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

MEMORANDUM IN SUPPORT OF STATE HEALTH PLAN DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY BY GEORGE BROWN, M.D., AND LOREN SCHECHTER, M.D.

I. Introduction

During discovery, Plaintiffs identified two expert witnesses to testify about gender dysphoria and the medical necessity of certain treatments associated therewith as part of their case-in-chief: George Brown, M.D., and Loren Schecter, M.D. Under Rule 702, this Court has "a special gatekeeping obligation" to "ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (emphasis in original).

The proposed testimony from Drs. Brown and Schecter is not reliable evidence for the medical necessity of the hormone and surgical treatments Plaintiffs seek. The expert reports for Drs. Brown and Schecter—which must provide the "complete statement of all opinions the witness will express and the basis and reasons for them," Fed. R. Civ. P. 26(a)(2)(B)(i)—do not support

their conclusions that hormone prescriptions and body-altering surgery are effective, let alone medically necessary, treatments for the psychiatric illness of gender dysphoria.

Under *Daubert*, this Court must evaluate "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993). The testimony from Dr. Brown and Dr. Schechter does not satisfy *Daubert* because their conclusions constitute the "vague *ipse dixit*" prohibited by Rule 702. *Sardis*, 10 F.4th at 289; *see also id.* at 290 ("The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.") (quoting the advisory committee's note to the 2000 amendments to the Rules of Evidence). Their testimony is based on neither reliable scientific evidence nor experience with an explained methodology, at least one of which is required for their conclusions to be admissible in an expert capacity. Instead, both experts simply note their experience treating transgender patients and testify about the contents of version 7 of the "Standards of Care" issued in 2012 by the World

Professional Association on Transgender Health ("***WPATH***"). (PLANDEF 0095985-0096104).

This is insufficient to establish the admissibility of their testimony. *Daubert* requires this Court to evaluate the methodology used by purported experts. A simple citation to past experience is not enough. Moreover, to the extent that the experts rely upon the WPATH guidelines, these are non-scientific, out-of-date, and accordingly inadmissible as proof that hormone treatment and surgery are medically necessary treatment for gender dysphoria. Rule 702 rejected the *Frye* standard; since *Daubert*, Plaintiffs cannot rely upon acceptance by professional associations as scientific proof. *Daubert*, 509 U.S. at 586; *compare Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).[1]

1 As discussed in further detail in Section IV below, this is especially true given the structure of the WPATH report. Peer-reviewed analysis of the evidence and recommendations in the WPATH guidelines noted that this document "originated nearly a decade ago from a special interest association," and the physicians who performed the analysis could not even reach agreement on what, precisely, are the key recommendations for treating providers in the WPATH document. Sarah Dahlen *et al.*, *International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment*, BRIT. MED. J. OPEN 11(4):e048943 (2021); *see* (PLANDEF00204500-510) at 8 (PLANDEF00204507).

Plaintiffs' experts must present opinions that are "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and [any] inferences must be derived using scientific or other valid methods." *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (emphasis in original). Plaintiffs' experts fail to do so. They present no reliable, testable, accepted, or otherwise valid methodology to support their views about the medical necessity of hormone treatment or surgery for treatment of gender dysphoria. Accordingly, this Court should exclude Dr. Brown and Dr. Schechter from offering testimony on this point.

II. Legal Standard

This Court's "gatekeeping role," *Daubert*, 509 U.S. at 597, is "to exclude speculative or unreliable testimony to ensure accurate, unbiased decision-making by the trier of fact," *Lovett v. Omni Hotels Mgmt. Corp.*, 2016 WL 777781 at *4 (N.D. Cal. Feb. 29, 2016) (Seeborg, J.). *Daubert* "applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Testimony by a qualified expert must (1) "help the trier of fact to understand the evidence or to determine a fact in

issue," (2) be "based upon sufficient facts or data," (3) be "the product of reliable principles and methods," and (4) "reliably appl[y] the principles and methods to the facts of the case." *Lovett*, 2016 WL 777781 at *4. Plaintiffs must prove admissibility of testimony by Drs. Brown and Schechter by a preponderance of the evidence. *Daubert*, 509 U.S. at 592 n.10.

