THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs reply to Defendants' Response in Opposition to Motion for Preliminary Injunction ("Response"), and state as follows:

INTRODUCTION

Resorting to rhetoric comparing gender-affirming care to eugenics, Defendants ask this Court to ignore decades of medical and clinical research supporting the provision of gender-affirming care, along with the prevailing opinion of every major medical organization in the country.

Defendants do not dispute—they cannot—that (1) Plaintiffs are transgender people with gender dysphoria—a serious medical condition—and that (2) Florida Medicaid has covered the medical treatment for their gender dysphoria. Instead, Defendants ask the Court to disregard the prevailing medical opinion and their

previous longstanding practice of providing coverage so that the State can disrupt the status quo and upend access to medically necessary care for transgender Medicaid beneficiaries like Plaintiffs.

Doing so is a violation, *inter alia*, of the Fourteenth Amendment and Section 1557, and would cause irreparable harm to transgender Medicaid beneficiaries across Florida, including Plaintiffs, without offering any benefit to the public.

ARGUMENT

A. The Challenged Exclusion is not Based in Science.

The Challenged Exclusion prohibits coverage for "medical treatment that conforms with the recognized standard of care for ... gender dysphoria," even though such care is "supported by medical evidence that has been subject to rigorous study." *Brandt by & through Brandt v. Rutledge*, 47 F.4th 661, 670 (8th Cir. 2022) (cleaned up). Its purpose "is not to ban a treatment but to ban an outcome that the State deems undesirable." *Id.* (cleaned up).

To reach their desired conclusion, Defendants replaced scientifically supported and prevailing standards of care by cherry-picking five consultants, all of whom disagree with the generally accepted medical standards for treating gender dysphoria. *See, e.g.*, Schechter Supp. Dec. ¶4. Even the GAPMS Memo and Defendants' experts acknowledge that their views are outliers, far outside the medical mainstream. The GAPMS Memo concedes that 300 Florida health care

professionals with expertise in the treatment of gender dysphoria support use of the treatments. Def. App. 033. And the American Medical Association, American Psychiatric Association, Endocrine Society, and American Academy of Pediatrics, among others, uniformly support the use of these gender-affirming treatments. Courts have adopted the generally accepted views of these national medical organizations as well. *Kadel v. Folwell*, 2022 WL 3226731, at *32 (M.D.N.C. Aug. 10, 2022); *see also Eknes-Tucker v. Marshall*, 2022 WL 1521889, at *8 (M.D. Ala. May 13, 2022). But with the Challenged Exclusion, Defendants seek to simply push these standards aside.

B. Plaintiffs Remain Likely to Succeed on the Merits.

Defendants' Response avoids any meaningful confrontation with the reasoning of *Bostock v. Clayton Cnty., Georgia*, 140 S.Ct. 1731 (2020): "it is impossible to discriminate against a person for being … transgender without discriminating against that individual based on sex." *Id.* at 1741. While *Bostock* was decided under Title VII, it is beyond peradventure that sex discrimination is barred by the Fourteenth Amendment; Defendants cite nothing supporting the notion that transgender people are strangers to its protections.[1] Instead, Defendants rely on *Geduldig v. Aiello*, 417 U.S. 484 (1974), and *Dobbs v. Jackson Women's Health*

[1] Federal courts' analysis of disparate treatment sex discrimination claims under the Equal Protection Clause often mirrors the Title VII analysis. *See*, *e.g.*, *Naumovski v. Norris*, 934 F.3d 200, 212 (2d Cir. 2019).

Org., 142 S.Ct. 2228 (2022).[2] But neither support Defendants' conclusions. Plaintiffs already explained why *Geduldig* does not affect the requisite scrutiny here, and Defendants arguments do not respond in any meaningful way. (ECF 11, at 29 n.25.)

Defendants admit the Challenged Exclusion distinguishes based on a diagnosis of gender dysphoria (ECF 53, at 17), and "[d]iscrimination against individuals suffering from gender dysphoria is also discrimination based on sex and transgender status." *Kadel*, 2022 WL 3226731, at *20; *Brandt v. Rutledge*, 551 F.Supp.3d 882, 889 (E.D. Ark. 2021), *aff'd*, 47 F.4th 661.

The classification in *Geduldig* was not premised on a sex stereotype like the one presented here. *See Knussman v. Maryland*, 272 F.3d 625, 638 (4th Cir. 2001) (distinguishing *Geduldig*). Indeed, "[t]he very acts that define transgender people as transgender are those that contradict stereotypes of gender-appropriate appearance and behavior." *Glenn v. Brumby*, 663 F.3d 1312, 1317 (11th Cir. 2011); *see also Boyden v. Conlin*, 341 F.Supp.3d 979, 997 (W.D. Wis. 2018); (ECF 11, at 23).

Moreover, the plain language of *Geduldig* and *Dobbs* call for the application of heightened scrutiny and hold that rational basis scrutiny is inappropriate when the regulation is a mere pretext meant to effect invidious discrimination. *Dobbs*, 142 S.Ct. at 2245-46; *Geduldig*, 417 U.S. at 496 n.20.

[2] *Dobbs* merely repeats *Geduldig*'s holding. *Dobbs*, 142 S.Ct. at 2235.

The Challenged Exclusion is a pretext for discrimination, not borne out of concern for persons experiencing gender dysphoria. To determine whether treatment is experimental, Defendants' must undertake a balanced, scientific inquiry, seeking out reliable, unbiased evidence and opinions and then assigning proper weight to that information. Here, Defendants ignored that process and instead employed a sham rulemaking process, amplifying the voices of unqualified and unreliable purported "experts."[3] This occurred at the same time Florida's government sought to degrade the rights of transgender people on multiple fronts. (ECF 1, ¶126; ECF 11, at 14.) This context underscores the Challenged Exclusion's discriminatory pretext. Facts like these, that demonstrate discriminatory animus, were missing in *Geduldig* and *Dobbs*.[4]

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[3] Defendants' proposed experts are unqualified and unreliable. "Expertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1368 (11th Cir. 2014). And *none* of Defendants' experts have experience providing gender-affirming care or treating gender dysphoria. A court has given Dr. Cantor very little weight based on his lack of experience with gender-affirming care, *Eknes-Tucker*, 2022 WL 1521889, at *5, and his qualifications were recently challenged in another case. *See B.P.J. v. West Virginia State Bd. of Ed.*, 21-cv-00316, ECF 320 (S.D.W.V. May 12, 2022) (Altman Ex. M). Likewise, Dr. Lappert was disqualified from testifying in a case about virtually anything beyond surgical risks and having encountered "de-transitioning" persons. *Kadel*, 2022 WL 2106270, at *15; Altman Ex. N. And Dr. Laidlaw has no experience providing or studying gender-affirming care. *See infra*; Altman Ex. O. By selecting "experts" that do not possess the requisite knowledge, Defendants failed to comply with the necessary process to analyze the efficacy of the care they have irresponsibly banned.

[4] *Arlington Heights* does not help Defendants, as the Complaint and Motion are

At bottom, the authorities cited by Defendants do not change the fact that the Challenged Exclusion is subject to heightened scrutiny.

