknowledged in this statement itself by the fact that this research is needed. It acknowledges the deficiencies that currently exist. So there's a whole host of other things that I could have included in my declaration. The point that was intended, I think, was

sufficiently made and supported even by this document that you put forward as a new exhibit.

Q. Sure. But in clinical qualification to your statement is that that doesn't exist yet, and that the DSM is the best current available tool that we have according to this statement?

MR. KNEPPER: Objection, form.

A. The point I made is that there are deficiencies in how it was -- or limitations how the DSM has been put together. And that is relevant to the understanding of how we put forward hypotheses for efficacious treatments. And so I would say that, you know, that's -- the state of knowledge in this area is -- is what is of concern and how we are using the DSM beyond its capabilities without knowledge of molecular or physiologic mechanisms for most of the psychiatric diseases is a major limitation which is acknowledged by the authors of this document. That is what I believe is important for the court to recognize and to understand as we move forward in this conversation.

Q. (By Mr. Gonzalez-Pagan) In your report you speak of three modalities of treatment for gender dysphoria; is that right?

A. I would say three different categories

based upon different underlying scientific premises. I think the reality of interventions are much broader than that and not as easily demarcated into three categories. But indeed, I do present those in my declaration.

Q. And these modalities, are they reparative therapy, watchful waiting and the affirming approach?

A. That is how I presented it, correct. And, again, if it would be helpful, if we're going to talk about it, if we can direct ourselves to that part of my declaration.

Q. We'll get there. Are you familiar with Ken Zucker's work?

A. Yes, I am.

Q. In fact, you repeatedly cite Dr. Zucker throughout your report; is that right?

A. Yes, I do, among other people, yes.

Q. What do you understand to be the model of care that Dr. Zucker employed?

A. Broadly speaking prior to his clinic being shut down was to approach care in a way to understand the underlying basis for the sex discordant gender identity in that era was referred to as gender identity disorder.

And to -- one of the approaches that he used was to help facilitate an individual to realign their gender identity with their sex. And if that was not possible, would then advocate for moving forward with affirmative approaches.

Q. So under Dr. Zucker's model, affirming care would be provided if there was persistence of cross-gender identification into adolescence and adulthood?

A. Based upon the information that Dr. Zucker had at the time that he was engaged in that care, that was how he proceeded, yes. He was not privy to the information that has come forward in the last several years about outcomes with that affirmative approach.

Q. What is the watchful waiting model?

A. Again, all of these approaches are based upon different scientific premises and it is based upon the experience that the majority of prepubertal children that experience sex discordant gender identity, if merely left alone, will have spontaneous realignment of their gender identity with their sex.

And it is again, whether it's intended or not, perceived as to be a desirable

outcome. And that those individuals that have that experience will not be exposed to gender-affirming medical interventions with all the associated risks and questionable benefits that we -- that I mentioned already. And I certainly can share more information if you would like.

Q. Let me introduce you to what's been marked as Exhibit 8.

(Whereupon Exhibit 8 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Do you have access to the exhibit?

A. Yeah. I'm seeing it now, correct.

Q. This is a publication on -- it's an article on adolescent health medicine and therapeutics; is that right?

A. I'm seeing that here. Is this a peer-reviewed journal -- a peer-reviewed article, just so I know?

Q. I'll answer that question for you then. The answer is yes, but it's the next exhibit.

A. Okay. I'm sorry. Did you have a question for me?

Q. Not yet.

A. Okay.

Q. I will represent to you that this is a peer-reviewed journal, but -- and I'll come back to -- to another exhibit to discuss that with you. But turning --

A. The reason I ask that was because it's a review article. And even in peer-reviewed journals, not all reviewed articles are reviewed with the same rigor. So that's -- but thank you.

Q. Let's exit out of that exhibit. And if my computer will cooperate.

(Whereupon Exhibit 9 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) All right. I'm introducing what's been marked as Exhibit 9.

A. I have the document, just so you know.

Q. Great. Do you see where it describes the journal as an international peer-reviewed, open access journal focusing on health, pathology and treatment issues specific to the adolescent age group?

A. That's true. Just below the ISSN number.

Q. Correct.

A. Yes, I see that.

Q. Okay. So you would agree that it is a peer-reviewed journal?

A. Yes. They're claiming it is. I would have no reason to doubt that.

Q. Okay. So going back to Exhibit 8. If you can turn to Page 61 of the document.

A. Okay. Are you referring to the highlighted area?

Q. Well, we're going to go to the bottom of the right-hand -- right-hand column.

A. Okay.

Q. Under the watchful waiting model.

MR. KNEPPER: And, Omar, let's identify on the record the highlighting is not in the underlying document, but it's been added.

MR. GONZALEZ-PAGAN: For the record, the highlighting in the exhibit has been added by me. Otherwise the document is unaltered.

Q. (By Mr. Gonzalez-Pagan) The highlighted portion states -- reads: In contrast to live in your own skin approach, a young child's demonstration of gender nonconformity, be it gender identity, expressions or both, is not to be manipulated in any way, but observed over time. If a child's cross-gender identification and affirmations are persistent over time, interventions are made available for a child to consolidate a

transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment as in the best interest of the child. These interventions include social transition (the shift from one gender to another, including possible name change, gender marker change and gender pronoun changes), puberty blockers and, later, hormone and possible gender-affirming surgeries.

Did I read that correctly?

A. Yes.

Q. So under the watchful waiting model, gender-affirming care is provided for adolescents and adults if they persist in the cross-gender identification; is that right?

MR. KNEPPER: Objection to form.

A. That's correct according to this use of the model, yes.

Q. (By Mr. Gonzalez-Pagan) Well, the watchful waiting model was developed by -- it's the Dutch model. It was developed in the Amsterdam Center of Expertise on Gender Dysphoria; is that right?

A. That's my understanding.

Q. Under the gender-affirmative model, medical and -- no medical and surgical interventions are initiated until after the onset of puberty; is

that right?

A. If you're talking about there's no reason to block puberty that hasn't started yet or to intervene with cross-sex hormones until that age; that is correct.

Q. Did you disclose to the -- in your report that under Dr. Zucker's model, under the watchful waiting model, and under the gender-affirmative model, gender-affirming medical treatment is indicated if cross-gender identification persists into adolescence and adulthood?

A. I would challenge you on the assertion that it's indicated. I would say that the model itself bases itself on the next step of intervention. Whether there's a prudent approach is really what is of concern with the literature that we have available. So the models itself indeed -- and they actually differ in not only in the timing of when one engages.

The affirmative model actually begins earlier with social affirmation, not just medical intervention. And there's different scientific premises that are underlying -- underlie these two different approaches.

Q. But under each of the models of the three

models that we've discussed, medical and surgical care is provided as a mode of treatment?

MR. KNEPPER: Objection, form.

A. Under the model. So let me be clear. Okay. So the reason for the watch and wait approach is to know that in prepubertal children that present with gender dysphoria, that the vast majority of them will have that spontaneous realignment, other gender identity with their sex, by varying estimates ranging from 50 to 98 percent. I think 88 -- 85 percent is a good average based upon the published literature.

That means that this would apply to 15 -- at most 15 percent, maybe even less, that would have persistence. It also makes the assumption -- and this is certainly one that one considers with the current social environment as to whether the influence of the social affirmation component, you know, is -- is provided.

So the underlying premises are different in the two models. One has a premise that there are a number of factors that led to the gender dysphoria. And the vast majority of individuals, that they may differ from one patient to another. There is no biological test that one can do to

determine which of these individuals are going to have persistence or have that spontaneous realignment. And the safest course of action is to do nothing until things are sorted out.

The gender-affirmative model makes a scientific premise that when one experiences sex discordant gender identity, it reflects something that is innate and immutable. And, therefore, a prudent approach would be to immediately engage in social affirmation followed by these hormonal interventions. I hope that I've stated that clearly enough for you and for the court.

Q. (By Mr. Gonzalez-Pagan) Sure. But ultimately as to the question for transgender people who persist in their cross-gender identification by definition into adolescence and adulthood, medical care and surgical care if indicated under any of the three models, that being Zucker's model, the watchful waiting model or the gender-affirming model?

A. I don't know that I would distinguish what we were talking about earlier with the Zucker model being -- I think you're doing that more as the reparative therapy.

And this is based upon again the

issue at hand of the emerging scientific evidence that leads one to question whether this provides a long-term solution to the problem of dysphoria. And, again, I will state again that there are many concerns about the presumption in proceeding with affirmative care that can be challenged by the outcomes that one is observing about how well these individuals are doing after receiving the gender-affirmative care.

So this is -- these are statements in this particular paper by Dr. Ehrensaft that is based upon the presumption that those are -- who receive the affirmative approach are going to be completely cured of their difficulties that they experience. And my point is that when you say indicated, it fails to recognize the -- the challenges that are emerging for that outcome.

Q. Sure. But my last question wasn't whether it was indicated. My last question is whether under each of the three models -- and let me clarify something. You discuss a reparative therapy model in your report; is that right?

A. Yes. Can we again go to that part just so you can direct me just so we can be looking exactly at what I wrote.

Q. Sure. It's Page 49 going into Page 50.
A. Thank you very much. Okay. Very good.
Q. My point is --
A. I do remember what I wrote. I just want to make sure we're talking about the same thing.
Q. My point is that -- that I'm trying to distinguish actually there are four models, if you will. The Ken Zucker model is distinguished from reparative therapy in that -- in a significant way.

And let's go to Page 61 of Exhibit 8, the highlighted portion above the watchful waiting model. It states: If by the arrival of puberty a child is still exhibiting cross-gender identification and expressing a cross-gender identity, that child should be supported in transitioning to the affirmed gender including receiving puberty blockers and hormones once it is assessed from clinical interviews and psychometric testing that the affirmed gender identity is authentic.

Did I read that correctly?

A. Yes.
Q. Okay. So my question was whether you disclose in your report that under the watchful waiting model and/or Ken Zucker's approach,

gender-affirming medical care is provided after the onset of puberty?

A. I'm trying to -- let's go back again to my report and the context of the discussion that I'm putting forward. You said that was -- we were on page -- page or bullet point No. 59, I think you said.

Q. Page 49, going into 50.

A. 49. Okay. That's where I -- that's where I lost you. I was on 59. Sorry. So I would also add that the presentation of three broad categories -- and you've mentioned a variation of one of those categories saying there are four approaches. I would -- I would posit it that there's a number of other hypotheses that have been put forward about treatment approaches that --

Q. Did you disclose any of those other approaches in your report beyond the three that you listed in this paragraph?

A. Let me explain what I mean by that. Okay? As I repeatedly said in my declaration that there are multiple hypoth -- alternative hypotheses that can be put forward about the most prudent approach to care. These broad categories provide the foundation for understanding the design and

implementation of these various applications of these broad categories.

The point of dividing it up into three categories is to really -- and I think that that is still valid -- that the starting underlying scientific hypotheses or the scientific premise, I should say, varies in these three different approaches. How that scientific premise is translated into hypotheses that lead to care approaches is -- is at issue here. And that I think is the important point that I wanted to illustrate for the court. And make it very clear that what is put forward by the plaintiff experts, and they said this repeatedly, is that the affirmation-only approach is the only accepted intervention in the care of gender dysphoria youth. And in this paper here and in my declaration, you know, challenge that as far as the most prudent approach. And that's the point of why it was included in a benefit for the court.

The affirmation approach is not the sole approach. And there are alternative approaches that haven't been adequately investigated and that need to be investigated. And this is an area of unsettled controversial treatment that is going on

currently.

Q. Sure. But ultimately there's a distinction that they are different, right? Under all three of these models, gender medical care and surgical care is provided after the onset of puberty?

MR. KNEPPER: Objection, form.

A. I would say that is an important distinction because if the underlying --

Q. (By Mr. Gonzalez-Pagan) The modalities of treatment, are they different?

A. If the outcome of the affirmation approach is proven to be not effective it would change the way that one applies that model to the effected patients.

Q. But on the altering model, you're providing medical care after the onset of puberty. So the real difference has to do with prepubertal children and how they're treated; is that right?

A. Well, let's talk a little bit about the emerging demographic of what we are experiencing right now. Many of the people --

Q. But that's not my question, though. Like --

A. Okay. I don't think it applies

exclusively to the prepub -- medical care -- I would say the hormonal interventions apply only to people that have progressed at least to stage two puberty. Social affirmation applies across the board and would be relevant whether one presented during adolescence or in childhood.

Q. But social affirmation is not a medical or surgical treatment.

A. Many would argue that. And I would say in a technical sense, that is true. However, there are many concerns that are evidenced in the literature, that that influences the trajectory of the children as to whether they go on to medical care. So many can and have argued that it is the first step that is leading them on to the subsequent hormonal interventions. So I think it is relevant.

Q. In Paragraph 50 in discussing -- in describing the watchful waiting approach, you note that this approach may include the use of scientifically validated treatment, e.g., CBT, for the patient's anxiety, depression, social skill deficits or other issues.

But you do not note that gender-affirming medical care and surgical care are provided under this approach. I'm just wondering

why you did not provide that context in your report?

A. Because that's under the premise that the affirmative approach actually provides benefit, and throughout my declaration I have raised multiple concerns with existing published data that lead to a presumptive or tentative conclusion that at best we should have more caution to that approach.

Q. So at best your description of the watchful waiting approach in this paragraph is incomplete?

MR. KNEPPER: Objection.

A. Let's read through and we can even read it into the record if you'd like, the way that I present that. Because that's where I think it's important to look at this in context.

Q. (By Mr. Gonzalez-Pagan) Actually let's just -- let's just go to Paragraph 53 of your declaration. It states: Another controversy --

A. Hold on. I'm not there yet.

Q. Okay. I'll wait for you.

A. It's a long paragraph.

Q. Well, I'm right at the beginning of Paragraph 53.

A. It starts with "assistance"?

Q. Paragraph 53.

A. Paragraph 53 talking about another controversy, the watchful waiting treatment; is that what you're talking about?

Q. Sure.

A. Okay.

Q. I'll just read the heading: Another Controversy, the watchful waiting treatment modality involves no medical treatment and is currently the best specifically -- sorry -- is currently the best scientifically supported intervention for young children reporting gender dysphoria.

But the watchful waiting model does involve medical treatment; isn't that right?

A. Perhaps to clarify that statement when I say young children when we're referring to prepubertal children, that is true, and it is actually included in the Endocrine Society guidelines. As far as the concerns about intervening and the caution that should be expressed precisely because of the high rates of desistence.

So that statement, again, when we're talking about social affirmation and your contention as I'm hearing it as you're stating it is social affirmation is not technically a medical intervention. And I think we've already discussed

that. That it is relevant as far as the first step in influencing the trajectory of these individuals.

Q. This case --

A. And there's also --

Q. So this case involves gender-affirming care, right?

MR. KNEPPER: Object to form.

MR. GONZALEZ-PAGAN: I apologize, Sheryl.

A. So -- so -- okay. Let's -- let's also move on. So if -- if you then look at the first stage of medical intervention which involves the administration of an GnRH agonist or also known as a puberty blocker, significant concerns that that normal trajectory where you see the majority 50 to 98, I would say 85 percent have the desistence. That demographic or that statistic changes drastically in those individuals that have received that first step of pubertal blockade and that actually most of the studies that have been published thus far says the vast majority of -- it's not 100 percent. It's very close to that -- will go on cross-sex hormones. So again that is not -- that is more the affirmative model.

The watch and wait model would posit that as a child begins into their puberty, that

acknowledging that the bodily changes that occur may heighten the level of dysphoria that they experience. But as they go through that developmental process, that experience of puberty is actually critically important in the overall integration of one's identity with their sex. And that would be consistent with the watch and wait model. So that again, as being presented in this one review article by Dr. Ehrensaft -- much more I could say about that -- I think there's much more to be said about the way that these models are being presented.

Q. The study that you -- the study to which you refer regarding persistent cross-gender identification following the provision of GnRH analogue, is that the de Vries study?

A. That's the one that shows a hundred percent persistence or a hundred percent moving that across sex hormones. There's been subsequent ones where it's not been a hundred percent, but it's been the 90 percent range.

Q. You say that those studies pertain to the application of the gender-affirmation model, but the de Vries study is actually speaking to the watchful waiting model. It is the Dutch model.

A. We need to say a lot more about that if we want to flesh that out for you. I don't know that you've adequately characterized the Dutch model. And I will add that the Dutch model was presented a decade ago with a different patient population that is currently presenting at the gender clinics across the world. And even --

Q. But that's a different point than -- than the one that we're talking about, right? You indicated that the affirmation model -- studies show that the affirmation model leads into persistence, but you're relying on a study based on the Dutch model.

A. Well, I would qualify that statement. I didn't say that it leads to that model, because the way the study was conducted, you know, causal effect cannot be inferred. Okay? So I would moderate that. But I would say it's certainly of concern that that number is drastically different than the prior studies that have shown that rate of spontaneously -- spontaneous realignment with gender identity with sex.

Q. But those are different populations, right? I mean, we're talking about prepubertal and pubertal youth versus prepubertal youth?

A. Not necessary -- so, again, you know, it would be much more helpful to talk about specific studies. In the de Vries study, the whole basis of giving pubertal blockers applied only to pubertal patients.

Q. That's by definition any person who's receiving puberty blockers.

A. No necessarily.

Q. It has to happen at the onset of puberty.

A. Well, yes, onset of puberty, that would be the only indication for giving it in the area of pediatrics.

MR. GONZALEZ-PAGAN: All right. How about we break now for lunch?

MR. KNEPPER: Dr. Hruz?

MR. GONZALEZ-PAGAN: Well, I'm -- I'm hungry, so.

MR. KNEPPER: I know. This works with your diet?

THE WITNESS: Yeah. I think as we go through this, I'm going to be happy just plowing through. So it's going to have to come from your end if you want to take a break.

MR. GONZALEZ-PAGAN: Well, it's coming from my end. Because I -- I'm running on a

have to demonstrate a concept of what we call non-inferiority. So if that's the natural outcome, so if there's a realignment with gender identity with sex and that obviates the need for them to go on to receive hormonal treatment of any sort at all, that would be a desired outcome.

The challenge is that in those individuals, there is no reliable diagnostic test to predict which of those children are in the category of 85 percent, like we go to this realignment versus the subset that's going to persist in that sex discordant gender identity.

So that's the challenge. So I would say I wouldn't be so firm to make an absolute determination of the best course of action, but I wouldn't say that any alternate approach would have to prove that non-inferiority outcome.

Q. (By Mr. Gonzalez-Pagan) Okay. And the desistence study speaks to prepubertal youth who were diagnosed with gender identity disorder under the DSM-III or the DSM-IV; is that right?

A. So this is -- I'm very much aware of that critique, and the way that people have attempted to dismiss that desistence literature based upon that difference of gender identity disorder versus gender

dysphoria. It's very interesting that if you look in detail for example at that same paper the number of people based upon the criteria --

Q. I'm sorry, Doctor. I apologize for interrupting. But I guess -- I'm happy to go into a conversation about this. But I guess I have a predicate question, which is I want to establish whether it's true or not that the desistence studies are based on prepubertal children diagnosed with gender identity disorder as opposed to gender dysphoria under the DSM-5?

A. Well, older studies would certainly necessitate that they use the diagnostic criteria that was available at the time the study was conducted. And some of them -- and most of those studies were the era prior to the revision of the DSM-5 giving the gender dysphoria diagnosis.

Q. Are you aware of any studies looking into the desistence in prepubertal youth using the DSM-5 criteria?

A. You know, that is an outstanding question and I'm very happy to share with you the problems with that question. In the fact that because of what has happened in the approach to the care of these individuals, the opportunity because of the

widespread adoption of the affirmation only approach and the early adoption of social affirmation makes it very challenging to be able to even put forward as a hypothesis a study that would be able to operate under the current diagnosis of gender dysphoria.

And I think that's very problematic as we seek to understand the natural history of this disease, and we seek to find ways to alleviate the suffering that will be sustained long-term in these individuals. I think it's the fact that the discussion is not allowed to occur and the studies have not been proposed and conducted. And even if they were, there would be challenges in the current environment of really encouraging that social affirmation approach.

So the answer to the question is that there are many problems that currently exist as to why those studies have not been reported and would be very difficult to perform at this point in time, yet would be essential to providing the best care for these individuals.

Q. Okay. But you do not know of any studies documenting an 85 percent desistance rate for kids diagnosed -- prepubertal kids diagnosed with gender

dysphoria mode in the DSM-5?

A. I'm not aware the question has actually been investigated by a scientific trial. Not that there's data that says it doesn't exist, but that it has not been investigated. The only data that's available right now are people that have received that social affirmation which clearly shows that that demographic has changed. And, you know, if you ask this as a hypothesis --

Q. I appreciate that, Dr. Hruz. We'll get to the demographic changes later on. But I want to stay focused. So going back, the studies have to do -- the studies in desistance that you reference have to do with prepubertal children; is that right?

A. The ones that were done previously that I'm referring to dealt with prepubertal children. Now, there's another component of this, that of -- you divided this between prepubertal and adults. And it's very necessary if we're going to adequately address this question to consider what happens during the period of puberty.

Q. Okay. Are there studies that document desistence during the period of puberty?

A. There are case reports. There are not -- and there's a growing -- this gets at the --

Q. In your report you state that case reports are not valid scientific evidence.

A. They are useful for hypothesis generation. They're not useful for making definitive causal conclusions. That is correct.

Q. So are there any studies showing high desistence among adolescence diagnoses with gender identity disorder?

A. There are not. And the reason for that, again, is because in many of the studies where one looks at this, there's a very, very high dropout rate in many of the subjects where one can't conclude at all what the outcomes were. Based upon the available evidence, more by case reports of growing number of people experiencing this desistence, that did occur when it's experienced post pubertally would lead one to raise hypotheses to be investigated in a rigorous scientific manner to address that question.

Q. You believe that all medical treatment needs to be subjected to randomized clinical trial?

A. It depends on -- so every medical decision that is made is based upon consideration of the overall risk and the overall benefit. And I think that the greater the risk, the greater the scrutiny

are certainly --

Q. But that's just a hypothesis; is that right?

A. You know, all along here, I've been tell -- I've been stating, and I hope very clearly, that much of my opinion is based upon hypotheses and alternative hypotheses, because there is no definitive answer to this question. But the prevailing current hypothesis that's not presented as a hypothesis, it's presented as an established fact, is that gender-affirming interventions are the solution to gender dysphoria. And that is what I challenge. And that is what, I think, is very important for this court to understand, is that the scientific evidence does not support that as being a cure for all of the difficulties that these individuals are experiencing.

Q. Going back to the desistence studies. What is the error rate for the desistence studies that you rely on?

A. So the error rate is -- there's a number of factors. I'm glad that you brought this up as far as, you know, how we think about the reliability of studies. So this is a problem throughout the literature. And I've addressed this in my

Q. (By Mr. Gonzalez-Pagan) Are you aware that the American Psychiatric Association opposes reparative therapy efforts regarding gender identity?

A. Now we're into a new line of questioning about medical societies. But I'm aware of -- of the general recommendations for affirmation only. That is entirely consistent with what has been put forward by WPATH, American Psychological Association. There's a little bit more caveat in the Endocrine Society guidelines. I think they're a little bit more cautious in the prepubertal children, at least in the 2009 document cautioned against social affirmation in recognition of the same desistence literature that I'm referring to. Again, not just my opinion. This is the professional societies in the 2009 guidelines acknowledged those studies of being relevant to that consideration of treatment.

Q. Sorry. I just don't want us to go down a different path. I'm not talking about the general position statement about gender-affirming care. I am talking about the physician statements regarding conversion therapy. Are you aware that the American Psychiatric Association opposes conversion therapy

eff -- conversion therapy efforts?

A. The reason I answered in the way I did to your previous question was not to evade the question. It was merely to -- you began with a professional association. And so it's necessary to acknowledge what the basis of those statements are. The APA recommends the affirmative approach to care.

Q. Okay. But that's not my question. That is a different position statement. And I'm glad -- yeah, the APA does do that. But does the American Psychiatric Association also have a position statement regarding conversion therapy?

A. Okay. Thank you. Because you used the word "conversion therapy" for the first time. I think it's very important for us to acknowledge when we're talking about reparative therapy and what people talk about as far as conversion therapy. That's actually a pejorative term that actually is trying to equate these efforts to realign gender identify with sex to a completely different condition related to same sex attraction with methods that virtually everyone would recognize as being unethical.

And so I think it's an injustice to -- and the statements are often made in the

literature published talking about conversion therapy.

Q. All right. One second. Let's just go -- let's just go to Page 49 of your report, Paragraph 52.

A. Sorry. Paragraph 52?

Q. Yeah. So very last sentence going into the next page of your report states: The first approach often referred to as conversion or reparative -- reparative therapy --

A. Correct.

Q. -- is directed to or actively supporting and encouraging children to identify with their biological sex.

Did I read that correctly?

A. I could add often incorrectly referred to as conversion therapy. I think that's probably something I could have added to my declaration to indicate that. I think it's incorrect and an injustice to use that term to describe the approach to -- to addressing gender dysphoria.

Q. Are you aware that the American -- you know what, let's -- I apologize. I forgot the stamp again. It is marked Exhibit 10. Do you see that?

(Whereupon Exhibit 10 was

introduced for identification.)

A. Correct. I see this.

Q. (By Mr. Gonzalez-Pagan) Okay. Under the position heading at the bottom of the page, in Paragraph 2, it states: APA recommends that ethical practitioners respect the identity for those with gender diverse expression.

Did I read that correctly?

A. I'm in the wrong paragraph. You said the second paragraph?

Q. Under -- under the heading position at the bottom of the page?

MR. KNEPPER: Omar, I think you made -- I think you swapped gender and diverse. But it's just -- in other words, I think you read gender diverse expression and it's diverse gender expression.

Q. (By Mr. Gonzalez-Pagan) Sure. Let me just read that again. Are you there?

A. I'm here. Okay. I'm sorry. I was reading the introductory paragraph. Sorry.

Q. Okay. It states, Paragraph 2, quote: APA recommends that ethical practitioners respect the identity for those with diverse gender expressions.

Did I read that correctly?

A. Yes.

Q. Then just below that on Paragraph 3 on the next page, it states, quote: APA encourages psycho -- psychotherapies which affirm individual's sexual orientations and gender identities.

Did I read that correctly?

A. Yes.

(Whereupon Exhibit 11 was introduced for identification.)

Q. (By Mr. Knepper) Showing you what's been marked as Exhibit 11.

A. I see it.

Q. Okay. This is a resolution by the American Psychological Association on gender identity change efforts. Is that right?

A. That's the title of this document, correct.

Q. It's dated February 2021; is that correct?

A. That's correct.

Q. Go to the second page, third to last paragraph on the right-hand side column. And it's use of GICE as an acronym for gender identity change effort; is that right?

A. I see that, yes.

Q. It reads: Whereas, GICE has not been

shown to alleviate or resolve gender dysphoria (Bradley and Zucker, 1997; Cohen-Kettenis & Kuiper, 1984; Gelder and Marks, 1969; Greenson, 1964; Pauly, 1965; and SAMHSA, 2015).

Did I read that right?

A. You did.

Q. If you go to Page 3, the last two paragraphs, on the right-hand side column, it states: Be it therefore resolved, that consistent with the APA definition of evidenced-based practice (APA 2005), the APA affirms that scientific evidence and clinical experience indicates that GICE put individuals at significant risk of harm.

Be it further resolved that the APA opposes GICE because such efforts put individuals at significant risk of harm and encourages individuals, families, health professionals, organizations to avoid GICE.

Did I read that correctly?

A. You did.

Q. Okay. So the American Psychiatric Association and the American Psychological Association both oppose reparative therapy as a form of treatment; is that right?

A. Gender identity change efforts as stated

in the document, which again is different than what people generally equate with conversion therapy, in quotes.

Q. And the American Psychiatric Association and the American Psychological Association consider gender identity change efforts to be unethical and harmful; is that right?

A. That's what's stated in these documents.

Q. All right. I will apologize in advance, that exhibit is large and will make navigating it a little difficult. Hopefully it will take a little bit longer to upload.

(Whereupon Exhibit 12 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 12. It's a document entitled Understanding the Well Being of LGBTQI Plus Population. Is that right?

A. That's the title in the document that I'm looking at, yes.

Q. It appears to have been published in 2010; is that right?

A. It says 2020.

Q. Sorry. 2020.

A. Okay.

correctly. And that many of the studies that are referenced here have major methodologic weaknesses and the strength of the statement based upon that evidence in light of the emerging evidence that is coming forward, for example, in the other studies that we've discussed already today --

Q. Well, let's --

A. -- this conclusion can be scrutinized.

Q. Let's move to the next page. The highlighted statement reads: The available evidence suggests that sexual orientation and gender identity conversion efforts were ineffective and dangerously detrimental to the health of SGD population, especially for minors who are unable to give informed consent.

Did I read that correctly?

A. I'll say again, you read it correctly. And the meaning of that statement and context of the whole paper is something that we can discuss later.

Q. Would you agree that it is the position of the National Academies of Sciences, Engineering and Medicine that conversion therapy is harmful?

MR. KNEPPER: Objection, form.

A. I don't know whether the small panel of people that were included in generating this

consensus statement represents the entire views of the entire membership of that society. I know from my own experience that for the other societies that I'm involved with these types of consensus statements are not brought to the entire membership of the organization. I can only conclude that the members that were present on this panel made those conclusions. I would not go as far as to say that it was supported by every member or even majority or even substantial number of the rest of that group.

Q. (By Mr. Gonzalez-Pagan) If you go to the fourth page of the PDF.

A. Back up to the top now? Okay.

Q. On the last sentence, the second clause, it states: It represents the position of the National Academies on the statement of facts; is that right?

A. That is what is stated here, and that is also stated by other organizations that have put forward similar statements. The same concern applies, that just because they put it forward, it does not mean that -- that the entire membership has been able to weigh into this question or those that wish to do so.

Q. Was the review that you referenced in

A. You know, again I don't have the answer. I don't know.

Q. Okay. Are you aware that in the United Kingdom, medical and surgical care is provided for transgender adolescents post puberty and for transgender adults?

MR. KNEPPER: Objection to form.

A. I guess I didn't understand the question there.

Q. (By Mr. Gonzalez-Pagan) Sure.

(Simultaneous speakers.)

Q. (By Mr. Gonzalez-Pagan) You talk about -- you talk about the reviews in the United Kingdom, in Finland and in Sweden. So I'm curious, are you aware -- are you aware whether in the national health system in the United Kingdom, they provide coverage and treatment for gender dysphoria in post prepubertal adolescents and adults?

A. So I think it's reflected in the recent Tavistock versus Bell decision. It is recognized that this is an area of controversy and that is an unsettled question about --

Q. Well, the Tavistock decision has to do with minors. I'm talking about adults and cross-sex hormones and surgery. Are you aware whether in the

United Kingdom they provide coverage and treatment of cross-sex hormones and surgery as a modality of treatment for gender dysphoria?

A. Yes, I do.

Q. Okay. Same question with regards to Sweden?

A. Sweden -- again, I'm a pediatric endocrinologist. And I think that the caution that is put forward in relegating this care to the setting of -- of an experimental setting is where it's been pulled back with concerns based upon the --

Q. The restrictions to which you speak all relate to the provision of puberty blockers; is that right?

A. No. I think it's more extensive than that. But it -- it acknowledges that based upon the literature that there's not very stong evidence and then instructs that this care be delivered with the safeguards exactly as I'm saying, you know, it should be done here in the United States. Recognizing that this is --

Q. That's in the context of minors, though; is that right?

MR. KNEPPER: Objection, form.

A. Again, that's what I've addressed in my declaration. And that is my --

Q. (By Mr. Gonzalez-Pagan) But with regards to transgender adults in Sweden, does the nationalized healthcare system in Sweden provide coverage and treatment for gender dysphoria in the form of hormones and surgical care?

A. You know, I would say this is outside the scope if we're getting into a discussion about insurance coverage. My expertise is in looking at the scientific data about the affirmation and other --

Q. Well, you rely on the national reviews of Sweden, Finland, and the United Kingdom. So --

A. Correct.

Q. -- I'm wondering if you rely on the national reviews, I think it's pertinent and relevant whether you disclose in your report that these countries provide for the treatment and coverage of this care?

MR. KNEPPER: Objection, form, scope.

A. As a pediatric endocrinologist and physician scientist, my service to this court is not to opine upon -- I know it's a big part about this case about insurance coverage. My role in this

gender-affirming treatment for adults?

A. Again, I would have to say for me to comment specifically about that, we would need to have the document in front of me to be able to look through all of the papers. It was a very extensive study. And there are a number of papers there.

And so I would have to look through the papers to specifically look at the inclusion criteria, whether it was exclusively in kids or included adults and, again, how he defined, you know, adulthood, whether it's post prepubertal, post 18, early 20s. You know, many people have different definitions of that. And so --

Q. All right. Same line of questioning with regards to Finland. Did you disclose that Finland provides through its national -- nationalized health care system gender-affirming treatment for gender dysphoria for adults?

MR. KNEPPER: Objection, form, scope.

A. I'm going to state again that for me to opine on that, I would need to look at, in those studies, what the inclusion -- inclusion criteria and whether it extended into adulthood.

Q. (By Mr. Gonzalez-Pagan) My -- my -- my question is not pertinent to the report. It's not a

question of whether they reviewed it. It's a question whether that care is provided in Finland.

MR. KNEPPER: Objection, form.

A. I will say again that this is a question related to insurance coverage. And I'm a pediatric endocrinologist, physician scientist opining on issues of science, not on medical coverage.

Q. (By Mr. Gonzalez-Pagan) One moment, please. Let's take a -- well, actually no. We'll come back. In your report you disclose the Bell v. Tavistock position; is that right?

A. That's correct.

Q. That was a decision from December 2020 in the United Kingdom?

A. Correct. And it was before the appeals court decision came out recently.

Q. And you submitted an expert report in Tavistock; is that right?

A. In that Bell versus Tavistock case, I did.

Q. Are you aware that the Bell v. Tavistock case dealt solely with the ability of a minor to provide informed consent on their own?

MR. KNEPPER: Objection to form.

A. So the decision was based on that. But that was not what I was opined [sic] to comment on.

there's no indication here that this was a peer-reviewed document. It wasn't published in a journal in the typical way that we do it. So it's a Council for Choices -- recommendations of the Council for Choices in Healthcare in Finland. So this is -- the council itself came to this conclusion to answer your question.

Q. Let's go back to Exhibit 12.

A. I'm there.

Q. All right. We're going to go to Page 12-10. It is Page 311 of the PDF.

A. I wish there was a way you could just type in the number and get to it.

Q. Don't we all.

A. Okay. This is with the section that's titled Guidelines and Policies Related to Gender-Affirmation?

Q. That's right.

A. Very good.

Q. The highlighted statement states: Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines. In 2012, the World Professional Association for Transgender Health, WPATH, published Version 7 of

the Standards of Care for the Health of Transgender, Transsexual, and Gender-Nonconforming People, which have been continuously maintained since 1979, and revisions for Version 8 are currently underway (Coleman, et al., 2012). Two newer guidelines have also published -- have also been published by the Endocrine Society (Hembree, et al., 2017), and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016). Each set of guidelines is informed by the best available data and is intended to be flexible and holistic in application to individual people. All of the guidelines recommend psychosocial support in tandem with physical interventions and suggest timing interventions to optimize an individual's ability to give informed consent. Mental and physical health problems need not be resolved before a person can begin a process of medical gender-affirmation, but they should be managed sufficiently such that they do not interfere with treatment.

Did I read that correctly?

A. You indeed read that correctly.

Q. Okay. This is a consensus study report by the National Academies of Sciences, Engineering and Medicine of the United States; is that right?

record. This is Media Unit No. 5. The time is 4:05 Eastern time.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, one of the critiques in your report is that puberty blockers have not been approved by the FDA as a treatment for gender dysphoria; is that right?

A. That is correct. Although it's important to understand why that is a relevant piece of information.

Q. Well, let's go to page 50 of your report.

A. I'm there.

Q. Okay. On the -- there's a number of statements that you bold and italicize, but on the third -- the sentence involving the third bold and italics.

A. Okay.

Q. It's like in the middle of the page. It states: The off-label prescription of this drug is legal but unethical outside the setting of a carefully controlled and supervised clinical trial.

Did I read that correctly?

A. You did.

Q. And why is that?

A. So, again, this relates to the statements that are made that these drugs are known to be safe

in this patient population. And we really don't have the scientific evidence to make that statement. Because it's unknown what the -- some of the effects are known, but many of the effects are unknown, to be able to expose people to this intervention, not only to expose them to that, but to make the statement that it is known to be safe with that absence of evidence, it really finds itself outside of what I'd consider ethical.

Q. Just for clarify, what do you understand "off-label" use to mean?

A. Oh, it's actually very common in the area of pediatrics. It's to prescribe a medication for something that it has not been FDA approved. So it could be for another -- a drug that's approved for one purpose and using it for another purpose. Most often that's how it's used.

Q. Have you personally ever prescribed any drugs on an off-label basis?

A. Very frequently do.

Q. Do you do so even in the absence of randomized clinical control trials?

A. Usually when I prescribe them off-label, there are randomized controlled trials in different populations that I turn to. I look at the relative

risk and -- but I don't make the statement that we know with definity [sic] about the safety of a medication in a way that we don't have that information.

Q. And you said usually. So there are times when you prescribe off-label drugs even in the absence of clinical controlled randomized trials?

MR. KNEPPER: Objection, form.

A. Usually when I'm prescribing it, what we would consider off-label most often, it is for a condition that is not markedly different for the use that it is being given only that it had been approved most often for adults rather than children.

Q. (By Mr. Gonzalez-Pagan) And clinical control trials are actually relatively rare in the pediatric population?

A. No. I would say that -- I mean, that's the standard that's accepted especially for medication use. The reason why they're not done in pediatrics is that usually there's a substantial cost associated with that. People are looking at market share and, you know, how much it's going to cost to be able to study that drug in that patient population. Yet it's already been studied in a randomized control trial in a similar population

without the same caveats that we consider when we look at this question of pubertal blockade.

Q. What is the FDA?

A. The Food and Drug Administration.

Q. Does the FDA regulate prescription drugs?

A. Yes.

Q. What is the FDA's decision with regards to a prescription of off-label use of drugs?

MR. KNEPPER: Objection, form, scope.

A. You know, I don't know that they have a statement that there is an ethical responsibility that all physicians who are prescribing off-label. It also applies both to the prescribing physician and it also applies to the pharmaceutical company that's making the medication.

If it's off-label, they cannot market it to a group of people that it wasn't approved for. Physicians that prescribe off-label medications accept the responsibility, you know, for the risks and benefits. And they're obligated to inform their patients of the evidence that they have, where it comes from, and the basis for recommending that medication.

That's true for all medications, but certainly when you're using it off-label, you know,

it involves consideration of the indication, how applicable the randomized control studies that have been done to approve the drug are applicable to the population that you're going to use it for.

(Whereupon Exhibit 14 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 14. Do you have that in front of you?

A. I do.

Q. This appears to be a notice by the Food and Drug Administration in the Federal Register dated November 18, 1994, pertaining to a citizen petition regarding the Food and Drug Administration's policy on promotion of unapproved uses of approved drugs and devices, request for comments.

A. I see that.

Q. Did I -- did I describe the document correctly?

A. I've not read the entire document. But that section that you read was read correctly.

Q. Okay. Going on to the second page. It's a highlighted portion. I will represent any highlights in the document were done by me. And

there are no other alterations to the document.

The highlighted portion reads: Over a decade ago, the FDA Drug Bulletin informed the medical community that once a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.

The publication further stated unapproved, or more precisely unlabeled uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to the drug therapy that have been extensively reported in medical literature. Valid new uses of drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations.

Did I read that correctly?

A. You did, indeed.

Q. Your report doesn't acknowledge that the long-standing position of the FDA has -- with regards to off-label use of drugs?

MR. KNEPPER: Objection, form.

A. I would say that this paragraph that you

read does not directly apply for the reason for my consideration of this use of GnRH agonist in pubertal adolescence for gender dysphoria is the same. And it's important to note in this paragraph, it says the word "may." It doesn't guarantee that it is. And it reflects the nature of the application that one is providing.

(Whereupon Exhibit 15 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Introducing what has been marked as Exhibit 15. Noted below, the creator of the document is a printout of a web page from the Food and Drug Administration's website. It is titled Understanding and Approved Use of Approved Drugs Off-Label.

Did I read the title of this web page correctly?

A. Yes, you did.

Q. Okay. Moving on to the second page, there's a highlighted portion. I will stipulate for the record that any highlights in this document were inserted by me and that there are no other alterations to the document.

The highlighted portion of the document states: From the FDA perspective, once the

FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient?

Did I read that correctly?

A. You indeed read it correctly.

Q. Before opining as to whether the use of off-label puberty blockers should be considered unethical, did you review the positions of the FDA with regards to off-label use?

A. Again, I'm very, very familiar with that. Maybe perhaps not these specific documents, but I -- this is entirely consistent with my understanding of the off-label use of drugs.

(Whereupon Exhibit 16 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 16. I'll represent this is a guidance for institutional review board for clinical investigators published by the Food and Drug Administration dated January 1998. It is titled Off-Label, an Investigational Use of Marketed Drugs, Biologics and Medical Devices.

Did I represent the document correctly?

A. You correctly read the title of this document.

Q. There is a highlighted portion in the first page of the exhibit. I'll represent that all the highlights were added by me to that exhibit. And there are no other alterations to the document.

The highlighted statement reads: If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well-informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of the marketed product in this manner when the intent is the practice of medicine does not require the submission of an Investigational New Drug Application, Investigational Device Exception or review by an Institutional Review Board.

Did I read that correctly?

A. You read that section correctly.

Q. Do you acknowledge this guidance of the FDA in your report?

A. You mean the statement that I made about the ethics of prescribing the medication and the need does not require that, but it does not mean

that it's not the approach that should be done. So that one -- for example, it's not malpractice and one's not going to lose their license by prescribing a medication off-label in this manner.

