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. JOSEPH V. PENN

INTRODUCTION AND BACKGROUND

In this case, Plaintiff seeks gender-affirming surgery that is medically necessary for the treatment of her gender dysphoria. She has sought this treatment from Defendants for years, and all providers with experience and expertise who have evaluated her agree that, for Plaintiff, gender-affirming surgery is medically necessary. Despite their inexperience and lack of expertise, Defendants continue to deny Plaintiff that surgery.

In an effort to support their refusal to provide the surgery Plaintiff needs, Defendants proffer the report of Dr. Joseph V. Penn. Dr. Penn is the Director of Mental Health Services for Texas's correctional health care system, in which he has never evaluated or referred a single patient for gender-affirming surgery. (Ex. 1, Penn

Dep. 68:22-74:9.) In Dr. Penn's view, Defendants' decision to "not approve the requested vulvoplasty as a treatment for gender dysphoria was a reasonable and appropriate decision." (Doc. 65-13, Penn Rep. at 29.) He asserts this for two principal reasons: first, because "there was no clinical indication that the surgery was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain;" and second, because "there is a lack of high-quality scientific research indicated the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria." (*Id.* at 35.)

Under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), Dr. Penn does not qualify as an expert to render these opinions. Dr. Penn has very limited training and experience regarding gender dysphoria and virtually no training or experience regarding the evaluation of patients seeking gender-affirming surgery. He does not claim to have published any relevant literature, offered any relevant prior expert testimony, or clinically evaluated patients with gender dysphoria for gender-affirming surgery. Further, as explained below, Dr. Penn's own testimony regarding what qualifies an individual to render an opinion on the medical necessity of gender-affirming surgery would disqualify Dr. Penn himself. Dr. Penn similarly testified to his own lack of qualification to opine on the validity of scientific studies on gender dysphoria, and his opinions on that topic therefore also must be excluded.

Moreover, Dr. Penn's methods for reaching his opinions are unreliable because they rest on a grossly deficient literature review that fails to acknowledge the broad

medical consensus that, for some individuals with gender dysphoria, gender-affirming surgery is critically necessary care. Even Defendants concede this point. (*See, e.g.,* Doc. 64 at 16-17.) Dr. Penn appears to dismiss much of the relevant literature because it does not account for incarcerated patients. He suggests that an incarcerated patient's medical needs are different than a non-incarcerated patient with the same condition. As a matter of medical practice, Fourth Circuit precedent, and common sense, that view is simply false.

Additionally, Dr. Penn never explains *why* Plaintiff's current course of treatment is adequate. Nor does he explain why the opinions of Dr. Figler, Dr. Caraccio, and MSW Dula—who personally evaluated Plaintiff and recommended gender-affirming surgery—are incorrect. Because his opinion lacks an identifiable scientific basis and otherwise contradicts what is generally accepted within the relevant scientific community, Dr. Penn's opinion is unreliable.

Finally, Dr. Penn's opinions in support of the Department's EMTO Policy, and in opposition to Dr. Ettner's articulation of medical necessity, must both be excluded as irrelevant, as they utterly fail to "help[] the trier of fact to understand the evidence or to determine a fact in issue." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021).

For these reasons, the Court should exclude Dr. Penn's purported expert opinions from consideration.

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 ensure that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Sardis,*10 F.4th at 281. (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. Penn is not qualified to opine on the efficacy or medical necessity of gender affirming surgery because he lacks the requisite training, experience, and specialized knowledge.

Dr. Penn offers testimony regarding "whether there were any clinical indications that [gender-affirming] surgery was necessary" for Plaintiff "to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain," and ultimately concludes that there was not. (Doc. 65-13, Penn Rep. at 28, 32.) Dr. Penn further opines that "there is a lack of high-quality scientific and medical literature indicating the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria." *Id.* at 33. However, because Dr. Penn has no experience or training in evaluating patients for gender-affirming surgery, and because he concedes that he lacks the expertise necessary to evaluate the quality of research regarding the surgery's efficacy, he is not qualified to render these opinions. Accordingly, this Court should exclude them.