C. The Balance of the Equities Favors Plaintiffs.

Defendants do not dispute that transgender Medicaid beneficiaries like Plaintiffs will lose access to health care as result of the Challenged Exclusion and that such loss constitutes irreparable harm. (*See* ECF 11, at 32-34.) Rather, Defendants attempt to balance Plaintiffs' irreparable harm with perceived harms to the public. But Defendants do not address how the preliminary injunction will harm the public—as the standard requires. *See Scott v. Roberts*, 612 F.3d 1279, 1290 (11th Cir. 2010). Rather, they disingenuously argue, in contravention to the prevailing medical consensus of health care providers and major medical organizations, that the treatments themselves are potentially harmful.

1. An Injunction Would Not Harm the Public.

Defendants misquote Justice Roberts' opinion in *Maryland v. King*, 567 U.S. 1301 (2012), when they say, "the State is irreparably harmed 'when it cannot effectuate its laws.'" (ECF 53, at 26-27.) The decision says: "[A]ny time a State is enjoined by a court from effectuating *statutes enacted by representatives of its people*, it suffers a form of irreparable harm." *Maryland*, 567 U.S. at 1303 (emphasis added). The Challenged Exclusion is not a "statute enacted by representatives of the

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replete with facts regarding each factor of its test.

people" but rather an administrative rule adopted over objections from the public and a legion of health care professionals with actual expertise. (ECF 11, at 13-14); *see also Eknes-Tucker*, 2022 WL 1521889, at *6. The public had little, if any, say in it.[5]

Defendants summarily conclude the Challenged Exclusion "serves the public interest" without explaining why. (ECF 53, at 32.) Plaintiffs assume their reasoning is captured in the bullet points immediately above, which summarize their "expert" declarations. *See id.* at 30-32. However, none of those declarations—save one—talk about how the treatments will harm the public, much less how the preliminary injunction, which preserves the status quo and allows Medicaid beneficiaries to continue care Florida Medicaid previously covered, will harm the public.

Nor is the fact that medical treatments have risks and side effects a sufficient reason to *disrupt* already established care. *See Flack v. Wisconsin Dep't of Health Servs.*, 331 F.R.D. 361, 374 (W.D. Wis. 2019).[6] That rationale would eliminate virtually all medical care, as none are without risk.

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[5] The Challenged Exclusion was adopted in circumvention of the legislature after it refused to adopt similar bills. *See* HB 1365 (2021); SB 1864 (2020); HB 935 (2021).

[6] Defendants express concern that gender-affirming treatments will cause infertility. This showcases their lack of understanding. Puberty blockers do not cause infertility. (ECF 11-2, ¶101.) Hormones do not necessarily either. (*Id*. ¶107.) Indeed, one of defendants' witnesses, who was purportedly on testosterone for four years, is now expecting a child. Def. App. 913. Most surgeries (like top surgery) do not cause infertility either. (ECF 11-2, ¶45.)

The Florida Medicaid program has covered these treatments for years. (ECF 11, at 36.) Defendants do not argue otherwise. And, over the years, the research and clinical evidence in support of these treatments has only grown. Only in the past several months have Defendants changed their stance on gender-affirming treatments, not coincidentally, amidst a wave of other actions by Florida's government attacking the rights of transgender persons.

2. Defendants Do Not Rebut the Irreparable Harm Caused by the Challenged Exclusion.

a. *Treating physicians are not required to show irreparable harm*.

Defendants take issue with the lack of medical records and testimony from Plaintiffs' treating physicians. But they do not explain why that is relevant or dispositive. Plaintiffs aver as to the harms they will suffer, and this testimony is consistent with Plaintiffs' expert testimony. Moreover, it is well-established that, *as a matter of law*, the loss of coverage or access to care constitutes an irreparable harm. (ECF 11, at 32.) Several decisions—cited in Plaintiffs' Motion—found irreparable harm based on evidentiary records like this one. In *Brandt*, the district court relied on the plaintiffs' testimony and expert testimony to conclude that a ban on hormone treatments would cause "physical and psychological harms to the Patient Plaintiffs by terminating their access to necessary medical treatment." 551 F.Supp.3d at 892. Likewise, in *Eknes-Tucker*, the district court relied on witness and expert testimony to conclude that "without transitioning medications, Minor Plaintiffs will suffer

severe medical harm, including anxiety, depression, eating disorders, substance abuse, self-harm, and suicidality." 2022 WL 1521889, at *12. Moreover, putting the question of records aside, Defendants do not dispute, nor could they, that the gender-affirming care Plaintiffs received prior to Defendants' adoption of the Challenged Exclusion was determined medically necessary *by Defendants* under Florida's Medicaid program as well as by their treating physicians or they would not have received such care.

Defendants do not address these decisions, nor any other decision cited in the Motion where Plaintiffs established irreparable harm. *See* (ECF 11, at 33.) Instead, Defendants rely on a single case, *Doe v. Snyder*, 28 F.4th 103 (9th Cir. 2022), to imply that medical records and physician testimony are always necessary to establish irreparable harm. But *Doe*, an outlier decision, is easily distinguishable and does not establish a bright-line evidentiary standard for purposes of this injunction.

In *Doe*, the plaintiff requested a "mandatory injunction" that would have forced Arizona's Medicaid agency, which had excluded coverage of gender-affirming care for over 30 years, to "take an affirmative action" and go "well beyond the status quo." 28 F.4th at 108. The district court subjected that request to "heightened scrutiny" and would only grant it upon a showing of "extreme or very serious damage" to the plaintiff. *Id*. The district court ultimately found that this "heightened burden" was not met. *Id*. at 11; *see also Hennessy-Waller v. Snyder*, 529

F.Supp.3d 1031, 1045-46 (D. Az. 2021). The Ninth Circuit narrowly affirmed, finding that the district court's decision was not "illogical, implausible, or unsupported by the record," but faulted the district court for its failure to apply heightened scrutiny to Plaintiffs' Equal Protection claim and for its "erroneous" reading of *Bostock*. 28 F.4th at 113.

Here, by contrast, Plaintiffs seek a "prohibitory injunction," intended to preserve the status quo. Plaintiffs are not asking Defendants to take any affirmative action but instead to refrain from action until the court decides the merits. *See, e.g.*, *K.G. ex re. Garrido v. Dudek*, 839 F.Supp.2d 1254, 1260 (S.D. Fla. 2011). Their request is not subject to the heightened scrutiny applicable to mandatory injunctions like the one in *Doe*. And unlike in *Doe*, Defendants here have previously covered the gender-affirming care Plaintiffs seek. Having done so, they cannot now claim that Plaintiffs have not provided sufficient evidence that those services are necessary. *See Eknes-Tucker*, 2022 WL 1521889, at *12 ("The risk of suffering severe medical harm constitutes irreparable harm.")

b. The Court should disregard Dr. Laidlaw's opinions.

Defendants rely on Dr. Laidlaw's report to argue Plaintiffs will not suffer irreparable harm if the Motion is denied. But Dr. Laidlaw never reaches that conclusion; nor does he opine on the irreparable harms discussed in Plaintiffs' declarations. *See* (ECF 11, at 33-34.) Rather he speculates as to the "increased risks"

Plaintiffs could hypothetically face if their treatments continue based on his review of a partial set of medical records. He does not address the central issue: what harm will result if the treatments are *dis*continued. And he never opines on how to treat Plaintiffs' gender dysphoria.