However, when we look at the use of this -- the GnRH agonist with a reference that I made to the FDA off-label use involves product use that is not the same as what it is used in the treatment of prepubertal children and the risks require -- and because of the risks of the intervention and the lack of knowledge, it's very different than many of the other times that I myself have used off-labeled use of medications.

So the statement itself is accurate. It is consistent with my understanding of the FDA guidelines for that. And I think my statement in my declaration fully reflects the reason why it is of ethical concern in this case.

(Whereupon Exhibit 17 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 17. Are you familiar with the American Academy of Pediatrics?

A. I was a member of the American Academy of Pediatrics for over 20 years.

Q. This is a policy statement by that organization titled Off-Label Use of Drugs in Children; is that right?

A. That is the title of the statement, yes.

Q. I'll represent that there are highlights within this document. Those highlights have been added by me. And there are no other alterations in the document.

On the abstract in the highlighted portion, it states: However, off-label drug use remains an important public health issue for infants, children and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated or investigational use. Therapeutic decision-making must always rely on best available evidence, the importance of the benefit for the individual patient.

Did I read that correctly?

A. You read it correctly. And I would

comment that the very last sentence is at the heart of my concern about how it's -- GnRH agonists are being used in the setting of gender dysphoria.

Q. So is your critique that the use of GnRH analogues [sic] for the treatment of gender dysphoria is unethical because it's not the best available evidence in your opinion?

A. There are many layers to the question. I would say that many of the people that are prescribing these drugs are not even aware of the emerging evidence that is coming forward about lack of efficacy and the risks of these medications. They're relying on their decision based upon statements made by many of the organizations that you mentioned earlier that -- that are not considering the relative risk-benefit analysis. And so a provider, unless they've had the opportunity like myself and others who have been familiar with the literature, are going to be misled with the assumption that this is the available evidence, supports its use.

Q. Well --

A. Many of the people that are prescribing these medications have not read those papers, not considered those papers, not considered the poor

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, how did you first come to be an expert in transgender litigation?

A. Well, I think it was a recognition of my knowledge of the -- of the subject area and -- that I had in a number of different settings including the grand rounds talks that I said previously and some of the things that I've been discussing for the last -- since almost ten years now.

Q. Do you know what the Alliance Defending Freedom is?

A. Yes.

Q. Have you met with staff from the Alliance Defending Freedom in order to discuss how to serve as an expert in cases involving transgender issues?

A. My involvement was mostly to tap into my knowledge and expertise in this area, to inform that organization of some of the relevant issues. I've never been coached on how to be an expert witness, nor have I necessarily been encouraged in any way. These requests have generally come from the litigating lawyers, how they received my name or to what extent and in what ways they became familiar with my knowledge and expertise in this area is not known to me.

Just like the other groups that I've spoken to, I've been more than willing to be -- to share the knowledge that I've accumulated over this last decade in this area.

Q. Did you attend a meeting at the Alliance Defending Freedom offices in Arizona in 2017?

A. I don't recall the exact date, but I did travel to Arizona to meet with other individuals that also had unique areas of expertise in the area, yes.

Q. Just to clarify, was that one or two meetings?

A. I think I've had two separate meetings. The first was much shorter. And the second one was much more of presentations with actual data.

Q. What was discussed in that first meeting?

A. Again, it was many years ago. But my recollection was just to understand what was going on. It was -- it was the same types of questions about the care that is being proposed and offered. But it was much less defined, I think, at that point in time. It was more of an informal type of meeting.

Q. Who was in attendance at that first meeting?

A. I suspected you were going to ask me. And, you know, honestly I don't remember the exact composition of the people that were there. If you happen to know, I can acknowledge or deny whether they were there or not. But I've met literally hundreds of people over the last ten years in various settings. I do know that at that first meeting, Allan Josephson was there. And I believe that Mark Ramirez was there as well.

Q. Was Jeff Shafer there?

A. Yes. He actually at that time was working for ADF.

Q. Was Gary McCaleb there?

A. Yes. And he was one of the first contacts I had from that group.

Q. When they invited you to this meeting, what was the invitation, what did they tell you it was going to be about?

A. They had desired to convene a group of people that had knowledge in this area and to be able to discuss that, is my recollection at that point in time.

Q. Was Ryan Anderson there?

A. He was at one of the meetings, the two meetings, I'm not sure which -- which one.

Q. About how many people were in that first meeting?

A. Probably about eight to ten if you include Jeff Shafer and Gary McCaleb. You know, no more than a dozen, probably less than that.

Q. And the second meeting, you indicated that it involved some presentations; is that right?

A. That's correct.

Q. Was it also in Arizona?

A. Yes.

Q. Who was present at the second meeting?

A. Similar to the first meeting. And, again, I may get mixed up, the first and second meetings. There were different people that were present. I know that Walt Heyer was at one of the meetings. Oxy Horvath was at one of the meetings as well. You'd have to give me the other names if there was any. I'm drawing a blank. It was a while ago.

Q. Was Mark Regnerus at the second meeting?

THE COURT REPORTER: I'm sorry. What was that name?

A. He was only at --

MR. GONZALEZ-PAGAN: Mark Regnerus, R-E-G-N-E-R-U-S.

A. I believe he was at one of the meetings.

I'm not sure which one.

Q. (By Mr. Gonzalez-Pagan) Was Patrick Lappert at one of these meetings?

A. He would have been likely at the second meeting.

Q. Was Paul McHugh at any of those meetings?

A. No.

Q. Was Michelle Cortella at any of these meetings?

A. I've encountered Michelle at a number of different settings. I'm trying to think back. I honestly -- I just can't remember. She may have been at one of them.

Q. Was Quinton Van Meter at any of these meetings?

A. I have met with him. I'm just trying to think of what the circumstances and when he was there. Again, you know, I've met so many people over many different years in many different venues. It's challenging for me to remember who was in what meeting.

Q. Did the ADF lawyers discuss the need to develop expert witnesses for litigation?

A. Again since it was several years ago, I'm trying to remember the exact content. I think the

main focus was -- was understanding what was going on to be able to understand from multiple different perspectives. One of the most helpful outcomes for myself was the opportunity to talk to the transitioners. These are adults that have had the experience of going through the affirmation approach only to discover eight to ten years after that, that it did not solve their problems.

It was similar to my efforts to connect with parents and -- that were experiencing this with their children as part of my understanding of the unique circumstances facing these individuals. That's what I walked away with more than anything else. Whether there was discussions about, you know, whether there were -- were litigation going on is -- I just don't recall.

Q. Were you aware that the Alliance Defending Freedom is a religious organization?

A. I think that's -- if you travel to their headquarters, that's hard to miss.

Q. Let's go back to your report, Exhibit 1. On the third page, Paragraph 7.

A. We're on my expert report. Okay.

Q. Page 3, Paragraph 7.

A. Thank you. I'm going to go to my clean

copy that I have printed out. Okay.

Q. Okay. It is mentioned that you also spoken with parents of children experiencing gender dysphoria and earlier you mentioned that you had spoken with Eli Coleman; is that right?

A. That is correct.

Q. And Eli Coleman is one the authors of the WPATH standards of the care; is that correct?

A. He's one of the lead authors, correct.

Q. In Paragraph 7 you state that you have met individually and consulted with several pediatric endocrinologists including Dr. Norman Spack, who had developed and led transgender programs in the United States; is that right?

A. That is correct.

Q. Who's Norman Spack?

A. Norman Spack was from Harvard. He was actually probably the first person to introduce the Dutch model of care to the United States. In the latter years of his career, he became a very outspoken advocate for that approach. In fact, Dr. Spack was invited to Washington University very early on when the question was being proposed to start the gender center at Washington University.

Q. And you discussed the treatment of gender

dysphoria and transgender people with Dr. Spack?

A. That's correct.

(Whereupon Exhibit 19 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 19.

A. So this is the declaration for Norm Spack for the Drew Adams case, correct?

Q. That's correct, yes. Have you seen this document before?

A. I've heard of it. I believe I saw that during the -- my involvement in the Adams case.

Q. He mentions that on or about October 19, 2014 -- sorry. On Paragraph 8 of the declaration on Page 2, he mentions that on or about October 9, 2014, he gave a presentation at St. Louis Children's Hospital regarding the foundation of GeMS, the workings of a gender management program at a pediatric hospital, and in medical treatment and care of gender and nonconforming and transgender children and adolescents; is that right?

A. Other than the word "gender" is misspelled, yes.

Q. It goes on to say on Paragraph 9 on the next page that following the presentation, he met

privately with medical staff including endocrinologists at St. Louis Children's Hospital to answer their questions and share his knowledge and experience.

He then goes on to say that he also in that context met privately with you at St. Louis Children's Hospital when you approached him after the presentation.

Do you recall that?

A. I recall the meeting both with the faculty -- I don't specifically remember the private meeting afterwards. I do remember we had kind of a round table. We actually sat around a circle with other colleagues of mine and addressed questions. But I -- it certainly would be in agreement with where I was at that point in time in an understanding for the proposal for care involving affirmation.

Q. He goes on say that during his meeting with you, you directly expressed that you had, quote, a significant problem with the entire issue, closed quote, and, quote, whole idea of transgender, closed quote. He then states that you followed up these comments by stating, quote, for me it is a matter of my faith, closed quote.

Do you recall making these statements to Dr. Spack?

A. I do not.

Q. Do you deny making these statements to Dr. Spack?

A. I do not recall making those statements. And it really seems to be -- I'm not sure of the context of the conversation, where that came from. This was a time shortly after our institution was considering the adoption of the affirmative care model for starting their gender center. And very clearly at that point in time, I was very early in investigating the literature and I remember talking with my colleagues at that very same time about the questions that I had about the science, about some of the statements that were being made.

One of the questions that came up related to some of the assertions about more in the area of anthropology as far as a human being and whether it was possible for one to change one's sex. I recall that at that point in time, you know, the people were just starting to make the comments like in one of the other cases where Dr. Atkins would make the statements gender is sex. And I certainly challenged those assertions at that time.

So this is a period of discovery for me. And for me to make a definitive statement like that is not really even logical from where I was at that point in time.

Q. Are you familiar with the St. John Paul, II, Bioethics Center?

A. Yes.

Q. Is St. John Paul, II, Bioethics Center a religiously affiliated institution?

A. I believe it is, yes.

Q. Did you speak at the St. John Paul, II, Bioethics Center in November of 2017?

A. I'm not sure of the exact date. But I did deliver a talk to that group.

Q. During that talk, did you not state about being transgender that, quote, in fact, probably goes back to some of the early heresies in the church, closed quote?

MR. KNEPPER: Objection, form, scope.

A. You know, I'd have to see the context of when that statement was made and how it was being portrayed to that audience, whether it was in response to a question with context that is not included in your question.

Again, as you mentioned, this was a

EXHIBIT B

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

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

Exhibit
0001
9/29/2021
Hruz

EXPERT WITNESS DECLARATION of

PAUL W. HRUZ, M.D., Ph.D.

1. RETAINED AS EXPERT WITNESS - VITAE: I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this declaration. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this declaration.

2. EDUCATION - ACADEMIC APPOINTMENTS: I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in

the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016.

3. HISTORY OF BOARD CERTIFICATIONS: I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

4. SCIENTIFIC PUBLICATIONS IN PEER REVIEWED JOURNALS: I have published 60 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See, my current Curriculum Vitae attached as Exhibit A.

5. EDITORIAL DUTIES - RESEARCH GRANTS: I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne. I have received over 4.6 million dollars in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J Quick Award for Excellence in Biochemistry, the Eli Lilly Award

for Outstanding Contribution to Drug Discovery, and the Julio V Santiago Distinguished Scholar in Pediatrics Award.

6. CLINICAL EXPERIENCE: During the more than 20 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.

7. CONSULTS-DISCUSSIONS REGARDING THE RELEVANT SCIENCE and CLINICAL ISSUES: In my role as a scientist and as the director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local and national meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental

investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

8. IN MY OPINION, A LACK OF SCIENTIFIC SUPPORT and THE ETHICAL PRINCIPLE OF INFORMED CONSENT CURRENTLY PROHIBIT MY PARTICIPATION IN HORMONAL "AFFIRMATION-TRANSITION" TREATMENTS FOR GENDER DYSPHORIA IN CHILDREN: Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest and professional knowledge and training in this rare patient population. Due to the documented, important, ethical concerns regarding the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than Gender Discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer

reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children prior to the widespread adoption of the "gender affirmation only" approach. Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions. See, J. Cantor, Ph.D. summary of multiple research studies at http://www.sexologytoday.org/2016/01/do-trans-kids-stay-trans-when-they-grow_99.html, and other publications reviewed in detail below).

9. PEER-REVIEWED, PUBLISHED RESEARCH IN CREDIBLE SCIENCE-MEDICAL JOURNALS: My opinions as detailed in this declaration are based upon my knowledge and direct professional experience in the subject matters discussed. The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject including hundreds of published, peer reviewed scientific research (and clinical) articles. A list of the most relevant articles is attached as Exhibit B to this declaration and many are cited and discussed in this report.

10. PREVIOUS LEGAL CASES AS AN EXPERT WITNESS: Over my career, I have provided expert medical record review and testified at deposition in less than a dozen cases. Related to the litigation of issues of sex and gender, I have been designated as an expert witness

in Joaquín Carcaño et al v. Patrick McCrory, Jane Doe v. Board of Education of the Highland School District, Ashton Whitaker v. Kenosha Unified School District, Terri Bruce v. State of South Dakota, and Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children. Only in the last case did I testify at trial. I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v Tavistock).

11. COMPENSATION: I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide. I am paid in advance for all written opinions or testimony to avoid potential conflicts of interest.

12. BASES FOR OPINIONS - My opinions documented in this report are based on my 1) knowledge, training, and clinical experience in caring for thousands of patients over many years; (2) detailed methodological reviews of hundreds of relevant peer-reviewed science publications; (3) consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences, and 4) analysis of evidence in this case including medical records, Plaintiffs' expert reports, the NC State Health Plan, legal documents (i.e. complaint, response, etc.). My investigation in this case is ongoing and I will supplement, amend or update this report as additional information becomes available for review including discovery, experts, and observations of witnesses. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.

Evidence Reviewed: My investigation is continuing and additional evidence will be reviewed as it becomes available.

12A. Peer Reviewed Published Research Articles and related materials, etc. (See citations below and also attached Exhibit B).

12B. Relevant case documents — legal complaint, response, disclosures, North Carolina Health Plan, Plaintiffs' medical records, all expert witness declarations, and other evidence as it becomes available.

13. OPINIONS regarding Plaintiffs' Expert Witness Disclosures:

A. The Plaintiffs' Expert Disclosures Failed to Accurately Report, Review, or Properly Disclose to the Court the Dangerous Methodological Limitations, Flaws, Errors, and Defects in the Gender Transition Industry's Research Base including the Well-Known, Well-Documented *International Controversies* regarding the Relevant Science and Interventions (sometimes mis-labeled as "treatments"). I have reviewed the expert declarations in this case from Plaintiffs' experts Drs Brown, Green, and Schechter. In my opinion, these appear to be political-ideological-advocate-activist opinions in support of the Gender Affirmation Medical Enterprise's ("transgender") movement and not competent, appropriate, scientific, methodological opinions. All three of Plaintiffs' experts improperly support the use of experimental, highly intrusive, and potentially harmful medical procedures despite the lack of credible, reliable, and valid scientific support for such treatments. In my opinion, their reports all failed to include a cogent, detailed, methodological discussion of *the serious, ongoing, scientific, medical, and societal controversies* regarding the etiology, treatment, and long-term outcomes of "gender affirmation" (sometimes mis-labeled as "transitioning") theories, methods, practices, procedures, and treatments. This omission in all three reports is quite remarkable as the scientific errors, omissions, failures, and

defective methodologies of the field of transgender medicine have produced heated controversy and garnered worldwide attention in 2020 and 2021. In the analysis that follows, I cite published analyses of Gender Transition Industry research noting significant and internationally recognized errors and defects such as low quality study designs, selective "cherry-picking" of data, and the improper misreporting of key study findings.

B. Specifically, the Plaintiffs' Expert Disclosures Failed to Accurately Report the Serious Methodological Limitations, Flaws, and Defects in the Gender Transition Industry's Methods for the Diagnostic-Labelling of "Gender Dysphoria": The Plaintiffs' expert disclosures offer misleading opinions about diagnostic systems. For example, the DSM (Diagnostic and Statistical Manual of the American Psychiatric Association) involves an often controversial consensus seeking, (not scientific evidence seeking), political-voting process that began historically as an attempt to construct a reliable dictionary for psychiatry. The DSM has historically included unreliable, since debunked, diagnoses such as "multiple personality disorder" that fueled a harmful "craze" damaging vulnerable patients until scientists, legal professionals, juries, and licensing boards put a stop to it. (See the detailed discussion below). It is important for legal professionals to understand that the DSM was created using a consensual, political process of committees and voting and does not depend upon an evidence-based, uniformly valid and reliable scientific process. Small groups of professionals, often with ideological agendas, can form committees and create "diagnoses" to be voted into the DSM. Much of DSM content is decided by the "voting" of small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with the plaintiffs' experts in this case.

C. The Plaintiffs' Expert Disclosures Failed to Accurately Disclose and Discuss the Well-Documented Methodological Limitations, Flaws, and Defects in Gender Identity ("transgender") Subjective Clinical Assessments: The clinical assessment methodology in Sex Discordant Gender medicine is currently limited to self-report information from patients without objective scientific markers, medical tests, or scientific assessment tools. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes. A few hours of conversation with often poorly trained social workers often provides the only gatekeeping process to severe and irreversible iatrogenic surgical and hormonal injuries. Most importantly, *the long-term effects of "transitioning" have never been scientifically validated*. No valid-reliable methodology for such assessments has been accepted by the relevant scientific community and it appears that no known error rates for such assessments have ever been published. A more detailed discussion of the foundational science documenting the limitations and methodological defects in this field is offered below.

D. The Plaintiffs' Expert Disclosures Fail to Accurately Report Essential Methodological Problems in the Gender Transition Industry. Foundational Research including Sampling Errors, the Misreporting of Findings, the Misreporting of Relevant History, misquoting of research studies, "low quality" research designs, failures to complete randomized clinical trials, and widespread Confirmation Bias including the failure to properly explore Alternative Hypotheses (e.g., Social Contagion, Mental Illness, Complex Developmental Processes, Family Dynamics, etc.), and Other Failures of Basic Scientific Methodology: The plaintiffs' expert disclosures failed to properly discuss and disclose alternative theories/hypotheses for the rapid and nearly exponential increase of transgender cases — such as social contagion, mental illness, and/or complex developmental processes—especially as reportedly driven by news media, social media

"YouTube "influencers" (who reportedly sell "transitioning" to vulnerable youth on social media), educational systems (that reportedly pressure 1st graders to "identify as non-binary"), as well as political-activist "pro-transition" health care workers (too few of whom seem to have carefully reviewed and understood the relevant scientific history and ongoing controversies in this field).

E. The Plaintiffs 'Expert Disclosures Failed to Accurately Report Methodological and Other Problems in the Plaintiffs' Medical Records: I have also reviewed the Plaintiffs' medical records in this case. These records demonstrate many of the scientific errors, limitations, methodological errors, and informed consent errors discussed in detail below. "This includes confirmation bias, reliance on unverified patient reports, failure to consider alternative hypotheses, and failure to provide patients with the information necessary for truly informed consent."

14. TERMINOLOGY - BIOLOGICAL SEX: Biological sex is a term that specifically refers to a member of a species in relation to the member's capacity to either donate (male) or receive (female) genetic material for the purpose of reproduction. Sex thus cannot be "assigned at birth" because it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized.

The measurement and assessment of biological sex has been documented by valid-reliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex is very low, below 1%.

15. TERMINOLOGY - GENDER: Gender, a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, but not biology. The term "gender" is currently used in a variety of ways and has thus become a controversial and unreliable term that means different things to different observers often varying according to political and ideological positions. The only definition of gender accepted by the worldwide, relevant *scientific* (biology, genetics, neonatology, zoology, medicine, etc.) community retains the historic biological connection to reproductive purpose with other definitions mired in controversy. The reliability and validity of various usages of the term "gender" is currently quite controversial and the relevant scientific community has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The serious dangers of incorrectly using the term "gender" is acknowledged by the Endocrine Society (Bhargava, A., Arnold, A. P., Bangasser, D. A., Denton, K. M., Gupta, A., Hilliard Krause, L. M., Mayer, E. A., McCarthy, M., Miller, W. L., Raznahan, A., & Verma, R. (2021). Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. *Endocrine reviews*, bnaa034. Advance online publication. https://doi.org/10.1210/endrev/bnaa034) In addition, the error rate for multiple uses of the term "gender" outside of the accepted biologically related use is unknown, untested, and unpublished. The measurement and assessment of biological sex and gender has been documented by valid-

reliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex and gender is very low, below 1%.

16. TERMINOLOGY - GENDER IDENTITY: Gender identity refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is currently controversial. It is a term that means very different things to different observers often varying according to political, ideological, religious, and other factors. There is no current worldwide definition of "gender identity" accepted by the relevant scientific (cf. clinical) community. The reliability and validity of the term "gender identity" is controversial and not accepted by the relevant scientific community. The measurement error rate for non-biological "gender identity" is unknown, untested, and unpublished and could be very high.

17. TERMINOLOGY - SEXUAL ORIENTATION: Sexual orientation refers to a person's enduring pattern of arousal and desire for intimacy with males, females, or both.

18. TERMINOLOGY - DNA and CHROMOSOMES: Sex is genetically encoded at the moment of conception due to the presence of specific DNA sequences (i.e. genes) that direct the production of signals that influence the formation of the bipotential gonad to develop into either a testis or ovary. This genetic information is normally present on X and Y chromosomes. Chromosomal sex refers to the normal complement of X and Y chromosomes (i.e. normal human males have one X and one Y chromosome whereas normal human females have two X chromosomes). Genetic signals are mediated through the activation or deactivation of other genes and through programmed signaling of hormones and cellular transcription factors. The default

pattern of development in the absence of external signaling is female. The development of the male appearance (phenotype) depends upon active signaling processes.

19. BIOLOGICAL SEX IS BINARY — NOT A CONTINUUM — FOR 99%+ of MAMMALS INCLUDING HUMANS: For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females). The recognition of an individual as male or female made at birth according to biological features has been documented by valid-reliable research published in credible journals, and is generally accepted by the relevant scientific community. The error rate for the measurement and assessment of an individual as male or female made at birth according to biological features is very low indeed, certainly below 1%.

20. THE GENITAL-BIOLOGICAL FUNCTION OF REPRODUCTION: Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e. reproduction). Internal structures (e.g. gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, developmental biology, genetics, and other relevant fields. In my opinion, all relevant sciences agree that the development of genital structures is intrinsically oriented to biological reproduction.

21. BIOLOGICAL ASSESSMENT OF SEX: Reliance upon external phenotypic expression of primary sexual traits is a highly accurate, reliable and valid means to assign biologic sex. In over 99.9% of cases, this designation will correlate with internal sexual traits and capacity for normal biologic sexual function. Sex is therefore not "assigned at birth" but is rather recognized at birth. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, psychiatry, neonatology, biology, genetics, gynecology, and other fields.

22. DISORDERS OF SEXUAL DEVELOPMENT ARE VERY RARE: Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births). Defects can occur through either inherited or de *novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, gynecology, psychiatry, biology, genetics, and other fields. **See,** Leonard Sax (2002) How common is lntersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139

23. DISORDERS OF SEXUAL DEVELOPMENT ARE NOT A THIRD SEX: Normal variation in external genital appearance (e.g. phallic size) does not alter the basic biologic nature of sex as a binary trait. "Intersex" conditions represent disorders of normal development, not a third sex. In my opinion, this view is generally accepted by the relevant scientific communities in

endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

24. DISORDERS OF SEXUAL DEVELOPMENT REQUIRE ASSESSMENTS OF OBJECTIVE EVIDENCE: The medical care of persons with disorders of sexual development (DSDs) is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g. assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict chromosomal sex nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert medical providers. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

25. INTERSEX CONDITIONS REQUIRE PROPER CONSIDERATION OF ALTERNATIVE HYPOTHESES AND TREATMENT PLANS: Standard medical practice in the treatment of persons with DSDs has evolved with growing understanding of the physical, psychological, and psychiatric needs and outcomes for affected individuals. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with

confidence, a presumptive sex assignment is made. Factors used in making such decisions include chromosomal sex, phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to sex reassignment. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent. See, Lee, P. A. et al. Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care. Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016)). In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

26. METHODOLOGICAL DEFECTS of the GENDER TRANSTION INDUSTRY - WHY IS THE TRANSGENDER MEDICINE FIELD STILL SO CONTROVERSIAL AFTER DECADES OF RESEARCH? :

A. The field of transgender medicine has long ignored basic, substantive, foundational science methodologies and ethics requirements (e.g. unverified patient reports are not a reliable basis for sterilizing vulnerable patients, unverified human memory reports are subject to contamination and misreporting, poorly designed-misreported treatment studies that show more damage than benefits are not a suitable basis for sterilizing vulnerable patients, etc.

B. Despite several highly defective research efforts, the Gender Transition Industry has failed to prove long term benefits that outweigh the reported harms, dangers, and serious injuries of “gender affirmation” interventions -- including inability to reach orgasm, vaginal atrophy, compromised cognitive function, lifelong reliance on medication and repeated surgical intervention to deal with the cumulative effects of these iatrogenic

harms, stunted growth, damage to social support systems, increased risk of serious suicide attempts, etc. In my opinion, the relevant scientific community agrees that Transgender Transition treatments are controversial, unproven, untested, and experimental – and thus not medically necessary – given the current state of scientific knowledge that exists.

C. The Gender Transition Industry has repeatedly presented false, deceptive, and misleading information to the public and to patients regarding the known risks, dangers, injuries and benefits of "affirmation treatments". (E.g. the Branstrom, Turban, and related research errors of omission and misreporting.)

D. Without competent, valid, peer reviewed published research support; the Gender Transition Industry relies upon support from "professional associations". Yet such associations are engaged in consensus-seeking-political voting methodologies and not evidence-based, peer reviewed science. Such political-professional associations have made similar, disastrous mistakes in the past. For example, the American Medical Association supported racist, "junk" science eugenics "treatments" in the 1930s and the American Psychiatric Association did not act to prevent or halt the harms of the repressed-memory/multiple personality industry of the 1990s.

E. As a result of these many defects of methodology and ethics, the Gender Transition Industry and its "treatments" are not generally accepted by the relevant scientific community.

F. As a result of these many defects of methodology and ethics, the Gender Transition Industry's assessments and "treatments" have no known nor published error rate.

G. A key investigative hypothesis is whether the Gender Transition Industry is simply the latest harmful "junk science" fad and consumer fraud in the medical-psychiatric industry following the misadventures of lobotomies, recovered memory therapy, multiple personality disorder, rebirthing therapy, and others.

H. National science reviews in England, Sweden, Finland and by the Cochrane Review have all uncovered serious methodological and ethical failures in the Gender Transition Industry – thus supporting the alternative investigative hypothesis that the Gender Transition Industry is engaged in a form of hazardous consumer fraud resulting in harm to many vulnerable patients. **(E.g., In Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094, the authors claim to have identified *60,000 case reports* of detransitioners world-wide on the Internet.)**

27. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY--LIMITATIONS and HAZARDS OF RELYING ON UNVERIFIED PATIENT SELF-REPORT DATA WITH NO OBJECTIVE EVIDENCE: IN CONTRAST TO DISORDERS OF SEXUAL DEVELOPMENT, GENDER DYSPHORIA CANNOT BE RELIABLY, OBJECTIVELY ASSESSED AS IT IS BASED ON PATIENT SELF-REPORTS (no blood tests, no x-rays, no lab results, no objective data) : Individuals who verbally report experiencing significant distress due to perceived discordance between gender identity and sex cannot currently be reliably, validly, and objectively assessed as experiencing "gender dysphoria". (See, American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed, (2013). Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals

report experiencing discordance in these distinct traits. Specifically, for example, biologic females may report experiencing that they identify as males and biologic males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity". There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments that might result in lasting, irreversible damages to normal, healthy organs and the destruction of normal biological functions (e.g. sterility) as the current research documents. In my opinion, my view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

28. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS -- THE RELEVANT SCIENCE DOCUMENTS THAT MENTAL HEALTH CARE PROFESSIONALS ARE UNRELIABLE HUMAN "LIE DETECTORS" ("often no better than flipping a coin"): Currently, there is no known methodology for reliably discerning true from false patient reports without corroborating evidence such as radiology, lab tests, or other objective evidence. The Gender Transition Industry's sole reliance upon patient self-report data carries unknown risks of errors, misinformation, deception and lasting harm to patients from treatments that deliberately damage healthy organs and destroy essential normal bodily processes thus often producing sterility. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-

reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors" — often no more reliable in discerning false reports than flipping a coin — and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors" many poorly trained physicians and mental health professionals personally – and falsely -- believe they are "experts" at this complex and difficult task. See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861. " The final error that I will highlight is that professional lie catchers tend to overestimate their ability to detect deceit. Research has consistently shown that when professional lie catchers and laypersons are compared, "*professionals are more confident in their veracity judgments but are NO more accurate*". Emphasis added. See also, Rosen, G. M. and Phillips, W.R., A Cautionary Lesson from Simulated Patients, *Journal of the American Academy of Psychiatry and Law*, 32, 132-133, (2004).

29. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS -- SOCIAL MEDIA "INFLUENCERS" ARE REPORTEDLY TRAINING PATIENTS TO FABRICATE SYMPTOMS TO GAIN RAPID ACCESS TO "TRANSITION" INTERVENTIONS. Because Mental Health Professionals and Physicians are not capable of reliably discerning true from false patient reports, nobody knows how many Gender Dysphoria

patients have been coached-trained to deceive providers to gain easier and more rapid access to hormones/surgery: An important methodological error of the gender transition industry is the reliance on patient self-reports alone — and the lack of objective corroborative evidence (no x-rays, no blood tests, no genetic tests, no MRI's, etc) — to engage in experimental "treatments" causing sterility and other long-term harms. One potential hazard of this limited, unreliable self-report methodology can be seen in the recently reported increase of "rapid onset gender dysphoria" ROGD in adolescent females. For decades, the large majority of GD patients were early onset males. In contrast, in just the past 5 years, the majority of new GD patients are female patients with no long-term GD history. Many of the "rapid onset" adolescent patients' parents have reported a very rapid onset of GD symptoms linked to peer or school pressures or YouTube "training" —thus coming out as "trans" in groups of friends or following school "gender training" programs. At the same time, there have been reports of YouTube "Trans Influencers" whose "video blogs" are watched by millions as they provide detailed coaching to their adolescent girl followers on how to "lie to medical providers to obtain easier access to TG hormone and surgical treatments rapidly". The reliance upon unverified self-report data –an unreliable diagnostic methodology -- may well be one source of the ongoing and internationally reported failure of research on Gender Transition Industry interventions (sometimes mislabeled as "treatments) to provide consistent, reliable and valid evidence of long term benefits that would offset the well-documented long-term harms, injuries, and damages (e.g. sterility, stunted growth, bone loss, etc) produced by this burgeoning medical industry.

30. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY MENTAL HEALTH PROFESSIONALS --

THE SCIENCE OF MEMORY SHOWS THAT UNVERIFIED PATIENT "MEMORY" REPORTS COULD BE QUITE INACCURATE THUS PRODUCING ADDITIONAL RISKS OF UNRELIABLE DIAGNOSIS AND HARMFUL INTERVENTIONS: Decades of scientific research studies have shown that human memory reports — often the sole source of evidence for providers to engage a Gender Dysphoria patient in hazardous, experimental "gender transition" treatments — are subject to manipulation, implantation, contamination by post-event sources, source amnesia, and other errors. As world memory expert Prof. Elizabeth Loftus has noted, "False memories, once created — either through misinformation or though suggestive processes — can be experienced with a great deal of emotion, a great deal of confidence and a lot of detail, even though they're false." See Loftus, E. F. (2002) Memory Faults and Fixes. Issues in Science & Technology, National Academies of Science, 18, # 4, pp 41-50 See, also, e.g., Loftus, E. F. (2005) Planting misinformation in the human mind: A 30-year investigation of the malleability of memory. Learning and Memory, 12, 361-366.

31. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the reliance upon often science-illiterate mental health professionals to assess unverified patient reports -- ALTHOUGH MUCH OF MEDICINE BECAME SCIENCE-BASED IN THE 20th CENTURY — THE MENTAL HEALTH FIELDS REPORTEDLY CONTINUES TO LAG BEHIND:

The Gender Transition Industry often involves social workers or other mental health professionals "assessing" patients reporting Gender Dysphoria to determine if they will benefit from "affirmation" medical interventions. Given the extraordinary lack of competent, methodologically sound research (See, reviews by England, Sweden, Finland, the Cochrane review and others below) justifying the use of gender affirmation "treatments" there is no method for

mental health professionals to reliably determine who might benefit from experimental interventions. Such unreliable assessment protocols risk harm to patients as they depend upon the widespread unreliable method of having psychotherapists depend upon "clinical judgment" methodologies to make life-changing decisions and offer "professional" opinions with little or no scientific validity. See, e.g., Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, November 2008, vol 9, no 2 i-ii. The past President of the Association for Psychological Science, Prof. Walter Mischel, stated "*the current disconnect between psychological science and clinical practice is an unconscionable embarrassment".* See, Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, Vol 9, No 2, 2009.

Over the past century many components of the health care system — surgery, radiology, laboratory testing, internal medicine, pharmacological systems, etc. — became science-driven and far more effective and reliable. Courts are often unaware that this transformation — moving from widespread use of unreliable methodologies ("junk science") to the widespread use of reliable science-based methodologies — has, in many ways, not yet occurred in the mental health system. See, e.g., West, Catherine, 'An Unconscionable Embarrassment', Association for Psychological Science, Observer, October 2009, See, http://www.psychologicalscience.org/index.php/publications/observer/2009/october-09/an-unconscionable-embarrassment.html ; See, also Baker, T., McFall, R. & Shoham, V., Current Status and Future Prospects of Clinical Psychology: Toward a Scientifically Principled Approach to Mental and Behavioral Health Care, Psychological Science in the Public Interest, Vol. 9, No. 2 (2009); see also, Harrington, A., Mind Fixers: Psychiatry's Troubled Search for the Biology of Mental Illness, W. W. Norton & Company; 1st edition, April 16, 2019 ; See also, Dawes, R.M.,

House of cards: Psychology and psychotherapy built on myth, New York: Free Press (1997); See also, Garb, H. N., & Boyle, P. A (2003). Understanding why some (mental health) clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudo-science in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.

32. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESSED BY MENTAL HEALTH PROFESSIONALS: DYSPHORIC REPORTS ARE COMMON FROM CHILDREN WITH A RANGE OF ILLNESSES: Reports of feelings of anxiety, depression, isolation, frustration, and embarrassment are not unique to children with gender dysphoria, but rather are common to children who differ physically or psychologically from their peers. Difficulties are accentuated as children progress through the normal stages of neuro-cognitive and social development. In my clinical practice of pediatric endocrinology, this is most commonly seen in children with diabetes. Attempts to deny or conceal the presence of disease rather than openly acknowledge and address specific needs can have devastating consequences including death. With proper acknowledgment of the similarity and differences between children with gender dysphoria and other developmental challenges, prior medical experience in treating a range of reported troubles can guide the development of effective approaches to both alleviate suffering and minimize harm to school aged and adolescent children experiencing gender dysphoria.

33. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESED BY MENTAL HEALTH PROFESSIONALS -- COURTS SHOULD

BE AWARE THAT CLINICAL EXPERIENCE IN THE MENTAL HEALTH FIELDS - WHERE CLINICIANS OFTEN LACK ACCURATE FEEDBACK — IS OFTEN OF LIMITED VALUE :

As the Gender Transition Industry routinely permits poorly qualified social workers or other mental health professionals to subjectively make life changing decisions in Gender Dysphoria cases — such mental health professionals often unreliably overestimate their ability to offer such "crystal ball" assessments and predictions. Few of these professionals seem aware of the research showing the grave limitations on the experience, judgment, and methodologies of mental health professionals. See, e.g., Tracey, T.J., Wampold, B.E., Lichtenberg, J.W., Goodyear, R. K., (2014) Expertise in Psychotherapy: An Elusive Goal, American Psychologist, Vol. 69, No. 3, 218-229. "In a review of expertise across professions, Shanteau (1992) identified several professions in which practitioners develop expertise, which he defined as increased quality of performance that is gained with additional experience. These professions, which demonstrate there can be a relation between experience and skill, include astronomers, test pilots, chess masters, mathematicians, accountants, and insurance analysts. Shanteau also identified several professions for which experiential expertise was not demonstrated, including [mental health professionals]. He attributed the differences between the two types of professions to the *predictability of their outcomes and the unavailability of quality feedback.*" For example, airline pilots, or even more clearly Navy fighter pilots who land on aircraft carriers practice their professions in full view of hundreds of people. If they err, people die. If they are, off course, unstable, or inaccurate in their performance, immediate consequences, retraining or loss of profession is the immediate outcome. In contrast, a social worker, psychologist, or psychiatrist, sitting alone in a room with a troubled patient can make erroneous statements, use unreliable methodologies (e.g., naively believing whatever

patients tell them or believing that they are "professional human lie detectors"), believe false and misleading notions about human memory, demonstrate ignorance of the serious defects in transgender treatment research, and fail to properly inform patients of the risks and benefits of treatments, etc. Mental health professionals can make such egregious errors for decades without receiving timely, accurate feedback. Without accurate feedback there is a failure of the learning process and improvements are difficult or not possible. Such limiting processes can continue for many years of practice. This is why mental health professions have been listed as doing the type of work that often does not lead to improvements in "clinical experience"— even over many years of practice. Gender discordant ("transgender") patients are rarely, if ever, informed of these limitations on mental health professionals' knowledge, training, or experience nor the limitations of mental health "assessments" based on unverified self-reported "memory" data.

34. HISTORICALLY, THE MEDICAL and SOCIAL SCIENCES HAVE AT TIMES BEEN IMPROPERLY TAINTED BY POLITICAL IDEOLOGIES. IT IS IMPORTANT FOR LEGAL PROFESSIONALS — ESPECIALLY JUDGES —TO UNDERSTAND THE ESSENTIAL DIFFERENCES BETWEEN METHODOLOGICALLY COMPETENT, TESTABLE-TESTED-RELIABLE-VALID PEER REVIEWED SCIENCE v. the CONSENSUS-SEEKING, VOTING PROCESSES OF POLITICAL-PROFESSIONAL ASSOCIATIONS and RELATED ORGANIZATIONS:

Professional Association voting processes are not a reliable nor valid scientific methodology. Professional, political, or other association consensus-seeking voting processes and procedures are neither reliable nor valid, nor tested and proven scientific methodologies. They are votes taken by committees - too often small committees of activists and ideologues with inadequate methodological training. Such non-scientific voting processes and procedures have never been

accepted as reliable and valid scientific methods by the relevant scientific community. Such voting processes and procedures have no known error rate. Historically, it should be noted that "professional associations" have a tainted history of supporting unproven, controversial notions that were later proven to be improper, unreliable, and/or unethical.

A. The American Medical Association (AMA): As an example of professional association support of controversial ideologies, AMA supported eugenic proposals to "improve the quality of the human stock" by coercive *sterilization* of "defective and undesirable Americans" and selective breeding. During the 1890's the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meetings of the American Medical Association. Dr. Ochsner recommended surgical vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868).

The controversial support of the AMA for such racist, eugenics ideologically-tainted pseudoscientific notion was a political and not a scientific process. Similarly, the American Breeders Association founded an Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and Alexis Carrel of the Rockefeller Institute for Medical Research, a recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

With the support of professional associations like the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of the "socially inadequate", that is, those supported in institutions or maintained at public expense. The model law encompassed the "feebleminded,

insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent" — including "orphans, ne'er-do-wells, tramps, the homeless and paupers". Eighteen states passed laws based on the 1922 model legislation and sixty-four thousand people were forcibly sterilized. Supporters included Margaret Sanger who in her 1932 essay "My Way to Peace" proposed that "the whole dysgenic population would have its choice of segregation or *sterilization*" (Sanger, M., My Way To Peace, Birth Control Review, Jan 17, 1932; Singleton, M.M. The 'Science 'of Eugenics: America's Moral Detour, Journal of American Physicians and Surgeons, Vol 19, No 4, Winter 2014.)

A key lesson from this tragic era is that the non-scientific, consensus-seeking voting processes of "associations" can produce danger to the public and patients. Although directed by persons who know or should know how to conduct proper scientific methods, association voting methods are politically-ideologically tainted processes — and not based upon valid-reliable, methodologically-competent science. Again, such professional "associations" operate via consensus-seeking and ideology and not evidence-seeking scientific methodologies. Such professional organizations make decisions by voting and not by conducting ethical, scientifically valid, methodologically reliable, peer reviewed and published science with known error rates.

B. The World Professional Association for Transgender Health (WPATH), The Amercican Academy of Pediatrics (AAP), and the Endocrine Society: This methodological critique and history of association **errors and misadventures** is quite informative when assessing the "professional association" consensus seeking methodologies including voting and political activities such as those of WPATH, the AAP, the American Endocrine Society and similar groups as they adopt support for the "politically correct" but scientifically defective, ideologically driven Gender Transition Industry. Consensus seeking (voting) methods are not scientific evidence-based

methodologies. Courts should take case not to be deceived by the "positions" of Associations – no matter how large or vocal. The net effect of many the Gender Transition Industry's methods and procedures is the sterilization of tens of thousands of children, adolescents, and adults. This is a sobering reminder of previous, now infamous, medical misadventures. (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320 ;

C. The Diagnostic and Statistical Manual of the American Psychiatric Association (DSM): A final example of the methodological limitations of relying upon "association voting" methods is the Diagnostic and Statistical Manual of the American Psychiatric Association. The DSM (and also the International Classification of Diseases- ICD) system(s) have confused some courts in the past. Simply put, reliability data, validity methodological analyses, and error rates are not supplied nor supported by the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM).

