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

KANAUTICA ZAYRE-BROWN, *Plaintiff*, v. THE NORTH CAROLINA DEPARTMENT OF ADULT CORRECTIONS, *et al.*, *Defendants*.	No. 3:22-cv-00191-MOC-DCK

BRIEF IN SUPPORT OF PLAINTIFF'S *DAUBERT* MOTION TO EXCLUDE THE TESTIMONY OF DR. FAN LI

INTRODUCTION AND BACKGROUND

Every major medical association in the United States supports gender-affirming surgery as treatment for gender dysphoria. *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020), *as amended* (Aug. 28, 2020); (Doc. 62-2 Ettner Rep. ¶30.) The World Professional Association for Transgender Health ("WPATH") and the Endocrine Society both have published clinical practice guidelines regarding gender-affirming medical care, including surgery, to treat gender dysphoria. *See* E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int'l J. of Transgender Health S1 (Sept. 15, 2022) ("WPATH SOC"); Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical*

Practice Guideline, 102 J. Clinical Endocrinology & Metabolism 3869 (Nov. 2017) ("Endocrine Society Guideline"). Defendants proffer the expert report of Dr. Fan Li to support their refusal to provide Plaintiff with gender-affirming surgery. Dr. Li is a statistician who opines on the strength of the evidence relied upon in certain assertions by WPATH and Dr. Ettner. She is not a health care provider of any kind, and her opinion is solely that of a statistician; she provides no opinion on whether gender-affirming medical treatment is effective, whether WPATH's Standards of Care are reasonable or reliable, or whether Plaintiff needs gender-affirming vulvoplasty. (*See generally* Doc. 65-15, Li Rep.; *see also* Li Dep. 87:25-88:11, 129:3-21.)

Under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Dr. Li's report and testimony should be excluded. Dr. Li is not qualified to opine that the evidence does not provide "reasonable support" for the assertions made by WPATH and Dr. Ettner (Doc. 65-15, Li Rep. at 25.) Dr. Li also reaches her conclusions using unreliable principles, and her views are ultimately irrelevant.

LEGAL STANDARD

Federal Rule of Evidence 702 "permits an expert to testify where the expert's 'scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue,' so long as the expert's opinion is 'based on sufficient facts or data,' 'is the product of reliable principles and methods,' and the expert 'has reliably applied the principles and methods to the facts

of the case.'" *In re Lipitor (Atorvastatin Calcium) Mktg.*, 892 F.3d 624, 631 (4th Cir. 2018) (quoting Fed. R. Evid. 702). "Rule 702 thus imposes a special gatekeeping obligation on the trial judge to ensur[e] 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) (alteration in original) (internal citations and quotation marks omitted).

Rule 702 applies with full force on a motion for summary judgment even when a case is scheduled in whole or part for a bench trial. A court cannot resolve summary judgment based on material that "cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2). Thus, when the evidence related to a material question of fact comes in the form of expert testimony, "the propriety of summary judgment hinges on whether [the] expert evidence is admissible" under Rule 702. *Rover Pipeline LLC v. Rover Tract No(s). WV-MA-ML-056.500-ROW & WV-MA-ML-056.500-ATWS*, No. 5:18-CV-68, 2021 WL 3424270, at *3 (N.D. W. Va. Aug. 5, 2021); *see also Kadel v. Folwell*, 620 F. Supp. 3d 339, 392-93 (M.D.N.C. 2022) (excluding defense expert testimony and granting plaintiffs partial summary judgment on claims concerning gender-affirming care).

ARGUMENT

I. Dr. Li's conclusion that the studies on gender-affirming surgery are "low quality" is not relevant and does not assist the trier of fact.

An expert's opinion is relevant if it has "a valid scientific connection to the pertinent inquiry." *Belville v. Ford Motor Co.*, 919 F.3d 224, 232 (4th Cir. 2019) (quoting *Daubert*, 509 U.S. at 592). "This ensures that the expert helps the trier of

fact to understand the evidence or to determine a fact in issue. Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Sardis*, 10 F.4th at 281 (quotation marks and citation omitted).