This Court must ensure that an expert's opinion is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (emphasis in original). To the extent an expert makes inferences based on the facts presented to him, this court must ensure that those inferences were "derived using scientific or other valid methods." *Sardis*, 10 F.4th at 281. "[E]xpert opinion evidence [must] be connected to existing data by something more than the 'it is so because I say it is so' of the expert." *Holesapple v. Barrett*, 5 F. App'x 177, 180 (4th Cir. 2001). Here, the expert testimony from Dr. Brown and Dr. Schechter on the medical necessity of the requested treatments has no supporting methodology.

In assessing reliability, the four "non-exhaustive guideposts" of *Daubert*'s analysis are: (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. *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 593–94). While the Court has "broad latitude" to apply "reasonable measures of reliability in a particular case," its focus must be on "the principles and methodology" the expert used to develop the challenged testimony. *Sardis*, 10 F.4th at 281.

These four *Daubert* guideposts "neither necessarily nor exclusively appl[y] to all experts or in every case;" the relevance of some factors can "depend on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Sardis*, 10 F.4th at 281 (quoting *Kumho* 526 U.S. at 141). This Court has therefore applied a different set of factors for expert witnesses who testify based upon their experience, rather than science. "[W]here an expert relies on his experience and training and not a particular methodology to reach his conclusions, application of the *Daubert* analysis is unwarranted." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F.Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.) (citing *Freeman v. Case Corp.*, 118 F.3d 1011,

1016 n.6 (4th Cir. 1997)). "When addressing an expert whose methodology is grounded in experience," the court analyzes "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." *Mod. Auto. Network*, 416 F.Supp. 3d at 537; *see also U.S. v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (While methodology for experiential witness is "somewhat more opaque, the district court must nonetheless require" the witness to explain how their testimony meets these three factors.).

As discussed below, however, Plaintiffs' experts must still present *some* methodology to support their conclusions about the medical necessity of hormone treatment and surgery for treatment of gender dysphoria. They do not present such information. Accordingly, this Court should exclude Dr. Brown and Dr. Schechter from offering testimony on this point.

III. Dr. Brown and Dr. Schechter should not be permitted to testify about the purported medical necessity of hormonal or surgical treatment for gender dysphoria.

A. Plaintiffs repeatedly allege the medical necessity of hormone therapy and surgery for treatment of gender dysphoria.

Plaintiffs assert a violation of equal protection "[b]ecause the only people

who require treatments related to gender-confirming health care are transgender people." Doc. 75 at ¶ 51. Plaintiffs assert that the failure to cover hormone prescriptions and surgery for the Plaintiffs is discriminatory because the Plan pays for these prescriptions and surgeries when used to treat other diagnoses. *Id.* at ¶ 65.[2]

The Equal Protection Clause of the 14th Amendment is "essentially a direction that all persons similarly situated should be treated alike." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 635 (4th Cir. 2020) (emphasis in original). Plaintiffs must therefore prove they "are in all relevant respects alike" to others whose medical care is paid for by the Plan. *Id.*

For conditions the Plan elects to cover, it does so for medical services that are "[p]rovided for" and "necessary for" the "diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease" or its symptoms. *E.g.* North Carolina State Health Plan for Teachers and State Employees, Benefits Booklet 70/30 PPO Plan 103 (2019) (PLANDEF0119816-0119940 at

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[2] Although language in the Plan benefit booklets has indicated otherwise, the Plan does not restrict—and since at least 1990 has not restricted—mental health counseling services on the basis of diagnosis. Doc. 137 at 13 n.2. There is, therefore, no reason for this Court or Plaintiffs' experts to address the availability of counseling services to Plaintiffs.