Nor could he. Dr. Laidlaw has never treated any of the Plaintiffs, nor does he treat any transgender patients for gender dysphoria. *See* Altman Ex. O. His report is based on his general experience as an endocrinologist, his "evaluation" of a "detransition," and his review of an incomplete portion of the Plaintiffs' medical records. Def. App. 771. He simply does not—and cannot—opine on the harm Plaintiffs or any other transgender Medicaid recipient will face as a result treatment coverage loss. Olson-Kennedy Supp. Decl., ¶¶25-28; Karasic Supp. Decl., 23.

In any event, his opinions are outweighed by the collective decisions made by each Plaintiff's health care team. *See* (ECF 11, at 15-19); *see also Flack*, 331 F.R.D. at 374 ("While all medical treatment has risks, an individual patient and their doctor would seem substantially better able to weigh those risks than the state, much less this court, and so the risk of a negative outcome does not weigh in defendants' favor either.").

c. The declarations of out-of-state opponents to gender-affirming care are irrelevant.

Defendants submitted multiple declarations from lay persons, all of whom are

out-of-state opponents[7] of gender-affirming care who purportedly had individual experiences with gender-affirming care or are parents who do not support their adult children's transgender identification.[8] None of them are transgender Medicaid beneficiaries in Florida nor do they have any medical expertise relating to the issue at hand; none of them address the irreparable harms caused by the Challenged Exclusion; and none identify any public harm stemming from the preliminary injunction. Defendants offer no basis as to why these individuals have any bearing on the issues before the Court.

The fact that a particular treatment was ineffective for a single individual does not mean it is not medically necessary for others or experimental. *See Flack*, 331 F.R.D. at 374. Medical decisions are made on a case-by-case basis by those who are qualified to make those determination, not random lay persons with no direct or personal knowledge or physicians with no relevant expertise.

D. The Preliminary Injunction Should Apply Statewide.

There is no rule that a statewide preliminary injunction is improper absent class certification as alleged by Defendants. "Once invoked, the scope of a district court's equitable powers ... is broad, for breadth and flexibility are inherent in

[7] Some joined an *amicus* in *Brandt* supporting defendants. 47 F.4th at 661.

[8] The declarations are irrelevant and inadmissible under Federal Rules of Evidence 401 and 403, and to the extent they offer opinions, inadmissible under Rule 701.

equitable remedies." *Brown v. Plata*, 563 U.S. 493, 538 (2011) (cleaned up); *see also City of Chicago v. Barr*, 961 F.3d 882, 917 (7th Cir. 2020) ("[A] court that in its discretion determines that the equities of the case and the substance of the legal issues justifies an injunction, should not be limited to imposing that relief only as to those few persons who could obtain attorneys or present themselves in court. Nor is the presence of the vehicle of a class action a realistic alternative in such a case. The difficulties, expense and delay inherent in pursuing a class action would render it inadequate for the type of situation presented …."). Plaintiffs facially challenge a newly adopted rule of general applicability. The proper remedy is to enjoin the rule *facially* to preserve the status quo. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 64 (D.D.C. 2020) ("[U]nlawful agency regulations are ordinarily vacated universally, not simply enjoined in application solely to the individual plaintiffs.").

Defendants rely on a cherry-picked quote from a vacated decision from the Eleventh Circuit to suggest that a statewide injunction is inappropriate. (ECF 53, at 27.) Defendants fail to acknowledge that, "in the case of a constitutional violation, injunctive relief must be tailored to fit the nature and extent" of the violation. *Georgia Advoc. Off. v. Jackson*, 4 F.4th 1200, 1209 (11th Cir. 2021), *vacated on mootness grounds*, 33 F.4th 1325 (11th Cir. 2022). Indeed, the "scope of injunctive relief is dictated by the extent of the violation established." *Califano v. Yamasaki*,

442 U.S. 682, 702 (1979). A statewide injunction is appropriate here because the Challenged Exclusion violates the constitutional rights of transgender Medicaid beneficiaries statewide. *See Flack*, 331 F.R.D. at 374; *Planned Parenthood of Southwest and Central Florida v. Philip*, 194 F.Supp.3d 1213, 1224 (N.D. Fla. 2016) (enjoining Secretary of AHCA and others from enforcing certain statutes statewide).

"[B]ecause the burdens that would fall on the plaintiffs upon the Final Rule's implementation would also fall on those similarly situated, a [state]wide preliminary injunction of the Final Rule is justified." *D.C. v. U.S. Dep't of Agric.*, 444 F.Supp.3d 1, 51 (D.D.C. 2020).[9]

CONCLUSION

Plaintiffs respectfully request the Court preliminarily enjoin the Challenged Exclusion.

Respectfully submitted this 7th day of October 2022.

[9] Defendants suggest a preliminary injunction is inappropriate with a pending en banc decision in *Adams v. Sch. Bd. of St. Johns Cnty., Fla.*, 9 F.4th 1369, 1372 (11th Cir. 2021). But Defendants chose to alter the status quo notwithstanding the pending en banc review. They cannot now suggest the proper course is to wait. The Court should follow the court in *Eknes-Tucker* and preliminarily enjoin the Exclusion.

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CERTIFICATE OF WORD COUNT

According to Microsoft Word, the word-processing system used to prepare this Reply, there are 3191 words contained within the Reply.

/s/ Jennifer Altman
Jennifer Altman

CERTIFICATE OF SERVICE

I hereby certify that, on October 7, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Jennifer Altman
Jennifer Altman

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SECOND DECLARATION OF ATTORNEY JENNIFER ALTMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Jennifer Altman, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am over the age of eighteen and make this declaration from my own personal knowledge. If called as a witness, I could and would testify competently to the matters stated herein.

2. I am an attorney with Pillsbury Winthrop Shaw Pittman in Miami, Florida, and I have been retained by Plaintiffs as co-counsel in the above-captioned matter.

3. I make this Second Declaration in support of Plaintiffs' Motion for Preliminary Injunction.

4. Attached as **Exhibit M** is a true and correct copy of the plaintiff's

Memorandum of Law in Support of Motion to Exclude the Expert Testimony of James M. Cantor, in *B.P.J. v. West Virginia State Bd. of Ed.*, Case No. 21-cv-00316, ECF 320 (S.D.W.V. May 12, 2022).

5. Attached as **Exhibit N** is a true and correct copy of the plaintiffs' Memorandum of Law in Support of Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert, in *Kadel et al. v. Folwell et al.*, Case No. 19-cv-00272, ECF 209 (M.D.N.C. Feb. 2, 2022).

6. Attached as **Exhibit O** is a true and correct copy of a deposition transcript for Dr. Michael Laidlaw, in *C.P. et al. v. Blue Cross Blue Shield of Ill.*, Case No. 20-cv-06145 (W.D. Wash. Sept. 2, 2022).

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

Executed on October 7, 2022

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EXHIBIT M

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and mother, HEATHER JACKSON,

Plaintiff,

v.

WEST VIRGINIA STATE BOARD OF EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST VIRGINIA SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA,

Defendants,

and

LAINEY ARMISTEAD,

Defendant-Intervenor.

Civil Action No. 2:21-cv-00316

Hon. Joseph R. Goodwin

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE EXPERT TESTIMONY OF JAMES M. CANTOR

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STATEMENT OF THE CASE AND FACTUAL BACKGROUND

Plaintiff, a twelve-year-old girl who is transgender, challenges the legality of H.B. 3293, a law that categorically bars Plaintiff and any other female athletes who are transgender from participating on girls' and women's sports teams in West Virginia. B.P.J. contends that the law violates her rights under the Equal Protection Clause of the Fourteenth Amendment and discriminates against her based on sex in violation of Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681, et seq.