In her report, Dr. Li opines "to a reasonable degree of statistical certainty[1] that the studies cited by [Dr.] Ettner and/or WPATH reviewed in [her] report simply do not provide reasonable support for the assertions made by Dr. Ettner and WPATH relative to the benefits in quality of life and well-being of gender-affirming treatments." (Li Rep. at 25.) She reaches this opinion based on her conclusion that none of the studies are randomized controlled trials and they are "low quality in terms of study design and statistical methodology." (*Id.*; *see also id.* at 12, 14-19, 21-22, 24.)

At her deposition, Dr. Li summarized her opinion as having four components: (1) there are no randomized controlled studies supporting the specific assertions made by WPATH and Dr. Ettner that defense counsel asked her to review; (2) there are no good quality prospective before/after observational studies in the studies she evaluated; (3) the vast majority of the studies cited are low quality retrospective studies that are subject to confounding bias and other biases; and (4) even many of the systematic reviews relied upon call for more prospective studies and describe many of the studies as low quality. (Li Dep. 145:19-146:10.)

[1] While this phrasing implies that Dr. Li's opinion was reached mathematically and with a near-certain probability that it is correct, she clarified during her deposition that this phrase does not mean "that there is certainty supported by numbers, but rather that [she is] confident and [she] relied on statistics." (Li Dep. 28:13-29:9.)

Dr. Li's opinion of the quality of the studies and the lack of "rigorous and consistent statistical evidence" is not helpful to the trier of fact because, as she admits, she is not providing an opinion on what degree of statistical methodology is needed for a treatment to be included in a clinical practice guideline, nor is she providing an opinion on whether the quality of the evidence impacts whether treatment can be provided. (Li Dep. 143:4-144:14.) In other words, Dr. Li's opinion has no bearing on clinical practice guidelines, treatment decisions, the practice of medicine, or—ultimately—the determinative issue of whether Defendants were deliberately indifferent to Plaintiff's need for gender-affirming surgery.

Even accepting Dr. Li's conclusion that the studies are of low quality, "that does not change the fact that the larger medical community considers these [gender-affirming medical] treatments to be acceptable." *See Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014 (W.D. Wis. 2019) (finding similar opinion "entirely unhelpful" to the issue of Wisconsin Medicaid's exclusion of gender-affirming medical care).

Clinical practice guidelines—like the WPATH Standards of Care—are developed to provide clinicians with helpful, evidence-based recommendations for care. (Doc. 68-2, Antommaria Rebuttal Rep. at 8.) Dr. Li does not know what clinical practice guidelines are or what quality levels of evidence they can rely on, and she does not claim to be providing an opinion on what quality of evidence clinical practice guidelines can rely upon. (Li Dep. 23:10-12; 88:8-11; 91:12-18.)

Only a minority of clinical practice guideline recommendations are based on "high" quality evidence, and such recommendations are not based solely on the quality of the evidence. (Doc. 68-2, Antommaria Rebuttal Rep. at 7.) A recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence.[2] (*Id.* at 9.)

Dr. Li describes randomized controlled trials as the "gold standard for evaluating the efficacy, effectiveness, and safety of an intervention or treatment." (Doc. 65-15, Li Rep. at 8.) Although she describes observational studies as "inferior" to randomized controlled trials, (*Id.* at 9), she admits that when randomized controlled trials are not available, researchers look to observational studies. (*Id.* at 8.) Within observational studies, she considers prospective observational studies to be subject to less bias than retrospective observational studies, and therefore superior. (*Id.* at 9.)

While Dr. Li repeatedly says that it is not her opinion that randomized controlled trials are necessary, (*see e.g.*, Li Dep. 30:15-31:12; 106:8-22), she repeatedly criticizes the studies relied upon by WPATH and Dr. Ettner for not being randomized controlled trials. (*See e.g.*, Doc. 65-15, Li Rep. at 4, 12, 14, 16.) When asked about her