Today's American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (Version 5) employs the term "Gender Dysphoria" and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to reiterate that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry. The process by which DSM classifications are created involves voting by committee — this is not a reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant

financial conflicts of interest — as appears to be the case with all three of the Plaintiffs' experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. In my opinion, these views are generally accepted by the relevant scientific community.

The DSM has become increasingly controversial in recent years – including being "dumped" by the National Institute of Mental Health as a key basis for research funding. See, Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is *withdrawing support for the APA's manual*. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency … would be "re-orienting its research away from DSM categories."] See also, https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment. Patients with mental disorders deserve better. NIMH has launched the Research Domain Criteria (RDoC) project to transform diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system."]

In sum, professional association "positions" are not based upon competent, credible, reliable and valid scientific methodologies. Professional association "positions" on gender affirmation assessments and treatments remain very socially, medically, and scientifically controversial – and increasingly so. The association "positions"—since they are produced by voting and not methodologically reliable-valid evidence -- have not been generally accepted by the relevant scientific community and they have no known, nor published, error rates.

35. MEDICINE and SOCIAL SCIENCE HAVE AT TIMES BEEN TRAGICALLY TAINTED AND THOUSANDS OF PATIENTS DAMAGED BY RELIANCE ON METHODOLOGICALLY DEFECTIVE PATIENT SELF-REPORTS and ANECDOTAL EVIDENCE:

Case histories, case reports, and verbal patient reports-statements and medical records of individual patients are all helpful sources of information and at times essential to the proper treatment of individual patients. Such information has often proven helpful in generating testable hypotheses for scientific research. Such self-report and anecdotal information, however, can contain errors, distorted memories, misinterpretations, delusions, confusions, manipulations, and other kinds of errors. In sum, case histories, case reports, and the statements and medical records of individual patients are anecdotal case histories or patient reports (stories of often unknown reliability). Such evidence is not sufficient for reliable, valid, tested, proven, peer reviewed scientific methodologies. Case histories, case reports, and the statements and medical records of individual patients have never been accepted by the relevant scientific community as reliable, valid, peer-reviewed published scientific research. Such case histories, case reports, and the statements and medical records of individual patients have no known error rates with some care

reports being highly accurate documentation of objective evidence and others being filled with highly subjective, uncorroborated, unverified verbal reports of patient emotional states.

An example of disastrous medical misdirection from anecdotal patient reports is the Repressed Memory Therapy (RMT) movement of the late 1980s and 1990s. This explosive epidemic of "recovered memories" and "multiple personality disorder" (MPD) patients led to the rapid creation of "specialty clinics" and hospital units throughout the nation as tens of thousands of new RMT and MPD patients accused parents of horrific crimes.

The intense furor resulted in the FBI investigating hundreds of anecdotal crime reports from psychotherapy patients. After years of investigations, Kenneth Lanning, the Director of the FBI Behavioral Unit, reported the lack of corroborative evidence for the patient allegations following "recovered memory therapy". He suggested that "therapists needed to explain" why so many therapy patients came to adopt, fervently believe in, and report radically transformed, terrifying alterations to their own biographies including "new memories" of torture at the hands of "satanic international cults" engaged in the rape, murder, and cannibalism of children. Social psychologist Richard Ofshe called the belief in satanic ritual abuse the "Achilles' heel" of the recovered memory movement, since the newly "remembered" reports of murder, cannibalism, and fetuses aborted in "rituals" not only sounded extreme and incredible but were not linked to corroborating evidence (e.g. many patients claiming "memories" of being ritually cut open for "sacrificial birth" had zero scars and upon OB-GYN exam had never given birth). Despite the lack of validating evidence as documented by the FBI's intensive, nation-wide investigation, in a national survey published in 1994, conducted by Gail Goodman and her colleagues, 13 percent of 7,000 therapists surveyed reported that they had "elicited recovered memories of ritual abuse", and these respondents "overwhelmingly believed" the "memories" were real. Two additional major studies—one

American, one British—came to the same conclusion as the FBI's Lanning in 1994. Funded with $750,000 from the federal government, Gail Goodman and her team examined many thousands of patient's anecdotal stories of satanic ritual abuse and failed to find any corroborative evidence for the stereotypical, rote, detailed patient reports of multi-generational cults that sexually abused, killed, and/or ate children. (See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.). Thus, prior to WPATH and prior to the ideological fervor of the Gender Affirmation Medical Enterprise, the Recovered Memory Therapy Industry had shown how "politically correct" ideological fervor can overcome a lack of credible scientific evidence and engage in unrproven, experimental "treatments" on tens of thousands of unsuspecting, vulnerable patients.

Subsequent research and many dozens of malpractice lawsuits and licensing revocations documented that the very similar to identical self-reported "memories" provided by "recovered memory" patients to law enforcement and the media were actually the result of memory contamination by unethical, pseudoscientific psychotherapy methods and media-therapist fueled social contagion fears of a criminally abusive "patriarchy". The patients' new, horrific pseudo-memories
were shown to be the result of ideologically driven pseudoscientific "treatments" including hypnosis, "age regression", dream interpretation, guided imagery, use of family photographs to stimulate "recovered memories", interpretation of physical symptoms as so-called "body memories", and coercive group therapy sessions similar to Maoist indoctrination groups. See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.).

Hundreds of lawsuits and media exposes shut down many of the Repressed Memory Therapy – Multiple Personality Disorder (RMT-MPD) clinics. State licensing boards then proceeded to revoke or restrict the licenses of multiple leaders of the RMT-MPD movement. See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; See also, Barden RC: Reforming the Mental Health System: Coordinated, Multidisciplinary Actions Ended "Recovered Memory" Treatments and Brought Informed Consent to Psychotherapy. Psychiatric Times. 2014;31(6): June 6, 2014.

It is important to note that the relevant professional associations including the American Medical Association, the American Psychiatric Association, the American Psychological Association and others (social worker and therapist associations, etc.) were not protective of the public and did little or nothing to expose the dangerous, pseudoscience fads and frauds of the RMT-MPD movement. In contrast, these political-professional associations protected the lucrative RMT-MPD industry that created tens of thousands of new patients requiring years of expensive treatments. The exposure of the dangers and damages of the RMT-MPD industry was done by a small number of civil attorneys, scientists, juries, and science-literate journalists. This example should give pause to those attempting to rush to fund and rapidly expand the experimental Gender Transition Industry.

In sum, some of the most tragic misadventures in the history of medicine involved the science illiterate reliance upon uncorroborated patient "stories"— self-reported evidence — as the sole basis for proceeding with controversial, experimental treatments on vulnerable patients (e.g. Lobotomies, Rolfing, Primal Screaming, Recovered Repressed Memories, Multiple Personality Disorder, Rebirthing Therapy, Coercive Holding Therapy, Reparenting, etc.). Understanding the important distinctions between scientifically valid-reliable, methodologically sound research

versus unreliable, anecdotal evidence and unverified patient "memories" is essential to efforts to protect the integrity of the scientific process as well as the quality and safety of medical care. Sex discordant gender ("transgender") assessments are currently made almost solely on unverified, uncorroborated "memory" reports of vulnerable patients.

36. PATIENTS' RIGHTS TO TESTED, PROVEN TREATMENTS and INFORMED CONSENT HAVE BEEN VIOLATED IN THE PAST BY ETHICAL FAILURES IN THE MEDICAL and MENTAL HEALTH SYSTEMS. USING EXPERIMENTAL PROCEDURES and UNPROVEN "TREATMENTS" ON UNINFORMED, VULNERABLE PATIENTS IS UNETHICAL and IMPROPER. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science — such is the case with the Gender Transition Industry. The history of the infamous Tuskegee studies, the Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia! See, https://www.nobelprize.org/prizes/medicine/1949/moniz/article/), recovered memory therapy-multiple personality disorders, rebirthing therapy (see, e.g. See, Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001, See, also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001, coercive holding therapy (See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005), and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions such as gender transition

"treatments". It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ["Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits"]. See, also, Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, Pediatrics, August 2016, 138 (2) e20161485; DOI: https://doi.org/10.1542/peds.2016-1485 at https://pediatrics.aappublications.org/content/138/2/e20161485

Tragically, however, as I will discuss in detail below, we now have much evidence supporting increasing concerns that the true risks and benefits of Sex Discordant Gender ("transgender") transition "treatments*" are NOT being properly and ethically presented to patients by providers* (surgeons, endocrinologists, therapists, etc). Similarly, many of the published "pro-transition" research studies reviewed in this declaration *have misrepresented to the public the actual risks and benefits of gender affirming medical interventions*. The Gender Transition Industry has produced research claiming evidence supporting the use of controversial "treatments" when, in fact, their own study data more likely support the alternative hypothesis that *so-called "transition" intervention procedures might produce higher risks of anxiety and more serious suicide attempts requiring hospitalization.* (See detailed discussions below). Expert witnesses in cases involving issues related to Sex Discordant Gender Transition interventions are duty bound

and required by licensing rules to truthfully and fully disclose to courts and legal professionals ***the well-documented risks, international controversies, and published misrepresentations*** involving the still unproven Gender Transition methods and procedures.

37. METHODOLOGICAL ERRORS - ONE OF THE MOST SERIOUS OF ALL METHODOLOGICAL ERRORS, CONFIRMATION BIAS, PLAGUES THE RESEARCH OF THE GENDER TRANSITION INDUSTRY:

Confirmation bias is one of the most serious and potentially dangerous errors in the assessment-diagnosis-treatment process of medicine. One of the key methodologies in science and in proper investigations-assessments of all kinds — including expert witness review and testimony— is *the generation and testing of multiple alternative investigative hypotheses*. From US Public Junior High Schools (typically first taught to 8th Graders) through competent MA, MSW, and all Ph.D. and M.D. graduate programs, students and professionals at all levels are taught that the central methodology for science and for a proper assessment-diagnosis-treatment or expert witness report involves the *generation and testing of alternative investigative hypotheses.* Investigative hypotheses, once generated, should be rationally, properly, and fairly explored to see if actual, factual evidence supports or refutes the hypotheses. A common and serious error in improper assessments-diagnoses-treatments is "confirmation bias," the failure to generate and then explore alternative investigative-assessment-diagnostic hypotheses. In confirmation bias the science-naïve physician, investigator, expert, or therapist applies a narrow "tunnel vision" process to support a single, favorite, biased, pre-conceived hypothesis in a case. [See, Garb, H. N., & Boyle, P. A (2003). Understanding why some clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudoscience in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.;

See also, See, Plous, Scott (1993). The Psychology of Judgment and Decision Making. p. 233; Nickerson, Raymond S. (June 1998). "Confirmation Bias: A Ubiquitous Phenomenon in Many Guises". Review of General Psychology 2 (2): 175–220. doi:10.1037/1089-2680.2.2.17 ; See, Joshua Klayman and Young-Won Ha, Confirmation, Disconfirmation, and Information in Hypothesis Testing, Psychological Review, 1987, Vol.94, No. 2, 211-228.] Currently, too many Gender Transition Industry advocate-activist-providers appear to violate the requirement to properly generate, explore, and disclose alternative hypotheses for assessments-diagnoses and treatments. In my opinion such failures, including the activist-ideologue demand that all alternative hypotheses and treatments be banned as forms of "conversion" therapy, risk ***institutionalizing confirmation bias*** —a dangerous form of negligent practice. See, Smith, T. Summary of AMA Journal of Ethics article on cognitive biases, Four widespread cognitive biases and how doctors can overcome them (e.g., confirmation bias, anchoring bias, affect heuristic, and outcomes bias) at https://www.ama-assn.org/delivering-care/ethics/4-widespread-cognitive-biases-and-how-doctors-can-overcome-them. ("Physicians are human and, therefore, constantly vulnerable to cognitive bias. But this imperfection is not just theoretical. It can have huge effects on patient care.")

38. METHODOLOGICAL ERRORS of the GENDER t INDUSTRY- CONFIRMATION BIAS CAN PREVENT COMPLEX, COMPREHENSIVE DIAGNOSIS AND TREATMENT EXPLORING ALTERNATIVE HYPOTHESES:

By demanding the immediate and un-investigated "affirmation" of a Sex Discordant Gender Identity ("transgender") patient's requests for so-called" transitioning" — without conducting a detailed, proper, medical assessment of alternative hypotheses — the Gender Transition Industry is attempting to enforce and institutionalize the methodological failure of "confirmation bias". By

labelling all forms of psychotherapy, coping and resilience training, cognitive behavioral therapy for depression-anxiety, or other options as "conversion therapy", the Gender Transition Industry is failing to treat individual patients according to the basic requirements and principles of competent medical assessment, diagnosis, and treatment. As I will discuss in detail in the methodological analyses below, the current scientific evidence does not support the current treatments nor methods endorsed and aggressively marketed and demanded by the Gender Transition Industry. The Gender Transition Industry's general refusal to properly investigate or even consider alternative hypotheses, alternative diagnoses, and alternative treatments is, in my view, unethical misconduct. For example, many peer reviewed, properly conducted, published research reports demonstrate that cognitive-behavioral therapy is a very low-risk, safe, and highly effective treatment for depression and anxiety disorders. See, e.g., Mor N, Haran D. Cognitive-behavioral therapy for depression. J Psychiatry Relat Sci. 2009;46(4):269-73. PMID: 20635774, https://pubmed.ncbi.nlm.nih.gov/20635774/ ; [A review of "Twenty-nine Random Control Trials were included in three separate meta-analyses. Results showed multi-modal CBT was more effective than no primary care treatment (d =0.59), and primary care treatment-as-usual (TAU) (d = 0.48) for anxiety and depression symptoms."] See, e.g., Twomey, C., O'Reilly, G. and Byrne, M. Effectiveness of cognitive behavioural therapy for anxiety and depression in primary care: a meta-analysis, Family Practice, Volume 32, Issue 1, February 2015, Pages 3–15, https://doi.org/10.1093/fampra/cmu060. The political taint is so strong that some activist-providers reportedly fail to offer and engage in CBT therapy with depressed-anxious Gender Dysphoric patients for fear of being attacked as engaging in "conversion" therapy. Again, the institutionalization of medical negligence (e.g., confirmation bias) harms vulnerable patients.

39. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT - Ideological Overreach can Lead to Unethical Misconduct and Licensing Violations. Misrepresenting medical-scientific research, deceptively hiding methodological errors, or failing to honestly report ongoing international controversies to courts, patients, or guardians should be properly investigated as misconduct. Licensing boards and professional associations produce and should properly enforce ethics rules and requirements governing the conduct of health care professionals to protect the rights of patients and parents.

40. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT - Plaintiffs' EXPERT DR BROWN's METHODOLOGICAL FAILURES SHOULD BE INVESTIGATED: In my opinion, Plaintiffs' expert Dr. Brown, appears to have engaged in misconduct by his signed opinion in this case stating "***Nor is there any uncertainty or dispute in the medical field regarding the medical necessity of this care***." As the detailed methodological analysis below amply documents, Dr. Brown's expert declaration in this case appears to document an example of unusual ignorance or potentially, a deceptive failure to properly report on, and inform the court of, the ongoing international controversies and debates regarding Gender Transition interventions ("treatments") (e.g. See the relevant multiple, national science reviews cited below from Great Britain, Sweden, and Finland, as well as the Cochrane Review all exposing the serious methodological defects, controversies, and methodological failings of Gender Transition research as documented below).

41. THE ACTUAL PREVALENCE OF GENDER DYSPHORIA and PATIENTS THAT IDENTIFY AS GENDER DISCORDANT ("transgender") IS UNKNOWN BUT IT APPEARS TO BE INCREASING AT A RAPIDLY ACCELERATING RATE THUS SUPPORTING AN ALTERNATIVE HYPOTHESIS OF SOCIAL CONTAGION: Estimates reported in in the DSM-

V (a diagnostic manual that functions via voting and more as a dictionary than a valid scientific methodology) were between 0.005% to 0.014% for adult males and 0.002% to 0.003% for adult females. Thus, gender dysphoria was, until just a few years ago, a very rare condition. It is currently unknown whether these DSM estimates were falsely low due to under-reporting or:

— whether changing societal acceptance of transgendered identity and the growing number of medical centers providing interventions for gender dysphoria has led to increased reporting of persons who identify as transgender

- or whether the reported educational programs aggressively promoting "non-binary" identification to elementary to high school students to college students have greatly increased the numbers of youth adopting a transgender identity

- or whether the reported wave of "trans You Tube influencers" watched by millions each day as they aggressively "sell" the transgender lifestyle has added to a social contagion effect with vulnerable lonely, depression, anxious, or autistic youth.

— or other causal process.

A key unanswered research question is whether a social contagion process is leading to vast and rapid increases in the numbers of patients identifying as gender discordant ("transgender"). How many of the new waves of thousands of cases are 'false reports' that will dissipate with time and normal development over time? For example, the Gender Identity Development Service in the United Kingdom, which treats only children under the age of 18, reported that it received 94 referrals of children in 2009/2010 and 1,986 referrals of children in 2016/2017 **a relative increase of 2,000%**. See, "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS. NHS.uk (undated), http://gids.nhs.uk / sites / default / files /content_uploads /referralfigures-2016- 17.pdf.

Reportedly, similar social contagion processes led to tens of thousands of patients and families being harmed by controversial diagnoses such as multiple personality disorder" (MPD and controversial interventions including "recovered memory therapy (RMT). RMT and MPD patients, once considered extremely rare (some 300 MPD patients reported worldwide prior to the 1980s-1990s social contagion epidemic) erupted into a flood of tens of thousands of patients and affected families in the 1990s. These very controversial disorders and treatments were greatly reduced by dozens of civil lawsuits against RMT-MPD therapists, international news exposure of scientific evidence debunking these notions, and international news reporting of the civil litigation, licensing prosecutions, and licensing revocations of well-known RMT-MPD practitioners. (See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer).

Recent data indicates that the number of people seeking care for gender dysphoria is rapidly increasing with some estimates as high as 20-fold and more. See, Chen, M., Fuqua, J. & Eugster, E. A. Characteristics of Referrals for Gender Dysphoria Over a 13-Year Period. Journal of Adolescent Health 58, 369-371, doi:https://doi.org/10.1016/j.jadohealth.2015.11.010 (2016) ; 4. "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content_uploads/referral-figures-2016-17.pdf.) See, Zucker K. J. (2017). Epidemiology of gender dysphoria and transgender identity. *Sexual health*, *14*(5), 404–411. https://doi.org/10.1071/SH17067. Data from England show *increases of 4,000% for female to male patients and in America data show increases of 20,000% for young women* ***(e.g. from .01 to 2%)***. Estimates vary considerably in relation to how sex-gender identity discordance is defined. See, Zhang, Q., Goodman, M., Adams, N., Corneil, T., Hashemi, L.,

Kreukels, B., Motmans, J., Snyder, R., & Coleman, E. (2020). Epidemiological considerations in transgender health: A systematic review with focus on higher quality data. *International journal of transgender health*, *21*(2), 125–137. https://doi.org/10.1080; Poteat, T., Rachlin, K., Lare, S., Janssen, A. & Devor, A. in *Transgender Medicine: A Multidisciplinary Approach* (eds Leonid Poretsky & Wylie C. Hembree) 1-24 (Springer International Publishing, 2019); Flores AR, Herman JL, Gates, GJ, Brown TNT. How Many Adults Identify as Transgender in the United States? Los Angeles, CA: The Williams Institute; 2016. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf. Accessed April 28, 2021.

42. EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS ***NOT*** GENETICALLY NOR BIOLOGICALLY DETERMINED: There is strong disconfirming evidence (e.g., Popperian falsifiability) against the theory that gender identity is determined at or before birth and is unchangeable. This comes from A) identical twin studies where siblings share genetic complements and prenatal environmental exposure but have differing gender identities. See, Heylens, G. et al. Gender identity disorder in twins: a review of the case report literature. J Sex Med 9, 751-757, doi:10.1111/j.1743-6109.2011.02567.x (2012) and B) the very recent and massive increase in the numbers of GD patients over a very short time span. This argues against a biological-genetic hypothesis. See Leinung MC, Joseph J. Changing Demographics in Transgender Individuals Seeking Hormonal Therapy: Are Trans Women More Common Than Trans Men? Transgend Health. 2020 Dec 11;5(4):241-245. doi: 10.1089/trgh.2019.0070. PMID: 33644314; PMCID: PMC7906237.

43. REPLICATED RESEARCH EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS ***NOT*** IMMUTABLE: Further evidence that gender identity is not fixed and immutable comes from established peer reviewed literature demonstrating that the vast

majority (80-95%) of children who express gender dysphoria revert to a gender identity concordant with their biological sex by late adolescence. This natural developmental "cure" of gender dysphoria requires no direct "treatment" and prevents the hormonal and surgical destruction of normal, healthy organs and bodily processes (e.g. prevents sterilization of the child). See Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. Front Psychiatry. 2021 Mar 29;12:632784. doi: 10.3389/fpsyt.2021.632784. PMID: 33854450; PMCID: PMC8039393. It is not currently known whether individuals with gender dysphoria persistence have differing etiologies or severity of precipitating factors compared to desisting individuals. See, Drummond, K. D., Bradley, S. J., Peterson-Badali, M. & Zucker, K. J. A follow-up study of girls with gender identity disorder. Dev Psychol **44**, 34-45, doi:10.1037/0012-1649.44.1.34 (2008); Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J. & Cohen-Kettenis, P. T. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J Am Acad Child Adolesc Psychiatry **52**, 582-590, doi:10.1016/j.jaac.2013.03.016 (2013).

44. VIRTUALLY ALL TRANSGENDER PATIENTS ARE BORN WITH HEALTHY NORMAL SEX ORGANS AND NO KNOWN BRAIN OR GENETIC ABNORMALITIES: Most people with gender dysphoria, do not have a disorder of sexual development. As documented in their medical record, such patients typically have normally formed sexual organs. The presence of normal, functional sex organs prior to the initiation of hormone administration or surgical "transition" operations is typical in transgender patients. I note that hormonal treatments and surgery to remove healthy, normal organs (the genitals of GD patients) both destroy the function of healthy organs (e.g., producing the life-long sterilization of GD patients). Such so-called apparently injurious "treatments" are very controversial and occur nowhere else in medicine that

I am aware of with the exception of requests for the amputation of healthy limbs in patients suffering from the very controversial "body integrity identity disorder". See, Elliott, T., Body Dysmorphic Disorder, Radical Surgery and the Limits of Consent, *Medical Law Review*, Volume 17, Issue 2, Summer 2009, Pages 149–182, https://doi.org/10.1093/medlaw/fwp001 [In 2000 there was a media furor, when it was disclosed that a Scottish surgeon had operated upon two adult male patients reportedly suffering from a rare form of a psychological condition known as body integrity identity disorder, in each case amputating a healthy leg. Since then, the question of whether such surgery is ethically or legally permissible has been a matter of debate. The subject raises issues as to the extent to which it is proper to treat adults with psychiatric or psychological disorders with radical surgery, particularly where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed]. Similarly, Gender Transition interventions also involve treating patients "with psychiatric or psychological disorders with radical surgery, where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed."

The primary use of psychotherapy as a means to treat body dysmorphic disorder contrasts with the approaches used by the Gender Transition Industry. See, Hadley, S. J., Greenberg, J., & Hollander, E. (2002). Diagnosis and treatment of body dysmorphic disorder in adolescents. *Current psychiatry reports*, *4*(2), 108–113. https://doi.org/10.1007/s11920-002-0043-4; Allen, A., & Hollander, E. (2000). Body dysmorphic disorder. *The Psychiatric clinics of North America*, *23*(3), 617–628. https://doi.org/10.1016/s0193-953x(05)70184-2

45. THE ETIOLOGY (CAUSE) OF GENDER DYSPHORIA IS CURRENTLY ***UNKNOWN*** and the "TREATMENTS" are of **UNCERTAIN EFFICACY** - THUS THE CURRENT THEORIES and TREATMENTS REMAIN EXPERIMENTAL and CONTROVERSIAL: The etiology of gender dysphoria in individuals with sex-gender identity

discordance remains unknown. Alternative hypotheses include some as yet unidentified biological cause, prenatal hormone exposure, genetic variation, postnatal environmental influences, family dynamics, other forms of mental illness, an abnormal detour from developmental identity processes, social contagion effects on suggestible-vulnerable subjects, or a combination of multiple factors. Based upon the available evidence, it is most likely that sex-gender identity discordance is multifactorial with both genetic and environmental influences, differing in both kind and degree in any affected individual. Importantly, these potential contributing factors are hypothesized to be contributory, but not determinative of the condition. See, Saleem, Fatima, and Syed W. Rizvi. "Transgender Associations and Possible Etiology: A Literature Review." Cureus 9, no. 12 (2017): e1984

46. THE CONCEPT OF "NEUROLOGICAL SEX" IS EXPERIMENTAL, UNVERIFIED, HAS NO KNOWN ERROR RATE and is NOT ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY: The recently coined concept of "neurological sex" as a distinct entity or a basis for classifying individuals as male or female has no scientific justification. Limited emerging data has suggested structural and functional differences between brains from normal and transgender individuals. These data do not establish whether these differences are innate and fixed or acquired and malleable. The remarkable neuronal plasticity of the brain is well known, well documented, and has been studied extensively in gender-independent contexts related to health and disease, learning, and behavior. See, Fatima Yousif Ismail, Ali Fatemi, and Michael V. Johnston, "Cerebral Plasticity: Windows of Opportunity in the Developing Brain," European Journal of Paediatric Neurology 21, no. 1 (2017).

47. GENDER IDENTITY IDEOLOGY IS A POLITICAL, NOT SCIENTIFIC THEORY: A key alternative investigative hypothesis in efforts to understand the rise of reports of gender

discordance and social-political-medical attempts to create a transgender movement is that such ideas are not based upon sound scientific biological, genetic, or related principles and data but rather are based upon ideology and driven by political advocacy. Although worldviews among scientists and physicians differ widely, similar to society at large, science must remain firmly grounded in testable, valid, and reliable assessments of physical reality — not ideologically tainted perceptions and belief systems. The inherent link between human sexual biology and teleology (e.g. human reproduction) is self-evident and fixed. Breithaupt H. The science of sex. *EMBO Rep*. 2012;13(5):394. Published 2012 May 1. doi:10.1038/embor.2012.45. As an investigative hypothesis, the historical foundation of gender identity ideology appears to be grounded in Critical Theory, which may provide a basis to understand the level of extreme methodological confusion, defects, and errors in the Gender Transition Industry. For example, "transgender" activists often support clearly contradictory theories and arguments at the same time (e.g. the claim that Gender Dysphoria (GD) and "trans identity" are" immutable", "genetic", or based on "brain structures" while simultaneously claiming GD is also "fluid" and thus capable of changing on a daily basis). Association of critical theory with the Gender Transition Industry reflects a controversial ideological foundation for the provision of hormonal and surgical interventions that have potential to permanently damage essential bodily functions including the sterilization of vulnerable patients. (See, e.g., Pluckrose, and Lindsay, J. , Cynical Theories: How Activist Scholarship Made Everything about Race, Gender, and Identity—and Why This Harms Everybody, Pitchstone Publishing, August 25, 2020).

48. GENDER IDENTITY IDEOLOGY and the GENDER TRANSITION INDUSTRY--INCLUDING INTERVENTIONS -- HAVE NO RELIABLE-VALID SCIENTIFIC BASIS and HAVE NEVER BEEN ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and

HAVE NO KNOWN NOR PUBLISHED ERROR RATE: The political-ideological claims of proponents of transgenderism, which include opinions such as "Gender identity is the primary factor determining a person's sex" and "Gender is the only true determinant of sex" and individuals have "sex assigned at birth" must be viewed in their proper philosophical context. There is no scientific basis for redefining sex on the basis of a person's subjective, psychological sense of 'gender'.

49. IN CONTRAST TO SEX DISCORDANT GENDER "TRANSGENDER" IDEOLOGY, THE BIOLOGICAL BASIS OF SEX IS FIRMLY GROUNDED IN VALID-RELIABLE SCIENCE, ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY AND HAS A VERY LOW ERROR RATE: The prevailing, constant, tested, proven, and accurate designation of sex as a biological trait grounded in the inherent purpose of male and female anatomy and as manifested in the appearance of external genitalia at birth remains the proper scientific and medical standard. Redefinition of the classification and meaning of sex based upon pathologic variation is not established medical fact. See, e.g., Mittwoch, U. (2013), Sex determination. EMBO reports, 14: 588-592. https://doi.org/10.1038/embor.2013.84

Potential Harm to Vulnerable Patients Resulting from Experimental Gender Dysphoria Treatments

50. THE ETHICAL FOUNDATIONS of MEDICINE — FIRST DO NO HARM: The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. Efforts to rely upon clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. The current Gender Transition Industry violates this essential principle by using experimental treatments on vulnerable

populations without properly informing them of the actual risks and limitations of the treatments. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998.

51. THE ETHICAL FOUNDATIONS of MEDICINE — REQUIRE US TO STRIVE TO HELP THOSE IN DISTRESS WITH COMPASSION, KINDNESS, and EMPATHY AND TO **NOT** VIOLATE PATIENTS' and PARENTS' RIGHTS BY ENGAGING IN EXPERIMENTAL, UNPROVEN, INTERVENTIONS ("TREATMENTS") LEADING POTENTIAL TO PERMANENT DAMAGE TO MANY PATIENTS – INCLUDING STERILIZATION: Persons with gender dysphoria as defined in the DSM-V report experiencing significant psychological distress related to their condition with elevated risk of depression, suicide, and other morbidities. Thus, attempts to provide effective medical care to affected persons are clearly warranted. Efforts to effectively treat persons with gender dysphoria require respect for the inherent dignity of those affected, sensitivity to their suffering, and maintenance of objectivity in assessing etiologies and long-term outcomes. In my opinion, the use of unproven, experimental treatments on vulnerable patients and the publication of grossly methodologically defective research are violations of the ethical foundations of medicine.

52. IN THE ETHICAL PRACTICE OF MEDICINE, VALID-RELIABLE SCIENCE SHOULD PRECEDE INVASIVE, RISKY, DAMAGING TREATMENT PROTOCOLS - THREE CURRENT APPROACHES: There is an urgent need for high quality controlled clinical research trials to determine ways to develop supportive dignity affirming social environments that maintain affirmation of the ***scientifically accepted biological reality***. To date, three approaches have been proposed for managing children with gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry **47**, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).) The first approach, often referred to

as "conversion" or "reparative therapy", is directed toward actively supporting and encouraging children to identify with their biological sex. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing that *the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex*. This approach may also include the use of scientifically validated treatments (e.g. CBT) for the patient's anxiety, depression, social skills deficits or other issues. See, van Bentum, J. S., van Bronswijk, S. C., Sijbrandij, M., Lemmens, L., Peeters, F., Drukker, M., & Huibers, M. (2021). Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. *Depression and anxiety*, 10.1002/da.23151. Advance online publication. https://doi.org/10.1002/da.23151; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. *Psychotherapy (Chicago, Ill.)*, *57*(3), 379–390. https://doi.org/10.1037/pst0000283. The third "affirming" approach is to actively encourage children to embrace transgender identity with social transitioning followed by hormonal therapy leading to potential surgical interventions and life-long sterilization. See, Walch A, Davidge-Pitts C, Safer JD, Lopez X, TangprichaV, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective.J Clin Endocrinol Metab. 2021;106(2):305-308. doi:10.1210/clinem/dgaa816 .

53. ANOTHER CONTROVERSY — THE "WATCHFUL WAITING" TREATMENT MODALITY INVOLVES NO MEDICAL TREATMENT AND IS CURRENTLY THE BEST SCIENTIFICALLY SUPPORTED INTERVENTION FOR YOUNG CHILDREN REPORTING

GENDER DYSPHORIA: Desistance (i.e. realignment of expressed gender identity to be concordant with sex) provides the greatest lifelong benefit and is the outcome in the vast majority of patients and should be maintained as a desired goal. Any coerced, required, societally mandated, scientifically untested, intervention that would or could unnecessarily interfere with the likelihood of a normal, non-traumatic, developmental, resolution of gender dysphoria is unwarranted and potentially harmful. The gender affirming approach, which includes use of a child's preferred pronouns, use of sex-segregated bathrooms, other intimate facilities and sleeping accommodations corresponding to a child's gender identity, has limited, "very weak", "sparse" scientific support for short-term alleviation of dysphoria and ***no long-term outcomes data demonstrating superiority over the other approaches***. (See, National reviews of England, Sweden, Finland, the Cochrane review, the Griffin review, the Carmichael review and others). Claims that the other approaches have been scientifically disproven are simply false. In stark contrast to the ideologically tainted, "voted in", recommendations of Professional Associations, decades of peer-reviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of a more conservative "watchful waiting" approach for the majority of patients experiencing gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 Years. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.). In sum, the treatment protocols and recommendations of politically influenced, non-science associations (WPATH, Pediatrics Assn, APA) who engaged in "voting", consensus-seeking methodologies (not science)

are not accepted by the relevant ***scientific*** community, are not based upon competent-credible, methodologically sound science, and have no known, nor published error rate.

54. HARMFUL EFFECTS OF AFFIRMATION TREATMENT — INCLUDING EFFECTS OF PUBERTAL SUPPRESSION TREATMENTS ARE ESTABLISHED and ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY:

"To sum up how puberty suppression works, a thought experiment might be helpful. Imagine two pairs of biologically and psychologically normal identical twins -a pair of boys and a pair of girls -where one child from each pair undergoes puberty suppression and the other twin does not. Doctors begin administering GnRH analogue treatments for the girl at, say, age 8, and for the boy at age 9. Stopping the gonadal hormone pathway of puberty does not stop time, so the puberty-suppressed twins will continue to age and grow -and because adrenal hormones associated with puberty will not be affected, the twins receiving GnRH analogue will even undergo some of the changes associated with puberty, such as the growth of pubic hair. However, there will be major, obvious differences within each set of twins. ***The hormone suppressed twins' reproductive organs will not mature***: the testicles and penis of the boy undergoing puberty suppression will not mature, and the girl undergoing puberty suppression will not menstruate. The boy undergoing puberty suppression will have less muscle mass and narrower shoulders than his twin, while the breasts of the girl undergoing puberty suppression will not develop. The boy and girl undergoing puberty suppression will not have the same adolescent growth spurts as their twins. ***So all told, by the time the untreated twins reach maturity, look like adults, and are biologically capable of having children, the twins undergoing puberty suppression will be several inches shorter, will physically look more androgynous and childlike, and will not be biologically capable of having children***. This is a thought experiment, but it illustrates some of the effects that puberty suppression would

be expected to have on the development of a growing adolescent's body." See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36.

55. METHODOLOGICAL FLAWS IN THE GENDER TRANSTION INDUSTRY—THE ENDOCRINE SOCIETY HAS REPORTED THAT THE QUALITY OF EVIDENCE FOR GENDER DYSPHORIA TREATMENTS IS CURRENTLY ***"LOW OR VERY LOW"*** (Key Quote: ***"ANY estimate of effect is VERY uncertain***") — THUS THERE IS CLEARLY NO GENERAL ACCEPTANCE IN THE RELEVANT SCIENTIFIC COMMUNITY AND THE ERROR RATE IS UNKNOWN and COULD WELL BE VERY HIGH : The Endocrine Society published 2009 clinical guidelines for the treatment of patients with persistent gender dysphoria. See, Hembree, W. C. et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab **94**, 3132-3154, doi:10.1210/jc.2009-0345 (2009). The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As directly stated in the Endocrine Society publication, ***"the strength of recommendations and the quality of evidence was low or very low."*** According to the GRADE system, low recommendations indicate "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that **"any estimate of effect is very uncertain"**. (See, Guyatt G H,

Oxman A D, Vist G E, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations BMJ 2008; 336 :924 doi:10.1136/bmj.39489.470347.AD). An updated set of guidelines was published in September of 2017. See, Hembree, W. C. et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, doi:10.1210/jc.2017-01658 (2017). The low quality of evidence presented in this document persists to the current day as ***the controversy over these "treatments" is accelerating in recent years***.

56. METHODOLOGICAL FLAWS IN RESEARCH of the GENDER TRANSITION INDUSTRY—THE WPATH GUIDELINES (7th version) NOTE SERIOUS LIMITATIONS OF THE EXISTING SCIENTIFIC DATA: Clinical Practice Guidelines published by the World Professional Association for Transgender Health (WPATH) - (an advocacy-political, consensus-seeking organization, whose positions are based on voting and not a scientific, evidence-based process) which is currently in its 7th iteration, similarly, though less explicitly, acknowledge the limitation of existing scientific data supporting their recommendations given and "the value of harm-reduction approaches". Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W. J., Monstrey, S., Adler, R. K., Brown, G. R., Devor, A. H., Ehrbar, R., Ettner, R., Eyler, E., Garofalo, R., Karasic, D. H., . . . Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *International Journal of Transgenderism, 13*(4), 165–232. https://doi.org/10.1080/15532739.2011.700873

57. INTERVENTIONS ("TREATMENTS") OF CHILDREN WITH POTENTIALLY HARMFUL HORMONES TO INTERVENE IN THE LIFE OF A CHILD WHO IS HIGHLY

LIKELY (80%+) TO RESOLVE THE GENDER DYSPHOTIA ISSUE NATURALLY — IS RISKY, UNSCIENTIFIC and UNETHICAL. IATROGENIC DAMAGES TO PATIENTS — INCLUDING LIFE-LONG STERILITY, STUNTED GROWTH, INCREASED HEART ATTACK RISKS, ETC. — ARE OFTEN IRREVERSIBLE: Treatment of gender dysphoric children who experience persistence of symptoms with hormones (pubertal suppression and cross-hormone therapy) carries significant risk. It is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility and often result in sterility, which in many cases is irreversible. See, Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health **61**, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017)). Emerging data also show that treated patients have lower bone density which may lead to increased fracture risk later in life. See, Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015)). Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. See, Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. *Hypertension (Dallas, Tex.: 1979)*, HYPERTENSIONAHA12016839. Advance online publication.

https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Annals of internal medicine*, *169*(4), 205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

58. LONG TERM EFFECTS OF THE CURRENT EXPERIMENTAL "GENDER AFFIRMING" MEDICAL INTERVENTIONS — FOR CHILDREN and ADULTS — ***ARE UNKNOWN and UNPROVEN*** – THIS HAS BEEN WELL KNOWN SINCE 2011 and EARLIER. SUCH TREATMENTS ARE ***NOT*** GENERALLY ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and HAVE ***NO*** KNOWN NOR PUBLISHED ERROR RATE. CURRENT GENDER TRANSITION INDUSTRY STUDIES OFTEN SUFFER FROM SEVERE METHODOLOGICAL LIMITATIONS: Since strategies for the treatment of transgendered children as summarized by the Endocrine Society guidelines are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions in psychological distress following social transition in a "gender affirming" environment remains inconclusive. When considered apart from advocacy-based agendas, multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design. See, Hruz, P. W. Deficiencies

in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* **87**, 34-42, doi:10.1177/0024363919873762 (2020). Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia continue to have ***rates of depression, anxiety, substance abuse and suicide far above the background population***. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

59. MEDICAL TREATMENTS BASED ON PSEUDO-SCIENCE and POLITICAL IDEOLOGIES CONTRARY TO THE RELEVANT-RELIABLE-VALID SCIENCE COULD RESULT IN IRREVERSIBLE HARMS TO MANY PATIENTS WHO WOULD OTHERWISE HAVE RECOVERED NATURALLY FROM GENDER DYSPHORIA: Of particular concern is the likelihood that forced-coerced, or naively requested gender transition "treatments" and social changes could interfere with known very high rates of natural-untreated resolution of sex-gender discordance. Any activity that encourages or perpetuates transgender persistence for those who would otherwise desist could cause significant harm, particularly in light of the current treatment paradigm for persisting individuals. As noted, sterility can often be expected with hormonal or surgical disruption of normal gonadal function. See, Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. Transl Androl Urol. 2019 Jun;8(3):209-218. doi: 10.21037/tau.2019.05.09. PMID: 31380227; PMCID: PMC6626312.

60. YOUNG CHILDREN and PARENTS ARE OFTEN NOT PROPERLY INFORMED or ARE NOT COMPETENT TO GIVE INFORMED CONSENT TO PROCEED WITH EXPERIMENTAL, HAZARDOUS TREATMENTS THAT COULD POTENTIALLY RESULT IN PERMANENT STERILITY: This is a particularly concerning issue given that children are likely to be incapable of giving truly informed consent. See, Geier, C. F. Adolescent cognitive control and reward processing: Implications for risk taking and substance use. Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013). This concern remains valid when applied to hormonal or surgical treatments that will result in lifelong sterility. In addition, parents are often manipulated and coerced by misinformed political activists or providers who threaten them with dire warnings that the only two options are "treatment or suicide". These "threats" ignore data that challenge this biased assumption. See, D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50,** 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2

61. AN ALTERNATIVE HYPOTHESIS FOR THE RAPID INCREASE IN GENDER DYSPHORIA — SOCIAL CONTAGION PROCESSES — HAS BEEN IMPROPERLY IGNORED BY TRANSGENDER ACTIVISTS and PROVIDERS: Social and psychological support with dignity for adolescents with gender dysphoria does not necessitate acceptance of a unproven, experimental understanding of human sexuality in schools. Rather, policy requirements including social contagion promoting educational processes that can increase the prevalence and persistence of transgender identification have significant potential for inducing long-term harm to affected children.