As part of their defense of H.B. 3293, Defendants identified and disclosed an expert report from Dr. James M. Cantor. Dr. Cantor disagrees with the views of the mainstream medical community and offers testimony that providing gender-affirming care to transgender youth, including permitting social transition for children and puberty-delaying medication and hormone therapy when indicated for adolescents, does not produce better mental health outcomes and is not the accepted standard of care. As discussed below, Dr. Cantor's testimony about the proper medical treatment for transgender youth is not relevant to the claims in this litigation, Dr. Cantor is an adult psychiatrist who is not qualified to present himself as an expert on transgender youth, and his speculative opinions have no grounding in reliable scientific principles and methods.

As the Fourth Circuit recognized in *Grimm*, the standards of care for treating gender dysphoria "[d]eveloped by the World Professional Association for Transgender Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) . . . represent the consensus approach of the medical and mental health community." *Grimm v. Gloucester Cnty. Sch. Bd*, 972 F.3d 586, 595–96 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (2021). "There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical

professional groups." *Id.*; *see also Edmo v. Corizon, Inc.*, 935 F.3d 757, 769 (9th Cir. 2019) (quoting *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Each of Dr. Cantor's proffered opinions is excludable for one or more of three reasons. First, Dr. Cantor's opinions are irrelevant because the opinions he offers about treatment for transgender youth fall outside the scope of the parties' dispute, which is simply whether a law can categorically bar transgender girls and women from girls' and women's sports teams in West Virginia. Second, Dr. Cantor is not qualified to offer opinions about the treatment of pre-pubertal transgender children or transgender adolescents as he does not work with and has not meaningfully studied this population. Third, Dr. Cantor's remaining opinions must be excluded because they are unreliable—they are not based on scientific methodology but rather untested hypotheses, pure speculation, and beliefs that lack any support besides Dr. Cantor's own *ipse dixit*. Because Dr. Cantor's opinions should be excluded pursuant to *Daubert* standards, and because any probative value offered by his testimony is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, and undue delay under Federal Rule of Evidence 403, this Court must exclude them. Dr. Cantor's testimony is not "relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). Dr. Cantor does not possess the "full range of experience and training" to provide expert testimony in this case. *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009)). And Dr. Cantor's testimony is not "the product of reliable principles and methods[.]" Fed. R. Evid. 702. Therefore, Dr. Cantor's proffered opinions do not qualify under Federal Rule of Evidence 702 as admissible expert testimony.

Plaintiff B.P.J. respectfully submits this memorandum of law in support of her motion to exclude the proffered expert testimony of James Cantor, Ph.D. from consideration at summary judgment or trial as inadmissible under Federal Rule of Evidence 702.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert*, 509 U.S. at 597; *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (quoting *Nease v. Ford Motor Co.,* 848 F.3d 219, 230 (4th Cir. 2017)); *see* Fed. R. Evid. 702 advisory committee note to 2000 amendments (amendment "affirms the trial court's role as gatekeeper," and that "all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful"). The party offering the expert carries the burden of establishing the admissibility of testimony by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

A trial court must also determine whether the proposed expert is qualified to render the proffered opinion. In doing so, a trial court considers an expert's professional qualifications and "full range of experience and training[.]" *Belk, Inc.*, 679 F.3d 162. If the purported expert lacks the knowledge, skill, experience, training, or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g., Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019), *aff'd*, 842 F. App'x 847 (4th Cir. 2021). Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis,* 10 F.4th at 282 (quoting *Daubert*, 509 U.S. at 592). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281 (quoting

Belville v. Ford Motor Co., 919 F.3d 224, 232 (4th Cir. 2019)) ("Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.").

If the opinions offered by the expert are deemed relevant and the expert is qualified to offer testimony, a trial court will inquire if the opinion is based on a reliable foundation, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Id.* at 281 (citations omitted). When evaluating whether an expert's methodology is reliable, a court considers, among other things:

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

Id.; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149–50 (1999); *Daubert*, 509 U.S. at 593–94. While trial courts have "broad latitude" to determine reliability, they must engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281 (quoting *Nease,* 848 F.3d at 229). When addressing an expert whose methodology is grounded in experience, courts use three factors: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015), *aff'd* 874 F.3d 370 (4th Cir. 2017); *see also Nat'l Ass'n for Rational Sexual Offense L. v. Stein*, No. 17 Civ. 53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021).

Finally, because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it[,]" "the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises *more* control over experts than over lay witnesses." *Daubert,* 509 U.S. at 595 (emphasis added) (quoting Weinstein, Rule 702 of the Federal Rules of Evidence Is

Sound; It Should Not Be Amended, 138 F.R.D. 631 (1991).) "As such, 'the importance of [the] gatekeeping function cannot be overstated.'" *Sardis*, 10 F.4th at 283 (quoting *United States v. Barton,* 909 F.3d 1323, 1331 (11th Cir. 2018)).

ARGUMENT

This is a discrimination case about the ability of girls and women who are transgender to participate on school-sponsored athletic teams. Although the fact that B.P.J. and many other girls and women who are transgender have had puberty-delaying medication or other endocrine care is relevant in responding to the State's argument that they have an athletic advantage rooted in physiology, Dr. Cantor does not purport to offer any testimony regarding these issues. And as this Court previously recognized in its decision issuing a preliminary injunction, "what is or should be the default treatment for transgender youth is not the question before the court." (Dkt. No. 67 (PI Op.) at 3 n.4.)

On their face, Dr. Cantor's opinions are irrelevant to the purported justifications of H.B. 3293. Dr. Cantor's opinion that providing gender-affirming care to transgender youth does not produce better mental health outcomes and is not the accepted standard of care is not relevant to this Court's consideration of whether West Virginia can categorically ban transgender girls and women from girls' and women's sports teams. In fact, even if the testimony about gender-affirming care provided to adolescents were relevant, Dr. Cantor offers irrelevant testimony about the treatment of prepubertal children and the treatment of adults. With respect to prepubertal children, Dr. Cantor's testimony and report focus on irrelevant debates about "desistance" and about the appropriateness of social transition for transgender youth. When discussing transgender adults, his testimony focuses on irrelevant and inaccurate theories about paraphilias and other causes of "transgenderism."

Dr. Cantor's testimony should thus be excluded.

A. Dr. Cantor's Primary Opinions Have No Relevance To This Case Because They Address Issues Beyond The Scope Of The Dispute.

The "court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is 'a precondition to admissibility.'" *Sardis*, 10 F.4th at 282 (quoting *Daubert*, 509 U.S. at 592). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id*. at 281 (quoting *Nease,* 848 F.3d at 232–33). "[I]t is axiomatic that 'expert testimony which does not relate to any issue in the case is not relevant [and] non-helpful.'" *Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 837, 846 (S.D.W. Va. 2018) (quoting *Edwards v. Ethicon, Inc.*, No. 12 Civ. 09972, 2014 WL 3361923 (S.D.W. Va. July 8, 2014)). In order to be relevant, an opinion needs to "fit" with the facts at issue. *Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004).