[2] The terms "high" quality evidence and "low" quality evidence are used here as they are used in the GRADE system, a widely used method in clinical practice guidelines for rating the quality of the evidence and the strength of recommendations. (Doc. 68-2, Antommaria Rebuttal Rep. 8-9.) All observational studies are initially rated as "low" quality (though the rating may change based on other factors), and "low" does not mean that the evidence is poor or inadequate. (*Id.* at 9-10.) Dr. Li is not familiar with the GRADE methodology. She stated that she uses the term "low quality" to reflect the study design and indicate that a study is prone to biases. (Li Dep. 47:3-18.)

statement that the "statistical methodology in the field of comparative effectiveness of [sex-reassignment surgery] is not up to the long-established standard in comparative effectiveness research in medicine" (Doc. 65-15, Li Rep. at 19), she explained the standard as "when you try to publish something, like about [the] comparative effectiveness of treatment, then you expect to provide either randomized study or high quality observational study." (Li Dep. 140:6-141:5; *see also id.* at 27:4-7 (discussing level of evidence from viewpoint of a reviewer of a medical journal), 36:12-23 (same).) Dr. Li does not explain why the purported standard of medical publishing[3]—requiring randomized controlled studies or high-quality observational studies—would be the appropriate standard here,[4] nor can she, because it is not. As is made clear by GRADE and clinical practice guidelines, recommendations can be—and the *majority* are—made based on evidence other than randomized controlled studies or high quality observational studies. (Doc. 68-2, Antommaria Rebuttal Rep. at 14-15.)

That Dr. Li concludes the studies at issue are of low quality has, by her own admission, no bearing on the clinical practice guidelines or treatment decisions. (Li Dep. 39:6-21; 52:11-17; 91:6-18.) As she herself points out, many of the studies and

[3] It is not clear where this standard comes from or the context that Dr. Li was referring to, as "low" quality observational studies are regularly published in medical journals, including most, if not all, of the studies that Dr. Li reviewed. (*See generally* Doc. 65-15, Li Rep. App. B.)

[4] Dr. Li reiterated her perceived requirement for "high" quality studies when she said that it does not matter if you have 50, 100, or 1,000 "low" quality studies, and that a few "high" quality studies would be better than 100 "low" quality studies. (Li Dep. 65:20-67:23.)

systematic reviews acknowledge the limitations of the studies as they relate to study design and potential biases, and still come to the conclusion that gender-affirming treatment is beneficial and effective. (*See e.g.* Doc. 65-15, Li Rep. at 20 (quoting systematic review that concluded that gender-affirming surgery "is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals" and also acknowledged that the "conclusion is based on methodologically less than perfectly designed studies"; *id.* at 14 (stating that study acknowledges its review is based on "seventy-nine low quality studies").) Indeed, the Endocrine Society Guideline rates all of the evidence as "low" or "very low" quality using the GRADE system, and still makes recommendations for gender-affirming treatment, including surgery.

With knowledge of the limitations of the studies and the evidence, the Endocrine Society and WPATH issued clinical practice guidelines based on the best available evidence. *See* Endocrine Society Guideline and WPATH SOC. These clinical practice guidelines regarding gender-affirming care are supported by every major U.S. medical association and are recognized as authoritative by numerous courts, including the Fourth Circuit. *Grimm*, 972 F.3d at 595. (*See also* Doc. 62-2, Ettner Rep. ¶30.) Dr. Ettner's expert opinion relies on these same studies as well as her clinical expertise. Dr. Li's opinion on the strength and quality of the evidence has no relevance to whether gender-affirming medical care and surgery is the best evidence-based treatment for gender dysphoria, and therefore has no relevance to this case. Accordingly, *Daubert* requires that her opinion be excluded. *Sardis*, 10 F.4th at 281;

Daubert, 509 U.S. at 592 (expert testimony must have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility.").

II. Dr. Li is not qualified to offer expert opinions on what constitutes "reasonable support" for assertions regarding the benefits of gender-affirming medical treatments.