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.* (quotation omitted). "'[G]eneral knowledge,' skill, experience, training, or education is insufficient to qualify an expert, and an expert qualified in one field may be unqualified to testify in others." *Kadel*, 620 F. Supp. 3d at 360

(quoting *Cooper v. Laboratory Corp. of America Holdings, Inc.*, 150 F.3d 376, 380-81 (4th Cir. 1998)).

In *Cooper*, for example, "a general knowledge of chemistry" and experience with breath alcohol testing did not qualify a witness to opine on the "particular scientific field" of urine alcohol testing. *Id.* at 380. Similarly, in *Smith v. Wyeth-Ayerst Laby's Co.*, this Court considered the qualifications of physicians who testified on the relationship between appetite suppressants and primary pulmonary hypertension. 278 F. Supp. 2d 684, 697 (W.D.N.C. 2003). Most of the physicians were unqualified because, though they were "surely experts in their specialty areas," they "lack[ed] the specialized knowledge or experience" with the specific drugs at issue. *Id.* at 698.

Kadel is especially instructive as it concerned a challenge to a state ban on gender-affirming care. One witness was an experienced plastic surgeon and was "thus qualified to opine on the risks associated with surgery used to treat gender dysphoria" and other issues related specifically to surgery. 620 F. Supp. 3d at 368. But he was *not* qualified to opine on diagnosing gender dysphoria, "non-surgical treatments," or "the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria." *Id.* at 369. Similarly, an endocrinologist was qualified to opine on hormone therapy, but not "the risks associated with surgery or the standard of care used by surgeons for obtaining informed consent for surgery." *Id.* at 365.

Here, Dr. Penn states that he is "a correctional and forensic psychiatrist," "a licensed physician triple-board certified in forensic psychiatry, general psychiatry,

and child and adolescent psychiatry, and a Clinical Professor in the Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch (UTMB), Galveston, Texas." (Doc. 65-13, Penn Rep. at 1.) He has focused his work "within correctional settings" since 1999 and is currently the Director of Mental Health Services within UTMB Correctional Managed Care ("CMC"), the health system that provides care to state prisoners in the Texas Department of Criminal Justice ("TDCJ"). (*Id*. at 2.)

Most relevant to this case, Dr. Penn states:

> As a practicing correctional psychiatric physician, I evaluate, diagnose, treat, and oversee the provision of mental health services for incarcerated individuals with mental disorders and behavioral issues. Similarly, I evaluate, diagnose, and treat patients with gender dysphoria evaluation, and supervise other clinicians that do the same. Additionally, I directly oversee the statewide clinical evaluation and treatment program for TDCJ patients who seek treatment for gender dysphoria. I also provide consultation on particularly complicated patients.

(*Id*.) Dr. Penn boasts that he has "treated more than 1,500 incarcerated transgender patients with or without gender dysphoria" within a gender dysphoria clinic in his time at UTMB CMC. (*Id*. at 4.) He further notes that he has "served as a consultant to several state prison systems . . . regarding gender dysphoria diagnoses, evaluation and treatment programs, policies, and practices, and medical and surgical interventions for various state inmates." (*Id*. at 5.) Dr. Penn asserts that he is "familiar with" the WPATH SOC, and "generally familiar with other scientific and peer-reviewed literature relevant to the provision of health care to this patient population both in community and in correctional settings."(*Id*. at 3.)

Dr. Penn's report claims that his expertise is in "the provision of psychiatric, mental health, and certain other medical and health care services across correctional settings," (*Id.* at 1), but not in gender dysphoria or gender-affirming surgery (although, when asked at deposition if he considered himself an expert in gender dysphoria, Dr. Penn said he did. (Ex. 1, Penn Dep. 114:15-114:25).)

Additionally, although Dr. Penn concedes he does not "have specific knowledge with regard to the exact surgical procedures," he claims expertise in the evaluation of gender-affirming surgery" based on his "background and training . . . direct work in correctional settings and in forensic capacities since 1999," and his "continuing education, attending conferences, discussion with other colleagues and review of the literature." (*Id.* 115:1-24.)