PLANDEF0119919). No coverage or payment is available for treatments that are for experimental, investigational, or cosmetic purposes. *Id.* So even in the absence of the exclusionary language, Plaintiffs must prove that the services they seek are medically necessary in order to demonstrate they are similarly situated.[3] Plaintiffs repeatedly allege this to be true, including claims that hormone-blocking prescriptions, prescriptions for hormones produced by individuals of the other biological sex (*e.g.* the use of testosterone by a biological female), and surgeries to alter the body (*e.g.* mastectomies or breast augmentation) are "medically necessary" to treat gender dysphoria. Doc. 74 at ¶ 3 (referring to "medically necessary gender-confirming health care"); ¶ 41 (hormone treatment is "medically necessary care"); ¶ 43 (surgery is "medically necessary for transgender people who need it"); ¶ 44 (asserting that an "established body of medical research demonstrates the effectiveness and medical necessity of gender dysphoria treatment").

To prove these claims, Plaintiffs offer two expert witnesses: George R. Brown, M.D. and Loren S. Schecter, M.D.. Dr. Brown is a psychiatrist who

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[3] This analysis must be conducted before applying scrutiny under the Equal Protection analysis. *Sandlands C & D LLC v. City. of Horry*, 737 F.3d 45, 55 (4th Cir. 2013).

currently serves as Professor of Psychiatry at the East Tennessee State University, Quillen College of Medicine. Brown Exp. Rep. ¶ 4. Dr. Brown is a clinician who has treated or evaluated individuals suffering from gender dysphoria throughout his career. *Id.* Loren S. Schecter, M.D., is a plastic surgeon who specializes in gender confirming surgeries, which he describes as "therapeutic tools to enable people to live authentically" in their gender identity. Schechter Exp. Rep. ¶ 3.

B. The psychiatric diagnosis of gender dysphoria relates to the distress suffered by the patient, not an internal feeling of gender discordance.

The most recent definition of "Gender Dysphoria" as a psychiatric disorder is from the FIFTH EDITION OF THE DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (2013) ("***DSM-V***"). (PLANDEF0202999-0203007). As a "general descriptive term," gender dysphoria "refers to an individual's affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category" under the DSM-V. *Id.* (PLANDEF0202999) (emphasis added). The DSM-V diagnosis of gender dysphoria "refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." *Id.*

(emphasis added). As Dr. Brown testified, the medical diagnosis "means that a person who has the symptoms of gender dysphoria" (discontent with one's gender) has reached "a clinically significant level of distress, disability, or dysfunction in occupational or other important areas of their life." Brown. Dep. 85:16–86:9; Brown. Exp. Rep. ¶¶ 24–25.[4]

Dissatisfaction with one's gender by itself is not a mental health issue, so treatment for such dissatisfaction by itself is not "treatment, cure, or relief of a health condition, illness, injury, or disease" (*i.e.* medically necessary). The treatment must be directed at the distress that interferes with the daily activities of life. To establish the medical necessity of hormone or surgical treatments, Plaintiffs must provide expert evidence that these treatments actually relieve the "clinically significant distress or impairment" suffered by patients with gender dysphoria. Neither expert does so.[5]

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[4] Dr. Schechter testified that he does not diagnose whether a patient has gender dysphoria. Schechter. Dep. 133:13–15. Rather, he relies upon the opinions of other mental health and medical professionals. *Id.*

[5] The Court and the jury cannot be permitted simply to infer that because gender dysphoria involves distress with one's biological sex, then treatments to make a patient appear as a person of the opposite sex will reduce this distress. The most recent studies, discussed by the Plan Defendants' experts, show no evidence that this distress diminishes. *See* Doc. 197 at 9 & n.3. Plaintiffs'

C. To demonstrate that the hormone treatment or surgery is medically necessary, Plaintiffs must provide scientific evidence.

Plaintiffs seek an injunction that would require the Plan to pay for hormone and surgical treatments for individuals suffering from gender dysphoria when the treating physician concludes such procedures are medically necessary. Doc. 75 at 45 (seeking injunction to prohibit Plan from "administering or offering health coverage that categorically excludes coverage for gender-confirming health care").