An expert is qualified if they have "specialized knowledge that will assist the trier of fact in understanding the evidence or determining a fact in issue." *United States v. Young*, 916 F.3d 368, 379 (4th Cir. 2019). "[A] person may qualify to render expert testimony in any one of the five ways listed" by Rule 702: "knowledge, skill, experience, training, or education." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). However, the expert must be qualified to testify "on the issue for which the opinion is proffered." *Id.*

Dr. Li's experience as a statistician does not make her qualified to opine on the level of evidence sufficient to support clinical practice guidelines (like WPATH SOC) or medical treatment recommendations for the treatment of gender dysphoria. She is not qualified to provide the opinion that the studies relied upon by Dr. Ettner and WPATH "do not provide reasonable support for the assertions made by Dr. Ettner and WPATH" (Doc. 65-15, Li Rep. at 25), because she has no expertise on what level of evidence is necessary for doctors and clinical practice guidelines to make treatment or clinical practice recommendations. In other words, she does not know what "reasonable support" is in the context of the practice of medicine.

Tellingly, Dr. Li stated that her standard was whether there was enough evidence for acceptance into a medical journal; she would expect to see a randomized

controlled trial or a well-designed observational study, but a retrospective study would not be enough.[5] (Li Dep. 27:4-22.) Dr. Li thus is utilizing a standard that is not the standard for medical treatment. (Doc. 68-2, Antommaria Rebuttal Rep. at 2-3, 6-7.) Even if she has the expertise to evaluate the studies for study design and bias, her expertise stops there: she cannot make the critical step of determining whether the evidence supports treatment recommendations or clinical practice guidelines, or whether or not it supports or contravenes Defendants' refusal to provide gender-affirming surgery to Plaintiff.

Further, Dr. Li had no familiarity with gender-affirming medical care before being retained as a statistician for this matter. The extent of her knowledge about gender dysphoria is that someone feels their gender is misaligned with their sex at birth, and she considered gender dysphoria simply a variable when preparing her report. (Li Dep. 14:5-17.) She did not know gender dysphoria was a diagnosis in the Diagnostic and Statistical Manual of Mental Disorders (DSM) (*id.* at 15:2-4), and she has not read any literature on the topic other than the studies underlying the assertions that Defendants' counsel hand-picked for her. (*Id.* at 11:13-12:18.)

Many of Dr. Li's criticisms underscore her lack of knowledge on the central issue in this case. For example, she criticizes several studies for not comparing gender-affirming surgery with alternative treatments, (Doc. 65-15, Li Rep. at 15, 18, 25), but could not name an alternative treatment the studies should have compared

[5] As discussed above in footnote 3 above, the source of this standard is unclear and while Plaintiff does not necessarily agree that such a standard exists or is accurate, that question need not be decided for purposes of Plaintiff's argument or this motion.

other than suggesting hormone therapy. (Li Dep. 120:6-121:13; 136:4-15 ("I say hormone therapy, it's just because when I review the literature, and I see people mention hormone therapy.")) Hormone therapy is not an alternative treatment, but in fact a recommended prerequisite to surgery under WPATH.[6] (*See* WPATH SOC, at S32.) Dr. Li also criticizes the studies for not comparing different types of gender-affirming surgeries, but this is nonsensical given the highly individualized needs of patients—surgeries are not interchangeable. Her near-total lack of knowledge regarding gender-affirming healthcare and her resulting misplaced criticisms of the studies further affirm that she is not qualified to provide an expert opinion in this matter.

III. Dr. Li's opinion is not the product of reliable principles and methods.

Even if Dr. Li were qualified and her opinion relevant, her opinion is not "the product of reliable principles and methods" and she has not "reliably applied the principles and methods to the facts of the case." *In re Lipitor*, 892 F.3d at 631 (quoting Fed. R. Evid. 702).

Dr. Li states that the studies on gender dysphoria and gender-affirming surgery do not constitute a rigorous and consistent body of evidence and do not provide reasonable support for the assertions by Dr. Ettner and WPATH. But she could not define what does or does not constitute reasonable support, and to the extent she is able to articulate a standard, it is an inappropriate one.

[6] Plaintiff has been receiving hormone therapy for 11 years. It has not reduced her need for surgery and would not appropriately be considered an alternative to surgery.