Dr. Penn also notes that he has "completed a specialized clinical training program regarding the evaluation and treatment of this patient population" with Dr. Walter Meyer, a former UTMB faculty psychiatrist and endocrinologist, and former WPATH member. (Doc. 65-13 at 4-5; Ex. 1, Penn Dep. 76:20-79:8) However, his "training" was informal, lacked benchmarks, and consisted predominantly of shadowing, consultation and collaboration on hormone therapy only—never surgery. (Ex. 1, Penn Dep. 79:14-81:10, 84:5-85:14.)

The only other training that Dr. Penn could point to regarding the treatment of gender dysphoria fails to confer expertise in the treatment at issue. The full extent of Dr. Penn's additional training amounts to one eight-hour training on the treatment of gender dysphoria, during which he does not recall whether gender affirming

surgery was discussed, as well as a one-to-two hour Continuing Medical Education panel where the criteria for evaluation for and treatment with gender-affirming surgery were discussed. (*Id*. 89:2-91:2.)

Dr. Penn's testimony on his clinical experience also betrays a lack of relevant qualifications. While he claims to have treated roughly 1,500 transgender patients with or without gender dysphoria, this number includes "anyone that [he] had any handprint or footprint involvement with," and thus reflected individuals for whom Dr. Penn had only ordered medication or cosigned a note and had never met. (*Id*. 70:25-73:23). Dr. Penn clarified that he has had some face-to-face interaction with about 450 patients with gender dysphoria. (*Id.*) And throughout his career, Dr. Penn admitted that he has *never* evaluated or referred a patient for gender-affirming surgery. (*Id.* 74:2-74:9.) Dr. Penn testified that "to date surgery is not part of the gender dysphoria clinic program." (*Id.* 68:22-70:3.)

In fact, when asked why the gender dysphoria clinic has never considered a request for gender-affirming surgery as treatment for gender dysphoria, Dr. Penn disavowed his own qualifications to render an opinion regarding gender-affirming surgery. (*Id.* 68:22-69:10 ("And so the gender dysphoria clinic, they're not surgeons so they wouldn't be involved in that."); 74:10-24 ("in the clinic we're not surgeons so we don't have like a urologist or an ob-gyn as part of the clinic. So we strictly focus on making the diagnosis, looking at other comorbid diagnoses or conditions and then looking at the eligibility or contraindications to hormonal treatment"); 75:1-8 ("we don't have that skill set, if you will.").)

Dr. Penn states that he has offered one second-opinion evaluation where he ultimately concluded in favor of providing gender-affirming surgery to a transgender prisoner suffering from gender dysphoria in another prison system. (*Id.* 91:13-94:13.) When asked why he rendered such an opinion despite his statements regarding his inability to do so competently within his own prison system, Dr. Penn responded that he did so because he was hired to:

> Q. You testified previously that one of the reasons that the gender dysphoria clinic does not provide recommendations for gender-affirming surgery for the treatment of gender dysphoria is because the gender dysphoria clinic does not employ any surgeons, correct?
>
> A. That's correct.
>
> Q. Why then did you provide a recommendation in your consultation capacity regarding whether or not an individual was a candidate for gender-affirming surgery in the treatment of gender dysphoria?
>
> A. Because I was answering the question that was posed to me by the correctional health care entity that retained me to do this consultation.

(*Id.* 94:1-94:13.) Being willing to offer an opinion one admits he is not qualified to provide is hardly a demonstration of expertise.

As for research, Dr. Penn testified that, to date, he has never published any—peer-reviewed or otherwise—on the treatment of gender dysphoria, the provision of gender-affirming surgery specifically, or the provision of gender-affirming care generally. (*Id.* 30:4-31:2.) Although Dr. Penn claims he was recently invited to write a journal article regarding gender dysphoria in correctional settings with two other co-authors, that article is still in draft form with no anticipated publication date, and he could not testify to any conclusions that article would make. (*Id.* 27:17-29:4.)