62. COMPETENT, METHODOLOGICALLY SOUND, LONG-TERM TREATMENT OUTCOME RESEARCH ON GENDER DYSPHORIA INTERVENTIONS HAS NEVER BEEN

DONE: There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals. (Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity **23**, 172-179, doi:10.1097/med.0000000000000236 (2016)). In particular, there is a concerning lack of randomized controlled trials comparing outcomes of youth with gender dysphoria who are provided public encouragement for "affirming" social gender transition and how such transitioning affects the usual and natural progression to resolution of gender dysphoria in most affected children. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to both treatment groups. See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html

63. DUE TO THE LACK OF QUALITY, CREDIBLE SUPPORTIVE RESEARCH GENDER AFFIRMING ("TRANSITION") INTERVENTIONS REMAIN EXPERIMENTAL and HIGHLY CONTROVERSIAL – "***GENDER AFFIRMING" USES OF THE RELEVANT HORMONAL MEDICATIONS ARE NOT APPROVED BY THE FDA***: Gender identity is consolidated during puberty and adolescence as young people's bodies become more sexually differentiated and mature. How this normally happens is not well understood, so it is imperative to be cautious about interfering with this complex natural process. Far from being cautious and prudent in using puberty blockers to treat gender dysphoria, too many providers engaged in gender affirming medical interventions are conducting an unethical and risky experiment that does not come close to the ethical standards demanded in other areas of medicine. No one really knows all

the potential consequences of puberty blocking as a treatment for gender dysphoria, but there are some known effects of pubertal suppression on children who are physiologically normal, and these carry long-term health risks. Children placed on puberty blockers have slower rates of growth in height, and an elevated risk of low bone-mineral density. Another possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation. (See, Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, *9*, 449–461. https://doi.org/10.2147/NDT.S39776). When followed by cross-sex hormones, known and potential effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. Tragically, those children who persist in their transgender identity and take puberty blockers and cross-sex hormones are ***expected to become sterile***. Given what we already know about puberty blocking and how much remains unknown, it is not surprising that the use of GnRH analogues for puberty suppression in children with gender dysphoria ***is not FDA-approved.*** The off-label prescription of these drugs is legal ***but unethical*** outside the setting of a carefully controlled and supervised clinical trial. See, Hruz, Mayer, and McHugh, "Growing Pains." Trans activist professionals act as if there is a firm scientific consensus that it is safe and effective to treat gender dysphoria by using GnRH analogues to suppress normal puberty indefinitely. But this is far from the reality, as I, together with Mayer and McHugh, have pointed out: ***"Whether puberty suppression is safe and effective when used for gender dysphoria remains unclear and unsupported by rigorous scientific evidence."*** Thus, is not generally accepted by the relevant scientific community. Instead of regarding puberty blocking as a "prudent and scientifically proven treatment option," courts of law, parents, and the medical community ***should view it as a "drastic and experimental measure.***"

(See, Hruz, Mayer, and McHugh, 2017) The use of any **experimental medical treatment on children** calls for "especially intense scrutiny, since children cannot provide proper legal consent to experimental medical treatments — especially treatments that may **harm natural gender processes and produce sterility**. The rapid acceptance of puberty suppression as a treatment for gender dysphoria with little scientific support or scrutiny should raise concerns about the welfare of the children who receive such treatments. In particular, we should question the claim that it is both physiologically and psychologically "reversible." This includes the alteration of a temporally dependent developmental process. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty (See, Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36.) See, also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123. ; See also, Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, *Social Cognitive and Affective Neuroscience*, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030

64. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE: The controversies regarding the risks and potential dangers of the transgender industry cannot be silenced by "cancel culture". As Steven Levine, MD of Case Western has noted, "Among psychiatrists and psychotherapists who practice in the area, ***there are currently widely varying views*** concerning both the causes of, and appropriate therapeutic responses to, gender dysphoria in children. Dr Levine went on to state, "***Existing***

studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals." Although political advocates have asserted that the "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals, many respected academics and providers in the field strongly disagree. For example, J. Cantor, Ph.D. (McGill) published the following opinion in 2019, "almost all clinics and professional associations in the world" do NOT use "gender affirmation" for prepubescent children and instead "delay any transitions until after the onset of puberty." See, "J. Cantor (2019), Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, J. of Sex& Marital Therapy, 1, DOI: 10.1080.0092623X.2019.1698481.

65. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – NOTE THE ATTACKS ON DR RYAN's BOOK:

In the midst of this ongoing international, raging controversy, transgender and allied political activists have attempted to silence open public debate on the risks and benefits of transgender medical procedures and political ideologies. For example, Ryan Anderson, Ph.D. a policy analyst wrote a book analyzing the scientific and policy issues involved in assessing the risks and benefits of the current practices of the Transgender Treatment Industry. See, Anderson, R., *When Harry Became Sally: Responding to the Transgender Moment*, Encounter Books. Despite widespread scientific interest and positive reviews, the book was banned from sale by the Amazon Corporation. Too many lives are at stake for such blatant suppression of open scientific discussion. Several positive reviews of Dr Ryan's book were posted by ***notable members of the relevant scientific-ethical community*** including: Paul McHugh, MD, University Distinguished Professor of Psychiatry, Johns Hopkins University School of Medicine. (Dr McHugh was trained

at Harvard College and Harvard Medical School. He served as the Chairman of Psychiatry at Johns Hopkins Medical School for decades) and Melissa Moschella, PhD, who served at Columbia University as Director of the Center for Biomedical Ethics in the Department of Medicine and currently at The Catholic University of America. (Dr. Moschella was trained at Harvard College and her PhD is from Princeton University) and Maureen Condic, Associate Professor of Neurobiology and Adjunct Professor of Pediatrics, University of Utah Medical School. (Dr. Condic's training includes a B.A. from the University of Chicago, and a Ph.D. from the University of California, Berkeley) and John Finnes, Ph.D., Professor of Law at Oxford University for 40 years, now Emeritus. (LL.B. from Adelaide University (Australia) and Ph.D. in 1965 from Oxford University as a Rhodes Scholar at University College Oxford.)

International experts from a variety of relevant science - legal - ethical fields consider the issue of proper and harmful transgender treatments ***to be a serious controversy that must not be silenced***. Other scholars in this contentious field have been threatened and/or silenced by the political and ideological allies of the Gender Transition Industry. Consider, for example, the case of Alan Josephson, MD, a distinguished psychiatrist. In the fall of 2017 Dr Josephson appeared on an off campus panel symposium — not affiliated with his university — at the Heritage Foundation and shared his scientific, professional opinions on the experimental medicalization of gender dysphoric youth. The university responded by demoting him and then effectively firing him. Professor Josephson has filed a federal lawsuit to protect this academic rights to free speech. (See, Josephson v. Bendapudi, filed in the U.S. District Court for the Western District of Kentucky). The ongoing attempts to ban books and aggressively silence academic debate or "cancel" professionals with alternative views are clear demonstrations of the ongoing and intense controversies surrounding the Gender Transition Industry. See, Kearns, M., Gender Dissenter Gets

Fired, Jan 12, 2019. "Allan M. Josephson is a distinguished psychiatrist who, since 2003, has transformed the division of child and adolescent psychiatry and psychology at the University of Louisville from a struggling department to a nationally acclaimed program. In the fall of 2017 he appeared on a panel at the Heritage Foundation and shared his professional opinion on the medicalization of gender-confused youth. The university responded by demoting him and then effectively firing him.". Theories in the midst of an international firestorm of controversy are clearly not "generally accepted" by the relevant scientific community.

66. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – E.G., ATTACKS ON DR LITTMAN's RESEARCH:

Consider also the example of Dr. Lisa Littman at Brown University. Lisa Littman, M.D., MPA was a researcher at Brown University Medical School. Dr. Littman conducted extensive surveys to assess the experiences of parents involved in an online community for parents of transgender children or "gender skeptical" parents and children. There were 256 completed surveys. Their children were mostly adolescents or young adults. The parents reported that about 80 percent of their (mostly adolescent) children announced their transgender identity "out of the blue" without the long-term history generally associated with gender dysphoria. The parents also reported that transgender identity was linked with mental health issues (an often repeated, reliable finding in multiple studies from multiple nations). The parents also reported that their children's mental health worsened after they came out as transgender as did relationships with family members. The parents also reported a ***decline*** in the children's social adjustment after the announcement (e.g. more isolation, more distrust of non-transgender information sources, etc.).

The publication of the Littman paper was greeted by the outrage of trans activists who denounced the paper and Dr. Littman, calling it "hate speech and transphobic". Brown University had initially produced a press release for the paper stating the Littman research provided bold new insights into transgender issues. Once the political attacks began, the university, removed it from their announcements. Fortunately, in this case, there was also a counter-outcry from scientists, decrying Brown University and the political activists for threatening academic freedom and censoring scientific research that might assist in the treatment of gender dysphoria.

There was also reportedly an academic petition signed by members of the relevant scientific community. For example, Lee Jussim, PhD., Chair of the Psychology Department at Rutgers University wrote, "If the Littman study is wrong, let someone produce evidence that it is wrong. Until that time, if the research p*sses some people off, who cares? Galileo and Darwin p*ssed people off too. Brown University should be ashamed of itself for caving to sociopolitical pressure. Science denial, anyone?" Similarly, Richard B. Krueger, MD (a Harvard Medical School graduate) of Columbia University College of Physicians and Surgeons, board certified psychiatrist specializing in the treatment of sexual disorders wrote, "Brown University's actions in its failure to support Dr. Littman's peer reviewed research are abhorrent". Similarly, Nicholas Wolfinger, PhD (UC Berkeley, UCLA), currently Professor of Family and Consumer Studies at the University of Utah wrote: "The well-being of trans youth and other sexual minorities is best served by more research, not less".

The onslaught of attacks resulted in the journal asking Dr. Littman to publish a "corrected" version of the paper. After careful review, the paper was again published with additional information but no methodological nor data corrections – as no such errors were found. See, https://www.psychologytoday.com/us/blog/rabble-rouser/201903/rapid-onset-gender-dysphoria.

See also, Littman, L. , Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, PLOS ONE March 19, 2019, https://doi.org/10.1371/journal.pone.0214157. Dr. Littman's paper was a key initial step in the alternative investigative hypothesis that the very recent and enormous increase in teenage girls seeking "gender transitioning" is due to a social contagion process at school, in peer groups, and on the internet. This theory has yet to be tested in detail.

67. UNDERLYING PATIENT BIOLOGY IS NOT CHANGED BY ALTERING BODILY FEATURES TO "PASS" AS THE OPPOSITE SEX NOR DO SUCH ALTERATIONS CHANGE BIOLOGICAL DISEASE VULNERABILITIES ASSOCIATED WITH GENETICALLY-DEFINED SEX: Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. (See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.) For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the individual with sex-discordant gender identity to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I

detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

68. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ONE OF THE MOST CONTROVERSIAL AND CONTENTIOUS ISSUES IN TRANSGENDER SCIENCE IS THE RECENT EPIDEMIC OF ADOLESCENT FEMALE TO MALE GENDER DISCORDANT PATIENTS:

How prevalent is the Sudden Onset Gender Dysphoria Epidemic in Teen Girls first described by the research of Dr Littman at Brown University?

In Great Britain, centralized medical care provides data to track health care phenomenon ... *the number of adolescent girls seeking sex transitioning exploded over FOUR THOUSAND 4,000% in the last decade.* Similarly, in America, where we lack the same kinds of centralized health care data, it has been reported that in 2018 2% (2 in 100) of high school students identified on surveys as "transgender" — this is 200 times greater response — a 20,000% increase — over reports during past decades which showed a rate of only .01 percent (one in 10,000 people). See, Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019;68:67–71.

Along with this increase in transgender patients and identifiers, has come ***a radical and recent transformation of the patient population*** from early onset males to rapid onset adolescent girls. Thus currently the majority of new patients with sex-gender discordance are not males with

a long, stable history of gender dysphoria since early childhood —as they were for decades — but instead adolescent females with no documented long-term history of gender dysphoria — thus they experienced "rapid onset" transgender identification. Whole groups of female friends in colleges, high schools, and even middle schools across the country are reportedly coming out together in peer group clusters as "transgender." These are girls who — by detailed parental reports and self-reports — had never experienced any discomfort in their biological sex until they heard a coming-out story from a speaker at a school assembly or discovered the internet (YouTube) community of trans "influencer video stars."

This extraordinary change in new patient demographics appears more consistent with a theory of social contagion than of "immutable identification", "brain structures", "genetics", or other biological hypotheses. Many unsuspecting parents, whose children have never shown any signs for gender discordant feelings or ideas, are awakening to find their daughters in thrall to hip trans YouTube stars and "gender-affirming" educators and activist therapists who push life-changing interventions on these young girls—including double mastectomies and hormonal puberty blockers that can potentially cause permanent infertility. See, Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

69. EXPLORING ALTERNATIVE HYPOTHESES: WHY ARE WE SEEING A RAPID RISE OF ADOLESCENT FEMALE TRANS IDENTITY PATIENTS… often in social clusters?

Generating, Considering, and Testing Alternative Theories prevents the Methodological Error of Confirmation Bias:

We should consider the genetics theory of transgender identity. But his theory cannot explain the rapid expansion of new GD (an 4,000% to 20,000% increase?) cases as our genome is simply not changing that fast.

We should consider the "brain structures" theory of transgender identity. Yet there is only weak medical evidence to support this theory and the theory cannot explain the rapid expansion of new gender dysphoria cases as brain structures are not changing that fast.

We should consider the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why *males and older women are not coming out in the same huge numbers* and not coming out in "social peer group clusters" as adolescent females are reportedly doing.

We should consider the "immutable gender identity" theory. Yet this theory fails to explain the rapid expansion of patients. In addition, the "immutable" theory fails to explain the rapid expansion of "Rapid Onset Gender Dysphoria" reports — newly "trans" adolescent girl patients who reportedly showed no indication of gender dysphoria previously.

Having considered alternative theories -- to avoid confirmation bias – it appears that another alternative theory might well be the most applicable, rational theory to explain the extreme, recent increases in the GD patient population. This is the Social Contagion hypothesis. Social contagion effects are also reportedly responsible for the massive, rapid increase in "recovered repressed memory" cases and also the extraordinary expansion of "multiple personality disorder" cases in the 1990s. I also note the alternative investigative hypothesis that ***social contagion effects would appear to be psychological/psychiatric problems and NOT physical medical problems requiring hormonal or surgical "treatments"***.

70. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ADOLESCENT FEMALE PSYCHOLOGY RESEARCH SHOWS WELL-DOCUMENTED PEER INFLUENCES on ANOREXIA, BULIMIA, DRUG ABUSE, and now GENDER DISCORDANT ("TRANSGENDER") SYMPTOMS:

The Social Contagion theory for the large increase in reported Rapid Onset Gender Dysphoria in adolescent girls appears to be the most rational explanation for the reportedly dramatic (rapid, media related, hundreds of times increase, YouTube influenced, Peer Group influenced) explosion of Gender Discordant ("transgender") patients among adolescent female friend groups.

Adolescent female social contagion effects in psychiatric illness are well-known and well documented. Consider, for example, Bulimia and Anorexia — both of which spread rapidly in adolescent female friend groups. See, Allison S, Warin M, Bastiampillai T. Anorexia nervosa and social contagion: clinical implications. Aust N Z J Psychiatry. 2014 Feb;48(2):116-20. doi: 10.1177/0004867413502092. Epub 2013 Aug 22. PMID: 23969627.

It has been known for decades that adolescent females are highly prone to social contagion effects spreading psychiatric symptoms — e.g. Anorexia, Bulimia, Drug Abuse, etc) are well known to be subject to "cluster" and "friendship" contagions as teens girls (and especially troubled teen girls) co-ruminate and share feelings at very high rates and with emotional depth. See, e.g., Crandall CS. Social contagion of binge eating. J Pers Soc Psychol. 1988 Oct;55(4):588-98. doi: 10.1037//0022-3514.55.4.588. PMID: 3193348.

For example, Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls show such susceptibility to social contagion with psychiatric symptoms — "Teenage girls share symptoms via social contagions because their friendship

processes involve "co-rumination", that is, taking on the emotional pain and concerns of their friends." See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths 'Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Developmental Psychology, Vol. 48, No. 5, 1355–1365 0012-1649/12/$12.00 DOI: 10.1037/a0027484. This could be one explanation for why we are hearing increasing reports of" clusters" and "friend groups" of teen girls who are adopting a "transgender identity" and "transitioning" as friends together.

71. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: SCHOOL ENVIRONMENT SOCIAL CONTAGION: Observers including journalists have reported that schools in America — 1st grade through College — during the past few years have been aggressively teaching that a "non-binary" identity is the real "norm" and far better than traditional gender roles. Such school programs present Male and Female roles in a very rigid, highly stereotyped manner then teach children (even 1st graders) that if they do or feel anything different than narrow binary sex roles (girls enjoying football, boys enjoying art) they are surely "non-binary" and should receive much social support, reinforcement, and encouragement for "transitioning".

The rapid and historic transformation of the Gender Transition Industry patient pool has been widely noted by researchers, journalists, and providers. This transformation from early onset, chronically dysphoric male patients to rapid onset adolescent female patients has occurred in just the last few years. The patient transformation from 3 to 1 males (for decades) to 7 to 1 females (just in the last few years) is not easily explained by any of the Gender Transition Industry theories such as "genetics" or "brain structures" or the mysterious and tautalogical "immutable characteristics" theory. It has been reported that during this enormous increase in "Rapid Onset

Gender Dysphoria" a growing set of YouTube Transgender "influencers" teach and entertain millions of followers daily as they aggressively sell gender transitioning as a quick and effective cure for Depression, Anxiety, Loneliness, and confusion about life.

For example, journalist Abigail Shrier's book, *Irreversible Damage* about the social contagion theory of why patient demographics changed so very rapidly and expansively. Shrier's book was reportedly named a "Book of the Year" by The Economist and "one the Best Books of 2021" by The Times (of London) and The Sunday Times (of London). Many famed scientists of various fields have praised Shrier's work in highlighting A) the lack of competent scientific research supporting "gender affirmation" interventions and B) the political contamination including censorship and "cancel culture" attacks on academics that make gender affirmation investigation ("transgender science") such a controversial field. For example, several highly credible and deeply respected members of the relevant scientific and public policy-ethics communities have reportedly posted positive reviews of Shrier's analysis on the Amazon bookseller site including:

"In *Irreversible Damage*, Abigail Shrier provides a thought-provoking examination of a new clinical phenomenon mainly affecting adolescent females—what some have termed rapid-onset gender dysphoria—that has, at lightning speed, swept across North America and parts of Western Europe and Scandinavia. In so doing, Shrier does not shy away from the politics that pervade the field of gender dysphoria. It is a book that will be of great interest to parents, the general public, and mental health clinicians."— Kenneth J. Zucker, Ph.D., adolescent and child psychologist, multi-publication scientist in this field, and *Chair* of the American Psychiatric Association DSM-5 Work Group on Sexual and Gender Identity Disorders.

Similarly, "Abigail Shrier's book is thoroughly researched and beautifully written." —**Ray Blanchard, Ph.D.,** head of Clinical Sexology Services at the Centre for Addiction and Mental Health from 1995–2010.

Similarly, "For no other topic have science and conventional wisdom changed—been thrown away—more rapidly than for gender dysphoria. For a small but rapidly growing number of adolescent girls and their families, consequences have been tragic. This urgently needed book is fascinating, wrenching, and wise. Unlike so many of the currently woke, Abigail Shrier sees clearly what is in front of our faces and is brave enough to name it. Irreversible Damage will be a rallying point to reversing the damage being done." —**J. Michael Bailey**, Ph.D. professor of psychology at Northwestern University. All quotes from the Amazon bookseller site at https://www.amazon.com/Irreversible-Damage-Transgender-Seducing-Daughters/dp/1684510317 These quotes are offered to demonstrate the breadth and depth and international scope of the raging controversies regarding the Transgender Treatment Industry.

72. THE SOCIAL CONTAGION HYPOTHESIS - IDENTITY POLITICAL IDEOLOGY PROVIDES SOCIAL SUPPORT REWARDS FOR ADOLESCENTS TO ADOPT A GENDER DISCORDANT IDENTIFY ("TRANSGENDER"): Journalists have reported, "In many high schools, there is an "identity politics" victims sweepstakes where white middle and upper middle class girls are simply left out of any coveted "oppressed victim" status groups — thus the decision to become "transgender" brings instant social support and acclaim from teachers and coaches for their courage in coming out." Nobody questions such personal transformation, even if the teen is deeply troubled, and even if the teen has no history of gender dysphoria. To even ask questions or explore alternative explanations could get the teacher, counselor, therapist, or physician labelled as a "conversion therapist" and cancelled.

73. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: "CANCEL CULTURE" and IDEOLOGICAL-POLITICAL PRESSURE SEEKS TO INSTITUTIONALIZE THE SYSTEMATIC NEGLIGENCE and METHODOLOGICAL ERROR OF CONFIRMATION BIAS: Because of the efforts of apparently science illiterate and/or gullible legal and medical professionals and the intense activity of political trans activists — health providers (in many fields) are now NOT permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of Gender Dysphoria patients. They are compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "transgender affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of Confirmation Bias. (See, detailed discussion above on confirmation bias.) Unexamined transgender affirming medical interventions — based on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories", with no alternative treatments offered, and no alternative explanations (social contagion) explored — may thus be viewed as engaged in medical, psychological, surgical, and endocrinological negligence and a violation of the most basic, essential scientific and medical practices and methods requiring the generation and testing of alternative hypotheses. In sum, such a politically tainted system actually requires "confirmation bias" — one of the most serious of all methodological diagnostic failures. See, e.g. Mendel, R. et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press, 20 May 2011. ["*Diagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions*. Experts assume that physicians' desire to confirm a preliminary diagnosis

while *failing to seek contradictory evidence* is an important reason for wrong diagnoses. *This tendency is called 'confirmation bias'.*]; See also, Doherty, T.S. and Carroll, A.E., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics, 2020;22(9):E773-778. ["Like all humans, *health professionals are subject to cognitive biases* that can render diagnoses and treatment decisions vulnerable to error. Learning effective debiasing strategies and cultivating awareness of confirmation, anchoring, and outcomes biases and the affect heuristic, among others, and their effects on clinical decision making *should be prioritized in all stages of medical education*…. ***Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them***….]; See also, Hershberger PJ, Part HM, Markert RJ, Cohen SM, Finger WW. Teaching awareness of cognitive bias in medical decision making. *Acad Med*. 1995;70(8):661.

74. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: GIVEN THE CURRENT LACK OF RELIABLE-VALID RESEARCH SUPPORT, IT IS A RECKLESS and EXPERIMENTAL INTERVENTION TO PERMIT CHILDREN TO ENGAGE IN SELF-DIAGNOSIS WHEN THE RESULTING "TREATMENTS" WILL LIKELY PRODUCE LIFE-LONG STERILIZATION and/or OTHER PERMANANT INJURIES TO NORMAL, HEALTHY ORGANS : In some jurisdictions in America now child or adolescent patients can — without parental permission or even parental notification -- receive hormones to begin the experimental treatment of "transitioning" with no competent diagnostic investigation or professional assessment of "Gender Dysphoria" and no competent medical investigation-testing-consideration of alternative hypotheses (there is no such reliable, objective assessment). Worst of all, providers can be coerced by law, collegial pressures, or "cancel culture" ideology to comply with the troubled child's/teen's/patient's amateur (potentially YouTube influenced) self-diagnosis or be faced with

potentially career ending allegations of "conversion therapy". Politically tainted, pseudo-science, experimental, unproven medical practices have caused grave harm to millions in the past (See the discussion of lobotomies, repressed memory therapy, multiple personality therapy, rebirthing therapy, etc above.) and unethical, politically driven, experimental medical errors should not be repeated today.

75. EXPERIMENTATION on SEX-GENDER DISCORDANT PATIENTS IS ESPECIALLY LIKELY TO CAUSE HARM TO MINORITY PATIENTS FROM HISTORICALLY MARGINALIZED COMMUNITIES — The development of effective strategies to impact long-term physical and psychological health in patients who experience sex-discordant gender identity should be undertaken with recognition of the disproportionate burden of this condition in a number of vulnerable minority populations of children. These include:

-- children with a prior history of psychiatric illness (See, e.g. Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y

-- children of color (See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.

-- children with mental developmental disabilities (See, e.g. Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* **28,** 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7

- children on the autistic spectrum (See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender

dysphoric children and adolescents. *J Autism Dev Disord* **40**, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

-- children residing in foster care homes and adopted children (See, e.g. See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

76. GENDER DYSPHORIA IS A VERY RARE PSYCHIATRIC CONDITION – THAT IS, RARE IN THAT IT IS TREATED WITH SURGERY THAT DAMAGES or DESTROYS WELL-FUNCTIONING, HEALTHY BODILY ORGANS LEADING TO LOSS OF ESSENTIAL BODILY FUNCTIONS (e.g. ***Medically Induced Sterilization***): Despite the fact that gender dysphoria represents a psychological condition (as catalogued in the DSM since the third edition of this publication), some conceptualize the condition as a medical illness similar to cancer. When considered from this viewpoint, the goal of "treatment" is to alter the appearance of the body to conform to a patient's perceived sexual identity, including the physical removal of unwanted "diseased" sexual organs. Since undesired body parts are fully formed and functional prior to hormonal or surgical intervention, the result of these "therapies" is injury to innate sexual ability. In particular, loss or alteration of primary sexual organs leads directly to impairment of reproductive potential. Recognition of this obvious consequence is the basis for the development of new arenas of medical practice where there is an attempt to restore what has been intentionally destroyed. See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: A Review. Mayo Clin Proc. 2020 Apr; 95(4):784-792. doi: 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195. As correctly noted by Levine, gender dysphoria is unique in that it is "the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified

biological abnormality". See, e.g., S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law, 44, 236 at 238 ("Reflections"), at 240.)

77. A MULTI-DISCIPLINARY, COMPLEX, DEVELOPMENTAL MODEL PROVIDES ESSENTIAL ALTERNATIVE HYPOTHESES TO THE SIMPLE, UNEXAMINED "AFFIRMATON" TRANSITIONING MODEL OF TRANS ACTIVIST PROFESSIONALS and the GENDER TRANSTION INDUSTRY: The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the etiologic contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition. Steven Levine, MD (Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine and Founder and Co-Director of the Case Western Reserve University Gender Identity Clinic) has described the developmental model — an alternative hypothesis of gender dysphoria conceptualization and treatment that is more in keeping with the known science and involves reduced costs and lowered risk of permanent physical harm (e.g., medically induced sterilization) to patients. Dr. Levine has written, "Gender dysphoria can be alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (See, e.g., S. Levine (2016),

Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238). Mental Health Professionals (MHPs) who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play." (See, Expert Report by Steven Levine, MD). A recent study documented "clustering" of new presentations in specific schools and among specific friend (peer) groups, pointing to social influences (See, the Littman study at Brown University discussed above). Both of these findings strongly suggest cultural factors. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, ***where the patient sex ratios were reversed*** as compared to North America and Europe, again demonstrating ***a powerful effect of cultural influences (e.g. social contagion)***. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ; S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy Psychiatry and Law, 44, 236 at 238.

78. NO COMPETENT, SCIENTIFICALLY VALID-RELIABLE COST-BENEFIT ANALYSIS HAS BEEN DONE ON GENDER DISCORDANT "TRANSGENDER" TREATMENTS — When the FDA tests a drug, the safety analysis looks at all related risks. Specifically, the drug (treatment) must not only be effective, but it must not cause side effects that are more damaging than the proposed treatment. This is one of the key weaknesses of the Gender

Transition Industry. Not only have the treatments NOT been proven reliably effective compared in NO treatment, but the "transgender transitioning" interventions "treatments" are *DESIGNED with existing knowledge of well-documented, long-term health problems and damages* (e.g., testosterone use by transgender men increases the risk of fatal heart disease, estrogen use by transgender women increases risk of blood clots and strokes, Gender Transition Industry treatments — if completed — can cause life-long sterility, etc.).

79. LACK OF INTEGRATION OF CARE BY PROVIDERS IN THE GENDER TRANSITION INDUSTRY INCREASES DANGERS TO PATIENTS: It is too often the case in the Gender Transition Industry that "nobody is in charge" of a patient's care. The mental health professionals know little about the risks of surgery and the surgeons know little about the defects in mental health methodologies and the endocrinologists are only following the hormonal treatments and many are not aware of the serious methodological research defects in this field. Such disjointed care can increase dangers to patients. On cases showing such a lack of integration and uncertain chain of command in Gender Transition Industry healthcare cases, reliable measurements of the divergent, multi-disciplinary risks to patients of Gender Transition Industry treatments (e.g. hormones, incomplete therapy, or surgical side effects) are precluded and too often ignored. The Plaintiffs' expert witness reports in this case appear to ignore this issue.

80. ADDITIONAL OPINIONS TO BE DISCUSSED AT DEPOSITION OR TRIAL: There are additional relevant data and important considerations regarding existing understanding of the role of physicians and other healthcare workers in alleviating suffering in patients who experience gender dysphoria due to sex-gender identity discordance that are not fully discussed in this report. This includes:

-- the inherent complexity of human psychological and physical development from birth to adulthood

-- the relationship and differences between puberty and adolescence

-- the molecular mechanisms of steroid hormone action in regulating cellular gene expression

-- the physiology of sexual function including the hypothalamic-pituitary-gonadal axis in males and females and diseases that are associated with dysfunction of these processes

-- the expansive and growing field of sex-specific personalized medicine in relation to human health

-- the historical development and use of the scientific method (e.g. principles of hypothesis generation, testing of the null hypothesis, fundamentals of statistical analyses, differences between statistical and clinical significance)

-- the design and conduct of human clinical trials

-- the proper role of institutional review boards in the approval and supervision of clinical trials to mitigate risk

-- the National Institutes of Health (NIH) processes for establishment of research priorities (e.g. research funding announcements), procedures for scientists to apply for grant funding, peer review of research proposals, requirements for examining sex as a biological variable, safety monitoring, and requirements for sharing study results

-- the process for gaining FDA approval for new medications and new medical indications for existing medications including objective assessment of relative risk versus benefit as demonstrated from properly controlled clinical trials

These topics will be discussed, as needed, at deposition and trial to provide the court with the necessary scientific and medical information for proper litigation of this case.

81. NOTES: GENDER TRANSITION RESEARCH SHOWING METHODOLOGICAL DEFECTS, ERRORS, and the UNETHICAL MISREPORTING OF RESULTS.

In sum, THE GENDER TRANSITION INDUSTRY APPEARS TO HAVE IMPLODED IN RECENT YEARS as the relevant scientific community exposed the serious methodological and ethical errors in this highly controversial industry.

DR HRUZ's NOTES ON RESEARCH EVALUATIONS and METHODOLOGICAL ANALYSES:

TIMELINE NOTES DOCUMENT THE LOW QUALITY EVIDENCE FOR THE GENDER TRANSITION INDUSTRY'S EXPERIMENTAL TREATMENTS FOR DECADES FOLLOWED BY THE PUBLIC EXPOSURE of DEFECTS and MISCONDUCT and IMPLOSION OF THE GENDER TRANSITION INDUSTRY IN 2020-2021:

2016 - OLSON-KENNEDY ET AL - "CLINICALLY USEFUL TO PREDICT OUTCOMES IS LACKING" … "EXTENSIVE RESEARCH IS NEEDED" … GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH ARE BEING EXPOSED **See,** GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH HAVE BEEN EXPOSED IN PUBLIC VENUES - Olson-Kennedy, J, et. al. listed a number of the serious defects in our current understanding of transgender patients. She noted:

—" ***Clinically useful information for predicting individual psychosexual development pathways is lacking.***" [Note: We can't predict outcomes because we don't understand the processes — thus "affirming" treatments are experimental].

— "Transgender youth are at high risk for poor medical and psychosocial outcomes." [Note: But we don't know why] …

— "Longitudinal data examining the impact of early social transition and medical interventions ***are sparse.***" [Note: Thus we don't know how to treat such patients.]

— "Existing tools to understand gender identity and quantify gender dysphoria ***need to be reconfigured*** to study a more diverse cohort of transgender individuals." [Note: For decades patients were uniformly males with early childhood onset, now most new patients are females with rapid onset in adolescence —are these even the same patient groups?].

Shared goals ***requiring much more research***: "Extensive research is needed to improve understanding of gender dysphoria, and transgender experience, particularly among youth. Recommendations include identification of predictors of persistence of gender dysphoria from childhood into adolescence [**the key research hasn't been done yet**], and a thorough investigation into the impact of interventions for transgender youth. **[the key research hasn't been done yet]** Finally, *examining the social environments of transgender youth is critical for the development of appropriate interventions necessary to improve the lives of transgender people*. [This kind of multi-disciplinary research, analysis of alternative hypotheses, and treatments for concomitant psychiatric-psychological symptoms is being tragically mislabeled and blocked as "conversion therapy" by political advocates.]

See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236 [Note: Should compare once again the demonstrated ***lack of***

methodologically sound scientific support for the still-experimental gender affirmation "trans" interventions and the many unresearched missing questions in our understanding of these complex patients to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2016 - See, **Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58–69**.) **Activists and too many providers have used a fear of suicide *to push experimental unproven treatments*.** Activists and too many providers have attempted to manipulate parents and patients with the fearful maxim 'better a live daughter than a dead son'. In addition, parents, teachers and doctors are encouraged to affirm unquestioningly the alternative gender for fear of the implied consequences. ***There is a danger that poor-quality data are being used to support gender affirmation and transition without the strength of evidence that would normally determine pathways of care. A 20-year Swedish longitudinal cohort study showed persisting high levels of psychiatric morbidity, suicidal acts and completed suicide many years AFTER medical transition*.** **(**See also, Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. Scott J, editor. **) PLoS ONE 2011; 6(2): e16885.** "***Such results are not reassuring*** and might suggest that more complex (untreated) intrapsychic conflicts remain, unresolved by living as the opposite sex."

2017 - LONG TERM STUDIES OF GENDER TRANSITION TREATMENT EFFECTS SHOW PERSISTENT PSYCHOLOGICAL-PSYCHIATRIC MORBIDITY INCLUDING ***HIGHER RISK OF SERIOUS SUICIDE ATTEMPTS*** AFTER TRANSITIONING TREATMENTS: Evidence often cited to support societal measures that promote or encourage gender transition, including the Plaintiffs' demand for use of multi-user sex-segregated restrooms corresponding with the Plaintiffs' gender identity, as a medically necessary treatment for gender dysphoria is limited. Recent studies reporting reductions in dysphoria following social transition of adolescent patients are small, poorly controlled and of insufficient duration to draw definitive conclusions regarding long-term efficacy. ***Long-term follow up of patients with gender dysphoria who have undergone social and hormonal transition with or without surgical intervention has shown persistent psychological morbidity far above non-transgendered individuals with suicide attempts 7-fold and completed suicides19-fold above the general population – AFTER "transition" interventions***. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term Follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

2019 — SWEDEN NATIONAL REVIEW = GENDER AFFIRMATION STILL EXPERIMENTAL = NO RANDOMIZED TRIALS: results. See, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e **)**

SWEDISH REVIEW —"*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."*

"This report was commissioned by the Swedish government and is a scoping review of the literature on gender dysphoria in children and adolescents. The report can be a basis for further evaluation of risk of bias and evidence.

Conclusions:

— We have *not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria*

— We have *not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria*.

— There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.

— *Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium*.

— The scientific activity in the field seems high. A large part of the identified studies are published during 2018 and 2019.

— Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. *No relevant randomized controlled trials in children and adolescents were found.*

We have not found any composed national information from Sweden on: – the proportion of those who seek health care for gender dysphoria that get a formal diagnosis NOR – the proportion starting endocrine treatment to delay puberty NOR – the proportion starting gender affirming hormonal treatment NOR – the proportion subjected to different gender affirming surgery."

2016-2017 London GIDS Study
NO *evidence that hormones or surgery improve long-term psychological well-being*.
See, "GIDS referrals figures for 2016/17, Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content_uploads/referral-figures-2016-17.pdf

2017 - ENDOCRINE SOCIETY REVIEWS - ONLY *WEAK EVIDENCE* SUPPORTS GENDER TRANSITION INTERVENTIONS: Two systematic reviews commissioned by the US-based Endocrine Society in 2009 and 2017 concur with the finding of a ***the weak evidence base***, stating that ***the finding of benefits of hormonal interventions in terms of "psychological functioning and overall quality of life" comes from "low-quality evidence*** (i.e., which translates into ***low confidence in the balance of risk and benefits***)."

MISCONDUCT by the Endocrine Society: Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines, which have now been broadly adopted by a number of medical societies. See, Transgender Health: An Endocrine Society Position Statement. December 15, 2020. Accessed January 6, 2021.https://www.endocrine.org/advocacy/position-statements/transgender-health

2017 - GENDER TRANSITION INTERVENTIONS REMAIN *EXPERIMENTAL* = The Society for Science Based Gender Medicine (SEGM)'s review, ***the "low confidence in the balance of risks and benefits" of hormonal interventions calls for extreme caution*** when working with gender-dysphoric youth, who are in the midst of a developmentally-appropriate phase of identity exploration and consolidation. While there may be short-term psychological benefits associated with the administration of hormonal interventions to youth, they must be weighed against the long-term risks to bone health, fertility, and other as yet-unknown risks of life-long hormonal supplementation.

Further, the irreversible nature of the effects of cross-sex hormones, and the potential for puberty blockers to alter the natural course of identity formation should give pause to all ethical clinicians. Studies consistently show that ***the vast majority of patients with childhood-onset gender distress who are not treated with "gender-affirmative" social transition or medical interventions grow up to be LGB adults.*** However, there is emerging evidence that socially-transitioned and puberty-suppressed children have much higher rates of persistence of transgender identification, necessitating future invasive and risky treatments. The trajectory of the novel, and currently the most common presentation of gender dysphoria, which emerges for the first time in adolescence following a gender-normative childhood is unknown, but the increasing voices of desisters and detransitioners suggest the rate of regret within this novel cohort will not be as rare as previously estimated.

It is The Society for Science Based Gender Medicine (SEGM)'s position that the significant uncertainties regarding the long-term risk/benefit profile of "gender-affirmative" hormonal

interventions call for noninvasive approaches (e.g. psychotherapy, social support, coping and resilience training, etc) as the first line of treatment for youth. If pursued, invasive and potentially irreversible interventions for youth ***should only be administered in clinical trial settings with rigorous study designs capable of determining whether these interventions are beneficial***.

In addition to undergoing ***rigorous psychological and psychiatric evaluations***, patients and their families should participate in a ***valid informed consent process.*** The latter must accurately disclose the limited prognostic ability of the gender dysphoria/gender incongruence diagnosis for young people, and ***the many uncertainties regarding the long-term mental and physical health outcomes of these poorly studied and largely experimental interventions***.

See, Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643

2017 Misleading, politically motivated-tainted Cornell University website's alleged "systematic literature review" was actually a form of misleading consumer manipulation. See, Anonymous. Cornell University, Public Policy Research Portal. "What does the scholarly research say about the effect of gender transition on transgender well-being?" Available: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/ [accessed 20 November 2019] The relevant scientific community reacted to expose misinformation in the Cornell "Review".

See, Horvath, Hacsi. (2020). ***Activist-driven transgender research methods are reckless and will lead to harms***. 10.13140/RG.2.2.22455.55206. "In 2017, anonymous authors at Cornell University produced a document titled "What does the scholarly research say about the effect of gender transition on transgender well-being?". This document purports to be a "systematic literature review." In reality, it is simply a piece of "junk science", political propaganda, created by activists…. Horvath employed two instruments commonly used to assess the quality of systematic reviews. See, Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008; and also Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097). ["The Cornell document fared poorly under examination with the AMSTAR 2 instrument. All questions answered with "No" or "Not reported" would optimally have been answered with 'Yes.' This review's methods appear to have been grossly inadequate.". The authors of the Cornell review failed to meet nearly every criterion of the PRISMA checklist. All items denoted as "Not done" would optimally have been answered 4 with "Done." Reporting of this review's methods and findings was very sloppy. Indeed, the review could hardly have been reported with less rigor].***Conclusions: The so-called "systematic literature review" produced at Cornell was nothing of the kind. Thus the "Findings" of this document should be ignored."***

The public should be warned regarding this kind of material misrepresentation of potentially dangerous, experimental treatments of vulnerable patients.

2018 AMSTERDAM RESEARCH DEBACLE : Deceptive Claims and Research Errors in the 2018 Amsterdam Cohort Study Debacle of (2018) See, Wiepjes CM, Nota NM, de Blok CJ, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. The Journal of Sexual Medicine 2018; 15(4): 582-90.

These authors deceptively claimed: "The percentage of people who regretted gonadectomy remained small and did not show a tendency to increase."

Noting research limitations, errors, and/or deceptions:

— "***Not all data were available*** from the hospital registries, particularly older data or surgeries performed in other centers" (p.590)

— "A large number of transgender people…**were lost to follow-up**. Although transgender people receive lifelong care, ***a large group (36%) did not return to our clinic*** after several years of treatment" (page 589). (**How many were suicides or detransitioning? The researchers did not assess and thus cannot report.**)

— The "Regret" measure used was only tabulated for those who had gonadectomies and ALSO then requested hormone therapy consistent with biological sex "**and ALSO** expressed regret" (p.584); they also apparently ***improperly excluded any patient who died*** (are they hiding suicides?) (p.584)

— No uniform statistics were used to measure average follow-up time and variance = a **research error increasing the unreliability of the data**.

Admitted ***average time to regretting engaging in "transition" interventions was 130 months (10+ YEARS)***. Page 589 admission: "…it ***might be too early to examine regret rates in people who started with HT within the past 10 years."*** Many patients counted as "non-regret" are thus LIKELY to express REGRET beyond the study cut-off date. **Misreporting results in this manner is another unreliable research error indicative of deception or negligence**.

2018 - The Endocrine Society guidelines were published prior to the implosion of the Gender Transition Industry. These guidelines are already outdated and based on assumptions since demonstrated to be false (See, e.g. the recent Cochrane, British N.I.C.E. review, Swedish review, Finnish review, Turban's debunked studies, and the Branstrom Debacle debunked research). **None of the recent exposes of massive errors and/or misconduct in transgender medicine research field was known at the time of the Endocrine Society guidelines of 2009 and 2018.**

See, THE ENDOCRINE SOCIETY (ES) position(s) on the claims of the Gender Transition Industry is ***a political consensus-seeking process (voting)— not an evidence-seeking scientific research process*** — and should be reviewed with care. The Endocrine Society clearly states that its practice guidelines "cannot guarantee any specific outcome, nor do they establish a standard of care".