To justify such relief, Plaintiffs must do more than show that these medical treatments will benefit them as individuals. Plaintiffs must demonstrate the injunction is in the interest of Plan beneficiaries generally. Such a conclusion is "scientific in nature" inasmuch as it raises "basic, testable" concepts of whether the desired treatments can be expected to provide relief from the psychiatric illness of gender dysphoria. *See Sardis*, 10 F.4th at 291. Since 1992, the emphasis in health care has been on "evidence-based medicine." "Reference Guide on Medical Testimony," National Research Council, *Reference Manual on Scientific Evidence* 741 (3d ed. 2011). Evidence-

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experts can disagree with this conclusion, but—for purposes of *Daubert*—they must also explain the methodology they use to reach a contrary conclusion.

based medicine is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient" and "integrating individual clinical expertise with the best available external clinical evidence from systematic research." *Id.* This contrasts with "the traditional informal method of practicing based on anecdotes, applying the most recently read articles, doing what a group of eminent experts recommend, or minimizing costs." *Id.*

Neither Dr. Brown nor Dr. Schecter provide an overview of the scientific evidence supporting the various treatment methods for transgender patients. At his deposition, Dr. Brown acknowledged/testified that his own testimony does not analyze the strength of the scientific evidence supporting the provision of hormone therapy for treatment of gender dysphoria. Brown. Dep. 149:23–152:22. "I wasn't asked to examine the complete literature on gender affirming hormone treatment as part of my mission in developing my expert reports. So I have not done that." Brown. Dep. 150:4–7. An opinion on the scientific literature about the efficacy of hormone therapy and surgery would require a "comprehensive review" and "was not something I was asked to opine on and nor have I conducted such a comprehensive review," Dr. Brown

explained. Brown. Dep. 150:13–19. "I can only speak to my clinical experience in those areas." Brown. Dep. 150:19–20.

Dr. Schecter provided a similar limitation on his testimony. He has not been retained to provide scientific knowledge. He was retained by Plaintiffs to testify about (1) "the standards of care for treating individuals diagnosed with gender dysphoria;" (2) "the safety, efficacy, and cost of gender confirming surgeries as treatment for gender dysphoria;" (3) similarities between surgical techniques to treat gender dysphoria and surgeries for treatment of other diagnoses; and (4) whether the exclusion of transition-related surgical care by the Plan "is consistent with the standards of care for treating transgender individuals diagnosed with gender dysphoria." Schechter Exp. Rep. ¶ 2.

When asked at his deposition whether surgery alleviates the effect of gender dysphoria, Dr. Schechter could not answer and instead deferred to the judgment of other physicians involved in a patient's treatment. He explained that as a plastic surgeon he works as one member of a larger multidisciplinary team, and other team members are responsible for diagnosing gender dysphoria and following the patient's mental health. Schechter Dep. 134:9-11; 136:2-7; 138:2-11. To the extent that Dr. Schechter has an opinion about

whether surgery is an effective treatment for gender dysphoria, he relies upon his "practice of over 20 years in caring for individuals," unspecified "discussions with professional colleagues at national and international meetings," and his "role as a teacher and educator at various universities in the Chicago area." Schechter Dep. 141:12-142:3.

Even if the Court concludes that experiential testimony—rather than the scientific testimony that underlies evidence-based medicine—is appropriate, Plaintiffs' experts must still provide sufficient information to permit this Court to assess the methodology underlying their opinions. "Whether expert evidence is reliable is primarily a question of the validity of the expert's methodology, not the quality of the data used, or the conclusions produced." *Krakauer v. Dish Network, L.L.C.*, No. 1:14-cv-333, 2015 WL 5227693, at *5 (M.D.N.C. Sept. 8, 2015) (emphasis added). The factfinder must be able to assess "how the expert's experience leads to the conclusion reached." *Mod. Auto. Network*, 416 F.Supp. 3d at 537. *Daubert* does not envision the admission of "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert," *Kumho*, 526 U.S. at 157, as is the case with the opinions of Dr. Brown and Dr. Schechter on the medical necessity of Plaintiffs' desired hormone and surgical treatments.