Similarly, Dr. Penn testified that he has never given expert testimony or been qualified by a court as an expert in litigation involving the treatment of gender dysphoria or the provision of gender-affirming surgery. (*Id.* 106:11-106:22.) While he is currently retained in another case relating to gender dysphoria, he is not opining about the provision of gender-affirming surgery, and the court has not yet passed judgment on his credentials. (*Id.* 106:23-109:6.)[1]

Dr. Penn's own testimony further reveals that he is not qualified to render the opinions he has provided with respect to the quality of scientific and medical literature regarding the efficacy of gender-affirming surgery. Dr. Penn cites only to his general background and knowledge conducting research in other areas as informing his expertise. (*Id.* 213:5-11.) Dr. Penn has conceded that he is not an expert in the quality of scientific evidence, statistical methodology, study design, biostatistics, or bioethics. (*Id.* 211:21-212:7.) Because he admittedly lacks expertise in these areas, and his background demonstrates his lack of experience in gender dysphoria, his opinion testimony on this topic is inadmissible. *See Kadel,* 620 F. Supp. 3d at 361 (noting general knowledge insufficient to qualify an expert and that "an expert qualified in one field may be unqualified to testify in others) (collecting cases);

[1] It is noteworthy that, in a case not relating to gender dysphoria, Dr. Penn's testimony has been rejected as unsupported and not credible. *See Jensen v. Shinn,* 609 F. Supp. 3d 789, 862-63 (D. Ariz. 2022) (referring to Dr. Penn's testimony as "flawed," "meaningless," "nonsensical," "absurd," "contradict[ory,]" and "unreliable and incredible"; adding that it "cannot withstand the slightest scrutiny"; and stating that "the Court cannot credit any of his opinions," which the court "rejected"). After denying that his expert testimony was ever rejected by that court, Dr. Penn ultimately reluctantly acknowledged that court's findings as to his credibility at his deposition. (Ex. 1, Penn Dep. 111:5-114:1.)

id. at 369 ("Just as an epidemiologist or statistician would not be qualified to perform surgery, a surgeon with little to no research experience is not qualified to opine on the veracity of statistical studies.") And once again, Dr. Penn's unqualified opinion is contradicted by his own practice: Dr. Penn notes that in the past, he has concluded that "high-quality evidence" was not necessary for him to feel comfortable giving medication to treat other conditions within the carceral setting. (Ex. 1, Penn Dep. 177:9-178:22.)

None of Dr. Penn's background shows the requisite "knowledge, skill, experience, training, or education" to be qualified to render an opinion on the provision of gender-affirming surgery or on the literature regarding its efficacy. *Kopf v. Skyrm*, 993 F.2d at 377. Such generalized statements of experience do not amount to expertise under Rule 702. For these reasons, the Court should exclude Dr. Penn's opinions.

II. Dr. Penn's methodology is unsound, and his testimony is unreliable.

Dr. Penn asserts that "the rigor of the medical and scientific literature is an integral component of a reasonable medical necessity formulation," and concludes that "there is a lack of high-quality research on the topic of the long-term efficacy of gender-affirming surgery in treating gender dysphoria." (Doc. 65-13, Penn Rep. at 34.) Even if Dr. Penn qualifies as an expert, this Court should nonetheless exclude his testimony as unreliable.

The Fourth Circuit considers the following *Daubert* factors pertaining to the reliability of evidence:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001). An opinion is unreliable if it lacks a basis in the relevant medical literature and contradicts what is generally accepted within the relevant scientific community. *See Kadel,* 620 F.Supp.3d at 366 (concluding that, where expert report lacked citations in support of his conclusion and expert could not testify competently to relevant literature, opinion was "not based on reliable science."); *id.* at 370 (rejecting testimony as unreliable where contradicted by "every major expert medical association" and not supported by any independent "data or methodology.") Having published on the topic at issue is "often a hallmark of expert witness reliability." *Young*, 916 F.3d at 380.