Dr. Cantor's opinions are simply not relevant to any purported justification Defendants have offered for H.B. 3293, which focus on athletic opportunities and notions of protecting women in sports. *See, e.g.*, W. Va. Code § 18-2-25d(a)(5) (2021) (offering sole justification of "promot[ing] equal athletic opportunities for the female sex"); (Dkt. No. 290 (Pl's Statement of Undisputed Facts ("SUF")) ¶ 48) (State's purported justifications are limited to "protect[ing]" women in sports and complying with Title IX). Indeed, Dr. Cantor disclaimed any intent to offer opinions about those issues. He is offering no opinion regarding the extent to which a person assigned male at birth purportedly has any athletic advantage, (Swaminathan Decl., Ex. B at 161:4-8); the extent to which transgender women or girls have any supposed athletic advantage, (*id*. at 223:3-10); or whether H.B. 3293 should apply to college athletics, (*id*. at 178:18-23.)

Instead, Dr. Cantor's opinions in this case focus on issues not relevant to this case: the standards of care for treatment of transgender youth. For example, Dr. Cantor proposes to offer the opinion that "[a]ffirmation of a transgender identity in minors who suffer from early-onset or adolescent-onset gender dysphoria is not an accepted 'standard of care.'" (Swaminathan Decl., Ex. A at 3 ¶ 8(e).) But this opinion is unrelated to any interest proffered by the State. (Pl's SUF ¶ 59.) And as this Court already has recognized, "what is or should be the default treatment for transgender youth is not the question before the court." (PI Op. at 3 n.4.) Accordingly, Dr. Cantor's disagreement with the established standard of care in this Circuit—untethered to any governmental interest proffered by Defendants—does not "fit" with the facts at issue and has no relevance here.[1]

B. Dr. Cantor Is Not Qualified To Offer Opinions About The Treatment Of Transgender Adolescents In This Case.

To render expert testimony, the witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *Wright v. United States*, 280 F. Supp. 2d 472, 478 (M.D.N.C. 2003) ("A witness may testify as to his specialized knowledge so long as he is qualified as an expert based on any combination of knowledge, skill, experience, training, or education."). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 13 Civ. 10-BO,

[1] Dr. Cantor's other opinions about adults are even farther afield. For example, Dr. Cantor opines on "adult-onset gender dysphoria" and mental health issues in transgender adults, which is completely irrelevant to the issue of whether a twelve-year-old transgender girl should be able to participate on the girls' cross-country team at her school. (Swaminathan Decl., Ex. A at 12–14); *see, e.g.*, *Edwards v. Ethicon, Inc.*, No. 12 Civ. 09972, 2014 WL 3361923, at *15 (S.D.W. Va. July 8, 2014) (excluding expert opinion about complications future patients might experience as irrelevant to the plaintiff's claims).

2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014); *see, e.g.*, *Mod. Auto. Network, LLC*, 416 F. Supp. 3d at 537 (affirming the district court's exclusion of an expert because they lacked experience relevant to the matters at issue); *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1369 (11th Cir. 2014) (holding expert witness was properly excluded who did not propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation).

Dr. Cantor is not qualified to offer his opinions regarding treatment protocols for transgender youth. "[A]n expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp., No. 04 C 1274*, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *see also Lebron*, 772 F.3d at 1369. "Generalized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362 at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has achieved certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F.Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994); *see also, e.g.*, *Hartke v. McKelway*, 526 F.Supp. 97, 100–101 (D.D.C. 1981), *aff'd*, 707 F.2d 1544 (D.C. Cir. 1983).

Dr. Cantor's primary area of expertise is the study of hypersexuality and paraphilias,[2] and nearly one hundred percent of his clinical practice focuses on adults. (Swaminathan Decl., Ex. B

[2] "The term 'paraphilia'…[m]ost broadly[] refers to the highly atypical sexual interest that dominate a person's life and interact with or prevent them from having an otherwise typical sexual life." (Swaminathan Decl., Ex. B at 139:20–25.)

at 140:5–141:24, 179:7-18.) He has publicly stated that his "primary research opportunities have involved studying sex offenders, mostly pedophiles and persons with other atypical sexualities whose behaviors led them into the legal system." (Swaminathan Decl., Ex. E; Swaminathan Decl., Ex. B at 140:5–141:24.)

At his deposition, Dr. Cantor admitted that he is not an endocrinologist, has not personally diagnosed any child or adolescent with gender dysphoria, has never personally treated any child or adolescent for gender dysphoria, and does not provide psychotherapy counseling to children or adolescents with gender dysphoria. (Swaminathan Decl., Ex. B at 179:1-14.) None of Dr. Cantor's professional roles have involved significant contact—or in many cases, any contact—with children or adolescents. During Dr. Cantor's fellowship at the Center for Addiction and Mental Health ("CAMH"), the average age of the patients he provided one-on-one therapy to was early 40s, the youngest being in their "late teens, early 20s." (*Id*. at 50:10-19.) Approximately 80 percent of the patients that Dr. Cantor saw at CAMH had been adjudicated as sex offenders. (*Id.* at 151:7-10.) When Dr. Cantor assumed his next professional role at Queen Elizabeth Hospital in Montreal, he did not provide psychotherapy to children or adolescents—he "predominantly worked with adults who came in with depression and anxiety disorders[.]" (*Id*. at 54:7-14.) Subsequently, while completing his post-doctoral studies within the law and mental health program, Dr. Cantor did not work with children and adolescents with gender dysphoria. (*Id*. at 61:4-8.) Dr. Cantor then became Senior Scientist at CAMH, where even while supervising the work of his interns, Dr. Cantor testified that he never worked directly with children or adolescents with gender dysphoria. (*Id*. at 68:22–69:2.) His supervision of the CAMH interns never involved research around puberty-delaying treatment prescribed to transgender adolescents nor hormone therapy prescribed to transgender adults. (*Id*. at 132:11-19.) In fact, in Dr. Cantor's current private practice, he has only

treated "about six to eight patents ages 16 to 18," and was unable to identify whether these patients were transgender or had gender dysphoria. (*Id*. at 179:15-18, 180:8-13.)

Dr. Cantor admitted at his deposition—as he must—that he has almost no experience researching and writing about or administering mental health treatment to transgender adolescents. Indeed, in the list of 64 articles he has authored or co-authored, only one even mentions transgender children ("The Recalled Childhood Gender Identity"), and Dr. Cantor was not a primary author of the article and did not himself carry out any portion of the study. (Swaminathan Decl., Ex. B at 102:8-14.)

In sum, Dr. Cantor is not recognized as an expert in providing treatment to transgender children or adolescents, does not have the requisite qualifications to provide treatment to transgender children or adolescents, has never treated nor delivered any psychiatric care to transgender children or adolescents in his day-to-day practice, has never written about or researched the provision of care to transgender children and adolescents, and has extremely limited experience working with children and adolescents in any capacity. (*Id*. at 179:4-14.) For all these reasons, Dr. Cantor is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children.