The 2009 ES guidelines noted the low quality (unreliable, invalid) of evidence in this field. E.g. "Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

See, Wylie C. Hembree, Peggy Cohen-Kettenis, Henriette A. Delemarre-van de Waal, Louis J. Gooren, Walter J. Meyer III, Norman P. Spack, Vin Tangpricha, and Victor M. Montori*Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, J Clin Endocrinol Metab. September 2009, 94(9):3132–3154. doi: 10.1210/jc.2009-0345.

First Corrected version: See, Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699]

Second corrected version: 2018 published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

2019 TAVISTOCK DEBACLE — Professor Michael Biggs of Oxford - THE AFFIRMATION DRUGS ARE EXPERIMENTAL TREATMENTS - AFTER TREATMENT PATIENTS REPORTED *GREATER* SELF-HARM, *MORE* BEHAVIORAL and EMOTIONAL PROBLEMS and *GREATER* DISSATISFACTION WITH THEIR BODY…

Regarding the UK's Tavistock and Portman NHS Trust's Gender Identity Development Service's ***experimental trial*** of puberty blockers for early teenagers with gender dysphoria. Oxford's Professor Michael Biggs wrote, "To summarize, GIDS launched a study to ***administer experimental drugs to children suffering from gender dysphoria.***" "After a year on GnRHa [puberty blockers] ***children reported greater self-harm***, and ***girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria***." (See,

Michael Biggs, "Tavistock's Experimentation with Puberty Blockers: Scrutinizing the Evidence," TransgenderTrend.com, March 5, 2019.)

2019 - IN GREAT BRITAIN, METHODOLOGICAL AND ETHICAL DEFECTS IN GENDER DISCORDANT "TRANSGENDER" RESEARCH and PRACTICES HAVE BEEN PUBLICLY EXPOSED, See, e.g. , The British Gids Clinic Controversies:

This reports noted below support my ongoing investigative hypothesis that the Gender Transition Industry is engaged in systemic, negligent, and/or unethical efforts to distribute misleading and/or incomplete information to patients, the scientific community, and the public. The Gender Transition Industry's systemic efforts appear to include multiple methods of deceptive misreporting including A) a failure to properly design research to search for key evidence, B) a misleading failure to properly report key evidence and methodological limitations and/or C) the improper minimizing of key evidence. The documented failures of the Gender Transition Industry with regard to informed consent, failures of scientific methodology, and the use of experimental treatments on unsuspecting patients-families appear to involve violations of standards of care and ethical requirements.]

E.G. : THE BBC REPORT of 2019: See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

"In 2019, England's only NHS youth gender clinic (Gids) lowered the age at which it offered children puberty blockers, partly based on research showing A) ***an increase in suicide risk following treatment*** and B) that virtually all young people who took the puberty blocker hormones went on to take cross-sex hormones (while ***80% or so of untreated children naturally grow out of their "gender dysphoria" phase by adulthood and accept their biological, natal gender***).

"Experts on clinical trials have criticized the design of the study, which they say makes it hard to tell if the reported effects were due to the puberty blockers or something else. But experts said they warranted further investigation."

[NOTE: An alternative hypotheses under investigation: Are the unusual methodological errors reported for Gender Transition Industry practices, research, and treatments the result of gross negligence, politically tainted pseudoscience, or something else?]

"Before 2011, the Gender Clinic (Gids) would give puberty blockers to children only once they had turned 16…. And in 2011, a medical study was approved through which younger children could access these drugs. "***Acknowledging the weak evidence for the use of these drugs (hormones),*** the research team, made up of Gids and University College Hospitals staff, set out to "evaluate the psychological, social and physical effects" of the blockers on a carefully selected group of young people.

Details about risks - such as potential adverse effects on bone strength, the development of sexual organs, body shape or final adult height - were provided in a patient information sheet. But ***BBC Newsnight found certain information had not been included*** . Previous research had suggested all young people who took the blockers went on to take cross-sex hormones - the next stage towards fully transitioning to the opposite gender. "But patients and parents were ***not*** told this in the information sheet." [***Note: This report appears to document a serious informed consent violation.]***

[NOTE: Are the unusual methodological-ethical errors reported for Gender Transition Industry practices and treatments the result of gross negligence, politically tainted pseudoscience, or something else?]

"I don't see that the parents and their children could really have given informed consent given the lack of information that was provided," said Michael Biggs, associate professor of sociology at Oxford University. Prof Biggs… added : "***They were not given the information they needed in order to take this momentous life-changing step***." He gave BBC Newsnight a series of documents relating to the research study he had obtained via freedom of information requests, which were independently looked at.

[NOTE: Such reported failures of informed consent, defects in methodology, and ***the use of experimental treatments on unsuspecting patients-families*** appear to be serious violations of ethical, practice, and/or licensing rules.]

Preliminary data for 30 of the 44 young people on the study was made available to the Tavistock's board in 2015. **It showed** that ***after*** a year on puberty blockers, ***there was a significant increase found in those answering the statement "I deliberately try to hurt or kill myself".*** See, Tavistock and Portman Foundation NHS Trust. Preliminary results from the early intervention research. In Tavistock and Portman Foundation NHS Trust, Board of Directors Part One: Agenda and Papers: Appendix 7; 50–55. Tavistock and Portman Foundation NHS Trust, June 2015 (https:// tavistockandportman.nhs.uk/about-us/governance/board-of-directors/ meetings/).

"Prof Susan Bewley (Emeritus Honorary Professor, King's College London Department of Obstetrics & Women's Health), who chairs Healthwatch, a charity for science and integrity in healthcare, ***is one of a number of doctors raising concerns about the lack of evidence in this area of medicine***. She said seeing any change around suicidal thoughts "is very worrying". "Good medical practice would normally be very reflective about an increase in harms," she added."

"Because of ***flaws [methodological defects] in how the study was set up***, it is not possible to infer cause and effect or even to say whether rates of suicidal thoughts are higher or lower in this group than in children with gender dysphoria who don't take puberty blockers. ***The study had no control group***, of children not taking the drugs, to compare with the observed results. In addition, the outcomes it was measuring were unclear. Nevertheless, experts say these observations should have given Gids pause for thought.

Gids told Newsnight: "All patients were seen regularly by mental health professionals. They concluded that there was no evidence of harms that could be directly attributed to the treatment and that continuation of the study was appropriate."

[**NOTE**: *This appears to be additional, publically exposed, documented evidence of Gender Transition Industry advocates* ***providing incomplete, misinformation to the public and patients***. Research has shown that mental health professionals have no relevant reliable-nor valid magical methods for deciphering the truth or falsity of patient reports of gender dysphoria and no reliable nor valid ways of predicting suicide in specific patients. They have no "lie detection" methodology better than flipping coins and they apply "clinical judgment" methods that are often no better than lay persons."(See a detailed discussion of the relevant science in this declaration.) For Gids to ward off responsibility for experimenting on children by assuring the public that "mental health professionals" were involved appears to be another example of not providing complete, accurate, proper information.]

The early data [showing an increase in suicidal ideation] was not shared with the Health Research Authority, despite its demands for updates on the study over a period of three years. In response to BBC Newsnight sharing this preliminary data and other concerns about the study, Teresa Allen, chief executive of the HRA, said: "The information that Newsnight has brought to our attention ***has not been raised with us before***. "We will therefore investigate further, which may include a review of the original ethics opinion."

[**NOTE**: This is apparently yet another public record of the Gender Transition Industry's deceptive misinformation and apparent unethical misconduct. Note that Dr Brown's expert declaration for the plaintiffs in this (Kadel v Folwell) case appears to be another example of this very same type of brazen misinformation — Dr Brown appears to claim there is no controversy in this field!**]**

BBC Newsnight's investigation comes amid growing concerns over the way Gids is operating. In an open letter, ***former Gids (Gender Clinic) clinician Dr Kirsty Entwistle raised concerns over the way puberty blockers were being presented to children as "fully reversible", when their long-term impact was unknown. She also said staff were unable to raise concerns without risking being branded transphobic. [politicized "cancel culture"]*** **See, open letter at [https://medium.com/@kirstyentwistle/an-open-letter-to-dr-polly-carmichael-from-a-former-gids-clinician-53c541276b8d].**

Tavistock and Portman Trust chief executive Paul Jenkins told BBC Radio 4's Today programme: "Puberty blockers are reversible."

[**NOTE**: This is apparently yet another public record - documented on BBC video — of Gender Transition Industry ***deceptive misinformation and unethical misconduct*** — a clear failure to provide

accurate information on risks and benefits of the treatment — providing such misinformation to a patient would be a serious violation of proper informed consent requirements.]

He said Gids was looking at processes to make it easier for clinicians to focus on their work, "rather than being swayed or influenced ***by the very heated debate"… (Note: This is the heated international medical, scientific, and ethical debate that Plaintiffs' expert Dr Brown apparently was not aware of or wishes to ignore.)*** See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

2020 and 2021 - THE GENDER TRANSITION INDUSTRY IMPLODES — RESEARCH DEFECTS and UNETHICAL MISCONDUCT ARE WIDELY EXPOSED:

2020 - THE COCHRANE REVIEW - GENDER AFFIRMATION REMAINS EXPERIMENTAL: "INSUFFICIENT EVIDENCE" FOR "AFFIRMATION" INTERVENTIONS = STILL AN EXPERIMENTAL TREATMENT : The widely respected Cochrane review examined hormonal treatment outcomes for male-to-female transitioners over 16 years. ***They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition."***

It is remarkable that ***decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking***. See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.

2020 - GRIFFIN REVIEW In the Bulletin of the Royal College of Psychiatrists - PSYCHIATRIC DISORDERS PERSIST (after "transitioning") so use a SUPPORTIVE, EXPLORATORY APPROACH (not Mandated Affirmation) — In the Bulletin of the Royal College of Psychiatrists See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, ***the authors noted the hazardous error of mandating "affirmation treatments" — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice***. … As Griffin discussed, "***Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to 'conversion therapy'.*** Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. **As there is evidence that *many psychiatric disorders persist despite positive affirmation and medical transition*, *it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity*. *When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties*. *Taking a supportive, exploratory approach with gender-questioning patients should not be considered conversion therapy*."**… In addition, Griffin et al wrote: "Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, *although* **underlying causality has not been convincingly demonstrated**. (**See, Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58–69**.) **Activists and too many providers have used a fear of suicide *to push experimental unproven treatments*.**

2020 – LONDON HIGH COURT: THE ETHICAL RISKS OF THE STILL EXPERIMENTAL GENDER AFFIRMATION INTERVENTIONS HAVE BEEN HIGHLIGHTED BY AN INTERNATIONALLY REPORTED LAWSUIT IN BRITAIN: See, Puberty blockers: Under-16s 'unlikely to be able to give informed consent', BBC, 1 December 2020 "Children under 16 with gender

dysphoria are unlikely to be able to give informed consent to undergo treatment with puberty-blocking drugs, three High Court judges have ruled…. "Given the long-term consequences of the clinical interventions at issue in this case, and given that ***the treatment is as yet innovative and experimental***, we recognise that clinicians may well regard these as cases where the authorization of the court should be sought prior to commencing the clinical treatment."… The judges have effectively split the issue into stages. They concluded a child under 13 is "highly unlikely" to be able to give informed consent and at 14 and 15 it is still "doubtful" they can fully understand the implications of the medication….Even for 16 and 17-year olds the ruling says it may be appropriate to involve the courts in the decision…. The judges point to the ***lack of evidence about the long-term effects of puberty blockers*** as adding to the difficulty of consent, but in effect, the courts will now play a much greater role in decisions, which are already highly emotionally charged… Paul Conrathe, the solicitor for both claimants, said the ruling was "an historic judgment that protects children who suffer from gender dysphoria". He said the judgment showed "that a culture of unreality has become embedded in the Tavistock". "This may have led to hundreds of children receiving this experimental treatment without their properly informed consent," he said. See, https://www.bbc.com/news/uk-england-cambridgeshire-55144148

2020 - D'ANGELO REVIEW OR TURBAN's DEFECTIVE RESEARCH … AN ONLINE "CONVENIENCE SAMPLE": D'Angelo, R., Syrulnik, E., Ayad, S. et al. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. Arch Sex Behav (2020). https://doi.org/10.1007/s10508-020-01844-2 …. ***"Turban used the 2015 USTS survey … a convenience sampling, a methodology which generates low-quality, unreliable data*** (Bornstein, Jager, & Putnick, 2013). Specifically, the ***participants were recruited through transgender political advocacy organizations*** and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but ***highly skewed politicized sample***."…." ***neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… "We call on the scientific community to ***resist the stigmatization of psychotherapy for GD and to support rigorous outcome research investigating the effectiveness of various psychological treatments aimed at ameliorating or resolving GD."***

2020 - THE TURBAN ONLINE SURVEY RESEARCH DEBACLE … PUBLIC EXPOSURE OF TURBAN's SERIOUS RESEARCH DEFECTS - Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research. … **See 2020 scathing D'ANGELO REVIEW….** ." ***neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… ***Turban used the 2015 USTS survey … a convenience sampling, a methodology which generates low-quality, unreliable data*** (Bornstein, Jager, & Putnick, 2013). Specifically, the ***participants were recruited through transgender political advocacy organizations*** and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but ***highly skewed politicized sample***."… Turban's defective project "does not differentiate between diagnostic evaluations or a specific therapeutic intervention. There is also no information about whether the focus of the encounter was gender dysphoria or another condition." … Turban's analysis is compromised by serious methodological flaws, including …. "***reliance on survey questions with poor validity***'… "Turban et al.'s (2020) finding of an association between the recall of GICE and scoring ≥ 13 actually suggests that ***the USTS participants recalling GICE were more likely to have a severe mental illnesses diagnosis*** than those not recalling GICE."… "Turban's ***failure to control for the subjects' baseline mental health makes it impossible to determine whether the mental health or the suicidality of subjects worsened, stayed the same, or potentially even improved after the non-affirming encounter.***"… "Another measure of psychological distress chosen by Turban et al.—substance misuse—was not significantly different between GICE and the non-GICE group. More importantly, there is a lack of consistency in the suicide measures. While lifetime suicide attempts were elevated among the GICE group, total suicide attempts in the prior 12 months, as well as suicide attempts requiring hospitalization, which generally indicate more serious attempts rather than non-suicidal self-injury, were

not significantly different between the two groups."… "Turban et al.'s choice to IMPROPERLY interpret the said association as evidence of harms of GICE ***disregards the fact that neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… "Arguably, even more problematic than the flawed analysis itself is the simplistic "affirmation" versus "conversion" binary, which permeates Turban et al.'s (2020) narrative and establishes the foundation for their analysis and conclusions." … ***"at worst, it effectively mis-categorizes ethical psychotherapies (e.g., CBT) that do not fit the "affirmation" descriptor as conversion therapies***. Stigmatizing non-"affirmative" psychotherapy for GD as "conversion" will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress."…

2020 - THE TURBAN PEDIATRICS RESEARCH ONLINE SURVEY DEBACLE: See, Turban JL, King D, Carswell JM, et al. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, Pediatrics Feb 2020, 145 (2) e20191725; DOI: 10.1542/peds.2019-1725.

Multiple Letters to the Editor criticized Dr. Turban's 2020 study in Pediatrics for multiple methodological errors. https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation

Scott S. Field, Den A. Trumbull, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.

Patrick H Clarke, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.

TURBAN used an Unreliable, biased sampling methodology: "Using a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years…" [2015 U.S Transgender Survey. Online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. NO ID, NO evidence of identities, NO way to measure bogus subjects, NO medical diagnosis for entry.]… ***No causation can be determined from this retrospective, cross-sectional design***…. **("…cross-sectional design, does not allow for determination of causation.")**…. ***TURBAN failed to even assess Desisters and Regretters*** … **Turban claimed that** desisters and regretters would "not be likely" in this study group, which also only included adults, so his study "does ***not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender***." …. "Turban's misleading (deceptive?) claim of lower suicidal ideation for treated patients excluded the most seriously mentally ill patients that would have been DENIED affirmation treatment — "those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression ***but did not receive it***, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6)."… … Turban appears to have "forgotten" to report that See, Table 3. Under "Suicidality (past 12 months)" reductions for suppressed group v non were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). ***But suicidal "ideation with plan and suicide attempt" for the suppressed group INCREASED after treatment to 24.4% v 21.5% for the non-treatment group***."… The most clinically significant result in this study — that **"Affirmation Treatments *INCREASED SERIOUS SUICIDE ATTEMPTS* — was IGNORED BY THE AUTHORS** (i.e., not statistically significant but clinically significant) = **"Suicide attempts resulting in inpatient care" = 45.5% for suppression groups** v. 22.8% for non. [**This is clearly a very "UN-successful treatment" if 45% attempted suicide!**]. In sum, Turban et al. ignored their own finding that a history of puberty suppression was associated with an **INCREASE in recent serious suicide attempts.**"… In sum, the Turban 2020 Pediatrics study, **based on an unverified US Transgender Online Survey, tells us little** about the effects of puberty suppression on children with gender dysphoria. See, **Michael Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, accepted 14 May 2020, DOI: 10.1007/s10508-020-01743-6**

2020 - LONDON COURT RULING … "*given that the treatment is as yet innovative and experimental*"… CHILDREN HIGHLY UNLIKELY TO BE ABLE TO CONSENT TO "AFFIRMATION" INTERVENTIONS:

See, Dyer, C. , Children are "highly unlikely" to be able to consent to taking puberty blockers, rules High Court BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4699 (Published 01 December 2020) Cite this as: BMJ 2020;371:m4699

Children under 16 cannot consent to the use of puberty blockers for gender dysphoria unless they can understand the immediate and long-term consequences of the treatment, which is unlikely, the High Court in London has ruled.

See, also Ruling on the application of Quincy Bell and A v Tavistock and Portman NHS Foundation Trust and others. [2020] EWHC3274 (Admin). https://www.judiciary.uk/judgments/r-on-the-application-of-quincy-bell-and-a-v-tavistock-and-portman-nhs-trust-and-others/.

The legal challenge was brought against the Tavistock and Portman NHS Trust, which runs the UK's only gender reassignment service for young people. Keira Bell, 23, who was treated as a teenager, and "Mrs A," the mother of a 15 year old with autism who was on the waiting list for treatment, challenged the service's policy and practice on the use of puberty blockers. They argued that children were unable to give informed consent for the treatment.

Victoria Sharp, president of the Queen's Bench Division, sitting with Lord Justice Lewis and Mrs Justice Lieven, said it was "highly unlikely" that a child aged 13 or under would be competent to give consent to the administration of puberty blockers. She said that the judges were "very doubtful" that a child aged 14 or 15 could understand and weigh the long term risks and consequences of the administration of puberty blockers.

For children of 16 and over there is a presumption that they have the ability to consent to medical treatment. But, "given the long term consequences of the clinical interventions at issue in this case, and ***given that the treatment is as yet innovative and experimental***, we recognise that clinicians may well regard these as cases where the authorisation of the court should be sought prior to commencing the clinical treatment," said Sharp.

Bell took puberty blockers at age 15 or16 and later was given male hormones and had her breasts removed. She has since "re-transitioned" back to living in accord with her female sex. Sharp said that puberty blockers had been prescribed to children as young as 10 years.

The trust, and other trusts to which it referred patients for treatment, had argued that taking hormone blockers and later cross sex hormones were entirely separate stages of treatment. Sharp concluded, "It is said therefore the child needs only to understand the implications of taking puberty blockers alone . . . in our view this does not reflect the reality. The evidence shows that the vast majority of children who take puberty blockers move on to take cross sex hormones, that stages 1 and 2 are two stages of one clinical pathway and, **once on that pathway, it is extremely rare for a child to get off it.**"

2020 -Schumm and Crawford Review SHOWING SEVERE DEFECTS IN AFFIRMATION RESEARCH BY Olson et al. 2016b; Durwood, McLaughlin, and Olson 2017 Schumm and Crawford asked the question: "Is good science being thrown under the bus for the sake of politically correct agendas?"

As Schumm and Crawford further noted: "The results should have been interpreted as evidence that ***even with high levels of parental support, transgender children have lower levels of mental health, especially with respect to higher levels of anxiety and lower levels of self-worth***…

Negligence, Fraud, or Political Ideology?: In the case of Olson et al. (2016b) and Durwood, McLaughlin, and Olson (2017), not only were there numerous statistical errors (Schumm et al. 2019), but ***a great deal of data and results, including some significant results, were not reported until the authors were queried***. Not reporting significant results may occur but when the apparent conclusion is that there were not any significant results, leaving out significant findings can be seen as self-serving to the idea of maintaining support for the null hypothesis regardless of the facts. Is good science being thrown under the bus for the sake of politically correct agendas? It's difficult to escape a sense that such is not an uncommon occurrence in areas of considerable political controversy. One has to wonder what other areas of controversial science may have been infected with this type of problem." (See, Schumm, WR and Crawford, DW, Is Research on Transgender Children What It Seems? Comments on Recent Research on

Transgender Children with High Levels of Parental Support, The Linacre Quarterly, 2020, Vol. 87(1) 9-24. DOI: 10.1177/0024363919884799

2020 - GREAT BRITAIN REVIEW OF GENDER AFFIRMATION INTERVENTIONS SHOWS "VERY LOW" QUALITY EVIDENCE: GB NICE REVIEW OF Oct 2020 - See, Deborah Cohen and Hannah Barnes for **BBC Newsnight - "Evidence for puberty blockers use *very low,* says NICE"**

The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding". **The assessment of the evidence into the drugs** was commissioned by NHS England. It is part of **a review into gender identity services** for children and young people. See, https://arms.nice.org.uk/resources/hub/1070905/attachment

NICE found it was ***difficult to draw conclusions from existing studies because of the way they had been designed.*** They were "all small" and ***didn't have control group***s, which are used to directly compare the effect of different treatments.

There were ***other issues with the studies too, such as not describing what other physical and mental health problems a young person may have alongside gender dysphoria***.

The review said there was ***"very little data" on any additional interventions*** - such as counselling or other drug treatments - the young people may have had alongside taking puberty blockers, and t***his could bias the results***.

The impact of puberty blockers on bone density has been raised as a potential concern by some experts previously. However, NICE found that without a "comparator group", it was not known whether any observed changes in bone density "are associated with GnRH analogues or due to changes over time".

Some argue that carrying out a controlled trial - which would provide better quality evidence - might be difficult because of the potential impact on mental health if treatment is withheld in one group. NICE accepted this, but said offering psychological support to compare puberty blockers ***"may reduce ethical concerns in future trials"***. The review found ***no evidence of cost-effectiveness of treatment.***

NICE also reviewed the evidence base for gender-affirming hormones - sometimes known as cross-sex hormones. See, https://arms.nice.org.uk/resources/hub/1070871/attachment

The review found the evidence of clinical effectiveness and safety of gender-affirming hormones *was also of "very low" quality*. "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria," NICE said. Both documents were prepared by NICE in October 2020 and will now help inform Dr Hilary Cass's independent review into NHS gender identity services for children and young people. See, https://www.bbc.com/news/health-56601386

2020 - THE MALONE, HRUZ, MASON and BECK et al. LETTER TO THE EDITOR DOCUMENTING RESEARCH DEFECTS IN THE GENDER TRANSITION INDUSTRY:

See, Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender-Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". The Journal of Clinical Endocrinology & Metabolism. **2020.**

Walch et al. endorse the ES Position that puberty suppression (PS), cross-sex hormones (CSH) and surgeries are "effective," "relatively safe," and have been "established as the standard of care" [2]. However, a growing body of evidence shows adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret.

Walch et al. also endorse the ES Position claiming there is an established "durable biological underpinning" to gender identity (GI) *2]. However, the first citation supplied by the ES for this position ***highlights contradictory studies*** and describes the biological origin of GD as simply ***a "current hypothesis"*** *7+. The other citation describes GI as a "complex interplay of biological, environmental, and cultural factors" *8+. Further, ***the concept of "durability" is challenged by the fact that most cases of GD in children naturally resolve by adulthood***. It is ***precisely this lack of durability that should give pause to***

administering potentially harmful and often irreversible medical interventions to young patients with GD.

The ES Position Statement also overlooks a key fact that the existing body of evidence regarding treatment outcomes for GD was not only **graded as "low quality"**, but has been ***derived from a vastly different population than the one presenting with GD today***. Currently, ***GD predominantly presents in adolescent females with no childhood history, in contrast to the prior population which was predominantly male with early onset of gender dysphoria***.

Walch A, Davidge-Pitts C, Safer JD, Lopez X, Tangpricha V, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective. J Clin Endocrinol Metab. Jan 23 2021;106(2):305-308. doi:10.1210/clinem/dgaa816

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. Nov 1 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

Rosenthal SM, Hembree WC, Cohen-Kettenis PT, et al. Response to Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". J Clin Endocrinol Metab. Nov 1 2019;104(11):5102-5103. doi:10.1210/jc.2019-00930

2020 - THE Branstrom DEBACLE - … EXPOSURE OF Branstrom et al's MULTIPLE, SERIOUS RESEARCH DEFECTS : Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research.

In 2020, Branstrom, et al, published a research report claiming that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." This research appeared to be an historic first — empirical evidence that gender transition surgeries demonstrated long-term benefits. (See, Branstrom, Pachankis: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734.)

Almost immediately, however, the relevant scientific community — including multiple MD, PhD methodology experts — exposed the Branstrom study ***as a series of methodological blunders and/or manipulative deceptions***. Multiple science experts concluded that, "These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender non-congruence based on the results presented in this article." They also noted evidence supporting the theory that these "errors" could well be purposeful and designed to support an ideological perspective when they noted, "people diagnosed with gender incongruence have a dramatically worse overall mental health outcome (after "transitioning" treatments) than the general population, which is, in fact, the answer to their stated aim and research question, but this (most essential) finding is not even referred to in the title or in the Conclusions section of the article."(See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

Additional methodology experts noted other serious flaws in the Branstrom study including : "For those whose last surgery was 10 or more years earlier, **how many completed suicide, died of other causes, or left Sweden prior to study initiation?***" The authors failed to find out (or hid negative results)*. The methodology experts also noted, "A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring. The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls."…"***The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality.*** In overlooking so much available data, ***this study lacks the evidence to support its pro gender-***

affirmation surgery conclusion." See, Van Mol, A., Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

Additional methodology experts noted that "The study confirms ***the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex***. However, ***the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity.*** It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors somehow ignored this most essential finding -*Note this appears to be more potential evidence of deception, research fraud, and/or licensing violations.]* …" See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

Still more reviewers concluded, "The data presented in Figure 1 in the article support findings from previous studies showing that ***transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress***."… "Because of the ***limitations in the study design***, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. (They failed to even measure increased suicides, etc) … "Therefore, the authors 'conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries ***cannot be supported***." See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149.

Finally, yet another (MD, PhD) reviewer noted in detail… "The Branstrom and Pachankis study on mental health treatment and suicide attempts … ***is misleading because the study design is flawed***." "The authors first found what was already known … ***the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning")***. The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but ***they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting HORMONAL treatment***. They somehow ***failed to publish this essential finding***. *[Note … more potential evidence of deception, research fraud, or licensing violations.]* In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate these negative outcomes to the number of years since surgery. ***Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question***. First, the authors include only persons who were alive in 2014. ***That means that those who died by SUICIDE before 2014—and hence were at highest risk for suicide attempt—are EXCLUDED from the data and confound the results***. *[Note …this appears to be still more potential evidence of deception, research fraud, and/or licensing violations.]* Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, *the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment;* it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, by definition, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors ' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and ***is not a proxy for improved mental health***. ***Because the authors do not present data prior to gender affirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity.*** Moreover, ***the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with HIGH risk for SUICIDE attempt***. *[Note … still more potential evidence of deception, research fraud, or licensing violations.]* ***Future research should use properly designed observational studies to answer***

the important question as to whether gender-affirming treatment affects psychiatric outcomes." See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165.

Yet another MD, PhD expert severely criticized the Branstrom, et. al. study noting : The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population. However, the title of the article implies that gender corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide gender affirming surgeries to transgender individuals who seek them." ***In my opinion, this conclusion is not supported by the data presented in the article***. *[Note ... more potential evidence of deception, research fraud, or licensing violations.]* The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not. Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment"). By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery. This corresponds to an odds ratio of 2.37 (95% CI= 1.01–5.56, p=0.047). ***Hence, among the individuals examined in the study, the risk of being hospitalized for a SUICIDE ATTEMPT was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not.*** *[Note this key finding was apparently hidden or not noticed by the authors ... more potential evidence of deception, research fraud, or licensing violations by the research authors.]* Whether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, ***the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria."*** See, Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170.

In addition, yet another pair of reviewers severely criticized the Branstrom study noting : " The qualitative approximation of this curve with the reduction described by Branstrom and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of INCREASED mental health treatment due to this surgery, fits *the data in the article and* ***OVERTURNS the authors stated conclusions***, *[Note ... more potential evidence of deception, research fraud, or licensing violations by the research authors.]* **suggesting that sex reassignment surgery is in fact associated with INCREASED mental health treatment.** See, Ring, A. (PhD) and Malone, W., Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

It should be noted, that after this very public exposure of **the Branstrom Debacle** by multiple expert reviews, ***the research authors admitted their conclusions were in error (confessed)*** and that ***"more research" is needed to answer the question of whether Gender Transition Industry treatments are helpful or harmful, long-term.*** The authors admitted, "**Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming**

care… (and)… When comparing the mental health treatment outcomes between the two groups (Table 1), we found ***no significant difference*** **in the prevalence of treatment for mood disorders and** ***no significant difference*** **in the prevalence of hospitalization-suicide attempts.** " and stunningly ***they admitted they had failed to note that "individuals diagnosed with gender incongruence who had received gender-affirming surgery were MORE likely to be treated for ANXIETY disorder compared with individuals diagnosed with gender incongruence who had NOT received gender-affirming surgery.*** 'and "While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, **like most extant research on the topic,** ***the design is incapable of establishing a causal effect*** **of gender affirming care on mental health treatment utilization**. This retreat and mea culpa was published as Branstrom, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals 'Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

[Underlines, italics, and emphases above are added]

In sum, like the Branstrom Debacle … too many ideologically tainted and methodologically defective research studies suffer from these kinds of ***serious errors, improper analyses and harmfully deceptive reports***. Such poorly designed and improperly conducted research studies continue to prevent gender transition "affirmation" treatments from being generally accepted by the relevant scientific community. Finally, the Error Rates for such unproven, experimental "treatments" as well as for the foundational politically-based transgender ideology, are unknown, un-peer-reviewed, and unpublished. [Note: Compare the multiple, scathing reviews by international scientist experts above to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2021 - The Singh, Bradley, and Zucker study — the largest sample to date - ***found support for the "watchful waiting" no affirmation treatment approach combined when needed with psychotherapy and coping-resilience training.***

This research supports the view that an aggressive, intrusive "affirmation" of the Gender Transition Industry's "transitioning treatments" is an unethical, experimental practice which brings an unnecessarily high risk of causing serious, lasting harm to most such children.

In a follow-up study reviewing data on **the largest sample to date of boys clinic-referred for gender dysphoria** (n = 139) with regard to gender identity and sexual orientation. At follow-up, gender identity/dysphoria was assessed via multiple methods with participants classified as persisters or desisters). Of the 139 participants, 17 (12.2%) were classified as persisters and the remaining 122 (87.8%) were classified as desisters**,** that is, patients who grew out of their gender dysphoric symptoms and came to accept their natal gender without further symptoms.

Clearly, given that the vast majority of these patients were on a natural developmental path to healthy adjustment without treatment, it would be unethical to engage in an intrusive "affirmation" treatment program using hormones and/or surgery that would be LIKELY to disrupt normal developmental processes producing iatrogenic (treatment caused injuries) harm to many patients. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.

In addition, these authors discussed the previous 9 studies with sample sizes (excluding those lost to follow-up) ranging from 6 to 79 subjects (Mean age, 26 years). Most of these studies also provided the age at time of first evaluation in childhood, which ranged from a mean of 7 years (47) to a mean of 9 years (48), with an age range from 4 to 12 years. At the time of follow-up, using different metrics (e.g., clinical interview, maternal report, dimensional measurement of gender dysphoria, a DSM diagnosis of GID, etc.), **these studies provided information on the percentage of boys who continued to have gender dysphoria (herein termed "persisters") and the percentage of boys who did not (herein termed "desisters" of those who grew out of dysphoria).** Of the 53 boys culled from the relatively small sample size studies (Bakwin, Davenport, Kosky, Lebovitz, Money and Russo, Zuger), the percentage classified as persisters was 9.4% (age range at follow-up, 13–30 years). In Green (47), the percentage of persisters was

2% (total n = 44; Mean age at follow-up, 19 years; range, 14–24); in Wallien and Cohen-Kettenis (52), the percentage of persisters was 20.3% (total n = 59; Mean age at follow-up, 19.4 years; range, 16–28); and in Steensma et al. (51), the percentage of persisters was 29.1% (total n = 79; Mean age at follow-up, 16.1 years; range, 15–19). Across all studies, the percentage of persisters was 17.4% (total N = 235), with a range from 0 to 29.1%. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org,

These studies appear to support a "watchful waiting" treatment approach combined when needed with psychotherapy and/or coping-resilience training. An aggressive, intrusive "affirmation" of transitioning treatment model appears highly unethical and produces an unnecessarily high risk of causing serious, lasting harm to MOST of these patients.

2021-2020 CARMICHAEL STUDY (2020 also) — *HORMONE TREATMENTS DO NOT HELP CHILDREN WITH GENDER DYSPHORIA*… BUT DO STUNT GROWTH:

See, Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 and Dyer, C. Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study. *BMJ* 372, n356, doi:10.1136/bmj.n356 (2021). **https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1 BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227**

Results 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex. All achieved suppression of gonadotropins by 6 months. At the end of the study one ceased GnRHa and 43 (98%) elected to start cross-sex hormones…."**We identified *no changes in psychological function***. Changes in BMD were consistent with ***suppression of growth***. ***Larger and longer-term prospective studies using a range of designs are needed*** to more fully quantify the benefits and harms of pubertal suppression in GD."

Self-harm did NOT improve and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed."

"We found **no differences between baseline and later outcomes for overall psychological distress** as rated by parents and young people, nor for self-harm."

CONCLUSION: "We found ***no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm…."***

Puberty blockers used to treat children aged 12 to 15 who have severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found.

However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

Media = See, Dyer, C. ***Puberty blockers: children under 16 should not be referred without court order, says NHS*** England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453FREE Full TextGoogle Scholar

Media = See, Dyer, C., ***Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study***, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021)

82. SUMMARY OPINIONS:

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

— A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

— A currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by a — peer group, social media, YouTube role modeling, and/or parental — social contagion and social pressure processes.

— Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

— It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any

patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmation" treatments.

— A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

— Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.

— NOT GENERALLY ACCEPTED: Affirmation medical treatments — hormones and surgery — for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc).

— NO KNOWN NOR PUBLISHED ERROR RATES: Gender transition "Affirmation" medical assessments and treatments — hormones and surgery — for gender dysphoria and "transitioning" have no known, peer reviewed and published error rates — the treatments and assessment methods lack demonstrated, reliable and valid error rates.

— POLITICS v. SCIENCE: Political activists, political activist physicians, and politically active medical organizations that operate by voting methodologies (e.g, WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and political ideologies (e.g., Critical Theory) rather than evidence-based scientific methodologies.

— ETHICAL RESTRICTIONS ON EXPERTS: Experts in legal cases have an ethical obligation to honestly, fairly, and accurately discuss the international controversy regarding the safety, effectiveness, reliability, and credibility of the Gender Transition Industry.

82. **LIMITATIONS ON EXPERT REPORTS:** My opinions and hypotheses in this matter are — as all expert reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to John Knepper (john@knepperllc.com), for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: 04/30/2021

Signed: Paul W Hruz

USCA4 Appeal: 22-1721 Doc: 41-3 Filed: 08/31/2022 Pg: 426 of 584

PAUL W. HRUZ, M.D., Ph.D.

THE END

Exhibit A

Curriculum Vitae

Date: 04/29/2021 09:26 AM
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: Hruz_P@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health
2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Department/Division

2008 – 2016	Director, Pediatric Endocrinology & Diabetes Fellowship Program
2014 – 2017	Director, Pediatric Diabetes Research Consortium

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO State License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry
1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014	Endocrinology and Metabolism Clinics of North America

Community Service Contributions

2009 - 2017	Boy Scouts of America CPR Red Card Training

Professional Societies and Organizations

1992 - 2004	American Medical Association
1994 - 2005	American Academy of Pediatrics
1995 - 2014	American Association for the Advancement of Science
1998 - Pres	American Diabetes Association
1998 - Pres	Endocrine Society
1999 - Pres	Pediatric Endocrine Society
2004 - 2007	American Chemical Society
2004 - 2018	American Society for Biochemistry and Molecular Biology
2004 - 2020	Society for Pediatric Research
2005 - 2020	Full Fellow of the American Academy of Pediatrics
2013 - Pres	International Society for Pediatric and Adolescent Diabetes
2017 - Pres	Catholic Medical Association
2018 - Pres	American College of Pediatricians
2019 - Pres	Society of Catholic Scientists

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children’s Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting, Vancouver, Canada

2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN
2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator

2008 - 2011	II Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure Role: Co-Investigator PI: Hruz Total cost: $249,999.00
2009 - 2012	Research Program Regulation of GLUT4 Intrinsic Activity Role: Principal Investigator Total cost: $268,262.00
2010 - 2011	Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function Role: Principal Investigator
2012 - 2015	II Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins Role: Principal Investigator Total cost: $375,000.00
2017 - 2020	Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8 Role: Co-Principal Investigator PI: DeBosch Total cost: $450,000.00
2018 - 2021	LEAP Innovator Challenge Novel Treatment of Fatty Liver Disease Role: Principal Investigator Total cost: $68,500.00

Current Non-Governmental Support

2017 - 2021	Matching Micro Grant Novel Treatment of Fatty Liver Disease (CDD/LEAP) Role: Principal Investigator Total cost: $68,500.00
2019 - 2021	Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation Novel Treatment of Non-Alcoholic Fatty Liver Disease Role: Principal Investigator Total cost: $379,000.00

Pending Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator

Trainee/Mentee/Sponsorship Record

Current Trainees

2019	Ava Suda, Other, Pre-med

Past Trainees

2002 - 2002	Nishant Raj- Undergraduate Student, Other Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009	Stephanie Scherer, Graduate Student Study area: Research
2010 - 2014	Lauren Flessner, PhD, Postdoctoral Fellow Present position: Instructor, Syracuse University
2010 - 2010	Constance Haufe- Undergraduate Student, Other Study area: Researcher
2010 - 2011	Corinna Wilde- Undergraduate Student, Other Study area: Researcher
2010 - 2010	Samuel Lite- High School Student, Other Study area: Research
2011 - 2016	Thomas Kraft, Graduate Student Study area: Glucose transporter structure/function Present position: Postdoctoral Fellow, Roche, Penzberg, Germany
2011 - 2011	Amanda Koenig- High School Student, Other Study area: Research
2011 - 2012	Lisa Becker- Undergraduate Student, Other
2011 - 2011	Melissa Al-Jaoude- High School Students, Other
2014 - 2014	David Hannibal, Clinical Research Trainee

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Journal Articles

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2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.

Invited Publications

1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
2. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. PMCID: PMC2680222 PMID: 19373039
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7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Clinician Educator Portfolio

CLINICAL CONTRIBUTIONS

Summaries of ongoing clinical activities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

EDUCATIONAL CONTRIBUTIONS

Direct teaching

Classroom

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

Clinical

2000 - Pres	Lecturer, Medical Student Growth Lecture (Women and Children's Health Rotation): Variable

2000 - Pres	Lecturer, Pediatric Endocrinology Journal Club: Presentations yearly
2009 - Pres	Facilitator, Medical Student Endocrinology and Metabolism Course, Small group
2016 - Pres	Facilitator, Medical Student Endocrinology and Metabolism Course, Small group

Other

	Facilitator, Cell Biology Graduate Student Journal Club, 4 hour/year
	Facilitator, Discussion: Pituitary, Growth & Gonadal Cases, 2 hours/year
2000 - Pres	Lecturer, Metabolism Clinical Rounds/Research Seminar: Presentations twice yearly
2009 - Pres	Facilitator, Biology 5011- Ethics and Research Science, 6 hours/year
2016 - Pres	Lecturer, Cell Signaling Course, Diabetes module, 3 hours/year

EXHIBIT C

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendant.)

VIDEOTAPED DEPOSITION OF PAUL W. HRUZ, M.D., Ph.D
Taken on behalf of Plaintiff
November 20, 2017
(Starting time of the deposition: 8:58 a.m.)

I N D E X O F E X A M I N A T I O N

INDEX OF EXHIBITS

(The original exhibits were retained by the court reporter, to be attached to Mr. Gonzalez-Pagan's transcript.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendants.)

VIDEOTAPED DEPOSITION OF WITNESS, PAUL W. HRUZ, M.D., Ph.D., produced, sworn, and examined on the 20th day of November, 2017, between the hours of nine o'clock in the forenoon and six o'clock in the evening of that day, at the offices of Veritext Legal Solutions, 515 Olive Street, Suite 300, St. Louis, Missouri before BRENDA ORSBORN, a Certified Court Reporter within and for the State of Missouri, in a certain cause now pending in the United States District Court for the Middle District of Florida, wherein Drew Adams, a minor, is the Plaintiff and The School Board of St. Johns County, Florida is the Defendant.