As noted above, Dr. Penn has not published on the issue of gender-affirming surgery for the treatment of gender dysphoria or his conclusions on the medical necessity and efficacy of gender-affirming surgery about which he opines. Rather, Dr. Penn's critiques of Dr. Ettner's formulation of medical necessity, the WPATH SOC, and the efficacy of gender-affirming surgery rest upon his grossly deficient literature review conducted in the early stages of this litigation, the similarly deficient literature review of Dr. Campbell, and the methodologically unsound and irrelevant expert report of Dr. Fan Li.

"Where proffered expert testimony is not based on independent research, but instead on such a literature review, the party proffering such testimony must come forward with other objective, verifiable evidence that the testimony is based on scientifically valid principles," which can be shown "by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication." *Doe v. Ortho–Clinical Diagnostics, Inc.,* 440 F. Supp. 2d 465, 470 (M.D.N.C.2006) (citation and quotation marks omitted). Dr. Penn's literature review and those upon which he relies cannot meet this degree of scrutiny, and Defendants offer no other evidence that Dr. Penn's conclusions are based on "scientifically valid principles." *Id.*

Dr. Penn gives considerable weight to the Expert Report of Dr. Fan Li. But for the reasons discussed in Plaintiff's contemporaneously filed motion to exclude Dr. Li's testimony, Dr. Li's report cannot provide a sound basis for Dr. Penn's opinions. And though he claims to have relied upon Dr. Campbell's literature review, Dr. Penn's deposition testimony undermines the reliability of that review. (Ex. 1, Penn Dep. 155:5-13 (noting deference to Dr. Li based on her Ph.D. in comparative effectiveness of studies and stating "no disrespect to Dr. Campbell, but I don't believe he has that"); 215:8-15 (stating Penn does not "really have an opinion" on "Dr. Campbell's qualifications to conduct research comprehensively in support of his conclusions" about Plaintiff).)

What's more, Dr. Penn testified that he has not actually read or made himself familiar with the sources cited by Dr. Li and Dr. Campbell. (*Id*. 226:20-227:22 (Penn

unable to testify as to how many full articles cited by Dr. Li he actually read and noting that he "pretty much" reviewed all of the abstracts); 153:10-155:13, 213:14-214:19) (Penn did not read any of the articles cited by Dr. Campbell related to detransition and that he did not recall the extent to which he went through other cited articles).)

Further, Dr. Penn's independent "literature review," which he conducted for his affidavit at the preliminary injunction stage of this case (*see* Doc. 18-8, Penn Aff.), does not present "other objective, verifiable evidence that [his] testimony is based on scientifically valid principles." *Doe*, 440 F. Supp. 2d at 470. In his search for literature regarding gender-affirming surgery in the correctional setting, Dr. Penn used an underinclusive list of exact-match search terms which were unlikely to yield comprehensive results. (Doc. 18-8, Penn. Aff. ¶53; Ex. 1, Penn Dep. 217:18-219:13.) As to literature on the effectiveness of surgery outside of prison, Dr. Penn acknowledged that he entirely failed to describe his methodology, and when asked to recount it, noted that he "believe[d]" he looked to WPATH as a starting point, but could not recall whether he utilized any search terms. (Doc. 18-8, Penn. Aff. ¶54; Ex. 1, Penn Dep. 219:14-220:11.) He cites only two sources[2] in his affidavit discussing the literature review "because those were the two studies that [he] found that met the criteria for the search engine that [he] utilized," and while he claims to have reviewed

[2] What's more, of the two articles he does cite, one is plagued by "questionable methodology," and the other, he mischaracterizes. (*See* Doc. 22-1, Second Ettner Decl. ¶¶37, 39.)

other studies to support his conclusions, he did not recall which, and did not generate a complete list of all sources reviewed or relied upon. (*Id.* 221:6-223:9.)