1. Dr. Cantor Admits That He Is Not Qualified To Offer Opinions On H.B. 3293 Or Transgender Athletes.

Astonishingly, Dr. Cantor admitted that he is not providing any testimony relating to the three purported governmental interests that the State of West Virginia ("State") asserts are advanced by H.B. 3293: 1) to protect women's sports; 2) to follow Title IX; and 3) to protect women's safety in female athletic sports. (Pl's SUF ¶ 59.) When asked whether he is "offering an expert opinion with respect to whether H.B. 3293 serves the interest of protecting women's

sports," Dr. Cantor responded he "[hadn't] been asked that, no." (Swaminathan Decl., Ex. B at 178:3-6.) When asked whether he is "offering an opinion with respect to whether H.B. 3293 serves the interest of following Title IX," Dr. Cantor responded that he "[hadn't] been asked that, no." (Swaminathan Decl., Ex. B at 178:7-10.) When asked whether he is "offering an opinion with respect to whether H.B. 3293 serves the interest of protecting women's safety in female athletic sports," Dr. Cantor again responded that he "[had not] been asked that, no." (Swaminathan Decl., Ex. B at 178:11-14.) When asked whether he has "any opinions on whether H.B. 3293 should apply to college athletes," Dr. Cantor responded that he has "no opinion in any direction." (Swaminathan Decl., Ex. B at 178:18-20.)

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The opinions expressed by Dr. Cantor are insufficiently tied to the facts of this case so that they will aid a factfinder in determining whether a categorical ban on transgender girls and women participating on girl's and women's sports team is lawful, and should therefore be excluded as irrelevant.

C. Dr. Cantor's Testimony Is Methodologically Unreliable And Unsupported By Science Or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Cantor's opinions fall far short of the reliability standard. Dr. Cantor's theory that "it remains entirely *plausible* that the psychotherapy [alone without] puberty blockers caused the improvements" in the mental health of transgender adolescents is pure speculation that has never been tested. (Swaminathan Decl., Ex. A at ¶ 54 (emphasis added).) But plausibility does not satisfy any standard for an expert opinion. Such speculative opinions should be excluded, especially given this Circuit's holding that "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *see also Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003) ("[S]peculation is unreliable evidence and is inadmissible").

Dr. Cantor asserts without any evidence whatsoever that his views are accepted and shared by the amorphous and unspecific "scientific community." (Swaminathan Decl., Ex. B at 210:2-25.) Dr. Cantor asserts that "several scores" of people, comprised of individuals he is "in regular contact with," agree with his opinions as to withholding social transition in prepubertal children with gender dysphoria. (*Id.*) He admitted that his communications with these individuals, primarily sex researchers and sex therapists (none of whom specialize in care of transgender patients), are his "primary source" of evidence for the assertion that "practitioners support withholding social transition in prepubertal patients with gender dysphoria." (*Id.* at 211:4-15, 211:17-22.) Dr. Cantor's opinions thus are not rooted in science—they are personal opinions he

has formed through communications with groups of individuals who he is in routine contact with, and who are not practitioners specializing in the treatment of children and adolescents with gender dysphoria.[3]

Furthermore, Dr. Cantor fails to address how his experience and communications with other "sexologists"—which he claims are sufficient foundation for his opinions—leads to the conclusions he draws in this case. *See*, *e.g.*, *Cooper,* 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); *SAS Inst.*, 125 F. Supp. 3d at 589; *see also Nat'l Ass'n. for Rational Sexual Offense L.*, 2021 WL 736375, at *3 (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

Another unreliable opinion presented by Dr. Cantor is that "the majority" of prepubertal children who experience gender dysphoria will cease to be transgender. (Swaminathan Decl., Ex. B at 191:11-24; 212:19-213:3 ("[R]esearch has unanimously shown that the majority of children with gender dysphoria desist – that is, cease to experience such dysphoria by or during puberty."). Dr. Cantor's only support for this concept is "11 studies listed on [his] blog." (Swaminathan Decl., Ex. B at 206:12–207:11.) Upon closer inspection, these sources are woefully inadequate to support his assertion. All of his sources suffer from the same malady: they purported to show desistance among children who were identified as having gender dysphoria under prior versions of the

[3] Even Defendants' other experts disagree with Dr. Cantor. Dr. Cantor opposes allowing transgender children to live in accordance with their gender identity, (Swaminathan Decl., Ex. B at 210:2-25), but Defendants' proposed expert, Dr. Stephen Levine, "cooperate[s] with" social transition and even has supported "people who already had social transition . . . in the face of their parents' objection." (Swaminathan Decl., Ex. H (Levine Dep.) at 141:7-11.)

American Psychiatric Association's Diagnostic and Statistical Manual ("DSM"). Those versions included a now-obsolete and overly broad diagnosis for "Gender Identity Disorder in Children," which differs in key ways from the current DSM-5 diagnostic criteria for "Gender Dysphoria in Children." As another expert in this matter explained, the older Gender Identity Disorder diagnosis did not require a finding that the child had a gender identity different from the sex assigned at birth. (Swaminathan Decl., Ex. D at 324:16–325:4.) As a result, those older studies tended to mischaracterize gender-nonconforming children as transgender. Such studies cannot be relied on to draw conclusions regarding "desistance" in prepubertal youth diagnosed with gender dysphoria.

Similarly, Dr. Cantor criticizes studies showing positive outcomes for transgender children who access puberty-delaying treatment as unreliable because there is "no method of separating how much of its result was due to psychotherapy versus due to medical intervention." (*Id*. at 252:6-10.) But this criticism is not meaningful: these studies nonetheless indicate that gender-affirming care leads to positive outcomes for transgender youth. (*See e.g.*, Swaminathan Decl., Ex. B at 233:1-10, 229:16-22.)

Chief among Dr. Cantor's many unreliable opinions is his assertion that wide disagreement exists about the appropriate treatment for gender dysphoria and that the SOC are not accepted by his amorphous and unspecified "scientific community." (Swaminathan Decl., Ex. A at ¶ 8(c).) Contrary to Dr. Cantor's personal feelings, which were formed as discussed above through communications with "several scores" of people who do not specialize in care of transgender patients, there ***is broad consensus*** about the appropriate treatment for gender dysphoria. All major medical associations endorse and follow the treatment protocols established by the WPATH in the SOC Version 7. (Swaminathan Decl., Ex. E ¶ 27.) This factual reality calls into serious question the reliability of this proffered opinion.

Additionally, Dr. Cantor's testimony directly contradicts the Fourth Circuit's recognition that "we now have modern accepted treatment protocols for gender dysphoria," which have been "[d]eveloped by the World Professional Association for Transgender Health (WPATH) . . . [and] represent the consensus approach of the medical and mental health community[.]" *Grimm,* 972 F.3d at 595. The Fourth Circuit recognizes these treatment protocols "as *the authoritative standards of care*," finding that "[t]here are no other competing, evidence-based standards . . . accepted by any nationally or internationally recognized medical professional groups." *Id.* at 595–96 (emphasis added) (quoting *Edmo*, 935 F.3d at 769).

1. Dr. Cantor's Assertions That Transgender Adolescents Are Receiving "Affirmation On Demand" And That Adolescents Transition Due To The "Unrealistic Expectation That Transition Will Help Them Fit In" Are Unsupported.

Dr. Cantor's most strikingly unreliable opinion is that "[b]ecause only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, 'transition-on-demand' . . . 'increases the probability of unnecessary transition and unnecessary medical risks.'" (Swaminathan Decl., Ex. B at 213:22–214:11.) Again, in making this broad and unfounded assertion, Dr. Cantor relies only on "those 11 studies" on his blog. (*Id*. at 215:17–217:19.) Dr. Cantor has no experience in his own practice with persistence or desistence in children with gender dysphoria, and he does not offer any support for this proposition from practitioners who actually treat gender dysphoria in children. (*Id.*)

When asked whether "any patient ever [came] to [him] asking for affirmation on demand," Dr. Cantor's response was "no." (*Id*. at 181:11-13.) When asked what his basis was for saying that providers are providing "affirmation on demand to children and adolescents with gender dysphoria," Dr. Cantor responded that his "only evidence" is from the following sources:

> "Through several venues. I get that information from parents, from people, you know, in society who e-mail me asking for help. There's a large number of media reports of it happening through the world, U.S., Canada and Europe. And there's now been – there are now several governmental entities, mostly in Europe, are now beginning more formal . . . investigations of it." (*Id*. at 181:14-25; 184:5-10.)