IV. The WPATH Guidelines cannot be simply cited as proof of the accuracy of the testimony of Dr. Brown and Dr. Schechter as the WPATH Guidelines lack sufficient rigor (or any described methodology) to provide scientific support for hormonal or surgical treatment for gender dysphoria.

Much of Dr. Schechter and Dr. Brown's testimony relies upon references to the conclusions of the WPATH guidelines. The text of the WPATH guidelines, however, is not admissible as proof of the truth of the information contained therein. Rule 703 does not permit an expert to act as a conduit for otherwise inadmissible hearsay. Fed. R. Evid. 703. "Rule 703 has been amended to emphasize that when an expert reasonably relies on inadmissible information to form an opinion or inference, the underlying information is not admissible simply because the opinion or inference is admitted." Fed. R. Evid. 703 advisory committee's note to the 2000 amendment.

Moreover, the existence of the WPATH standards cannot justify the expert testimony of Dr. Brown or Dr. Schechter. Plaintiffs argue that "general acceptance" of these guidelines demonstrates that the conclusions therein are reliable science. But neither the WPATH, nor the Endocrine Society standards related to hormone treatment, are "standards of care" or "high quality clinical practice guidelines" as these terms are used in the medical community. More

significantly, *Daubert* overruled *Frye*'s general acceptance test. This Court cannot reinstitute *Frye* and admit the opinions enshrined in these documents simply because Plaintiffs' experts state they are authoritative. *See* Brown Exp. Rep. ¶ 33; Schechter Exp. Rep. ¶ 9. To do so would be to admit purported scientific evidence without performing the required methodological scrutiny.

WPATH uses the term "standards of care" interchangeably with "practice guidelines." WPATH at 2 (PLANDEF 0095992). These are terms of art, however, and they are not interchangeable. "Standards of care" are "authoritative, unbiased consensus positions designed to produce optimal outcomes." Letter to the Editor from William J. Malone, *et al., Proper Care of Transgender and Gender-diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective*, THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM (June 14, 2021) (PLANDEF0204965-0204966). In contrast, "practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased." *Id.* The WPATH document is entitled "Standards of Care," but its own authors acknowledge that they are actually "practice guidelines": "As in all previous versions of the [WPATH Standards of Care], the criteria put forth in

this document for hormone therapy and surgical treatments for gender dysphoria are clinical guidelines; individual health professionals and programs may modify them." WPATH at 2 (PLANDEF 0095992) (emphasis added). The Endocrine Society more accurately calls their recommendations "clinical practice guidelines." William Hembree, *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 (PLANDEF 0204637-0204661).

However, neither WPATH nor the Endocrine Society guidelines represent the level of high-quality practice guidelines recommended for use by clinicians. WPATH cannot guide medical treatment when it explicitly states that individual health professionals may modify any recommendations contained therein. WPATH at 2. (PLANDEF0095992). The Endocrine Society guidelines cited by Plaintiffs have an explicit caveat: "The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care." Endocrine Guidelines at 3895 (PLANDEF0204653).

The first systematic review, using a validated appraisal instrument to assess evidentiary quality, of all existing clinical practice guidelines ("CPGs")

for transgender individuals found that none of the existing transition-focused guidelines have the methodological rigor or evidentiary quality necessary to be used as high-quality CPGs. Sarah Dahlen *et al.*, *International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment*, BRIT. MED. J. OPEN 11(4):e048943 (2021); (PLANDEF00204500-510) at 2, 6 (PLANDEF00204501 & PLANDEF00204505). "High-quality CPGs support high-quality healthcare delivery. They can guide clinicians and policymakers to improve care, reduce variation in clinical practice, thereby affecting patient safety and outcomes." *Id.* at 1 (PLANDEF0204500).