Dr. Penn further acknowledged that he spent somewhere between two-and-a-half and, at most, five-and-a-half hours in total on the literature review noted in his affidavit and relied upon in his report. (*Id.* 225:5-226:11.) Dr. Penn ultimately testified "probably I could do a better job with it. This is, again, not my area of expertise," in reference to his literature review. (*Id.* 222:6-223:9.) Such a cursory, highly selective literature review is inherently unreliable. *See Doe,* 440 F. Supp. 2d at 472; *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1255 (11th Cir. 2005) (district court should have excluded expert testimony because "the medical literature does not support such opinions" and doctor "has simply substituted his own *ipse dixit* for scientific proof").

Given the cursory nature of this literature review, it is no surprise that Dr. Penn's conclusion contradicts the vast literature on the topic, as well as the generally accepted conclusions of the scientific community. Dr. Ettner's report details the numerous studies concluding that gender-affirming surgery can alleviate a patient's gender dysphoria. (Doc. 62-2, Ettner Rep. ¶¶48-66) She further discusses how medical organizations and institutions in the United States and around the world agree with that conclusion, including the Federal Bureau of Prisons, numerous state prisons, and the NCCHC – an organization in which Dr. Penn boasts his involvement. (*Id.* ¶¶30, 63-65; Doc. 68-1, Ettner Reb. Rep. ¶¶19, 21; Doc. 65-13, Penn Rep. at 2.) Moreover, in both carceral and community settings, the Fourth Circuit has recognized

that the WPATH SOC "represent the consensus approach of the medical and mental health community . . . and have been recognized by various courts, including this one, as the authoritative standards of care." *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020) (quotation marks omitted) (citing *De'lonta v. Johnson*, 708 F.3d 520, 522–23 (4th Cir. 2013)), *cert. denied*, 141 S. Ct. 2878 (2021). The Fourth Circuit similarly recognizes that for individuals like Plaintiff, for whom serious symptoms of gender dysphoria persist, "surgery is not considered experimental or cosmetic; it is an *accepted, effective, medically indicated treatment*." *De'lonta,* 708 F.3d at 523 (emphasis added).

Dr. Penn's methodology regarding Plaintiff's "Risk-Benefit Analysis" is just as cursory as that for his literature review. (Doc. 65-13, Penn Rep. at 29-32.) Dr. Penn notes that his analysis is based on his review of Plaintiff's medical records, including her mental health visits, routine check-ups, sick calls, endocrinology appointments, and other medical records. (*Id.* at 30.) But Dr. Penn does not meaningfully engage with these records apart from his contention that Plaintiff was well-adjusted. Of note, despite his apparent belief that surgeons with expertise in gender-affirming surgery are most qualified to evaluate patients for the provision of that care, *see supra* p. 9, Dr. Penn makes no mention of the recommendation of Dr. Bradley Figler—urologist, surgeon and Director of UNC Transhealth—that Plaintiff should receive vulvoplasty for treatment of her gender dysphoria. (Doc. 62-17, Figler Decl. ¶¶10-12, & Ex. A thereto). Nor does he engage with the recommendations of Dr. Caraccio or MSW Dula, which reached the same medical necessity determinations. (Doc. 62-18, Caraccio Decl.

¶¶21-23; Doc. 62-19, ¶¶10-13.) His report also lacks any analysis regarding the actual risks of surgery for Plaintiff, or the risks that she would face without surgery—risks he acknowledged are real. (Ex. 1, Penn Dep. 210:8-17.)

Just like Defendants, then, Dr. Penn has no foundation to determine a patient's need for gender-affirming surgery. And like Defendants' documented decision, his report fails to explain why the opinions of actual experts with directly relevant experience are wrong.

This hollow endorsement of Defendants' course of action is not helpful to the trier of fact. Because Dr. Penn's methods are "wholly lacking in independent research," and there is no evidence that his opinion was "the product of reliable principles and methods, and [was] based upon sufficient facts or data," this Court should therefore exclude his purported expert testimony. *Berlyn, Inc. v. Gazette Newspapers, Inc.*, 214 F. Supp. 2d 530, 539-40 (D. Md. 2002).