When asked whether he had ever spoken to providers who claim to provide affirmation on demand to children and adolescents with gender dysphoria, his response was "no." (*Id.* at 182:17-21.) When asked whether any provider at CAMH (his former employer) provides affirmation on demand, his response was again "no." *Id*. at 183:16-24. In other words, Dr. Cantor was unable to identify a single instance of a provider providing affirmation on demand, and his "evidence" is woefully inadequate to support any conclusion that such practice is occurring. Similarly, Dr. Cantor was unable to identify any scientific literature that demonstrates that providers are providing affirmation on demand to children and adolescents with gender dysphoria. (*Id*. at 184:11-14.)

Another stark example of Dr. Cantor's opinions failing to meet methodological reliability is his assertion that "a child experiencing depression from social isolation might develop hope – and the unrealistic expectation – that transition will help them fit in, this time as and with the other sex." (Swaminathan Decl., Ex. A at ¶ 69; Ex. B at 218:18–219:20.) Dr. Cantor himself admitted at his deposition that this "hypothesis hasn't been . . . tested," and therefore has no probative value. (Swaminathan Decl., Ex B at 219:15-20.)

None of Dr. Cantor's unsubstantiated hypotheses justify denying treatment to transgender adolescents, which is not at issue in this case regardless.

2. Dr. Cantor Testified That Transgender People Are One Of Three Things: Autogynephilic, Homosexual, Or Mistaken.

The Fourth Circuit has held conclusively that "just like being cisgender, being transgender is natural and is not a choice." *Grimm*, 972 F.3d at 594. The Fourth Circuit also acknowledges that "[b]eing transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Id.* (quotation marks omitted). By contrast, Dr. Cantor egregiously espouses that only three factors can "motivate a person to want to live as the other sex." (Swaminathan Decl., Ex. B at 143:8-10.) At his deposition, Dr. Cantor testified that "anyone who is transgender is transgender either due to autogynephilia,[4] homosexuality, or a mistake they've made as a . . . younger individual." (*Id*. at 145:7-15 ("[T]hat's the best summary we have of the – of the existing research").) Dr. Cantor asserted that homosexuality "can motivate a person to feel gender dysphoric" and "be the source of the desire to change." (*Id*. at 143:20-144:1.) In justifying his third theory, Dr. Cantor stated that young individuals "mistake the emotions that they're having to be gender dysphoria when they're actually motivated by something else, for example, a desire to not be associated with the sex that they would be biologically associated with." (*Id*. at 144:9-15.) Dr. Cantor's testimony is not only in direct conflict with Fourth Circuit precedent, but is a harmful, outlier opinion in the scientific community. Dr. Cantor does not believe that individuals can be transgender unless they fall into one of his three purported pathways. His views, which pathologize transgender people in stark contradiction to the Fourth Circuit's recognition that being transgender is a normal variation in human development, are irrelevant, harmful, and unfit for use by the Court.

[4] Autogynephilia refers to an extreme outlier hypothesis that transgender people become transgender out of a sense of sexual arousal. (*Id.* at 142:3-8.)

3. Dr. Cantor's Opinion That No Professional Organization Has Articulated A Meritorious Position Calling Into Question The Basis For The Act Directly Contradicts The Fourth Circuit's Holding In *Grimm*.

Dr. Cantor spends a great deal of time in his report critiquing the statements of preeminent medical and behavioral health organizations that recognize the standard of care for treating gender dysphoria. (Swaminathan Decl., Ex. A at ¶¶ 107–39.) Dr. Cantor's critiques, however, are misleading, misconstrue the current standards of care, and flout Circuit law. As just one example, Dr. Cantor quotes selectively from the Endocrine Society's clinical guidelines to misleadingly suggest that the guidelines recommend "address[ing] mental health issues *before* embarking on transition," and that they do "not endorse any affirmation-only approach." (Swaminathan Decl., Ex. A at ¶ 119–20 (emphasis added).) But this is incorrect. In fact, the guidelines affirmatively *recommend* that adolescents with gender dysphoria receive medical treatment and endorse "gender-affirming" care throughout. (*See, e.g.*, Swaminathan Decl., Ex. F at 3871 §§ 2.1-2.5 (recommending treatment with puberty-delaying medication and hormones).)

Dr. Cantor is additionally unqualified to opine on these professional organizations as he lacks any involvement with them. He testified that he is not a member of WPATH, has never advised the WPATH in any capacity, has never been involved in developing the SOC, and could not recall the most recent version of the SOC. (Swaminathan Decl., Ex. B at 203:1–204:24.) Similarly, Dr. Cantor is not a member of the Endocrine Society, was not involved in the development of the Endocrine Society guidelines in 2009 or in 2017, is not aware of the scientific literature conducted by the Endocrine Society in developing the guidelines, and does not hold himself out as an expert in how the guidelines were developed. (*Id.* at 201:8–202:19.)

Dr. Cantor's attack on these professional organizations also defies this Circuit's recognition that they constitute the "*leading* medical, public health, and mental health organizations" regarding treatment for transgender adolescents. *Grimm*, 972 F.3d at 594 n.1 (emphasis added). *Grimm* relied heavily on the amici curiae brief submitted by many of the same organizations to explain the treatment protocols for transgender adolescents, citing these organizations as "our foremost medical, mental health, and public health organizations." *Id.* at 612; *see also id.* at 594–613 (citing the amici curiae brief nine times).

4. Dr. Cantor Has Offered Harmful Opinions Related To Transgender People And Has Been Removed From Respectable Scientific Societies For Posting Disrespectful Material.

Dr. Cantor is unfit to provide testimony in this case given his history of promulgating disturbing and offensive content about transgender people.[5] In Dr. Cantor's blogpost, Sexology Today, for example, Dr. Cantor suggests that transgender people are "atypical," and writes that "only very few trans kids still want to transition by the time they are adults. Instead, they generally turn out to be ***regular*** gay or lesbian folks." (Swaminathan Decl. Ex. G; Ex. B at 187:17–188:9 (testifying that "non-regular gay or lesbian folks" are people "with a paraphilia or with a fetish that makes the determination of their sexual orientation a bit moot"); Ex. B at 188:15–189:1 (testifying that "if a child's gender dysphoria were to persist and they continued to want to transition by the time they are adults," that would be "atypical") (emphasis added).)

[5] Dr. Cantor was a member of the Society for the Scientific Study of Sexuality, a group dedicated to "forward[ing] and promot[ing] the conduct and dissemination of sex research," for twenty-seven years. (Swaminathan Decl., Ex. A. at 96; Ex. B at 284:19-22; 287:11-13.) After his twenty-seven-year membership, Dr. Cantor was suspended and removed from the society's online forum after its Board determined that Dr. Cantor had violated one of its guidelines by posting "disrespectful" content relating to transgender people. (Swaminathan Decl., Ex. B. at 288:10-13 ("[T]hey told me what I said they deemed to be disrespectful"); 288:16-18 ("Q . . . [D]id what you say deal with issues relating to transgender people or gender dysphoric people? A. Yes."))