The Dahlen review notes that "[g]lobally, many national and local guidelines are adaptations of, acknowledge being influenced by, or are intended to complement [WPATH], despite expressed reservations that [WPATH] is based on lower-quality primary research, the opinions of experts and lacks grading of evidence." *Id.* at 2. (PLANDEF0204501). Although WPATH's stated overall goal is "'to provide clinical guidance for health professionals,' it contains no list of key recommendations nor auditable quality standards, yet it is widely used to compare procedures covered by U.S. providers." *Id.* at 4-6 (PLANDEF0204503-0204505). Neither WPATH nor any

of the other clinical practice guidelines that discussed gender transition have had independent external peer review of the treatment recommendations. *Id.* at 5-6 (PLANDEF0204504-0204505) (Table 1). This was in contrast to the transgender clinical practice guidelines that addressed HIV prevention and treatment, which had independent external review and strong evidentiary support. *Id.*

One of the principal findings of this peer-reviewed article has direct relevance here. Not a single one of the individual reviewers concluded that physicians should use the current WPATH guidelines to direct patient care, and only one recommended that clinicians refer to the Endocrine Society guidelines. *Id.* at 6. (PLANDEF0204506). This peer-reviewed article, in the prestigious British Medical Journal, concluded that, despite its global influence, the WPATH treatment guidelines "cannot be considered 'gold standard.'" *Id.* at 8 (PLANDEF0204507). This Court cannot, and should not, defer to hearsay medical recommendations that an evidence-based review has concluded should not guide transgender patient care. If the Plaintiffs' experts wished to provide more evidence, then they should have done so.

Additional shortcomings undermine reliance upon WPATH. Neither WPATH nor the Endocrine Society's guidelines are endorsed by the ECRI Guidelines Trust, the independent non-profit patient safety organization that analyzes clinical practice guidelines. *See also* Institute of Medicine, National Academies of Sciences, *Clinical Practice Guidelines We Can Trust* (2011) (PLANDEF0203414-0203704) (Report identifying the standards used by ECRI). Second, the WPATH guidelines are more than 10 years old and therefore do not incorporate or analyze any scientific research in the past decade. They are out-of-date. Finally, the WPATH guidelines were not created through a process that protects against conflicts of interest. The Institute of Medicine Report on guideline development states that, when clinical practice guidelines are created, the Chair or Co-chairs of the committee must not have a conflict of interest. *Guidelines We Can Trust* at 83 (PLANDEF 0203521). A conflict of interest includes any financial, professional or intellectual interests that "create[d] a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." *Id.* at 78 (PLANDEF0203516). The WPATH guidelines fail this test. Eli Coleman, Chair of the WPATH Guidelines committee in 2011 and the current chair considering

revisions, is the Director and Chair of the Institute for Sexual and Gender Health at the University of Minnesota. *See* https://bit.ly/3mx6Eyu. This organization receives multi-million-dollar grants from the Tawani Foundation, a transgender advocacy organization. *E.g.* Tawani Foundation, "Major Donation Will Improve, Sustain Sexual Health Research and Care" (March 6, 2017) *available at* bit.ly/3QdctPl. *See generally* tawanifoundation.org (identifying purposes of the foundation and the grants it has awarded).

Testing the "reliability of proffered scientific literature is incomplete without exploration of an expert's knowledge of and attitude toward the scientific literature." *Milward v. Acuity Specialty Prod. Grp., Inc.*, 969 F.Supp. 2d 101, 113 (D. Mass. 2013). The existence of the WPATH or Endocrine Guidelines, without further investigation, does not establish the admissibility of expert opinions that simply repeat their conclusions. And as noted below, Dr. Brown and Dr. Schechter offer no additional evidence.

V. Dr. Brown and Dr. Schechter do not present any methodology by which this Court can conclude that there is credible experiential support for hormonal or surgical treatment for gender dysphoria.

Experts must do more than provide opinions, they must explain the process through which they have reached this opinion. And this Court must be

able to assess the process by which the expert reached the opinion. *Ipse dixit* is not enough.