When asked how much evidence would be necessary for her to conclude that there is reasonable support for an assertion, Dr. Li appears to be employing an "I'll know it when I see it" test. (*See* Li Dep. 26:12-19 ("What do I mean by reasonable is reasonable judged by me…"); *Id.* at 109:16-20 ("Q. And you know that this is not enough evidence to be considered rigorous and consistent, but you don't know how much would be needed to be rigorous and consistent? A. Correct.")) Such an arbitrary and subjective standard is not a reliable principle or method. *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) ("inferences must be derived using scientific or other valid methods") (citation omitted).

At times, Dr. Li appears to be using a standard of whether the evidence would be sufficient to be published in a medical journal but does not explain why that standard would be appropriate in a treatment context, and as discussed above, this is not a standard used by clinical practice guidelines or doctors when making treatment recommendations. (Li Dep. 27:4-7 (describing a lack of reasonable support as "if I'm a reviewer of a medical journal…I would reject it on the ground that the evidence is not enough"); *id.* at 36:12-23 (same); *id.* at 140:6-141:5 (discussing the standard for publishing about the comparative effectiveness of treatment); (Doc. 68-2, Antommaria Rebuttal Rep. at 6-7, 14-15)). By applying an inappropriately high standard, Dr. Li's opinions are not the product of reliable principles and methods.

Dr. Li's critiques of Dr. Ettner further demonstrate the unreliability of Dr. Li's methods. Dr. Li says that Dr. Ettner's assertion that the absence of gender-

affirming treatment "often leads to attempts at self-surgical treatment"[7] is incorrect, and instead concludes that self-surgical treatment is "relatively rare rather than often." (Doc. 65-15, Li Rep. at 23.) The study relied on by Dr. Ettner found that five percent of transgender prisoners reported they attempted (2%) or completed (3%) self-surgical treatment while incarcerated. (*Id.*) When asked how she defines "often" in that situation, she responded that it was "just [] common sense." (Li Dep. 154:18-155:14.) After initially saying that "often" "probably means something like over 50 percent," she then acknowledged that the definition may "depend on the context," (*id.* at 154:2-9), and stated, "10 percent or 20 percent, that sounds often." (*Id.* at 155:8-9.) She continued, "I would not – I mean, from a common sense perspective, regard 2 percent or 3 percent as often." (*Id.* at 155:12-14; *see also id.* at 155:23-25; 156:25-157:2.) In other words, relying just on her "common sense" and with no methodology—and without knowing what the comparator rate of attempted or completed surgical self-treatment is among non-transgender adults—Dr. Li, as a statistician, concludes that 1 in 20 transgender adults attempting or succeeding in *cutting off their genitals* is "rare." (Doc 65-51, Li Rep. at 23; Li Dep. 157:3-6.)

CONCLUSION

Even accepting Dr. Li's evaluation of the evidence at face-value, it has no relevance to this case. She is not providing—nor is she qualified to provide—an

[7] Self-surgical treatment refers to auto-castration (removal of one's testicles) and/or auto-penectomy (removal of one's penis). (Doc. 62-2, Ettner Rep. ¶¶75-78.)

opinion on what level of evidence is needed to support the WPATH Standards of Care or treatment recommendations, on the efficacy or necessity of gender-affirming care, or on whether or not Defendants' refusal to provide Plaintiff gender-affirming surgery can be justified. The WPATH Standards of Care do not claim to rely on "high" quality evidence as defined by the GRADE system, nor do they need to: only a minority of recommendations in clinical practice guidelines rely on "high" quality evidence. (Doc. 68-2, Antommaria Rebuttal Rep. at 14-15.) That Dr. Li finds the evidence she evaluated to be "low" quality has no bearing on the fact that WPATH, the Endocrine Society, and all major U.S. medical associations all support gender-affirming surgery as an evidence-based treatment for gender dysphoria.

Furthermore, Dr. Li is not qualified to provide an opinion on what level of evidence is "reasonable" to support the assertions made by WPATH and Dr. Ettner, and she failed to utilize a reliable methodology in reaching her conclusions. Dr. Li's report and testimony accordingly should be excluded from consideration.

Respectfully submitted, this the 26th day of October, 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2023, I electronically filed the foregoing document using the ECF system which will send notification of such filing to all counsel of record.

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