A P P E A R A N C E S

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The Videographer: Ms. Kimberlee Lauer

Q. So is that a "yes" or a "no"?
A. That is a -- to make sure I understand the question again, please address it again.
Q. If Drew asked you to use male pronouns, would you use male pronouns?
A. Yes.
Q. In your practice -- and I take it you've been practicing for several years, so in your practice, how many transgender patients have you treated in the past five years?
A. As stated explicitly in my declaration, I intentionally do not treat transgender patients.
Q. At all?
A. That is correct.
Q. In any -- for any treatment?
A. Oh, the ones that I'm aware of, I have not encountered any patients that have presented to me as transgendered for any other conditions. I have certainly encountered many patients where that was something under consideration or something that I suspected, but nobody has ever mentioned directly to me that they were transgendered.
Q. Okay. So to your knowledge, you have not treated any person that you knew was transgender?
MR. KOSTELNIK: Form.

A. Well, again, if you would -- yeah, that is true for -- for the -- the patient -- somebody like Drew Adams that was biologically normal. I have certainly cared for hundreds of patients that have disorders of sexual development. Many practitioners will include those in that designation. I believe that they are a completely different patient population than Drew Adams.

Q. (By Mr. Gonzalez-Pagan) What is gender dysphoria?

A. Gender dysphoria is the discomfort that one experiences related to gender identity that does not conform with one's biological sex.

Q. Is that the definition in the DSM?

A. Yes.

Q. It uses the word "discomfort"?

A. I'd have to go look back at the exact wording of that. It's the difficulty that they experience, psychological difficulty with that, yes.

Q. Okay. And based on your testimony, would you agree that you have not treated any transgender patients for gender dysphoria?

A. Yes, I would agree.

Q. Would you agree that Drew's treating physicians have diagnosed him with gender dysphoria?

the person putting forward this clinic and trying to understand what care that was being proposed to be provided in the setting of that context in my role as the director of our -- or the chief of our division of endocrinology.

Q. Just to be clear, though, you have never sat in a meeting between a provider and a patient discussing their treatment options for gender dysphoria?

A. That is correct, I've never been in the room with a patient while that care is being discussed.

Q. All right. Would you agree that Drew Adams' doctors have concluded that gender-affirming treatment is appropriate treatment for him?

A. That is what they concluded, yes.

Q. Would you agree that Drew Adams' doctors have concluded that the gender-affirming treatment has been helpful to Drew?

A. I believe that that's what they claim, yes.

Q. Do you agree that Drew Adams' gender-affirming treatment has been beneficial for him?

A. It depends on what you mean by beneficial. I think that it is far too early to know what the long-term outcome -- outcomes are going to be from what is being provided for Drew Adams.

Q. As we stand here today, has the gender-affirming treatment been beneficial to Drew with regards to his gender dysphoria?

MR. KOSTELNIK: Object to form.

A. So similar to the literature that has already been published in this area, Drew, by the reports that I've read, is experiencing a -- a lessening of the dysphoria in relation to the gender discordance, and I would say that based on the information that I saw, the answer is yes.

Q. (By Mr. Gonzalez-Pagan) As we stand here today, do you agree that Drew Adams' gender-affirming treatment has improved his quality of life?

A. So again, I can't say with certainty what actually has improved his quality of life. I can say, based on the record, that he is better adjusted than previously.

Q. Dr. Hruz, you're an endocrinologist, correct?

A. That is correct.

Q. You're not a psychiatrist, correct?

A. That is correct.

Q. You're not a psychologist?

A. That is correct.

Q. Are you a licensed mental healthcare

provider of any kind?

A. I am not.

Q. Can you diagnose gender dysphoria?

A. I can -- I can diagnose gender dysphoria to the extent that my colleagues, as pediatric endocrinologists, follow the DSM-5 and look at the criteria and put the check boxes there. That is the extent of what my colleagues, as pediatric endocrinologists, do, and I'm just as capable of doing that as they are.

Q. As an endocrinologist, do you routinely diagnose conditions in the DSM-5?

A. I -- I do not -- well, let me -- I'm trying -- the reason I'm waiting is I'm trying to think as I put in my ICD9 codes in my visits, I do believe that I've actually added them, but I do not consider myself as a psychiatrist to making those diagnoses, no.

Q. Do you have any basis to know whether Drew Adams has suffered distress as a result of being denied access to the restroom consistent with his gender identity?

A. I can only evaluate what is contained within his patient chart and the literature -- or the information that was provided to me.

whether the person they're using right now is not specifically dedicated to the clinic, but there are many psychologists there at Children's Hospital, and I certainly could refer them to one of those psychologists, that's correct.

Q. Just to clarify, would you discourage them from using the transgender center at your university?

A. I would neither encourage nor discourage. I would merely state that I do not agree with the treatment that is being done in that clinic.

Q. And that treatment is the treatment that is in accordance with the Endocrine Society's clinical guidelines?

A. That is correct.

Q. And in accordance with the WPATH standards of care?

A. As I understand it.

Q. And the treatment that is being allowed by the Washington University at the clinic?

A. Yes.

Q. Would you tell the patient that?

A. Excuse me. Tell them what?

Q. That the care provide -- would you tell the patient that the care provided at the transgender center is in accordance with the Endocrine Society's

clinical guidelines?

A. I would let them know that the clinic was available, and I would let the people in that clinic, if they chose to attend that clinic, present all of the information for the basis for their treatment approach.

Q. So you wouldn't inform the patient that the treatment is in accordance with the clinical guidelines?

A. I'm envisioning the hypothetical situation that you're talking about, and the extent of my normal clinic visit and how much time I have to present all of the -- the important aspects of clinical care, and I'm envisioning that there would be a limit of the -- the length of that conversation if I was going to adequately address all of the other relevant issues that I was caring that patient for [sic].

Q. Would you suggest that the patient seek conversion therapy?

A. No.

Q. Is the treatment at the transgender center consistent with the position and recommendations of the American Medical Association?

A. I -- as I understand it, yes.

Q. Is the treatment at the transgender center

consistent with the position and recommendations of the American Academy of Pediatricians?

A. The AAP, yes.

Q. Is the treatment at the transgender center consistent with the position and recommendations of the American Psychiatric Association?

A. I don't follow those as closely, but I would assume yes.

Q. Is the treatment at the transgender center consistent with the position and clinical guidelines of the American Psychological Association?

A. The same as the last answer. To my knowledge, I don't know them specifically, but I would say yes.

Q. Okay. Let's go a little bit for some of your memberships. You're a member of the American Medical Association, right?

A. No.

Q. Were you a member of the American Medical Association?

A. I was in the past, yes.

Q. Are you a member of the American Academy of Pediatricians?

A. Yes.

Q. Is your position in your report and as you

sit -- sit here today consistent with the position of the American Academy of Pediatricians?

A. It is not consistent with the -- the opinion that is presented by the AAP. Again, I will note that is not a -- a position that has been voted upon by the entire membership of the AAP.

Q. Are the -- all the positions adopted by the AAP voted upon by the membership?

A. No. In fact, they're usually voted on by a very small select committee, a -- a very minority of the entire academy.

Q. So the position of the AAP on this subject has been adopted via its regular procedures?

A. Yes. Which -- which I would add do not involve membership of the entire academy.

Q. Are you a member of the Endocrine Society?

A. Yes, I am.

Q. Are your positions here today and in your report consistent with the clinical guidelines of the Endocrine Society?

A. They are at odds with the recommendations that are put forward, the guidelines that are put forward for the treatment of gender dysphoria.

Q. You're a member of the Pediatric Endocrine Society, correct?

A. Yes, I am.
Q. Are your positions here today and the positions in your report consistent with the positions adopted by the Pediatric Endocrine Society?
A. They are not, and I've actually written to the PES on more than one occasion with my opinions and invited them to dialogue about the -- the scientific evidence that I have in dispute from -- that are included per the recommendations.
Q. And we've requested those comments, right?
A. Yes. And everything I have on file, I gave you everything I have. I don't have records of anything that I did not send you.
Q. You have published a body of literature in your career, correct? Right?
A. That is correct.
Q. How many peer-reviewed articles have you written and published regarding gender identity?
A. I have not published peer-reviewed articles on gender identity.
Q. How many peer-reviewed articles have you written and published regarding transgender people?
A. I have not written peer -- peer-reviewed papers on that topic.
Q. How many peer-reviewed articles have you

written and published regarding the treatment of transgender children and adolescents?

A. Again, as peer-reviewed, I have not written any.

Q. How many peer-reviewed articles have you written and published regarding the treatment of gender dysphoria?

A. I have not written any.

Q. How many peer-reviewed articles have you written and published regarding the use of restrooms by transgender students?

A. I have not written any.

Q. How many studies have you conducted regarding gender identity?

A. Conducted, I have not conducted any, but I am in the process right now of responding to a research funding announcement by the NIH to be able to engage in that research.

Q. But just to be clear, you haven't conducted any as we stand here today?

A. That is correct.

Q. And you -- have you submitted that proposal to the NIH?

A. I -- I have not.

Q. How many studies have you conducted

regarding transgender people?
A. I have not.
Q. How many studies have you conducted regarding the treatment of transgender children and adolescents?
A. I have not.
Q. How many studies have you conducted regarding the treatment for gender dysphoria?
A. I have not.
Q. How many studies have you conducted regarding the use of restrooms by transgender students?
A. I have not.
Q. So you have no experience treating gender dysphoria, right?
A. Treating gender dysphoria?
Q. Yes.
A. I have not -- as I said earlier, I have not treated patients with gender dysphoria.
Q. And you have no experience conducting studies regarding transgender youth and adolescents, correct?
A. Conducting studies, I have not, as I said, have not participated in any studies to date.
Q. And you have no experience conducting

studies regarding gender dysphoria?

A. I have not conduct -- as I said, I have not conducted any studies on gender dysphoria.

Q. Nor have you published any literature regard -- regard -- peer-reviewed literature regarding gender dysphoria?

A. Peer-reviewed, no.

Q. So having no experience treating transgender patients for gender dysphoria, no experience conducting studies regarding transgender people, and no experience publishing peer-reviewed literature regarding transgender people, you consider -- do you consider yourself an expert on transgender issues?

MR. KOSTELNIK: Object to form.

A. I am a physician/scientist who has extensively read the literature for the merits, as I do in any other condition, and I believe I have expertise related to my role as a physician and a scientist and a pediatric endocrinologist to adequately assess the quality and quantity of the literature that's present on this area.

Q. (By Mr. Gonzalez-Pagan) And having no experience treating gender dysphoria, no experience conducting studies -- scratch that.

Let's talk a little bit about your article,

references that I provided, that it would not be sufficient.

Q. (By Mr. Gonzalez-Pagan) Okay. Can you please read for me the last paragraph?

A. "In summary, as researchers and clinicians with expertise in gender and sexuality, we affirm that the 'Sexuality and Gender' report does not represent prevailing expert consensus opinion about sexual orientation or gender identity, related research or clinical care."

Q. Do you agree with that statement?

A. To the extent that the paper, the "Sexuality and Gender" paper, addresses the issue of consensus, what we define by consensus -- so the -- there are many individuals that signed this letter that have an opinion that is not supported by the literature that's cited in the "Sexuality and Gender" paper. So if you look to the specific information contained within that paper and critically evaluate it, I think that it would be at odds with what these individuals that have signed this paper have put forward.

Q. Is the position of the American Medical -- Medical Association at odds with the position of this [sic] several hundreds of signatories?

A. So the American Medical Association, all of

the -- the organizations that we already mentioned earlier in this deposition have similar statements related to the treatment guidelines, and all of them are limited by the lack of scientific justification or evidence supporting those recommendations.

Q. Okay. And just to clarify, that's the American Medical Association, right?

A. That's one of the organizations, correct.

Q. And the American Academy of Pediatricians, right?

A. That is correct.

Q. And the American Psychological Association?

A. That is correct.

Q. And the American Psychiatric Association?

A. That is correct.

Q. And the Endocrine Society?

A. That is correct.

Q. And the Pediatric Endocrine Society?

A. That is correct.

Q. And the World Professional Association of Transgender Health?

A. That is correct.

Q. All right. Would you agree that your article, Growing Pains, similarly does not reflect current scientific or medical consensus about gender

with that, so --

Q. Is "Growing Pains" your only article on transgender people and gender dysphoria?

A. Yes.

Q. Are you familiar with the St. John Paul II Bioethics Center?

A. Absolutely.

Q. Is this St. John Paul II Bioethics Center a religiously affiliated institution?

A. Yes, it is.

Q. Is it part of the Holy Apostles College and Seminary?

A. Yes, it is.

Q. Did you speak at the St. John Paul II Bioethics Center just three days ago, on Friday, November 17th?

A. I did, yes.

Q. During your speech last Friday, did you -- you said, "The identity of the individual is interactively linked to the body and the soul of the person." Is that right?

MR. KOSTELNIK: Form.

A. Repeat that again, just so I make sure you said that accurately.

Q. (By Mr. Gonzalez-Pagan) During your speech

last Friday, you said, "The identity of the individual is interactively linked to the body and soul of a person." Is that correct?

MR. KOSTELNIK: Form.

A. That is correct.

Q. (By Mr. Gonzalez-Pagan) During your speech last Friday, you said about being transgender, that, in fact, it probably goes back to some of the early heresies in the church; is that correct?

A. The introduction that I was providing to that audience was trying to put the context of the discussion in the proper framework, and I specifically made the statement that I am not a philosopher, that I'm going to be talking about issues of science and medicine. And it was an introduction to that talk to -- for that audience.

Q. Okay. Do you know who Caitlyn Jenner is?

A. Yes, I do.

Q. Caitlyn Jenner is a transgender woman, correct?

MR. KOSTELNIK: Form.

A. Caitlyn Jenner, formerly known as Bruce Jenner, is somebody that has been widely advertised in -- in the media related to the gender transition that -- that Caitlyn underwent.

Q. (By Mr. Gonzalez-Pagan) Is Caitlyn Jenner transgender?

A. By definition, yes.

Q. In referring to a picture of Caitlyn Jenner, did you not say these pictures are often disturbing?

A. I did. And that was the slide -- specifically was the statement, not Caitlyn Jenner, but there were two other pictures presented in that talk of children saying I hate my body. That was what I was referring to.

Q. Just to be clear, when it comes to the treatment of transgender people and gender dysphoria, your only publication is in a religiously-affiliated journal and you've spoken to -- about the topic to religiously-affiliated institutions?

MR. KOSTELNIK: Form.

A. I have offered to speak at all institutions that have invited me. And to date, yes, that was -- that was the institute that -- that invited me to speak last Friday.

Q. (By Mr. Gonzalez-Pagan) When did you first become interested in the matter of transgender people and the treatment of -- for gender dysphoria?

A. It was about five to six years ago, as chief of our Division of Endocrinology, when the question

A. I provided everything that I have access to right now that I can recall. I'm only stating that there are likely other papers that I do not have access to, because I did not keep track of it at the time that I read them or looked at them.

Q. Okay. Have you spoken with Dr. Allan Josephson?

A. Yes, I have.

Q. When?

A. On multiple occasions.

Q. Can you please describe?

A. I met Dr. Josephson within the last year as -- it was probably in the spring at some point in time, the first time that I actually met him. We've had a number of conversations over this past year, specifically related to his expertise as -- as a psychiatrist and mine as an endocrinologist. I have drawn upon him for questions related to psychiatric issues that -- that I did not have expertise in, to gather his opinion.

Q. In what capacity did you first counter-interact with Dr. Josephson?

A. It was at a conference that was put together to bring experts from various disciplines to this question of -- of gender dysphoria.

Q. Who put that conference together?
A. The Alliance Defending Freedom.
Q. The Alliance Defending Freedom is a religiously-affiliated institution, isn't it?
A. If you say so. I don't pay attention to what their religious affiliation is.
Q. When was this conference?
A. It was in the -- I don't know the exact date, but it was in the spring.
Q. Where was this conference?
A. It was in Phoenix.
Q. Aside from you and Dr. Josephson, do you recall any other experts, physicians or clinicians that attended this conference?
A. Yes, there were -- there was several other psychiatrists and psychologists. I don't remember their specific names, unfortunately. There were people that are in the social sciences. There was one other endocrinologist. I'm trying to remember who else was there. There were several lawyers from the ADA.
Q. Do you have any documents pertaining to this conference?
A. Not that I saved, no.
Q. Just to clarify, is there anything you

university, they offer gender-affirming treatment for gender dysphoric youth?

A. Yes, they do.

Q. Do they offer reparative treatment as a treatment for gender dysphoria at Boston Children's Hospital?

MR. KOSTELNIK: Form.

A. The word reparative therapy covers a lot of connotation by different people but to my understanding, they do not make any specific effort in counseling to lead to the realignment of gender with sex, if that's what you mean by conversion therapy.

Q. Before you started researching the issues of dysphoria around five years ago, had you met with Dr. Spack then?

MR. KOSTELNIK: Form.

A. Prior to five years ago, I do not recall a specific encounter yet. I'm sure we interacted at some point at one of the international meetings.

Q. (By Mr. Gonzalez-Pagan) In Paragraph 7, you state that you have met with parents of children with gender dysphoria; is that correct?

A. That is correct.

Q. In what capacity have you met with the parents of transgender children?

A. Again, this was at the very early time frame when I was trying to investigate the claims for the treatment and care, and I wanted to get as comprehensive of a viewpoint as I could. The first encounter I had was with a mother of an organization called Trans Parent Child, and I sat down for lunch with her for an extended period of time, more to listen to the experience that she had in countering a transgender child that she had.

Q. With how many parents of transgender children have you met?

A. Met or spoken on the phone? I think lately many of them have been over the telephone. I would say it's less than a dozen, but it's quite a few, and it's actually increased certainly since the publication of the "New Atlantis" article.

Q. So in the last five years, you've spoken to less than a dozen parents of transgender children?

A. Yes.

Q. When you first met with the parent of the -- associated with the organization Trans Parent, was this before you dealt -- scratch that.

MR. GONZALEZ-PAGAN: You're going to object anyway.

Q. (By Mr. Gonzalez-Pagan) When you met with

the parent associated with the association Trans Parent, had you already delved into the literature regarding gender dysphoria?

A. I was starting the process. It was very early on, so I don't recall the exact timing. I had read some papers, but I was still in the very early investigative phase.

Q. You said you have been contacted by parents since the publishing of your article "Growing Pains." Is that correct?

A. That is correct.

Q. How many have contacted you since the publishing of the article "Growing Pains"?

A. I'm not keeping track of that.

Q. Less than 35?

A. It may be more than five. Probably less than a dozen.

Q. What did you discuss with the parents of the transgender children that have contacted you since the publishing of your article "Growing Pains"?

A. I specifically discussed the context of my "New Atlantis" article in my role as a physician, which I always take as being a teacher. I try to educate them on my understanding of the condition and the treatment paradigm that was being offered to their

outcome and one with no bias as to what the outcome is. The goal, my understanding, of the people that I would recommend for psychiatric care would be interested in the best interest of the child for their best psychosocial functioning moving forward. That is the goal.

Q. Are you aware that reparative therapy is considered harmful by the American Medical Association?

A. I find no scientific justification to support that statement, but they do say that, yes.

Q. Are you aware that the Department of Health and Human Services commissioned a study with regards to conversion therapy?

A. I am familiar with the evidence that's available that's put forward as the evidence that says that it's harmful, and it's by no means definitive information. There are problems with the studies that limit the ability to make those conclusions.

Q. Just to clarify, you believe reparative therapy is an appropriate option for treatment?

A. I don't believe there's enough evidence to make a definitive statement one way or the other, but I believe that there -- that the psychotherapy that I believe can be helpful, whether it leads to conversion

access the bathrooms as the cause of Drew's distress is not supported.

Q. But you're not a mental health provider, right?

A. That is correct.

Q. And you've never met with Drew, right?

A. That is correct.

Q. Let's go back to the meetings with parents that you had when you were first delving into this topic?

A. Very good.

Q. You discussed that you met with a parent associated with an organization called Trans Parent; is that correct?

A. That is correct.

Q. What did you learn from that meeting?

A. I learned quite few things. The most important thing that I learned, and that was what I was actually seeking in the interaction, was to really understand the suffering that was going on in this family. I wanted to understand the dynamics of what was going on in the family, the approach that the parents had in dealing with the presentation of their child, what they had attempted to do to address this particular issue, and at that point in time, I was

approaching this in a purely investigative manner. I did more listening than anything else, asking questions about their lived experience.

Q. What did the parent tell you?

A. Well, that was many years ago, but I will try to summarize my recollection of that conversation. This was with the mother. And she shared that this child, who was a prepubertal in early grade school, told her, when the mother was talking -- they were combing hair or something of that nature -- that she would -- he, at that time, was a girl, so she was referring to him as a girl, and that the parents' reaction initially was shock, fear, trying to understand what was going on, trying to be able at that time -- this was early on in this resurgence -- or emergence, I should say of this discussion that's going on socially, so there wasn't, at that time, a lot of resources being published on the Internet.

So she shared her attempt to look at what experience people have had with this particular condition. And I saw at that time, certainly a parent that was desiring to do the best for their child, but having questions that were not answered, and at that time, with the information I had, I was certainly not able to provide any answers. And, in fact, at this

point in time, I don't think I would have been able to specifically answer the questions that she had as far as long-term outcomes, because we don't have that information. It was a very respectful conversation. It was very helpful. I think that it was mutually beneficial, but, again, the purpose was for me to understand this particular family and their experience with transgender identity.

Q. What is the organization Trans Parent?

A. All I know is it's a -- it's supposed to be a support group, and I think that the parents themselves, the woman I talked to at that time was trying to get out information so other people understood what they were experiencing.

Q. In that meeting with the parents of a transgender -- let me scratch that.

The next set of the questions I'm just going to be focusing on that one parent.

A. Okay.

Q. In that meeting with the parent of the transgender child, did you ever tell the parent that their child was not normal and would never be normal?

A. I did not, because I was still investigating and trying to understand what was going on.

Q. In that meeting with the parent of that

transgender child, did you ever tell that parent that their transgender son was a girl and would never be a boy?

A. I never said that, no.

Q. In that meeting with the parent of that transgender child, have you ever told -- scratch that.

In that meeting with the parent of a transgender child, did you ever tell the parent that surgeries attempting to change sex was wrong and went against God's plan for humanity?

A. No, not that I recall. That was many years ago, but I don't remember that, no.

Q. In that meeting with the parents of the transgender child, did you not urge them to read Pope John Paul II's writing on gender to fully understand God's plan regarding gender?

A. Thank you for reminding me. That was a long time ago, so this is bringing back some information. I believe that -- this was a personal conversation. This was a one-on-one conversation, and I think at the time that we began talking about that, she started relating her personal faith training, and I never back away from those conversations when people are asking me those questions, and I think that that's what led to that particular conversation.

Q. Are you aware that the AMA, quote, "opposes the use of reparative or conversion therapy for sexual orientation or gender identity"?

MR. KOSTELNIK: Form.

A. I'm aware of the WPATH saying that, and I -- I believe it may also be in the AMA statement as well.

Q. (By Mr. Gonzalez-Pagan) Are you aware that the American Academy of Pediatricians has stated that, quote, "In no situation is a referral for conversion or reparative therapy indicated"?

A. I'm aware of that statement, yes.

Q. Are you aware that a publication by the American Psychological Association and the U.S. Department of Health and Human Services states that interventions -- quote, "Interventions aimed at a fixed outcome, such as gender conformity or heterosexual orientation, including those aimed at changing gender identity, gender expression and sexual orientation are coercive, can be harmful and should not be part of the behavior health treatment"?

MR. KOSTELNIK: Form.

A. I am aware of that statement, but there is no scientific evidence to support that statement.

Q. (By Mr. Gonzalez-Pagan) On what basis do you disagree with that statement?

amount of experience that somebody who is a clinical -- a full-time clinician versus -- now, I -- I know from my own experience many people that are listed on those clinical studies were not the ones that designed the trial. They're not the ones analyzing the data. Their role usually in those studies, as clinical faculty, are usually in filling out and the protocols that are present for those. And now the specifics of the trial that she's involved with, I would have to look in more detail to assess that in -- in greater detail.

Q. Okay. Do you know what her role is?

A. You'll have to tell me what the study is and -- and give me more information to be able to do that.

Q. Did you review Dr. Ehrensaft's expert -- expert report in this case?

A. I did.

Q. Have you published any peer-reviewed literature regarding gender dysphoria or transgender youth?

A. These are questions that I've already answered, and the answer is no.

Q. Okay. Are you aware that Dr. Ehrensaft has published a number of peer-reviewed articles regarding

EXHIBIT D

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

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. PAUL W. HRUZ, M.D., Ph.D.
TAKEN ON BEHALF OF THE PLAINTIFF
JULY 16, 2018

(Starting time of the deposition: 8:49 a.m.)

Exhibit
0003
9/29/2021
Hruz

I N D E X

PAGE

E X H I B I T S

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of the South Dakota Bureau)
of Human Resources,)
Defendants.)

Deposition of DR. PAUL W. HRUZ, M.D., Ph.D., produced, sworn and examined on the 16th 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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clarify what you mean by formal education.

Q Well, I'll ask broadly; any kind of training of any sort that a doctor would get in the course of, you know, either their initial medical education or continuing education.

A So, working at a major academic institution, we're actually charged with providing medical education and so, to the extent that we've held journal clubs that we've had presentations with my colleagues where we've discussed the scientific evidence, where we've gone formally through the DSM Guidelines, where we've gone through the Endocrine Society Guidelines, that has been done at my institution. Have I sought out and gone to a separate conference related to gender dysphoria? The answer is no.

Q But, at your own institution, you've participated in these interactions, these journal clubs and other activities that address gender dysphoria and the treatment for gender dysphoria?

A That is a standard -- that is one of the components of what we do for all the conditions that endocrinologists are engaged in.

Q Okay. Have you conducted any research related to gender dysphoria or the treatment of

gender dysphoria?

A No formal trials, no.

Q Any other research?

A I've been in the area of HIV research for 20 years and conducted a number of scientific studies that -- but not directly related to gender dysphoria.

Q Yeah, I'm sorry if I was unclear. I didn't -- I know you've done research, but in the area of gender dysphoria, no research, is that right?

A I have not done any -- I'm not a clinical trials physician scientist. I'm a bench scientist.

Q What does that mean?

A I conduct laboratory research, so I'm engaged in hypothesis-driven research.

Q Okay. So, talking about research broadly, you haven't conducted any form of research relating to gender dysphoria, is that right?

A No, I have. I would consider research in looking at the extensive literature that's there is research. It's not a randomized controlled trial, it's not a formal study, but that would fit within the domain of research.

Q You mean reviewing research that was

published by other people? Is that what you mean?

A So, again, we can define research in many different ways. If you're asking the question about research, about gathering information, about the evidence that's available, I've done a considerable amount of research and that has consisted of looking at what published data is available supporting the recommendations that are being made. That I would consider research, but it is not a clinical trial.

Q Okay. And what people might call studies, scientific studies, have you done any scientific studies?

A Again, how you define studies, again, I have not done clinical trials.

Q Okay. When you were deposed in the Adams case, November, I believe it was, last year, you mentioned you were in the process of responding to a research funding announcement by the NIH to do research related to gender dysphoria or gender identity issues. Did I get that right?

A Yes.

Q Can you tell me the status of that?

A Yes. There are a number of logistical issues that are needing to be worked out. There is no funding for that particular study going on,

recruiting the people that are going to be necessary to conduct that study, again, I'm a pediatric endocrinologist. And to my knowledge, you know, that hasn't moved much beyond the initial planning stages. The proposal itself was a suggestion to address the question of -- a very particular question of the effects of pubertal blockade on the trajectory as far as the number of individuals that went on to cross hormone therapy and those that did not.

Q So, did you ever submit a proposal to NIH to do this research?

A No.

Q Okay. Did you ever respond to the funding announcement in any way?

A Depends on how you say "respond." I've already said I did not submit a proposal. I have taken that to colleagues. In fact, I've had very recent discussions with my colleague at Washington University that is interested in starting some sort of research effort. And I could speak at length of what I've recommended to him as far as how these studies should be conducted. I've been very disappointed that the rigor -- scientific rigor that's necessary for those studies is not currently

realignment of gender identity with sex that occurs when people do not get pubertal blockade, to the results of that particular -- again, it was a very small study -- would lead to that being asked as a hypothesis as to whether that intervention itself might have been influencing the outcome.

Q So, just to make sure I'm clear, it is still just a hypothesis that pubertal blockade could lead to persistence? That's not been proven?

A That is correct. And the opposite has not been proven as well.

Q I understand. Okay. Let's take your report from this case. Actually, before we turn to that, I forgot to ask one other question. Do you have experience conducting clinical trials on any topic?

A I've only been involved in one clinical trial. It's a very small study and my role was very minor.

Q And what was that topic?

A It was on the influence of insulin sensitivity on cardiac function.

Q I see. So clinical trials isn't your area of expertise?

A That is correct.

the meeting was?

A He was trying to convene a meeting so we could discuss the issues related to gender dysphoria. There was -- they were searching for somebody from the endocrine field that would be willing to talk over the issues that I had expertise in, that I had developed my understanding of what the literature showed, and he specifically said, You've got expertise in this area and we'd like to learn.

Q And did they talk about a need to develop expert witnesses for litigation?

A You know, I think that was implicit. I don't think that was -- I mean, I was not surprised when I was asked to serve as an expert. I'd actually submitted a declaration prior to that meeting. And I'm not sure exactly how that -- any of the details how I was asked to do that, but so I had already done some of the work there, so I made the assumption that that was one of the reasons why he invited me down.

Q Okay. So, the folks there were people who would potentially be expert witnesses in litigation?

A Not everyone that was there. I think there were people that explicitly said, I'm not

EXHIBIT E

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Adolescent Health, Medicine and Therapeutics

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REVIEW

Gender nonconforming youth: current perspectives

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Abstract: Beginning with a case vignette, a discussion follows of the reformulation of theories of gender development taking into consideration the recent upsurge of gender nonconforming and transgender youth presenting for gender services and also in the culture at large. The three predominant models of pediatric gender care are reviewed and critiqued, along with a presentation of the recently developed interdisciplinary model of gender care optimal in the treatment of gender nonconforming youth seeking either puberty blockers or cross-sex hormones.

Keywords: gender nonconforming, transgender, pediatric gender care, puberty blockers, cross-sex hormones

Introduction

The field of interdisciplinary treatment for gender nonconforming children and youth has not just expanded at an astronomically fast rate; to switch metaphors, it has rather been such as a tsunami, with a swell of children and families seeking support and services and stretching existing gender clinics and programs at their seams. This cohort of young people includes those who do not accept the sex assignment given to them at birth, those who do not accept their culture's expectations and rules about gender roles and gender behaviors, and those who present with a combination of both.

The case of Daniel is presented to launch this review of current perspectives on gender nonconforming youth. Daniel was 19 years old and in his first year of college (note: all identifying information has been changed to preserve confidentiality. In addition, the patient in the case vignette has provided written informed consent for the publication of the anonymized case details). Just a few months earlier he had announced to each of his parents, who were divorced, that he was transgender. For some years before that, he had been living as a girl, assuming that he was either a "butch dyke" or a masculine identified bisexual young woman. His father and stepmother's response was, "Yes, of course, it makes perfect sense. We'll support you in whatever you need". His mother's response was quite different, "God gave you a body, why would you want to go against God's will? I am so ashamed. What will I ever tell my family? I've always supported you, but I can't do this".

Taking a history, Daniel reported that by the end of his sophomore year in high school he discovered that he was transgender. Before that, he never had the language for who he was. Up until second grade, he, then she with the name Daisy, truly believed that when she reached puberty she would simply switch gears, grow a penis, get a beard,

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and become a man. From early childhood she dressed like a boy, insisted on wearing her hair short, and was perceived by all as the neighborhood tomboy. When she learned about the physical changes that accompanied female–menstruating, growing breasts, she responded, by her own report: "Whew, I'm so glad I'll never have to go through that". When an older youth disabused her of her misconception, informing her that she would receive no exemption and she would never grow to be a man because she was born a girl, she was temporarily devastated, coming to the realization that she was now doomed to walk the plank of female development. For her, this was a horrible thought. When she actually got her period in the sixth grade, she experienced, with trepidation, that her fate had been sealed – "I'm cooked, there's no turning back now".

In middle school, Daisy had her first girlfriend; she confided in her older brother about her new romance, and he promptly issued her a label, "You're a dyke". Except Daisy kept protesting, "I like boys, too". For high school, Daisy chose to go to a boarding school, the prime reason being that she was tired of going back and forth between two houses in her postdivorce family, and just wanted one place to settle into. It was a Catholic all-girls school and she got in trouble for having a romantic relationship with another girl at school. She persisted in dating girls, just not ones from her school, and through her peer connections first learned about the concept of transgender. She surfed the internet, joined chat rooms, and came to discover that "transgender would be me". Her then girlfriend, beginning to recognize who her partner really was, began referring to Daisy as D. and using male pronouns for D. D. never felt happier. But D. kept it a secret for 2 years, waiting out the end of high school and the opportunity to start a new life in college before affirming a male identity publicly. D. chose a liberal arts college far away from home and within weeks came out at school as Daniel. By Thanksgiving break, Daniel was ready to disclose to his parents, and that circles back to the beginning of the story.

After disclosing to his parents, Daniel then wanted hormones to align his body with his male identity, envisioning surgeries, including top and genital surgery, in his future, but not right then. Daniel's story is presented as an opener to highlight the two questions, "What is your gender?" and "What is to be done once discovered?" that underlie all existent adolescent gender care.

Daniel's case is not a unique one. One might even say that it is emblematic of the increasing number of youth who are seeking professional services, along with their parents, to sort out their authentic gender and discover ways to affirm that authenticity. In most Western cultures gender has historically been considered bedrock: one is assigned a sex at birth, either male or female, typically based on external appearance of genitalia, and this assignment determines one's gender for the duration of that individual's life. Upon entrance into the 21st century, that paradigm of gender bedrock has been hit with a sledge hammer; in its stead, we now have gender as moving boulders, with a sensibility of gender not coming in two boxes, but in infinite varieties, and not necessarily stable over the course of one's lifetime. As this has occurred, providers struggle to keep up with newly emerging theories of gender development and standards of care for the proper care of these youth. Just as an example, the World Professional Association for Transgender Health 7th Edition of the Standards of Care,[1] released in 2011, is already outdated and in the process of being revamped, with the section on children and adolescents in particular need of an update. The needed changes come most significantly in the area of social gender transitions for prepubertal youth, minimum ages for medical interventions, particularly puberty blockers and cross-sex hormones, but also surgeries for individuals before reaching the age of majority. Regarding numbers, the cohort of gender nonconforming youth seems to have expanded exponentially in the most recent decade, as reported by gender programs serving these children throughout North America and beyond.[2,3] In negotiating these phenomenal changes in the gender terrain, four major areas have needed to be addressed: the necessity of relearning gender so that health professionals can retool themselves to best serve this group of youth; the tensions between the three models of care; the importance of interdisciplinary collaboration in care; the introduction of medical interventions in the care of the youth.

Reformulate theories of gender development in light of gender nonconforming youth

Most professionals in the field of gender care have had to unlearn everything taught in training about gender and relearn a new model of gender development. To review the traditional model, children at birth are assigned a sex, male or female, typically based on appearance of external genitalia. If the genitalia were ambiguous in appearance, genital surgical procedures to establish a stable singular sex assignment with matching gender were to be performed as soon as possible, and no later than 18 months. The reasoning behind this, as propounded by Dr John Money and his associates,[4] was that after 18–24 months a child is firm in a core gender identity – I am male, I am female, and thereafter it becomes very difficult to change that identity as it is

already cognitively fixed. Once knowing one's gender label, which is both facilitated and mediated by parents' conscious and unconscious messages and reflections, a child's next developmental task is to learn how to "do" gender. Known as gender role socialization, this process is done in close relationship to one's mother and father, with the underlying assumption that all children will have both.[5,6] Within the psychoanalytic paradigm, during this same period a tumultuous drama unfolds, the Oedipal phase – children have intense erotic fantasies about their parents: boys will want to marry their mothers, girls their fathers. Through successful negotiation of these fantasies, facilitated by parents' empathy and boundary setting, children will emerge from the Oedipal phase relinquishing those infantile incestuous desires, firming their own heterosexual identities as they forestall gratification and await an opposite sex partner of their own when they reach adulthood.[7] Within that process they will establish a firm gender identity with a new understanding that one is and always will remain the sex listed on one's birth certificate or assigned early in life (for intersex children).[8] Throughout middle childhood youth will continue to internalize the gender norms of their culture, and learn to conform to them. With the advent of puberty and the entrance into adolescence, a new phase of gender consolidation occurs as youth awaken to their adult sexual urges and prepare for their gender-divided roles as men or women.

Within the traditional model of gender development, if this developmental trajectory takes a course other than that described above, there is cause for concern for the child, along with scrutiny of the parents, as parents are held accountable for the child's anomalies. To quote Robert Stoller, a pioneer in the treatment of gender disorders in youth in the 20th century,[9] speaking of "primary transsexual" boys (those nonintersex boys who have been feminine from the first year of life): "As an infant, such a boy usually has an excessively intimate, blissful, skin-to-skin closeness with his mother. This, unfortunately, is not interrupted by his father, a passive distant man who plays no significant part in bringing up his son" (p. 16). In family situations like the one inscribed above by Stoller, professional help was recommended to cure the youth's gender anomalies and to treat the parents so they cease veering their child's gender development in wrong directions because of their own internal conflicts.

For a theory of development to be robust, it should be evident in empirical observation or investigation. The traditional theory of gender development and disordered gender, which is still in use by many, fails that test, for the following reasons:[10]

- Many individuals continue renegotiating their gender throughout childhood or adulthood, with no observable detriment to their mental health;
- Youth may establish a gender identity in concordance with their assigned sex, be firm in that identity, yet not embrace a heterosexual identity, with no aspersion on their emotional well-being. Gender development and sexual identity development are two separate developmental tracks, albeit crossing at certain points.
- Whereas core gender identity is typically concordant with assigned sex based on observable external genitalia, for a minority of people this is not the case, with increasing evidence that gender identity lies not between our legs, in our genitalia and primary sex characteristics, but in our brains and minds.[11]
- Therefore, one's assigned sex at birth may differ from one's core gender identity, not because of poor parental handling or infantile confusions, but because of brain and mind gender messages overriding signals from genitalia, chromosomes, or parental expectations. Recently, this phenomenon of mind over matter has been referred to as "neurological sex", defined as a uniform standard of legal sex based on gender identity, in which brain messages are privileged over anatomy and chromosomes in determining an individual's authentic gender.[12]

In contemporary versions of gender development theory that take into account gender variations as a normal part of the human condition, the understanding is that the sex assigned at birth may match the gender a youth will eventually know themselves to be, but it might not. Each child is presented with a developmental task of weaving together threads of nature, nurture, and culture to establish their individual and unique authentic gender self. This self will be composed of both gender identity – who I know myself to be as male, female, or other, and gender expressions – how I choose to perform my gender, including clothing choices, activity preferences, friendship choices, and so forth. Recently, this transactional relationship between nature, nurture, and culture in gender development has been referred to as the gender web,[13] broken up into components that consist of the items in Table 1.

In this contemporary model of gender development, added to the three dimensions of nature, nurture, and culture is the fourth dimension: time. Each child alters their gender web as they weave together nature, nurture, and culture, "over time". In other words, gender is neither fixed by age 6, as in the traditional model, nor static throughout all stages of child and adult development, thus explaining how an individual

Table 1 Gender development: elements of the gender web

- Chromosomes
- Hormones
- Hormone receptors
- Gonads/primary sex characteristics
- Secondary sex characteristics
- Brain
- Mind
- Socialization: family, school, religious institutions, community
- Culture: values, ethics, laws, theories, and practices

at age 40 or 50 could come to the realization that the gender they had identified as being is no longer a good fit. It is also recognized that gender development is a discrete and separate track from development of one's sexual identity, and typically proceeds it in a youth's development.

In this model the role of parents and socialization agents is not to shape or reinforce a child's gender identity or expressions, but rather to facilitate it, mirroring back to the child the messages that the child communicates about their preferred gender expressions and articulated gender identity, which may or may not be in concordance with the sex assigned to the child at birth. With the advent of adolescence, it is recognized that some youth's gender trajectories may benefit from medical interventions, including puberty blockers (gonadotropin-releasing hormone [GnRh] agonist) and cross-sex hormones to bring the youth's body in better alignment with their affirmed gender identity.[14] To that end, the model of care that extends from this contemporary theory of gender development is one that strongly relies on interdisciplinary care, especially between mental health and medical providers as they address the holistic medical and psychosocial needs of the emergent cohort of gender nonconforming youth from the perspective of both their psychological and physical development.

Major mental health treatment models for gender nonconforming children and youth

As of the second decade of the 21st century, three major treatment models are available for addressing the needs of gender nonconforming children and their families, with overlapping premises based on the contemporary model of gender development outlined above but with distinct differences between them. The first model, represented in the work of Drs Susan Bradley and Ken Zucker, assumes that young children have malleable gender brains, so to speak, and that treatment goals can include helping a young child accept the gender that matches the sex assigned to them at birth. The second model, represented in the work of practitioners in the Netherlands, allows that a child may have knowledge of their gender identity at a young age, but should wait until the advent of adolescence before engaging in any full transition from one gender to another. The third model, represented in the work of an international consortium of gender affirmative theoreticians and practitioners, allows that a child of any age may be cognizant of their authentic identity and will benefit from a social transition at any stage of development. To situate and compare each of the three models, a typical referral that may come the way of a gender specialist, regardless of their orientation, is presented, with the assumption that this potential patient may be in need of services from a young age through adolescence:

> Hi Dr, I came across your information while I was researching for my son.
>
> He recently just turned 4 and wants to be a girl and is only drawn to girl toys/clothes for the past 2 years.
>
> We have not spoken with a professional doctor. But wanted to reach out early and find ways we as parents can support him.
>
> Please let me know if you could help.
>
> Thank you!