III. Dr. Penn's Opinions Regarding the EMTO Policy and Dr. Ettner's Articulation of Medical Necessity Are Irrelevant.

Finally, the Court should exclude Dr. Penn's opinion regarding the adequacy of the department's EMTO Policy, (Doc. 65-13, Penn Rep. at 7-8, 10-18), as well as his opinion criticizing Dr. Ettner's formulation of medical necessity as "unworkable" "within correctional settings," (*id.* at 8, 20-28), as both opinions are wholly irrelevant to the inquiries at issue.

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).

Dr. Penn's opinion regarding the reasonableness of the EMTO Policy is irrelevant because Plaintiff has not asserted a challenge against or sought to enjoin the EMTO Policy in this litigation. (*See* Doc. 1 at 46.) Rather, she asserts that Defendants' refusal to provide *her* with the surgery violated her civil rights. Dr. Penn's opinions on the "quality and effectiveness" of Defendants' policy and process as written, (Doc. 65-13, Penn Rep. at 13), ultimately has no bearing on Defendants' actions toward her specifically.

Additionally, Dr. Penn's criticism that Dr. Ettner's articulation of medical necessity, which references the American Medical Association and WPATH, "cannot be appropriately or reasonably applied in a correctional system," (Doc. 65-13, Penn Rep. at 28) has no "connection to the pertinent inquiry." *Belville,* 919 F.3d at 232. Significantly, Dr. Penn is alone in his assertion that what constitutes medically necessary treatment changes somehow in correctional settings–Defendants have denied that any administrative or security concerns factor into their medical necessity determinations, and Dr. Penn's arguments are plainly contradicted by Defendants' own policies requiring community-consistent care. (Doc. 63 at 7-8, 30.) Moreover, as noted *supra* p. 17*,* Dr. Penn's assertions find no basis in the law. Further, Dr. Penn's opinion offers nothing to contradict the fact "that various organizations (e.g. WPATH, the AMA, and others) all support surgery in accordance

with the SOC as 'medically necessary' treatment," (Doc. 65-13, Penn Rep. at 23), because his contentions about "workability" in the corrections context, even if true, do not change the consensus of the broader medical community regarding gender-affirming surgery being medically necessary. *See e.g. See Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014 (W.D. Wis. 2019) (rejecting as irrelevant criticisms that had not impacted accepted standards of the larger medical community.). And as Plaintiff has repeatedly argued, she requires gender-affirming surgery under every definition or standard of medical necessity set forth in this litigation, including the WPATH SOC and Defendant Campbell's own articulation of medical necessity, (*see* Doc. 66 at 10-13), which Dr. Penn's report adopts and endorses. (Doc. 65-13, Penn Rep. at 19-20, 28.)

These opinions thus lend no help to the trier of fact in determining the questions at issue in this case, and as such, *Daubert* requires their exclusion. *Sardis*, 10 F.4th at 281.

CONCLUSION

For the foregoing reasons, the Court should exclude the expert report and testimony of Dr. Joseph V. Penn.

Respectfully submitted this the 26th day of October.

/s/ Jaclyn A. Maffetore
Jaclyn A. Maffetore
NC Bar No. 50849
Daniel K. Siegel
NC Bar No. 46397
Michele Delgado
NC Bar No. 50661
ACLU OF NORTH CAROLINA

LEGAL FOUNDATION
jmaffetore@acluofnc.org
dsiegel@acluofnc.org
mdelgado@acluofnc.org

Christopher A. Brook
NC Bar No. 33838
PATTERSON HARKAVY LLP
cbrook@pathlaw.com

Jon W. Davidson*
(admitted only in California)
L. Nowlin-Sohl*
(admitted only in Washington)
AMERICAN CIVIL LIBERTIES
UNION FOUNDATION
jondavidson@aclu.org
lnowlin-sohl@aclu.org

*admitted *pro hac vice*

Counsel for Plaintiff

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.

/s/ Jaclyn A. Maffetore
Jaclyn A. Maffetore
American Civil Liberties Union of North Carolina Legal Foundation
P.O. Box 28004
Raleigh, NC 27611
Tel: (919) 256-5891
Fax: (919) 869-2075
jmaffetore@acluofnc.org