A. Dr. Brown

Dr. Brown's expert report is replete with statements that provide no analysis or methodology. Indeed, during his deposition, Dr. Brown expressly disclaimed that his expert report was intended to provide a scientific analysis of the efficacy of treatments of gender dysphoria. Dr. Brown testified that "I can only speak to my clinical experience in those areas." Brown. Dep. 150:19–20.

Dr. Brown's testimony cannot therefore be credited as a summary of scientific testimony. Rather, Dr. Brown's testimony is based on "research and clinical practice," which has "included extensive study of health care for transgender individuals, including leading and authoring three of the largest studies ever conducted." Brown Exp. Rep. ¶ 8. Dr. Brown must do more, however. He must explain "how [his] experience leads to the conclusion reached" or "why that experience is a sufficient basis for the opinion." *Mod. Auto. Network*, 416 F.Supp. 3d at 537. To be admissible, Dr. Brown must

explain how his experience as a treating physician leads to his conclusions, but he does not.

Indeed, Dr. Brown provides no support at all for some statements. *See*, *e.g.*, Brown. Exp. Rep. ¶ 36 ("Counseling, hormone therapy, and surgical care for gender dysphoria—including procedures such as mastectomies, hysterectomies, and genital reconstruction—are routinely performed as medically necessary care for other medical conditions."). For other statements, Dr. Brown provides a generalized mention of, or citation to, the WPATH guidelines (a 120-page document), without explanation, discussion, or even a specific page number. *See*, *e.g.*, Brown. Exp. Rep. ¶¶ 30,37,38. For other paragraphs, Dr. Brown does not cite medical literature at all, citing instead position papers or other political statements. *See*, *e.g.*, Brown. Exp. Rep. ¶¶ 40–42.

To the extent that Dr. Brown identifies articles that support his claims, he does not explain the findings of these articles, why he relies upon them, or how the conclusions and studies within these articles support the conclusions for which he cites them. For example, Dr. Brown asserts that "sixty years of clinical experience have demonstrated the efficacy of treatment of the distress

resulting from gender dysphoria" but he cites only a position paper issued by a professional organization. Brown Exp. Rep. ¶ 40.[6]

The Advisory Committee Note for the revised Fed. R. Evid. 702 makes clear that while experience alone may be enough to qualify an expert, "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Yet this is precisely what Plaintiffs have asked this Court to do.

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[6] As another example, Dr. Brown provides no citation to a decision by an appeals board in the U.S. Department of Health and Human Services, even when he provides a summary of the decision. Dr. Brown states a "robust body of research" led "an independent medical board in the U.S. Department of Health & Human Services [to] issue[ ] a decision in 2014, rescinding a Medicare policy that had excluded surgery from Medicare coverage." Brown. Exp. Rep. ¶ 41. This mischaracterizes the panel's decision. HHS, as an agency, refused to submit any evidence whatsoever to the appellate panel. Dep't App. Bd., NCD 140.3, Transsexual Surgery, No. A-13-87 (May 30, 2014) at 6, *available at* bit.ly/3GWUtob. The prior conclusion was made in 1981, and the only party that presented any evidence after that date was the individual plaintiff. The panel's decision was therefore based on a record that included no contrary medical information. The beneficiary prevailed, but the Panel did not conduct any testing or evaluation of existing medical science.

B. Dr. Schechter

Dr. Schechter's expert report fares no better. Dr. Schechter explicitly disclaims responsibility for the evaluation of his patients' psychiatric concerns. He is a plastic surgeon, "not a mental health professional." Schechter Dep. 138:2-11. Dr. Schechter's treatments "occur after the diagnosis" of gender dysphoria, Schechter Dep 136:2–7, and his follow-up appointment "isn't specific to mental health conditions," Schechter Dep 138:7–11.