Dialing back a generation, if this child's name was Kyle and the same query came to a mental health professional participating in, for example, Dr Richard Green's clinic at the University of California Los Angeles, the treatment recommended and then implemented could very well have looked like this:

> When he was five, Kyle entered a behavior modification program. [...] Kyle received blue tokens for "desirable" behaviors […] red ones for "undesirable" behaviors […]. Blue tokens were redeemable for treats […]. Red tokens resulted in a loss of blue tokens, periods of isolation, or spanking by father.[15]

Setting a precedent for other clinicians of the time treating children who presented as gender nonconforming, Kyle's treatment at the UCLA program is emblematic of the model implemented during this era, with the goal of helping children accept the sex assigned to them at birth and adopt the culturally defined appropriate gender behaviors that would match that sex assignment, in alignment with the traditional model of gender development. Underlying the treatment was the intent of warding off a homosexual outcome for young effeminate boys. It should be mentioned

that this model is still practiced today, referred to by some as the reparative model.

Focusing now on contemporary approaches that stand in contrast to the above mode, all of which are to be differentiated from the UCLA program, the three major models, outlined earlier, are typically referred to, in order of presentation, as the following:

- The "live in your own skin" model
- The watchful waiting model
- The gender affirmative model

Below is a review of the manner in which each of these models would approach the treatment of a child or youth who is presenting as gender nonconforming, in their gender identity, gender expressions, or both.

The "live in your own skin" model

As mentioned earlier, this model was developed by Drs Susan Bradley and Ken Zucker at the Center for Alcoholism and Mental Health gender clinic in Toronto.[16] The treatment goal of facilitating a young child accepting the gender identity matching the sex assigned to that child at birth, based on the supposition that younger children, in contrast to older youth, have a malleable gender brain, is tied to a medical–social rationale. Specifically, being transgender is a harder way to live one's life, both because of social stigma and potential requested hormonal treatments and surgeries to align a youth's body with their transgender identity. Given the perceived plasticity of the young child's gender brain, best practice would be to introduce interventions to help a child accept the sex assigned to them at birth as their gender identity, with no harm done and indeed added benefit to their psychological and social well-being. As explained by Dr Zucker, employing this strategy results in lowering the odds that "as such a kid gets older, he or she will move into adolescence feeling so uncomfortable about their gender identity that they think that it would be better to live as the other gender and require treatment with hormones and sex reassignment surgery".[17] In addition to presuming gender identity malleability in young children, the model also assumes that parents' own conflicts or issues about gender likely contribute to a young child's gender dysphoria. With the parents' consent, the "live in your own skin" model employs a combination of behavior modification, ecological interventions, and family system restructuring to facilitate the child arriving at a place of accepting the gender matching their sex assigned at birth. Practices could include taking away cross-gender toys at home and replacing them with "gender-appropriate" toys, altering children's playmate choices to include more same-sex contacts, enrolling the children in "gender-appropriate" activities, encouraging the like-sex parent to become more actively involved and the opposite-sex parent to step back in relationship to the child, and offering psychotherapy to both the child and parents. The aim of treatment of the child is to explore the child's gender and solidify a "live in your own skin" outcome, and the treatment with the parents is aimed at investigating conflicts or psychological issues stemming from or contributing to the child's gender dysphoria. If by the arrival of puberty a child is still exhibiting cross-gender identifications and expressing a cross-gender identity, that child should be supported in transitioning to the affirmed gender, including receiving puberty blockers and hormones, once it is assessed through clinical interviews and psychometric testing that the affirmed gender identity is authentic. The reasoning behind this shift in adolescence is as follows: 1) by adolescence it is too late to intervene in facilitating a child living in their own skin, as the sensitive period of malleable brain development of gender has closed; 2) this individual can now be reliably identified as one of the small minority of youth who persist with a cross-gender identity from early childhood into adolescence, an indicator that this identification will most likely remain stable into adulthood. In the live in your own skin model, the parent reaching out for support of her 4-year-old son might be encouraged to engage in the treatment program outlined above, with the goal of helping her child accept that he is a boy, not a girl and with the intent of warding off a transgender outcome.

The watchful waiting model

The "watchful waiting" model was designed by the members of the interdisciplinary team at the Amsterdam Center of Expertise on Gender Dysphoria, VU University Medical Center, under the leadership of Dr Peggy Cohen-Kettenis. Borrowing from the medical use of GnRH agonists for children exhibiting precocious puberty, the Netherlands team is responsible for introducing the use of puberty blockers for gender purposes, to put a pause on pubertal growth and allow more time for a youth to explore their gender and consolidate their adolescent gender identity, with the future possibility of cross-sex hormone therapy to align their bodies with their affirmed gender identity. In contrast to the live in your own skin approach, a young child's demonstration of gender nonconformity, be it in identity, expressions, or both, is not to be manipulated in

any way, but observed over time. If a child's cross-gender identifications and affirmations are persistent over time, interventions are made available for a child to consolidate a transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment, as in the best interests of the child. These interventions include social transitions (the shift from one gender to another, including possible name change, gender marker change, and gender pronoun changes), puberty blockers, and later hormones and possible gender-affirming surgeries. No attempts are made to alter a child's gender identity or expressions; yet it is postulated in this model that it would be better to hold off until puberty on any social transitions of a child from one gender to another, and instead give them safe spaces to fully express their gender as they prefer before facilitating any full gender transitions.[18,19] The rationale for holding off on any social transitions until adolescence is not to ward off a transgender identity but rather that 1) it would be advantageous that a child experiences the first stages of physical puberty for that child to best make a determination of the gender that feels most authentic to him/her; 2) given developmental stages of childhood, facilitating a social transition from one gender to another at a young age may create a form of cognitive constriction – the child may be prematurely blocked from considering any other possibilities once moved into a cross-gender status and socially constricted from further childhood gender exploration because now they know the cross-gender identity is what everyone has come to expect from them; 3) socially transitioning a child at a very young age may preclude the child from maintaining a realistic understanding of their body and historical status – as a penis-bodied (once a boy) or a vagina-bodied (once a girl) person. In informing their practices, this model, like the live in your own skin model, relies on the data gathered about "persisters" and "desisters", both at their own clinic in the Netherlands and in other international studies, particularly those conducted at the Centre for Addiction and Mental Health (CAMH) gender program in Toronto. In the most recent review of these studies, it was found that 63% of the children seeking services at a gender clinic at a young age, and diagnosed with gender dysphoria, no longer had that diagnosis at puberty, while 37% did have the diagnosis consistently from early childhood to adolescence.[20] Since a large majority of gender nonconforming young children seeking services at gender clinics desist in their gender dysphoria by adolescence, best practices would be to wait and see if the child persists into adolescence before making any significant changes in a child's gender identity.

During the preadolescent waiting period, the children are followed carefully by the clinical team in the watchful waiting model, with the support of outside therapists in the community (which is required before a child can receive medical services), to assure that the children are growing well and getting their emotional needs met, and in preparation for later transitioning and medical interventions if the child proves to be a good candidate. Like in the live in your own skin model, the children going through the program also receive a full battery of psychological tests, documenting not only their gender status but also their cognitive–social–emotional functioning. Some of these instruments are delivered to the children directly, some to their parents or teachers.

If the mother asking for help with her 4-year-old were to attend the Amsterdam clinic with her child, the team might do an assessment and advise that the 4-year-old be followed over time, with the understanding that if her son's declarations of wanting to be a girl persisted over time and if he continued to be drawn only to "girl" toys and activities, consideration of puberty blockers to buy more time to explore gender could certainly happen later, but for now it would be best to let her son continue to be a son free to explore whatever activities he enjoyed, with no corrections on his expressed desire to be a girl.

The gender affirmative model

The third model of care, the gender affirmative model, is closely aligned with the watchful waiting model but in opposition to the live in your own skin model. Where the gender affirmative model parts ways with the watchful waiting model is in the waiting part.

The gender affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Interventions include social transition from one gender to another and/or evolving gender nonconforming expressions and presentations, as well as later gender-affirming medical interventions (puberty blockers, cross-sex hormones, surgeries). A particular set of premises informs the model, as listed in Table 2.

The model is informed by the contemporary theory of gender development outlined above, with a recognition that although gender evolves over the course of a lifetime, gender identity appears to be a relatively more stable and consistent construct compared to gender expressions. Gender health is defined as a youth's opportunity to live in the gender that feels most real and/or comfortable, or, alternatively, a youth's

Table 2 Basic premises of the gender affirmative model

- Gender variations are not disorders.
- Gender presentations are diverse and varied across cultures, requiring cultural sensitivity.
- Gender involves an interweaving, over time, of biology; development and socialization; and culture and context.
- Gender may be fluid; it is not always binary.
- If present, individual psychological/psychiatric problems are more often than not secondary to negative interpersonal and cultural reactions to a child.
- Gender pathology lies more in the culture than in the child.

ability to express gender with freedom from restriction, aspersion, or rejection.[21] When considering a child's gender status, attention is paid to both gender identity and gender expressions, with the understanding that a child's gender identity may communicate something very different about the child than a child's gender expressions might.

Therapeutic goals in the gender affirmative model include:

- Facilitating an authentic gender self
- Alleviating gender stress or distress
- Building gender resilience
- Securing social supports

In contrast to the first two models, no assumption is made that every child exhibiting a gender nonconforming presentation is in need of mental health treatment. Because of the emphasis on social factors affecting the youth, interventions may be targeted at the surrounding environment, rather than the child's individual psyche. This might include interfacing with schools, social and religious institutions, and policy-making bodies to remove the "social" pathology impinging on the child, such as transphobic attitudes and responses, gender policing, or bullying and harassment. Relatedly, parent consultations often take precedence over individual treatment of the child,[22–24] with provision of services to help a parent make sense of their child's gender nonconformity, work through any extant conflicts and anxieties about their child's gender, and move toward acceptance of their child.

Individual treatment for the child is indicated for one of five reasons: 1) to assess a child's gender status; 2) to afford the child a "room of their own" to explore their gender; 3) to identify and attend to any co-occurring psychological issues; 4) to address and ameliorate a child's gender stress or distress; 5) to provide sustenance in the face of a nonaccepting or rejecting social milieu, which might include family, school, religious institution, or community. Some professionals working in this model will call on psychometric or projective measures to gather information about the child; others will rely on observation, play, interviewing, and dialog. If assessment instruments are employed, every effort is made to use protocols that do not rely on binary measures of gender (e.g., Are you a boy or a girl?) and are not pathology oriented, but instead assess strengths as well as weaknesses and differentiate between gender expressions and gender identity.

The basic therapeutic tenet of the gender affirmative model is quite simple: When it comes to knowing a child's gender, it is not for us to tell, but for the children to say. In contrast to the watchful waiting model, once information is gathered to assess a child's gender status, action is taken to allow that child to exercise that gender. Therefore, if after careful consideration, it becomes clear that a young child is affirmed in their gender, demonstrating that the gender they know themselves is different than or opposite to the gender that would match the sex assigned to them at birth, the gender affirmative model supports a social transition to allow that child to fully live in that gender, whether that child is 3, 7, or 17 years old. Such decision-making is governed by stages, rather than ages, both for social transitions and later for medical interventions. Once the child's gender comes into clear focus, which is posited as happening with a child of any age, no need is seen to hold off until adolescence to affirm that gender. This viewpoint is informed by data indicating the psychological harm that can be done, including heightened risk for generalized anxiety, social anxiety, oppositional behaviors, depression, compromised school performance, if a youth experiences themselves living in a gender that is inauthentic to them.[25]

In the gender affirmative model, the mother of the 4-year-old querying about her son's cross-gender interests would be invited in to the consultation room, along with any other parenting figure involved, to report more about what she had been observing in her child's behaviors from infancy to the present; to determine whether her son is showing any signs of stress or distress about his interest in all things girly things; to explore whether her child is indicating cross-gender expressions vs identity. If there was evidence of stress or distress, by parents' report, or if the parents desired to get a clearer picture of their child's gender status, the family would be invited to bring their son in for observation and play sessions. There would then be the opportunity to reflect, in collaboration with the parents or caregivers, on any evidence that this child was consistent in cross-gender declarations, as in "I'm a girl, not a boy", and that these declarations were persistent over time and not attributable to any other problems in life. If that evidence made clear that this child was communicating about a cross-gender identity rather than desired cross-

gender expressions, and if the parents were supportive of their child's gender identity affirmations, it would not be found necessary to recommend to this mother that she wait until puberty to take action regarding her child's gender identity. Instead, a present social transition to the gender that was more authentic for this child, in this case, female, would be considered. If, on the other hand, the child was happy as he was, if given the latitude to play with whatever he wanted and wear whatever he desired, as a boy, the recommendation to the mother might be to give her son the opportunity to express his gender freely, with the opportunity to return for services as requested. Along with this recommendation would be a reminder that all that can be known is the cross section of this child's gender as he presents it at age 4, a gender that may evolve into another configuration later in childhood, at which point a new assessment may be in order.

Critique of the three models

In brief, the live in your own skin model has been challenged as causing potential harm to gender nonconforming youth. A Canadian study conducted by Wallace and Russell assessed that in the living-in-your-own-skin model "there appears to be an enhanced risk of fostering proneness to shame, a shame-based identity and vulnerability to depression."[26] Major health organizations, including the World Professional Association for Transgender Health, the American Psychological Association, and the American Psychiatric Association, have issued statements stipulating that mental health professionals are not to engage in practices that attempt to alter the gender expressions or identity of an individual, including children and adolescents. The watchful waiting model is a highly respected model of care worldwide, offering careful and cautious procedures; but it has run into a snag: many contemporary families in the Netherlands are not content to hold their children back from social transitions until puberty, and have, through both local and international support networks of parents and professionals, proceeded to facilitate their children's social transitions without awaiting clinical approval or waiting until puberty arrives. Parents do this not because they dismiss professional care, but because evidence is accruing that young children thrive when given permission to live in the gender that is most authentic,[27,28] and are at risk for symptomatic behaviors if prevented from doing so. At the same time, the watchful waiting model is effective in its thorough attention and assessment of the child over time, integrating the services of mental health and medical professionals.

The gender affirmative model is questioned by some on the basis of the lack of evidence-based data that indicates that young children can reliably communicate and have self-knowledge of a transgender identity or benefit from a social transition. There is also concern that the model of listening to the children puts too much weight on a child's self-report. This is a valid concern, and to address it the self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Together, the team will be making informed determinations about the most appropriate gender pathways to promote a child's gender health, be it a gender social transition, expanded opportunity to express gender in ways that feel authentic to the child, or deeper exploration of underlying issues that may be presenting as gender stress or distress. Such determinations typically involve extensive consultation and observation, but with no requirement for ongoing psychotherapy or psychometric testing, in comparison to the other two models.

Integration of medical and mental health care in adolescence

All of the three models of care referenced earlier share in common the administration of hormonal treatment in adolescence. The first category would be consideration of GnRH agonists (puberty blockers) to put a temporary pause on puberty, providing a youth with additional time to explore gender or, alternatively, warding off an unwanted puberty. The latter is particularly true for youth who socially transitioned early in life, living consistently in their affirmed gender from a young age; in those instances administration of puberty blockers could be considered a form of continuity of care, from social transitions to hormonal intervention. The second category includes feminizing or masculinizing hormones to bring a youth's body in better alignment with their affirmed gender identity. The minimal age for being eligible for such treatments may vary among approaches and indeed among clinics adopting the same approach, but there is common agreement that these treatments are in the best interests of the child who has a documented transgender identity.[29] It should be noted that there is probably no other aspect of adolescent care in which the medical and mental health professionals are so vitally interdependent in both assessment and treatment of the youth.[30] The reason for this is that each of the interventions has vital interconnected psychological and medical components, requiring an integration of medical evaluation and mental health assessment both to determine appropriateness, assess any medical or psychological impediments to treatment, and monitor follow-up, in terms of effects and supports over time as the youth is administered either the puberty blockers or hormones.

The role of the medical professional is first to assess the youth's level of puberty development, with an assessment of physical readiness for considerations for puberty blockers, which can be administered as soon as the youth enters Tanner Stage 2 of puberty. The medical professional will be responsible for ordering the lab work and bone density scans necessary to monitor a youth's progress and also to screen for any medical counter-indications to administering the blockers. As RnGH agonists are a completely reversible procedure regarding development of secondary sex characteristics, the medical provider will not need to worry about untoward permanent effects in that regard if the youth decides to go off blockers and return to the unfolding of a physical puberty in concordance with the sex assigned at birth. It should be noted, however, that the provider will need to alert the child and family about any side- or long-term effects of RnGH agonists, including effects on bone mineral density and overall bone health. If, on the other hand, the youth decides to proceed with cross-sex hormones to affirm a gender identity not in concordance with the sex assigned at birth, the medical provider will then be faced with the task of determining if the youth is a good candidate for this next step of treatment. Some youth will have already gone through full puberty before discovering or communicating to others a transgender identity, and the medical provider will be faced with the same task with these youth, with the added feature of explaining to the youth that certain of the developed features of the puberty they have already gone through will not disappear as they go through a second puberty on cross-sex hormones. In either case, cross-sex hormones involve a weightier decision than puberty blockers, as these interventions are only partially reversible in terms of secondary sex characteristics, so the provider will want to be cautious and judicious in determining if cross-sex hormones are appropriate for a particular youth.

This is where the mental health professional enters. In all of the models of gender care, the mental health professional is asked to weigh in as to 1) the authentic gender identity of the youth or level of gender dysphoria exhibited by the youth; 2) the youth's level of maturity and ability to assent to and follow through on the recommended hormonal treatment; 3) the evidence of any coexisting psychological conditions that might interfere with the hormone treatment or that alternatively might bear no weight on the requested treatments or even be alleviated by the hormonal interventions; and 4) the level of family support and willingness to consent to the treatment. In consultation with the medical professional, a decision will be made as to whether a youth is a good candidate for either puberty blockers or cross-sex hormones.

Another critical task for the medical-mental health team is the necessary discussion of fertility implications for each of these interventions. Although advances are being made in reproductive medicine to preserve immature gametes or reproductive tissues for later reproduction, at this point in history a child who begins puberty blockers at Tanner Stage 2 and proceeds directly to cross-sex hormones will be rendered infertile. Administration of testosterone or estrogen to a postpubertal adolescent may compromise a youth's later fertility, or might require going off the hormones for a period of time if a transgender youth who has not had gonad or genital surgeries later in life desires to have a genetically related child. Alternatively, a youth can bank gametes for the future before going on a course of cross-sex hormones, which is a medical possibility but also a psychological challenge for many transgender youth who find this antithetical to their affirmed gender status, requiring a transgender female to attend a fertility clinic and masturbate or a transgender male to undergo a gynecological vaginal ultrasound. Exploring fertility issues before making decisions about blockers or hormones are necessary but sensitive discussions to be had with both the youth and parents, and are best done with the presence of both a medical and a mental health professional who together can provide medical and psychological counsel to the family in this decision affecting later family-building.[31]

Not only is there no other aspect of adolescent care where the teamwork between medical and mental health provider is critical; there is no other domain of youth services in which a mental health provider is so actively involved in medical decision making. Where this has surfaced most recently is in the recent emergence of youth in gender clinics who present as neither male nor female, but rather gender nonbinary or "in the middle", adopting the platform of the multiplicity of gender. The challenge is when these youth ask for a particular medical intervention that achieves that goal of a middle ground – perhaps a touch of testosterone, or chest surgery with no other intervention and a chosen pronoun of "they" rather than "he" or "she". These are new horizons for both medical and mental health professionals today, and there is a mutuality, therefore, in the medical professional training the mental health professional while the mental health professional is in turn training the medical professional in order to integrate the biopsychosocial aspects of care to include the gamut of all the gender nonconforming youth presenting for care.[32]

With that said, it has proved to be critical that mental health professionals involved in this team work be trained gender specialists, with a basic understanding of the medical interventions involved in transgender care, expertise in

assessing gender dysphoria and identifying a youth's gender identity, and recognition of psychological issues other than gender that might drive a youth's request for a hormonal treatment. For example, a nurse practitioner on a gender team had administered a puberty blocker implant, Supprelin, which could stay in place for a year, after receiving a letter of support from a trained mental health expert recommending such treatment for this youth who presented as gender dysphoric and in need of further exploration of his gender before going forward with puberty. Over the course of the following year, he failed to return for follow up visits. A year had gone by and it was now time to replace the implant, which the nurse practitioner was prepared to do. The mental health member of the team first did a follow-up evaluation of the youth and discovered that he had made no efforts to explore his gender any further, with his motivation to continue on blockers driven by a desire to remain prepubertal for as long as possible. With the psychologist's guidance, the medical provider was able to recognize that the medical intervention as it stood was inappropriate for this youth. The interdisciplinary team informed the youth that he would be able to receive a new implant only if he was simultaneously working with a mental health gender specialist to further explore his gender identity. If that condition was met, once the twelve additional months on the puberty blockers was completed, the youth would then have to make a determination of which puberty path he would take – cross-sex hormones or the unfolding of his male, testosterone-producing puberty.

Conclusion

In the course of only two decades, sophisticated models for the care of gender nonconforming and transgender youth have evolved. There is an urgent need to provide more research data documenting the efficacy of these different programs, but the recent findings of the Amsterdam group provide hope that the care, particularly within the watchful waiting and gender affirmative models, is promoting gender health. In the Dutch authors' words, the treatment, including puberty suppression, cross-sex hormones, and then in adulthood gender affirmation surgery, "leads to improved psychological functioning of transgender adolescents. While enabling them to make important age-appropriate developmental transitions, it contributes to a satisfactory objective and subjective well-being in young adulthood".[33] The authors propose that not only early medical intervention, but also a comprehensive multidisciplinary approach contributes to the youth's gender health. Reflecting back on Daniel, the youth introduced at the opening of this review, the ability of professionals to aid youth such as Daniel in getting his authentic gender into focus and providing the appropriate treatments to bring that gender in alignment with his body is the key to overall well-being for all youth seeking professional gender care.

Disclosure

The author reports no conflicts of interest in this work.

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EXHIBIT F

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

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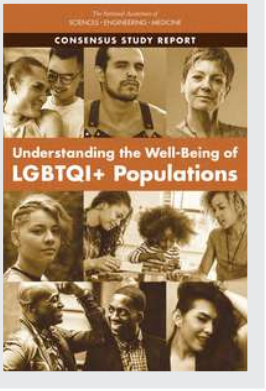

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Understanding the Well-Being of LGBTQI+ Populations

Committee on Understanding the Well-Being of Sexual and Gender Diverse Populations

Charlotte J. Patterson, Martín-José Sepúlveda, and Jordyn White, *Editors*

Committee on Population

Division of Behavioral and Social Sciences and Education

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Guidelines and Policies Related to Gender Affirmation

Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines. In 2012, the World Professional Association for Transgender Health (WPATH) published version 7 of the *Standards of Care for the Health of Transgender, Transsexual, and Gender-Nonconforming People*, which have been continuously maintained since 1979, and revisions for version 8 are currently underway (Coleman et al., 2012). Two newer guidelines have also been published by the Endocrine Society (Hembree et al., 2017) and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016). Each set of guidelines is informed by the best available data and is intended to be flexible and holistic in application to individual people. All of the guidelines recommend psychosocial support in tandem with physical interventions and suggest timing interventions to optimize an individual's ability to give informed consent. Mental and physical health problems need not be resolved before a person can begin a process of medical gender affirmation, but they should be managed sufficiently such that they do not interfere with treatment.

A major success of these guidelines has been identifying evidence and establishing expert consensus that gender-affirming care is medically necessary and, further, that withholding this care is not a neutral option (World Professional Association for Transgender Health, 2016). A number of professional medical organizations have joined WPATH in recognizing that gender-affirming care is medically necessary for transgender people because it reduces distress and promotes well-being, while withholding care increases distress and decreases well-being (AMA, 2008; American Psychiatric Association, 2018; American Psychological Association (APA), 2008, 2015; American Academy of Family Physicians, 2012; American Academy of Pediatrics, 2018; American College of Nurse Midwives, 2012; American College of Obstetricians and Gynecologists, 2011; Endocrine Society, 2017). Accordingly, public and private insurers have expanded access to gender-affirming care; some have done so proactively, while others have been required by state and federal nondiscrimination laws to remove coverage exclusions (Baker, 2017).

Coverage requirements for gender-affirming care typically rely on an overarching principle of parity between medically necessary services for transgender and cisgender people. Treatments that are gender-affirming for transgender patients are covered by public and private insurers for intersex and cisgender people for a variety of conditions, including genital difference, endocrine disorders, cancer prevention or treatment, and reconstructive surgeries following an injury. Examples of these services include testosterone or estrogen replacement therapy after surgery or menopause, vaginoplasty after pelvic surgery or for women with vaginal agenesis in the context of an intersex condition, and phalloplasty for cisgender male service members injured in war (Spade et al., 2009; Baker et al., 2012; Balzano and Hudak, 2018).

As this report goes to press, 24 states and the District of Columbia have enacted laws or made administrative changes prohibiting transgender-specific insurance exclusions in private coverage (Movement Advancement Project, 2020a). However, Medicaid programs in 10 states continue to explicitly exclude gender-affirming care for transgender individuals, and many states do not address the issue of this coverage in Medicaid (Mallory and Tentindo, 2019). At the federal level, the Medicare program removed its exclusion for "transsexual surgery" in 2014 (U.S. Department of Health and Human Services, 2014), though coverage decisions related to gender-affirming surgeries are still made on a case-by-case basis (CMS, 2016). As discussed

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European samples, a United States-based comprehensive registry that tracks patient-centered outcomes for both youth and adults could lead to valuable insights on the benefits of medically supervised gender affirmation (Kimberly et al., 2018). Much remains to be learned regarding optimal timing and risk profiles for surgeries and other medical interventions, aided by standardized and validated tools for body satisfaction, gender-related quality of life, gender dysphoria, and mental health (Olson et al., 2016). Standardized assessment and reporting of outcomes are particularly essential for helping clinicians and patients understand surgical options. In this area, too, more attention is needed to populations that tend to be invisible or underrepresented in clinical research, especially transgender people of color and non-binary individuals. Very little is known about the experiences and options for treatment for transgender individuals with intersex traits, especially those who had irreversible treatments as children. Overall, however, the evidence indicates that gender-affirming interventions, including social affirmation, hormonal treatment, and surgeries, are medically necessary for reducing distress and improving the health and well-being of transgender people.

CONVERSION THERAPY

Efforts to change sexual orientation or gender identity, which initially gained traction in the 1960s and which are often referred to as conversion or reparative therapies, assume that non-cisgender and non-heterosexual identities are abnormal. In 2009 the American Psychological Association (APA) produced a landmark report that systematically reviewed the evidence of efficacy for sexual orientation change efforts (APA, 2009). Most of this research was conducted prior to 1981, and very few studies were experimental in design. The task force found that some people sought sexual orientation change efforts due to distress over their sexual orientation but that the treatments were unable to reduce same-sex attractions or increase other-sex attractions. Furthermore, there was evidence that individuals experienced harm from these treatments, including sexual dysfunction, depression, anxiety, and suicidality. With regard to gender identity, while interest in the so-called “desistence” of transgender identity has been informed by studies suggesting that as high as 80 percent of prepubertal youth presenting to pediatric gender clinics ultimately do not identify as transgender, many of the youth included in these studies did not meet full DSM criteria for a gender incongruence diagnosis (Olson, 2009). Recent evidence supports that early social affirmation of transgender identity is associated with good outcomes (Olson et al., 2016; Durwood, McLaughlin, and Olson, 2017) and that lack of social affirmation correlates with depression, anxiety, and suicidality (de Vries et al., 2016; James et al., 2016).

Consequently, sexual orientation and gender identity conversion efforts have fallen out of favor in mainstream psychological and psychiatric practice. By the time of the 2011 Institute of Medicine report, many medical organizations had issued statements condemning sexual orientation change efforts based on the lack of efficacy and evidence of harm. Many of these organizations have since updated their positions to decry conversion therapy for both sexual orientation and gender identity (Streed et al., 2019a; SAMHSA, 2015; Rafferty et al., 2018; American Academy of Child and Adolescent Psychiatry, 2018; AMA and GLMA, 2018).

However, there is recent evidence that LGBTQ youth and adults continue to be exposed to conversion therapy. A 2019 report from the Williams Institute estimated that 698,000 adults between ages 18 and 59 have undergone conversion therapy from a licensed professional or religious advisor, of whom 350,000 were adolescents when treated (Mallory, Brown, and Conron, 2015). The same study estimated than additional 57,000 youth will receive conversion

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therapy from a health care or religious provider before 18 years of age. Among 25,000 LGBTQ youth respondents to a 2019 national survey, 67 percent reported that someone attempted to convince them to change their gender identity or sexual orientation (Trevor Project, 2019). A survey of 762 marriage and family therapists and members of the American Academy of Marriage and Family Therapists, which has a position statement against conversion therapy, found that 19.4 percent of respondents believed it was ethical to practice sexual orientation change therapy, and 3.5 percent of respondents had done so. This belief was associated with higher levels of negative beliefs about LGB clients than those of other therapists (McGeorge, Carlson, and Toomey, 2015).

A recent survey was among the first to evaluate the link between sexual orientation change therapy and the health of young people: among 245 white and Latinx LGBT individuals between the ages of 21 and 25, exposure to conversion efforts within or outside of their families during adolescence was associated with higher family religiosity, lower family socioeconomic status, and higher individual gender nonconformity (Ryan et al., 2018). In addition, exposure to conversion efforts during adolescence was significantly associated with increased suicidal ideation, suicide attempts, and depression, as well as diminished life satisfaction, self-esteem, social support, educational attainment, and lower income in young adulthood.

A systematic narrative review of gender identity conversion efforts found few data and a notable absence of research about their effects on both adolescents and adults (Wright, Candy, and King, 2018). However, a recent study using data from the 2015 USTS found that 14 percent of respondents had been exposed to gender identity conversion therapy during their lifetimes; exposure was associated with significantly higher rates of past-month severe psychological distress and lifetime suicide attempts compared with respondents who had not been exposed to such therapy (Turban et al., 2019). Exposure to gender identity conversion therapy before age 10 was associated with nearly twice the rate of lifetime suicide attempts.

The available evidence suggests that sexual orientation and gender identity conversion efforts are ineffective and dangerously detrimental to the health of SGD populations, especially for minors who are unable to give informed consent. As of early 2020, 20 states, the District of Columbia, Puerto Rico, and a number of municipalities had outlawed sexual orientation and gender identity conversion therapy for minors (Movement Advancement Project, 2020d). As growing numbers of professional organizations and governments call for or legislate an end to conversion therapy, particularly for minors, it is important for clinicians working with SGD populations to understand the effects that these experiences can have on individuals, even many years later. Research on strategies for helping individuals who have experienced conversion therapy to heal and recover is essential. In order to end the practice of conversion therapy, it is not sufficient for professional organizations to recommend against conversion therapy; rather, professionals may require dedicated and specific training on the inefficacy and danger of conversion treatments, and insurance providers should consider limiting coverage for these non-evidence-based practices.

INTERSEX GENITAL SURGERY

The most expansive estimations of the prevalence of intersex traits, including any variation in any marker of sex (chromosomes, internal reproductive anatomy, external genital shape, and secondary sex traits) concludes that up to 1.7 percent of the population has an intersex trait (Fausto-Sterling, 2000). Estimates based on the number of people with clinically identifiable

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EXHIBIT G

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

Understanding Unapproved Use of Approved Drugs "Off Label"

Exhibit
0015
9/29/2021
Hruz

Has your healthcare provider ever talked to you about using an FDA-approved drug for an unapproved use (sometimes called an “off-label” use) to treat your disease or medical condition?

It is important to know that before a drug can be approved, a company must submit clinical data and other information to FDA for review. The company must show that the drug is safe and effective for its intended uses. “Safe” does not mean that the drug has no side effects. Instead, it means the FDA has determined the benefits of using the drug for a particular use outweigh the potential risks.

When you are prescribed a drug for its approved use, you can be sure:

- That FDA has conducted a careful evaluation of its benefits and risks for that use.
- The decision to use the drug is supported by strong scientific data.
- There is approved drug labeling for healthcare providers on how to use the drug safely and effectively for that use.

The approved drug labeling for healthcare providers gives key information about the drug that includes:

- The specific diseases and conditions that the drug is approved to treat.
- How to use the drug to treat those specific diseases and conditions.
- Information about the risks of the drug.
- Information that healthcare providers should discuss with patients before they take a drug.

Some drugs may also have labeling information for patients such as Medication Guides, Patient Package Inserts and Instructions for Use.

Why might an approved drug be used for an unapproved use?

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.

You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition.

What are examples of unapproved uses of approved drugs?

Unapproved use of an approved drug is often called “off-label” use. This term can mean that the drug is:

- Used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
- Given in a different way, such as when a drug is approved as a capsule, but it is given instead in an oral solution.
- Given in a different dose, such as when a drug is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day.

If you and your healthcare provider decide to use an approved drug for an unapproved use to treat your disease or medical condition, remember that FDA has not determined that the drug is safe and effective for the unapproved use.

Questions you may want to consider

If your healthcare provider is thinking about using an approved drug for an unapproved use, you may want to ask your healthcare provider questions like these:

- What is the drug approved for?
- Are there other drugs or therapies that are approved to treat my disease or medical condition?
- What scientific studies are available to support the use of this drug to treat my disease or medical condition?
- Is it likely that this drug will work better to treat my disease or medical condition than using an approved treatment?
- What are the potential benefits and risks of treating my disease or medical condition with this drug?
- Will my health insurance cover treatment of my disease or medical condition with this drug?
- Are there any clinical trials studying the use of this drug for my disease or medical condition that I could enroll in?

Resources For You

- FDA Approved Medication Guides (/drugs/drug-safety-and-availability/medication-guides)
- Drugs@FDA Database (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)
- DailyMed (https://dailymed.nlm.nih.gov/dailymed/index.cfm)

EXHIBIT H

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

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FROM THE AMERICAN ACADEMY OF PEDIATRICS

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

POLICY STATEMENT

Off-Label Use of Drugs in Children

Policy Statement–Reaffirmed with Reference & Data Updates

This policy statement has been reaffirmed with reference and data updates. New or updated references or datapoints are indicated in bold typeface. No other changes have been made to the text or content of the policy.

The AAP would like to acknowledge Jennifer Foster, MD, MPH, for these updates.

COMMITTEE ON DRUGS

KEY WORDS
off-label drug use, pharmaceuticals, pediatrics, infants, children, adolescents, prescribing

ABBREVIATIONS
BPCA—Best Pharmaceuticals for Children Act
FDA—US Food and Drug Administration
PREA—Pediatric Research Equity Act

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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Exhibit
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9/29/2021
Hruz

abstract

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The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than **800** labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. *Pediatrics* 2014;133:563–567

INTRODUCTION

The purpose of this statement is to further define and discuss the status of off-label use of medications in children. Since publication of the 2002 statement from the American Academy of Pediatrics on the off-label use of drugs,[1] the number of drugs approved by the US Food and Drug Administration (FDA) with pediatric indications or expanded labeling that informs drug use in pediatric patients (eg, pharmacokinetic/pharmacodynamic data, safety data) has substantially increased. The passage of the Best Pharmaceuticals for Children Act[2] (BPCA) and the Pediatric Research Equity Act[3] (PREA) has resulted in more than **800** pediatric labeling changes. However, despite this success and advances in both basic science and clinical trials in pediatrics, off-label drug use remains a common and important issue for children and adolescents. Moreover, off-label use of drugs presents an even larger and more complex issue in preterm and full-term neonates, infants and in children younger than 2 years,[4] and children with chronic and/or rare diseases.[5,6]

DEFINING OFF-LABEL USE

The term "off-label" use refers to use of a drug that is not included in the package insert (approved labeling) for that drug. The purpose of off-label use is to benefit an individual patient. It is important to note that the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. To approve a drug for sale and marketing within the United States, the FDA requires substantial

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evidence for efficacy and safety, usually in the form of 2 well-controlled trials. Subsequent requests by a sponsor to add a new indication to drug labeling must also be accompanied by additional evidence in support of that indication. If the FDA finds that such evidence supports approval, the new indication is added to the product labeling. If the evidence is deemed insufficient or if the sponsor chooses not to submit evidence, the indication is not added.

According to the Code of Federal Regulations,[7] a sponsor is the entity that holds an investigational new drug application and that both takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. A sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual who uses 1 or more of his or her own employees to conduct an investigation that he or she has initiated is considered to be a sponsor, not a sponsor-investigator. In this case, the employees are investigators. Sponsor-investigators both initiate and conduct an investigation and direct the administration or dispensing of the investigational drug. The requirements applicable to a sponsor-investigator include both those applicable to an investigator and a sponsor. It is important to note that sponsors are not allowed to promote or even speak to off-label use. If a physician speaks on behalf of a sponsor, the same rule applies. It is acceptable to use drugs off label and to publish results related to off-label use, but it is not acceptable to receive remuneration from the sponsor for these uses.

The absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the drug's use is improper for that age or disorder. Rather, it only means that the evidence required by law to allow inclusion in the label has not been approved by the FDA. Additionally, in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children. Instead, it specifically means that evidence for drug efficacy and safety in the pediatric population has not been submitted to FDA for review or has not met the regulatory standards of "substantial evidence" for FDA approval. In contrast to the absence of pediatric-specific information on some medications, other drug labels contain statements such as "the safety and efficacy in pediatric patients have not been established," and explicit evidence-based warnings and contraindications are included on the label where indicated. Understanding the distinction between the lack of FDA approval for a particular use or dosing regimen in the former case versus explicit warnings or contraindications against use in the latter is essential for the pediatric practitioner. In addition, when considering best practices for therapeutic decision-making, it is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine.[8]

THE ROLE OF THE FDA

The FDA is the federal government agency charged with oversight responsibility for the manufacturing, labeling, advertisement, and safety of therapeutic drugs and biological products. The Food, Drug, and Cosmetic Act[9] requires that "substantial evidence," resulting from "adequate and well-controlled investigations" demonstrating that a new drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," be submitted to and reviewed and approved by the FDA before the drug is marketed in interstate commerce. For drugs and biological agents (eg, vaccines, antibodies), proof of effectiveness consists of "adequate and well-controlled studies" as defined for new drugs in the Code of Federal Regulations.[10] Biological agents are approved under the Public Health Service Act.[11] Given these requirements as well as the rapid pace of medical discovery, it is not surprising that labeling does not reflect all possible uses of an agent. Off-label use of drugs in children is not overseen by the FDA, because the FDA does not regulate the prescription practices of individual practitioners.

The FDA maintains a system for postmarketing drug surveillance, compiling and analyzing information about the incidence and severity of adverse events reported by practitioners, sponsors, hospitals, and other health care facilities. It is important to note that this postmarket surveillance system is passive and that the total number of adverse event reports in pediatrics relative to adults is small. To address this issue, the BPCA provides for a systematized review of adverse event reports in pediatric patients through the FDA Pediatric Advisory Committee. When the FDA notes an apparent association between use of a drug and an adverse event, the FDA may choose from several actions: to request further focused study of the drug, to add a contraindication or warning to the drug labeling, to issue a warning about use of the drug, or to seek voluntary or compulsory removal of the drug from the market. Therefore, although the FDA does not regulate the practice of medicine, practitioners should be aware of new information brought forward by the FDA, because it can serve as a valuable resource for information regarding the potential or proven adverse effects of drugs (see www.fda.gov).

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THERAPEUTIC DECISION-MAKING

Therapeutic decision-making should always be guided by the best available evidence and the importance of the benefit for the individual patient. Practitioners are in agreement regarding the importance of practicing evidence-based medicine. However, for the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice. There are now many resources available to help assess the quality of evidence-based medicine, including but not restricted to articles in peer-reviewed journals, American Academy of Pediatrics practice guidelines and policy statements, consensus statements, and handbooks and databases (ie, Cochrane, Lexicomp, and Harriet Lane). At times, there may be little or no published information to guide therapy. This situation is especially true when treating rare diseases or sparse populations such as neonates. In such situations, the practicing physician can play an important role in adding to therapeutic information by publishing his or her experience with off-label uses of drugs. These reports can serve as the basis of more formal efficacy and safety studies and can serve as a therapeutic decision-making resource for other physicians. The practicing physician also has a responsibility to report adverse events to the FDA through the Medwatch program (www.fda.gov/Safety/MedWatch).

In most situations, off-label use of medications is neither experimentation nor research. The administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest.[8]

In general, if existing evidence supports the use of a drug for a specific indication in a particular patient, the usual informed-consent conversations should be conducted, including anticipated risks, benefits, and alternatives. If the off-label use is based on sound medical evidence, no additional informed consent beyond that routinely used in therapeutic decision-making is needed.[12,13] However, if the off-label use is experimental, then the patient (or parent) should be informed of its experimental status.[14] It would be prudent for pediatricians to know and abide by the appropriate informed consent laws in their respective states. In addition, particular risk-benefit ratios presented by the unproven therapies must be carefully considered and disclosed, and standard of care practices should be reviewed. When use of a drug is truly investigational, drug use should be performed in conjunction with a well-designed clinical trial whenever possible. This is especially true when the physician proposes to treat a group of patients rather than a single individual. Patients and/or their legal guardians should be specifically informed that the proposed therapy is investigational, and their consent to proceed despite the risks of investigational therapy should be carefully documented. Whether institutional review, consultation, or written consent are required for a given intervention depends on the degree of risk or departure from standard practices and the extent to which research, rather than individual patient care, is involved.

Practitioners may be concerned that the off-label use of an approved drug may invite a variety of legal actions. To conform to accepted professional standards, the off-label use of a drug should be done in good faith, in the best interest of the patient, and without fraudulent intent. A practitioner may be accountable for the negligent use of any drug in a civil action, regardless of whether the FDA has approved the use of that drug. Labeling is not intended to preclude the practitioner from using his or her best medical judgment in the interest of patients or to impose liability for off-label use. Indeed, the practice of medicine will more than likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient. However, because the use of drugs in an off-label capacity can increase the liability risk for a practitioner should an adverse event or poor outcome ensue, it is essential that practitioners document the decision-making process to use a drug off label in the patient's medical record.

FEDERAL LEGISLATION TO INCREASE DRUG TESTING IN CHILDREN

The BPCA and the PREA are 2 complementary federal laws that have substantially increased clinical evaluation and labeling of drugs in children both by the pharmaceutical industry and through government-sponsored trials.[10] The PREA mandates that almost all new drugs and certain approved drugs must be studied in children for approved uses of the product if there is potential for use of that drug in children and that the application for new drug approval include the results of adequate pediatric studies unless the studies are deferred or waived by the FDA. The BPCA allows sponsors to qualify for an additional 6 months of market exclusivity if the sponsor completes and submits pediatric studies to the FDA, as outlined in an FDA-issued written request. A written request may include off-label as well as approved uses of a drug. In addition, the BPCA authorizes the National Institutes of Health, in conjunction with the FDA

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and physicians from clinical disciplines, to work together to assign priority for testing of specific drugs in children. The National Institutes of Health, acting through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, then solicits proposals for pediatric drug testing concordant with the drug prioritization recommendations and funds clinical studies that are judged meritorious by external review. The ratification of these 2 laws has been considered a significant success, because there have been more than **600** pediatriclabeling changes. Also as a result of these laws, increased prospective pediatric drug testing has occurred via industry-sponsored studies, investigator-initiated studies, and consortia, such as the National Institute of Child Health and Human Development–funded Pediatric Trials Network. The net result has been an expansion of both pediatric labeling information and the knowledge base from which practitioners can draw to make informed therapeutic decisions.[15,16]

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act,[17] reauthorizing and strengthening the BPCA and PREA. The legislation aims to ensure that pediatric evaluations under PREA are conducted earlier in the drug development process to improve the quality of and accountability for completion of such studies and to advance the neonatal drug studies under the BPCA and PREA. The legislation also makes both the BPCA and PREA permanent law.

CONCLUSIONS

Off-label drug use remains an important public health issue, especially for infants, young children, and children with rare diseases. Evidence, not label indication, remains the gold standard from which practitioners should draw when making therapeutic decisions for their patients. The PREA and BPCA have been extremely successful and represent an essential first step in expanding this evidence as a means of achieving the ultimate goal that any and all drugs used to treat children will have age-appropriate evidence sufficient to provide information for labeling. However, labeling with pediatric information still exists in less than 50% of products,[18] such that much work remains to be done to ensure the best possible practice for therapeutic decision-making in pediatrics.

RECOMMENDATIONS

1. The practitioner who prescribes a drug is responsible for deciding which drug and dosing regimen the patient will receive and for what purpose.
   a. This decision should be made on the basis of the information contained in the drug's labeling (when available) or other data available to the prescriber.
   b. The use of a drug, whether off or on label, should be based on sound scientific evidence, expert medical judgment, or published literature whenever possible.
   c. Off-label use is neither incorrect nor investigational if based on sound scientific evidence, expert medical judgment, or published literature.
2. Pediatricians should continue to advocate for necessary incentives and requirements to promote the study of drugs in children.
3. Physician researchers are encouraged to continue the rational and critical study of drugs in children through conducting and/or collaborating in well-designed pediatric drug studies, including national consortium studies.
4. Journals should be encouraged to publish the results of all well-designed investigations, including negative studies.
5. Institutions and payers should not use labeling status as the sole criterion that determines the availability on formulary or reimbursement status for medications in children. Similarly, less expensive therapeutic alternatives considered appropriate for adults should not automatically be considered appropriate first-line treatment in children. Finally, off-label uses of drugs should be considered when addressing various drug-related concerns, such as drug shortages.

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Off-Label Use of Drugs in Children

COMMITTEE ON DRUGS

Pediatrics 2014;133;563
DOI: 10.1542/peds.2013-4060 originally published online February 24, 2014;

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Off-Label Use of Drugs in Children

COMMITTEE ON DRUGS

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http://pediatrics.aappublications.org/content/133/3/563

Data Supplement at:
http://pediatrics.aappublications.org/content/suppl/2021/02/08/peds.2013-4060.DCSupplemental

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EXHIBIT I

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

DREW ADAMS, et al.,

Plaintiff,

v.

THE SCHOOL BOARD OF ST. JOHNS COUNTY, FLORIDA,

Defendant.

No. 3:17-cv-00739-TJC-JBT

DECLARATION OF DR. NORMAN P. SPACK, M.D.

I, Norman P. Spack, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am over the age of eighteen and submit this declaration based on my personal knowledge.

2. If called to testify, I would testify truthfully based on my own experience and knowledge regarding the matters discussed herein.

3. I am a pediatric endocrinologist. I began practicing pediatric endocrinology in 1976 at Boston Children's Hospital. I have an undergraduate degree from Williams College, a medical degree from the University of Rochester, and completed my pediatrics residency and fellowship in Pediatric Endocrinology and Adolescent Medicine at Boston Children's Hospital.

Exhibit
0019
9/29/2021
Hruz

4. I am an Associate Physician in Medicine at Boston Children's Hospital, the Co-Founder and Co-Director *Emeritus* of the Gender Management Service (GeMS) Program at Boston Children's Hospital, and an Associate Clinical Professor of Pediatrics at Harvard Medical School in Massachusetts.

5. In 2007, I co-founded the GeMS Program at Boston Children's Hospital. The first-of-its-kind program in the United States, GeMS provides comprehensive care to the unique group of gender nonconforming and transgender children and adolescents. The GeMS team consists of providers from Endocrinology, Psychology, and Social Work, and works closely with specialists in other departments in the hospital such as Adolescent Medicine, Urology, and Plastic Surgery to develop individual care plans that meet every child's medical and emotional needs, as well as the family's need for information and support.

6. Since its founding, the GeMS Program has been replicated by over 60 similar programs at pediatric academic centers in North America, including the now Transgender Center at St. Louis Children's Hospital.

7. In 2012, I was awarded a Bicentennial Medal by Williams College in recognition for distinguished achievement in the field of pediatric endocrinology and for helping reduce the suicide rate among transgender adolescents through my work with GeMS.

8. On or about October 9, 2013, I gave a presentation at St. Louis Children's Hospital regarding the founding of GeMS, the workings of a gender management program at pediatric hospital, and the medical treatment and care of ender nonconforming and transgender children and adolescents.

9. Following my presentation, I privately met with medical staff, including endocrinologists, at St. Louis Children's Hospital to answer their questions and share my knowledge and experience.

10. It was in the aforementioned context that I also met privately with Dr. Paul W. Hruz at St. Louis Children's Hospital when he approached me after my presentation.

11. During my private meeting with Dr. Hruz, Dr. Hruz directly expressed that he had "a significant problem with the entire issue" and "whole idea of transgender."

12. Dr. Hruz followed up his comments by stating, "For me, it is a matter of my faith."

13. During our conversation, Dr. Hruz did not discuss or mention that his issues or concerns were based on science.

14. In my experience, someone who acts out of science would go and see how gender management clinics work in order to form their opinions.

This declaration was executed on this ___ day of December, 2017 in Boston, Massachusetts.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

_____
Norman P. Spack, M.D.

9. Following my presentation, I privately met with medical staff, including endocrinologists, at St. Louis Children's Hospital to answer their questions and share my knowledge and experience.

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This declaration was executed on this 5 day of December, 2017 in Boston, Massachusetts.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Norman P. Spack, M.D.

EXHIBIT J

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendant.)

TELEPHONIC DEPOSITION OF KIM G. HUTTON
Taken on behalf of Defendant
December 5, 2017
(Starting time of the deposition: 3:00 p.m.)

I N D E X O F E X A M I N A T I O N

(No exhibits were marked.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendants.)

TELEPHONIC DEPOSITION OF WITNESS, KIM G. HUTTON, produced, sworn, and examined on the 5th day of December, 2017, between the hours of nine o'clock in the forenoon and six o'clock in the evening of that day, at the offices of Veritext Legal Solutions, 515 Olive Street, Suite 300, St. Louis, Missouri before BRENDA ORSBORN, a Certified Court Reporter within and for the State of Missouri, in a certain cause now pending in the United States District Court for the Middle District of Florida, wherein Drew Adams, a minor, is the Plaintiff and The School Board of St. Johns County, Florida is the Defendant.

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center in St. Louis.

And that's how that happened. Dr. Hruz e-mailed me -- it's either the same day or the next day, and invited me to lunch.

Q. Where did you go -- did you end up going to lunch?

A. We did.

Q. Where did you go?

A. At the Wild Flower in the Central West End.

Q. And what -- you said it was in 2013?

A. Yes.

Q. Do you recall what month?

A. October.

Q. Okay. Was anybody else at the lunch?

A. No.

Q. Do you recall approximately how long the lunch was?

A. Maybe 45 minutes.

Q. Was your conversation recorded?

A. No.

Q. I guess, to your knowledge, you may not know, right?

A. To my knowledge. I did not record it.

Q. Okay. What -- what did you -- when you were going to have that lunch with Dr. Hruz, what was the

purpose of it, in your mind?

A. Well, the e-mail that he sent me stated that he wanted to meet to -- I think he kind of positioned it as wanting to learn more about this experience, and he shared that he -- he was well aware that Dr. Abby Hollander was working with me, or that I had approached her about starting a pediatric gender center inside the hospital, and that he was having great difficulty being open to that concept based on his morals.

He said that he did not -- part of the note I remember said something about he did not agree with the -- the recommended standards of care, or something like that, for our children, that he didn't believe that it was appropriate medically or spirit -- or that it -- or that it wouldn't meet their spiritual needs, or something like that.

And so I realized -- I realized -- I felt like it was going to be not a great meeting, but I was still willing to meet with him because I felt that maybe, you know, the parent perspective could be helpful to him.

Q. Now, was that document, was that in an e-mail that he conveyed that information to you?

A. Yes.

Q. Do you still have that e-mail?
A. I do.
Q. Okay. Have you shown that e-mail to counsel in the room?
A. I did.
Q. Do you have it with you now?
A. I don't.
Q. Okay. To the best of your knowledge, can you tell me everything, aside from what you've already told me, that that e-mail says in it?
A. Those -- those were the sticking points for me, because I found it very odd that he would be talking about faith or morals or spiritual needs in the context of this conversation. It was not -- I talk to many medical professionals in my work with TransParent, and it's the first time that somebody was so overtly upfront that it was problematic due to their faith on some -- at least on some level. So I can't remember it. It wasn't -- it was longer -- the -- the note was longer than that, but those were the points that have stuck out with me.
Q. Okay. Other than that e-mail, do you have any other document that reflects communication you have had with Dr. Hruz?
A. There's -- I mean, after he e-mailed me, I

e-mailed him and told him that I, you know, was very excited to meet with him, although I was -- you know, I think I expressed some disappointment because Dr. Spack had shared that he was, you know, I guess against a pediatric gender center at St. Louis Children's Hospital and -- but that, you know, I was -- I would be very happy to have the conversation or something like that. And then he e-mailed me back and said, "Thank you for responding so quickly," and he would have his secretary reach out to me to set a date and time.

Q. Okay. So this meeting that you were going to have with him that ended up being a lunch, was any part of that meeting in the context of receiving medical care, opinions or services?

A. No.

Q. Okay. Were you going to learn anything from Dr. Hruz you would personally use with you or your family members when it comes to treatment for any type of disorders?

A. No.

Q. Was it just to learn about Dr. Hruz's position on the pediatric gender center at the Washington University?

A. Well, he called the meeting, so I -- I --

again, I really wanted to go, because I understood that he had a lot of influence on whether or not the center moved forward. And I had been talking with other doctors and people on their DSD team at St. Louis Children's Hospital about moving this forward, but it really had stalled.

And so I -- I just felt like being the head of Endocrine, that he would have a lot of influence over that decision. And so for me, that is why I wanted to go and meet with him, to see if I could say anything that would might make -- that might make him more interested in doing something like that.

Q. So would you characterize this as a business meeting?

A. Not really. I'm -- not really. I guess -- I guess --

Q. Were you hoping to come away from that meeting with some type of support from Dr. Hruz for the establishment of the pediatric gender center?

A. I guess I just felt like all of the treatment for our kids was going through a person that reported to Dr. Hruz. And so I guess I felt like he may not have enough information to support it or not support it. He wasn't seeing any of our kids. There -- there were only a handful of our kids at the

time.

You know, this is four years ago before everything really opened up in St. Louis as far as treatment and care for kids. But I just understood that he -- and especially since he had already said in his e-mail that he didn't support the center, I guess I was hopeful that the parent perspective might be helpful.

Q. Okay. Now, did I understand you to say that you were aware that Dr. Hruz was providing treatment to your -- when you say "our kids," are you referring to TransParent --

A. Yes.

Q. -- members' kids?

A. Yes.

Q. Okay. So to your knowledge, as of 2013, to your knowledge, was Dr. Hruz treating transgender children?

A. He was not, that I -- to my knowledge.

Q. Okay. So in terms of that -- that lunch meeting, can you tell me everything you can remember from the meeting?

A. Yes.

MR. GONZALEZ-PAGAN: Form.

Q. (By Mr. Harmon) Well, let me ask it a

different way. Can you tell me, to the best of your recollection, everything Dr. Hruz said to you during the lunch meeting?

MR. GONZALEZ-PAGAN: Form. You can answer.

THE WITNESS: Oh.

Q. (By Mr. Harmon) Yeah, you can answer.

A. Yeah. So after, you know, introducing ourselves I started off with trying to tell him a little bit about my family and our experience, but I -- I really didn't get very far. He interrupted me fairly quickly, probably within a minute or so, two minutes tops, and said that he had reviewed my brochure from TransParent and that he knew that my aim was to normalize the transgender experience, but that it would never be a normal experience. It was not a normal experience, and it would never be normal.

We went on to talk more about, you know, his -- he -- he actually started talking about Pope John Paul II's writings on gender and -- and how they explain God's plan for gender, and that I should consider reading them. And he said, you know, this idea that -- the idea of doing surgeries on transgender people is -- is wrong, that, you know, we should not be, you know, changing bodies.

And I said -- I -- I argued with him on that

point that, you know, there are men that have man boobs, and I said they have theirs surgically removed or altered. And I said wouldn't that be the same thing, and -- and why is that okay, but not removing the breast for a transgender boy, and he said, "Because male breasts aren't used for anything, but female breasts lactate and provide nourishment to babies. So, therefore, it would be -- it would go against, you know, God's plan to remove breasts from women." Something -- something very close that.

He said several times during this conversation, as I tried to tell him, you know, how hard it was for my child living a transgender life, you know, but that -- but what a great -- what a great son I've had since I allowed him to transition, how happy he was. And he said that, you know, what a -- I kept saying, "What a normal life -- like if you met my son, you would never know. He's a very normal little boy."

And he kept saying, he kept insisting that my child was not normal and would never be normal. And he said that to me at least three or four times during our conversation.

He said -- and -- and at the same time he just kept saying, "If only you would read Pope John

Paul II's writings. If only you would read them, you would understand everything." And I said, "Well, you know, the Bible tells a story about, you know, man was -- woman was created from the rib of man," and I said, "You know, maybe this all started with Adam and Eve because God took a rib from a woman -- or from a man and put it into women, and maybe he crossed that DNA, you know, at the very beginning, and maybe that's why we have transgender people."

He said -- he got very irritated with me, and he said, "Not all the stories in the Bible are true."

And I said, "Well, then how do you decide which ones you're going to believe and which ones you're not? How do you determine that, like, which ones you follow and which ones you don't follow?"

And he -- he reverted right back to -- he goes, "You just need to read Pope John Paul II's writings on gender. It will -- it will explain it all to you."

And I said, "Do you realize that kids like mine are at a 41 percent risk of suicide if they don't have acceptance and -- and care from their parents and -- and if they don't get their medical needs met?"

And he said, "Some children are born in this

world to suffer and die." And he said, "Do you think I don't ask myself all the time why some people get cancer?" He goes, "I -- I ask myself that all the time."

And I said, "Well, people with cancer, at least we try to help them. At least we give them care." And I think the conversation ended shortly after that, and he stood up, and he said, "I -- I have to tell you there will never be a pediatric gender center at St. Louis Children's Hospital. I won't allow it." And I --

Q. Did he say why?

A. Pardon me?

Q. Did he say why he would not allow it?

A. Well, based on every -- no, he did not say why. That's how he ended the conversation, but my interpretation would have been based on everything we -- he had just shared with me that he was in disagreement from -- based on his faith.

Q. Did he ever say that he would not allow a gender center because of his faith?

A. He did not.

Q. Okay. That was your interpretation of --

A. Yes.

Q. -- what the conversation was?

A. I am.
Q. How are you aware of what his position is now?
A. I saw a -- some papers that he's publishing, and I understand that he is involved in other cases involving students, so Internet searches.
Q. Did your conversation with Dr. Hruz anger you?
A. My conversation?
Q. Yes.
A. It -- it perplexed me. I found --
Q. Why did it perplex you?
A. Again, because it was so religious-based. I -- I was very taken off guard by the religious tone of the conversation, because I -- I figured it would at least be based on science. He would have some science behind his feelings over children like mine, but that is not what I heard in our conversation at all.
Q. So your conversation with Dr. Hruz, is it fair to say that it was based on religion and moral viewpoints as opposed to science?
A. Yes.
MR. GONZALEZ-PAGAN: Form.
Q. (By Mr. Harmon) What was the answer?

EXHIBIT K

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

(https://thegenderandsexconference.org)

I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success

I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success (https://thegenderandsexconference.org/i-international-conference-on-gender-sex-and-

education-in-madrid-against-the-lgbti-doctrine-which-is-taking-hold-of-western-countries-is-a-resounding-success/)

Prensa HO (https://thegenderandsexconference.org/author/prensa/)

Nota de Prensa (https://thegenderandsexconference.org/category/nota-de-prensa/) Feb 28, 2018

53 ORGANIZATIONS FROM 17 COUNTRIES SUPPORT THE MADRID DECLARATION OF UNDERSTANDING, RESPECT AND FREEDOM

- *At the #GenderAndSex Conference, organized by HazteOir.org and its international platform CitizenGO, eight speakers from four countries participated and more than 250 people attended. At some point over 5,000 people connected to follow the conference online.*
- *Ignacio Arsuaga: "This conference is a rebellion against the gender ideology and its freedom-destroying, damaging laws – laws that mustn't and cannot succeed. At HazteOir.org and CitizenGO we will keep on fighting to stop the LGBTI agenda from being forced upon citizens".*

MADRID, 28. FEBRUARY 2018.– Ignacio Arsuaga, President of HazteOir.org and CitizenGO, sums up the success of the I **International Conference on Gender, Sex and Education** (http://thegenderandsexconference.org) **#GenderAndSex** which took place in Madrid last week Friday, with the following words: "This conference was **the world's first great public objection to totalitarian LGTBI laws**. We have now marked a "before" and an "after" (the conference), because we have made known the essential lie that hides behind the ideology of gender, contrary to the foundations of science, biology, reason and the anthropological truth of the human being".

Eight speakers from four countries took part in the #GenderAndSex Conference, organized by HazteOir.org and its international platform CitizenGO, **and over 250 people attended. At some point over 5000 people connected via the internet to follow the conference online**.

What's more, **53 organizations from 17 countries supported the Madrid Declaration for Understanding, Respect and Freedom** (https://drive.google.com/file/d/10fDoT_wlOu2npgzkli4pKErfLpyBaqT9/view?usp=sharing)**, which defends rights in the face of the "gender lie" .**

A conference to oppose gender ideology

In his keynote address, **Arsuaga** urged attendees not to allow "**damage made to children**" and **called on politicians** to "**leave the children in peace**".

Apart from the President of HazteOir.org and CitizenGO, **Miriam Ben-Shalom,** (http://thegenderandsexconference.org/speaker/miriam-ben-shalom-2/)US Lesbian activist, also spoke at the **I International Conference on Gender, Sex and Education**, saying that she feels "**very**

uncomfortable in showers or changing rooms for transgender women".

Agustín Laje (http://thegenderandsexconference.org/speaker/agustin-laje/), political science expert, called his listeners to speak out against the LGBTI offensive, saying: **"We need to bring the masses into the streets against gender ideology".** Laje believes that the left has adopted **the issue of sex and the gender ideology as a sort of "political strategy,** in order to keep their beliefs in the public domain."

The third presentation came from **Rubén Navarro,** (http://thegenderandsexconference.org/speaker/mr-ruben-navarro/)who condemned the fact that the **"LGTBI agenda has infiltrated the United Nations".** As an example of how pressure groups push their agenda, Navarro referred to legislation known as **"LGBTI gag law"** which the leftist group Podemos is promoting in Spain.

Michelle Cretella (http://thegenderandsexconference.org/speaker/mrs-michelle-cretella/), President of the American College of Pediatricians, also took part in the conference, explaining that **"schools need to avoid gender ideology because it is contrary to science and harmful to all children".**

The rest of the panel of experts and lecturers was made up by Professor **Glenn Stanton,** (http://thegenderandsexconference.org/speaker/mr-glenn-stanton/)Doctor **Paul Hruz** (http://thegenderandsexconference.org/speaker/mr-paul-hruz/), the sociologist **Gabriele Kuby** (http://thegenderandsexconference.org/speaker/mrs-gabriele-kuby/) and the former transexual **Walt Heyer.** (http://thegenderandsexconference.org/speaker/walt-heyer-2/)

Stanton assured that **" the gender theory is unscientific and full of contradictions".** Doctor **Hruz for his part** warned: **"Sex change is impossible. You cannot change your sex, the only thing you can change is the appearance".** In her explanations, **Kuby** affirmed that **"the sexual revolution has one objective only: to destroy the fertility, procreation and the family".**

The **I International Conference on Gender, Sex and Education** (#GenderAndSex Conference) was brought to a close by the testimony of **Heyer,** who had undergone gender reassignment surgery at the age of 42 years. He affirmed that **"there is nothing real in gender ideology".**

He added: **"I speak about this because I receive hundreds of letters from people all over the world who experienced the same as I did and this is a tragedy.** Will they get paid again for trying to put back that which they previously removed?"

53 organizations sign the Declaration of Madrid

The **I International Conference on Gender, Sex and Education** closed with a reading of the **Madrid Declaration for Understanding, Respect and Freedom** (https://drive.google.com/file/d/1cMpObKRmsbbRdDlHpuvpHXjFuants023/view?usp=sharing) **which** was joined, among others, by the **Foundation of Values and Society**, the **Association of Researchers and Professionals CiViCa,** and the **European Association of Family Lawyers –** all Spanish

institutions. The declaration was also supported by European organizations: **Generation Family** (Italy), **Free Society Institute** (Lithuania), **Family Alliance** (Austria) and **Femina Europa** (France). Among North and South American institutions who gave their support, were **Real Women of Canada** and **Population Research Institute** (United States), **National Family Forum** (Columbia), **National Union of Parents** (Mexico), **Center for Civic Studies** (Chile), **Argentinians Alert** and **Institute for Civic Action** (Peru). **A list of all organizations supporting the declaration can be found here.** (http://thegenderandsexconference.org/asociaciones-adheridas/)

I International Conference on Gender, Sex and Education Resources:

Vídeos:

All videos from the #GenderAndSex Conference: https://www.youtube.com/playlist?list=PL4bbuT69ULV_LIymyK7jh7PNEBkxSUPEJ (https://www.youtube.com/playlist?list=PL4bbuT69ULV_LIymyK7jh7PNEBkxSUPEJ)

Ignacio Arsuaga intervention: https://youtu.be/Dq-LwrPRoRo (https://youtu.be/Dq-LwrPRoRo)

Miriam Ben-Shalom intervention: https://youtu.be/f7vY1g-xK7w (https://youtu.be/f7vY1g-xK7w)

Agustín Laje intervention: https://youtu.be/w4PmcFf6Iw4– (https://youtu.be/w4PmcFf6Iw4--)

Ruben Navarro intervention: https://youtu.be/6MLSiiw11ac (https://youtu.be/6MLSiiw11ac)

Michelle Cretella intervention: https://youtu.be/3dzgFaE-dXo (https://youtu.be/3dzgFaE-dXo)

Glenn Stanton speech intervention: https://youtu.be/oHdM89IA4f8 (https://youtu.be/oHdM89IA4f8)

Paul Hruz intervention: https://youtu.be/-kUB4o5XFz8 (https://youtu.be/-kUB4o5XFz8)

Gabriele Kuby intervention: https://youtu.be/LxiXHYiAI4E (https://youtu.be/LxiXHYiAI4E)

Walt Heyer: https://youtu.be/OYvkiq8EEJc (https://youtu.be/OYvkiq8EEJc)

Madrid Declaration: https://youtu.be/X17JpYrEIRA (https://youtu.be/X17JpYrEIRA)

Reading of the Madrid Declaration: https://youtu.be/Gd526vRnnsI (https://youtu.be/Gd526vRnnsI)

Images from the I International Conference on Gender, Sex and Education:

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EXHIBIT L

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

Journal Pre-proof

Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?

Greta R. Bauer, PhD, MPH, Margaret L. Lawson, MD, MSc, FRCPC, Daniel L. Metzger, MD, FAAP, FRCPC, for the Trans Youth CAN! Research Team

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Journal Pre-proof

Title: **Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?**

Authors: Greta R. Bauer[a], PhD, MPH; Margaret L. Lawson[b], MD, MSc, FRCPC; Daniel L. Metzger[c], MD, FAAP, FRCPC, for the Trans Youth CAN! Research Team*

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Abbreviations: ; OASIS = Overall Anxiety Severity and Impairment Scale; MDS = Modified Depression Scale; K6 = Kessler-6 Scale; TYC-GDS = Trans Youth CAN! Gender Distress Scale

Journal Pre-proof

Although emergence of gender dysphoria at puberty is long established, a distinct pathway of "rapid onset gender dysphoria" (ROGD) was recently hypothesized based on parental data. Using adolescent clinical data, we tested a series of associations that would be consistent with this pathway, however our results did not support the ROGD hypothesis.

Puberty has long been understood as one period when gender dysphoria often first emerges.(1) Although most transgender (trans) older adolescents and adults report needing gender-affirming medical care (hormones and/or surgeries), and also report having been aware of their gender at young ages,(2) only a small proportion receive gender-affirming care as adolescents. Use of hormonal suppression with a gonadotropic-releasing hormone agonist (GnRHa), and hormones such as estrogen and testosterone therapies in trans and gender-diverse adolescents is supported by the American Academy of Pediatrics, the Pediatric Endocrine Society, the Endocrine Society, and the World Professional Association for Transgender Health.(1,3–5) Referrals to adolescent gender clinics have increased internationally, particularly among those assigned female at birth.(6–9)

In 2018, a phenomenon of "rapid onset gender dysphoria" or "ROGD" was hypothesized as a distinct pathway involving social contagion among youth vulnerable due to mental or neurodevelopmental disorders,(10–12) raising public concerns regarding potential for later regret following gender-affirming medical care. This discussion has occurred primarily in the context of data from a single online parental survey.(10,11) Although this parental study has generated controversy,(13) methodological and social critique,(12,14,15) and calls for additional research,(16,17) its hypotheses have not yet been tested on data from youth themselves. Specifically, ROGD is hypothesized as a phenomenon in youth with gender dysphoria emerging

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at or after puberty, socially influenced through peer contagion, and with contributing factors including poor mental health, neurodevelopmental disabilities, parent-child conflict, and maladaptive coping strategies.(10,11)

If the "ROGD" hypothesis indeed characterizes a distinct clinical phenomenon, and these youth access referrals for hormone suppression or gender-affirming hormones, then we would expect to see differentiation within clinical samples between those with more-recent (ie, "rapid-onset") vs. more-remote knowledge regarding their gender. Based on the published hypothesis,(10) we would expect more recent gender knowledge to be associated with self-reported mental health measures, mental health and neurodevelopmental disability diagnoses, behaviors consistent with maladaptive coping (e.g. self-harm), support from online and/or transgender friends but not parents, and lesser gender dysphoria. We aim to test these hypotheses.

Methods

Baseline data (2017–2019) from the Trans Youth CAN! Cohort included pubertal/postpubertal adolescents aged <16 attending a first referral visit for hormone suppression or gender-affirming hormones at 10 Canadian medical clinics that provide specialized gender-affirming care to adolescents through a range of different care models. Ethics approval was received from all study sites. Years gender was known was missing for one participant (excluded), for a final sample of n=173. Methods and measures are described in detail elsewhere.(18)

Self-reported measures were obtained from baseline interviewer-administered adolescent surveys,(19) and diagnoses from baseline clinical records.(20) *Recent gender knowledge* was

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coded by subtracting age in years from age adolescents self-reported they "realized your gender was different from what other people called you". As ages were whole numbers, a difference of 1 could indicate <1 year to just under 2 years. Values ≤1 were coded as recent gender knowledge, with an alternate definition (values ≤2) for sensitivity analysis. *Mental health symptoms* were assessed with the Overall Anxiety Severity and Impairment Scale (OASIS),(21) the Modified Depression Scale (MDS),(22) and the Kessler-6 (K6) scale for psychological distress.(23) *Mental health diagnoses* extracted from chart included anxiety, depression, personality disorder, eating disorder, and *neurodevelopmental disorder diagnoses* included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. *Gender dysphoria symptoms* were assessed using the Trans Youth CAN! Gender Distress Scale (TYC-GDS).(24) Self-reported *mental health behaviors* included self-harm, substance use, and suicidal behavior. Three measures captured *social connections* to online and trans communities: having gender-supportive online friends was coded if adolescents reported online friends who knew their gender and were "very supportive", and having online or trans friends as general sources of support was indicated in checklist items. *Parental support* was coded if youth indicated all biological/step/foster parents were "very supportive" of their gender identity or expression.

Statistical analyses were conducted using SAS version 9.4.1, weighted to account for clinics' different recruitment periods due to staggered start dates, to improve generalizability.(18) For analyses of associations between recency of gender knowledge and hypothesized correlates, a series of multiple regressions was conducted, with recency as the independent variable of interest, controlling for age and sex assigned at birth. Linear regressions were used for continuous dependent variables (e.g., psychometric scales). For dichotomous dependent variables, modified Poisson regression with robust variance estimation was used.(25)

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As "rapid-onset" has not been precisely defined, we conducted a sensitivity analysis repeating these analyses using the alternate (value ≤2) definition of recent gender knowledge.

Results

Recency of gender knowledge is presented in the Figure, results of hypothesized associations (recency value ≤1) in Table I, and variable means and frequencies in Table II (available at www.jpeds.com). Controlling for age and sex assigned at birth, recent gender knowledge was not significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, gender dysphoria symptoms, self-harm, past-year suicide attempt, having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents. Recent gender knowledge was associated with lower scores on anxiety severity/impairment (b= −3.272; 95% CI: −5.172, −1.373), and lower prevalence of marijuana use (PR=0.11; 95% CI: 0.02, 0.82), counter to hypothesized directions of effect. For sensitivity analysis using the alternate (value ≤2) definition of recent gender knowledge, we found all results substantively the same in statistical significance and direction of effect, except past-year marijuana use, which now only approached statistical significance (p=0.0677).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of "ROGD" during adolescence. Among adolescents under age 16 seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in ROGD were either not statistically significant, or were in the opposite direction to

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what would be hypothesized. This putative phenomenon was posited based on survey data from a convenience sample of parents recruited from websites,(10) and may represent the perceptions or experiences of those parents, rather than of adolescents, particularly those who may enter into clinical care. Similar analyses should be replicated using additional clinical and community data sources. Our finding of lower anxiety severity/impairment scores in adolescents with more recent gender knowledge suggests the potential for longstanding experiences of gender dysphoria (or their social complications) playing a role in development of anxiety, which could also be explored in future research.

Acknowledgment: The Trans Youth CAN! Study Team thank the trans youth and their families who have generously shared their time and experience with us. We acknowledge the contributions of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

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Figure 1. Recency of gender knowledge among adolescents age <16 referred to Canadian clinics for hormone suppression or gender-affirming hormones (n=173). Age at which knew gender was different was subtracted from current age in years; thus, "2 years" could range from more than 1 year to less than 3 years. Lighter gray represents recent gender knowledge in this analysis, with a sensitivity analysis also including the patterned bar.

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Table 1. Associations between short-term awareness of gender and variables hypothesized to be associated with "rapid-onset gender dysphoria," controlling for age and sex assigned at birth

Dependent variable	B [a]	SE	p	PR [a]	95% CI [b]
Mental health scales					
Anxiety severity/impairment (OASIS)	-3.272	0.961	0.0008		(-5.172 -1.373)
Depressive symptoms (MDS)	-1.276	0.845	0.1328		(-2.944, 0.392)
Psychological distress (K6)	-1.156	1.060	0.2771		(-3.248, 0.936)
Record of diagnosis with mental health disorder [c]	-0.509	0.315	0.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder [d]	0.066	0.362	0.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	-0.193	0.122	0.1139		(-0.434, 0.047)
Mental health related behaviors					
Self harm, past year	-0.052	0.191	0.7833	0.95	(0.65, 1.38)
Marijuana use, past year	-2.178	1.010	0.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	-0.592	0.785	0.4505	0.55	(0.12, 2.58)
Social connection indicators [e]					
Reports having online friends supportive of gender	-0.050	0.157	0.7505	0.95	(0.70, 1.29)

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Indicates online friends as source of general support	-0.223	0.286	0.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	-0.049	0.298	0.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	-0.004	0.202	0.9836	1.00	(0.67, 1.48)

a. Estimates adjusted for age in years and sex assigned at birth. B = beta, regression parameter estimate; PR = prevalence ratio.

b. 95% confidence intervals for betas (for linear regressions) or PRRs (for modified Poisson regressions)

c. Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n=2) and no youth had a record of eating disorder diagnosis.

d. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.

e. Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.(10)

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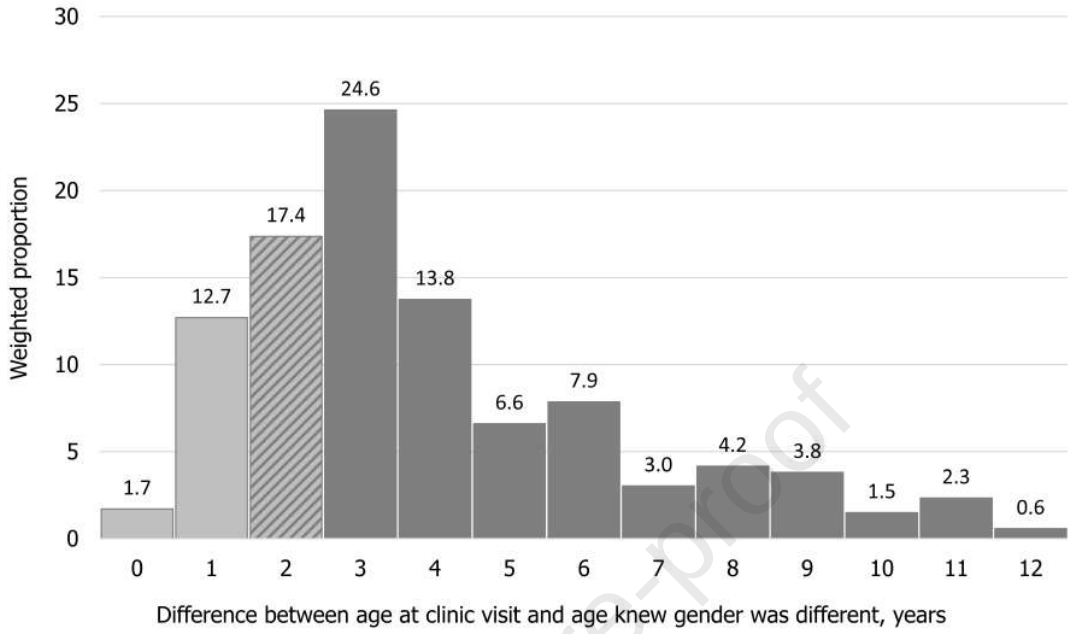

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Appendix

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Online content to accompany the following Brief Report:

Bauer GR, Lawson ML, Metzger DL, for the Trans Youth CAN! Research Team. Do clinical data from transgender adolescents support the phenomenon of "rapid-onset gender dysphoria"? *Journal of Pediatrics*, 2021.

Online Table 2.
Weighted frequencies or means for sociodemographic and study variables (n=173)

Variable	Value
Age, n (%$_w$)	
10–11 years	17 (8.5)
12-13 years	37 (22.6)
14–15 years	119 (68.9)
Ethnoracial background,[a] , n (%$_w$)	
Indigenous	33 (18.4)
Non-Indigenous visible minority [b]	10 (6.6)
Non-Indigenous white	128 (75.0)
Immigration background, n (%$_w$)	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n (%$_w$)	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n (%$_w$)	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Non-binary [c]	14 (8.3)
Mental health scales, mean$_w$ (SD)	
Anxiety severity/impairment (OASIS)	8.842 (4.548)
Depressive symptoms (MDS)	15.077 (4.030)
Psychological distress (K6)	10.746 (5.100)
Record of diagnosis with mental health disorder,[d] n (%$_w$)	92 (51.6)
Record of diagnosis with neurodevelopmental disorder,[e] , n (%$_w$)	44 (25.9)
Gender dysphoria/distress (TYC-GDS), mean$_w$ (SD)	4.048 (0.557)
Mental health related behaviors, n (%$_w$)	
Self harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,[f] n (%$_w$)	
Reports having online friends supportive of gender	109 (69.9)
Indicates online friends as source of general support	79 (49.3)
Indicates trans friends as source of general support	92 (55.8)
All parents supportive of gender identity/expression	109 (61.8)

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a. Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Non-white, Non-Indigenous ethnoracial backgrounds were indicated by the following numbers of participants: 6 Black Canadian or African-American, 2 Black African, 4 Latin American, 4 East Asian, 1 Indo-Caribbean, 3 Black Caribbean, 1 Middle Eastern, and 1 Southeast Asian (participants could indicate more than one).
b. The Canadian government defines visible minorities as "persons, other than Aboriginal peoples, who are non-Caucasian in race or non-white in colour".(1)
c. Response option was "non-binary or something other than male or female".
d. Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n=2) and no youth had a record of eating disorder diagnosis.
e. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.
f. Hypothesized by other authors based on a survey of parents.(2)

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EXHIBIT M

Declaration of Omar Gonzalez-Pagan in support of
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz
Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

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

CIVIL ACTION NO.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.
Plaintiffs

v.

DALE FOLWELL, et al.
Defendants

REMOTE VIDEOTAPED VIDEOCONFERENCE
DEPOSITION TESTIMONY OF:
PATRICK LAPPERT, M.D.
September 30, 2021

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ALSO PRESENT (via remote videoconference):

Andrew Baker, Videographer

these meetings in more detail. So, how many -- strike that.

You've been to two meetings organized by ADF?

A. That's my recoll- -- yeah, two meetings. I think that's right.

Q. All right. Let's start with the first one. This was in 2017?

A. That sounds about right, yeah.

Q. What --

A. I think it was 2017, yeah.

Q. What month roughly?

A. I don't remember now.

Q. Do you know how they came to invite you to that first meeting?

A. I do not.

Q. Before that meeting, you had not published anything about gender dysphoria, had you?

A. No.

Q. Before that meeting, you had not published anything about the risks of use of hormone blockers in minors; right?

A. No. I've given -- I gave some -- some -- I think they may have heard of me not through publications, but through public speaking.

Q. How long have you been doing public speaking on the issues related to gender dysphoria?

A. Since 2014.

Q. Let's start with the first meeting. So, Dr. Hruz was also present at that meeting?

A. Yes.

Q. Was Dr. Levine present at that meeting?

A. I don't think I've ever met Dr. Levine, so I don't -- he couldn't have been there because I would have remembered meeting him, and I don't remember ever having met him.

Q. How about Dr. McHugh?

A. No. I would have remembered him. He's a very famous person.

Q. How many people were present at

heart of the presentation was what's the state of the science and where is the reliable science coming from and what is it -- what is it showing us, so. But they also -- the audience wanted to have an understanding of what these plastic surgery interventions were. So there was an extensive discussion of the particulars of the surgeries, the details about the surgeries, the typical outcomes of the surgeries, so.

Q. I want to -- strike that.

One of the topics of discussion at that meeting was about the need to have expert witnesses for litigation; right?

MR. KNEPPER: Objection, form, scope.

A. I remember -- I remember a fairly long discussion about the poverty of people who are willing to testify because of the risk that they take in testifying. That was a -- that was a

fairly long discussion. And the difficulty that that -- that people have in finding expert witnesses because of the risks they place themselves in, in testifying.

Q. And people at that meeting were asked whether they would be willing to participate as expert witnesses; right?

A. Yes.

Q. Before that meeting, you had never testified as an expert witness?

A. Before this moment, I never testified as an expert witness.

Q. Who made the introductory remarks at the beginning of this meeting?

MR. KNEPPER: Objection, form, scope.

A. I'm trying to remember. It was a -- it was an attorney whose first name is Jeff, and I'm trying to remember what his last name was. But he seemed to be the -- the -- kind of the emcee, if you will. Yeah, Jeff. I'll see if, in the

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MOTION TO EXCLUDE
EXPERT TESTIMONY OF DR. PAUL R. McHUGH

Now come, Plaintiffs, by and through their counsel, and respectfully move this Court to exclude the expert report, opinions, and testimony of State Health Plan Defendants[1] proposed expert, Dr. Paul R. McHugh, pursuant to Federal Rules of Civil Procedure 26 and 37, and Federal Rules of Evidence 104, 403, and 702. Dr. McHugh is not a qualified expert on gender dysphoria or its treatment, and his opinions and testimony are neither relevant nor reliable, under Federal Rule of Evidence 702 and the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions and testimony are likewise inadmissible because any probative value they may have (and they have none) is substantially outweighed by the danger of unfair prejudice,

[1] The State Health Plan Defendants are the North Carolina State Health Plan for Teachers and State Employees ("NCSHP"); Dale Folwell, in his official capacity as State Treasurer; and Dee Jones, in her official capacity as Executive Administrator of the NCSHP.

confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. *See* Fed. R. Evid. 403.

A memorandum of law is filed contemporaneously herewith.

Dated this 2nd of February, 2022.

Respectfully submitted,

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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

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