Dr. Schechter's conclusions are similarly conclusory and uncited. Schechter Exp. Rep. ¶¶ 19, 20, 27–32, 35, 38. To the extent that he identifies the reasoning in specific articles, he fails to disclose the methodological limitations. For example, Dr. Schechter states that one study found that "100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and would undergo the operation again." Schechter Rebut. Rep. ¶ 15. This is false. The cited study surveyed 34 male-to-female transgender patients who received breast augmentations over a 30-month period. Travis J. Miller *et al.*, *Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes*, 21 JPRAS OPEN 63–74 (2019). Only 12 of the 34 patients answered the survey,

and none of them were the patients who had experienced complications from their surgery. *Id.* The conclusion of the study is not, as Dr. Schechter stated, that "these are appropriately characterized as reconstructive procedures." Schechter Rebut. Rep. ¶ 15. The conclusion of the peer reviewed article is much more cautious: "Breast augmentation in transwomen poses technical challenges unique to this patient population. While there are strategies to cope with the anatomic differences between male and female chests and NACs, certain characteristics are difficult to overcome and hence should be discussed with patients before proceeding with surgery. Overall, this operation is clinically meaningful, and additional research is needed to continue to offer this population optimal and reliable results." Travis J. Miller, *et al*, *Breast augmentation in male-to-female transgender patients: Technical considerations and outcomes*, 21 JPRAS OPEN 21 (2019) 63-74 at 74 *available at* bit.ly/3xyKLoR.

C. Failure to Identify or Discuss Contrary Information

Finally, neither Dr. Brown nor Dr. Schechter address recent scientific research that is contrary to their conclusions. "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the

expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Yates v. Ford Motor Co.*, 113 F.Supp. 3d 841, 858 (E.D.N.C. 2015). The expert does not have to "review every single study in the relevant body of literature," but "[i]t is axiomatic that "[w]here an expert ignores evidence that is highly relevant to [her] conclusion, contrary to [her] own stated methodology, exclusion of the expert's testimony is warranted." *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F.Supp. 3d 116, 194 (D.N.J. 2020). *See also Tyree v. Bos. Sci. Corp.*, 54 F.Supp. 3d 501, 520 (S.D.W. Va. 2014) ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively chooses his support from the scientific landscape.").

Medical science is trending strongly away from the conclusion that hormonal and surgical treatment improves the distress suffered by patients suffering from gender dysphoria. As noted in earlier filings to this Court, Finland, Sweden, and the United Kingdom have all retreated from their prior medical policies that made cross-sex hormones and surgical treatments widely available. Medical providers in these countries now restrict the use of hormones and surgery in minors based on identified gaps in the medical

science. Doc. 197 at 14-15. Dr. Schechter testified that he had only limited familiarity with these developments. Schechter Dep. 100:22-104:22.

Dr. Brown's discussion of these international developments is affirmatively misleading. In his rebuttal report, Dr. Brown states that these international reviews can be disregarded because they "focus exclusively on pre-pubertal children." Brown Rebut. Rep. ¶ 23. This is false. Every one of the reviews examined the treatment of minors (those under 18): patients who are of the same age as two Plaintiffs here.[7]

VI. Conclusion

This Court must evaluate the methodology of the two Plaintiff experts who have opined on the medical necessity of hormonal and surgical treatment for gender dysphoria. When it does so, the Court should find their conclusions unreliable and exclude or limit the testimony accordingly.

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[7] For example, a 2020 review by the U.K.'s National Institute for Health and Care Excelled (NICE) examined the use of hormone suppression treatment in "children and adolescents aged 18 years or under." Evidence Review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria (2020) at 1. (PLANDEF0204216-0204346). The review found that existing studies "suggest little change"—that is, improvement—in the "critical outcomes of gender dysphoria and mental health" from use of puberty blockers. *Id.* at 13 (PLANDEF0204228).

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of June, 2022, the foregoing was filed electronically with the Clerk of Court using the CM/ECF electronic filing system, which will send notification of such filing to all registered users.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that the State Health Plan Defendants' Motion in Limine to Exclude Testimony by George Brown, M.D., and Loren Schechter, M.D. complies with the Court's word limit as calculated using the word count feature of the word processing software. Specifically, the Memorandum in Support contains less than 6,250 words, including the body of the Memorandum and headings, butnot including the caption, signature lines, this certificate, or the certificate of service.

This the 10th day of June, 2022.

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