D. Dr. Cantor's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Cantor offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and other experiences—issues unrelated to whether transgender girls and women should be allowed to participate on girls' and women's sports teams in West Virginia. Accordingly, Dr. Cantor's testimony fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiff respectfully request that this Court grant the instant motion and exclude all of Dr. Cantor's purported expert testimony because it is not admissible under *Daubert* and the Federal Rules of Evidence.

Dated: May 12, 2022

Respectfully submitted,
/s/ *Loree Stark*

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and mother, HEATHER JACKSON, *Plaintiff*, v. WEST VIRGINIA STATE BOARD OF EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST VIRGINIA SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA, *Defendants*, and LAINEY ARMISTEAD, *Defendant-Intervenor*.	Civil Action No. 2:21-cv-00316 Hon. Joseph R. Goodwin

CERTIFICATE OF SERVICE

I, Loree Stark, do hereby certify that on this 12th day of May, 2022, I electronically filed a true and exact copy of ***Plaintiff's Memorandum of Law in Support of Motion to Exclude the Expert Testimony of James M. Cantor*** with the Clerk of Court and all parties using the CM/ECF System.

/s/ Loree Stark
Loree Stark
West Virginia Bar No. 12936

EXHIBIT N

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

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

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PATRICK W. LAPPERT

TABLE OF CONTENTS

Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Patrick W. Lappert.

INTRODUCTION[1]

Dr. Lappert holds himself out as being board-certified in both plastic surgery and general surgery. He is neither: his certification in plastic surgery lapsed in 2018, and he has not been board-certified in surgery since ***2002***. Moreover, in his entire career, Dr. Lappert has never performed a single surgical procedure to treat gender dysphoria—which is not surprising, since he considers those procedures to be "intentional mutilation" and "child abuse." Dr. Lappert has no reliable basis to opine about gender-affirming surgery, and his purported expert opinions about those procedures should be excluded.

And Dr. Lappert's opinions outside of surgery are even more ripe for exclusion. Straying far afield from his surgical experience, Dr. Lappert gives a smorgasbord of opinions that he is not qualified to provide, and for which he has no basis. For example, he criticizes how organizations like the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have developed guidelines for diagnosis and treatment of gender dysphoria, despite admitting that he does not know the first thing about how those guidelines were created. He speculates about whether puberty-blocking treatment is appropriate for adolescents, even though he is not an endocrinologist and he admits "that's not [his] area of expertise." He criticizes the process by which patients are

[1] Unless otherwise noted, all emphasis is added, and all citations, alterations, and ellipsis are omitted. Exhibits referenced herein are attached to the concurrently-filed Declaration of Dmitriy Tishyevich.

diagnosed with gender dysphoria, despite admitting that he has "very limited psychiatric / psychological knowledge," is not "a licensed mental healthcare provider of any kind," and is not qualified to make this diagnosis himself. And he also offers rank speculation about patients with gender dysphoria who "detransition" or experience "regret," even though he concedes he has no reliable data to quantify these phenomena. These and other of Dr. Lappert's many non-surgery opinions are both unreliable and irrelevant, and they should all be excluded accordingly.

Dr. Lappert's deposition also made clear that he is certainly not a dispassionate expert who will offer neutral "specialized knowledge" to "help the trier of fact to understand the evidence," as Rule 702 contemplates. Far from it. In addition to calling gender-affirming surgery "intentional mutilation," Dr. Lappert says that parents who talk to their children about gender identity issues are "sexualizing them" and "grooming" them for abuse. He accuses doctors who provide gender-affirming treatment of being part of a "Transgender Treatment Industry" cabal—a term that he concedes is certainly not "commonly used" in his professional field, and is instead "idiosyncratic" to his report. He has given inflammatory presentations on gender-affirming surgery, opining that performing these surgeries is a "moral violation" for physicians and that "changing a person's sex is a lie." He tours the country, urging state legislatures to outlaw gender-affirming treatment for minors. And he also thinks that states should "criminally prosecute doctors" that provide this critically-needed treatment—even though ***every*** reputable

medical organization in the country, including his own professional society, has said that such treatment is medically necessary and appropriate.

Even if Dr. Lappert's opinions were reliable under Rule 702 (and they are not), and even if they had any minimal probative value (and they do not), that value would be far outweighed by unfair prejudice and confusion of the issues under Rule 403. For these reasons, and as explained below, all of Dr. Lappert's opinions should be excluded.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on the trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). As the Fourth Circuit recently reaffirmed, "the importance of the gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283.

"The proponent of the testimony must establish its admissibility by a preponderance of proof." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019). The first step is to determine if the expert is qualified to give the proffered opinion, which requires examining the expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012). If the expert is not qualified, the testimony should be excluded. *See SMD Software, Inc. v. EMove, Inc.*, 945 F. Supp. 2d 628, 639 (E.D.N.C. 2013).

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

The opinion must also be based on a reliable foundation, with the inquiry focusing on the expert's "principles and methodology" to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* at 281-82. In evaluating reliability, courts consider, among other things, whether: (1) the theory "can be and has been tested"; (2) has been "subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "whether the technique is generally accepted in the scientific community." *Id.* at 281.

When an expert relies upon experience and training rather than a specific methodology, the application of the *Daubert* factors is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). In those cases, courts consider: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015).

Finally, the Fourth Circuit has cautioned that although the trial court has "broad latitude" to determine reliability, it must still engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-

examination is not a substitute for the court's gatekeeping role. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017).

ARGUMENT

I. Dr. Lappert Is Not Qualified to Offer Any of His Purported Opinions.

An expert witness must have "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "[Q]ualifications alone do not suffice," however. *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *Patel ex rel. Patel v. Menard, Inc.*, 2011 WL 4738339, at *1 (S.D. Ind. Oct. 6, 2011). Even "a supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant." *Clark*, 192 F.3d at 759 n.5.

Moreover, "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014).

Importantly, this qualification inquiry is subject-specific, because "[g]eneralized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362, at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has achieved

certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994). Dr. Lappert fails these requirements, for reasons below.

A. Dr. Lappert Has Never Performed Gender-Affirming Surgery and Is Not Qualified to Opine on Such Procedures.

Dr. Lappert's report represents that he is "Board Certified in Surgery and Plastic Surgery." (Ex. 1 at 1.) This is not true. As he admitted, his "plastic surgery board certificate expired at the end of 2018." (Ex. 2 at 23.) His "board certification in surgery" expired "in 2002"; thus, he has not "been board-certified in surgery" for "over nineteen years." (*Id.* at 31-32.)

These are not trivial fibs, because physicians are not allowed to hold themselves out as board-certified unless they actually have a ***current*** board certificate. The American Board of Plastic Surgeons unequivocally prohibits such misrepresentations, stating that "when a physician misrepresents certification status," as Dr. Lappert did here, "ABPS may notify local credentialing bodies, licensing bodies, law enforcement agencies, and others." (*Id.* at 30; Ex. 3 at 3.) And the American Board of Surgery takes a similarly dim view of such misrepresentations, as Dr. Lappert also acknowledged. (Ex. 2 at 32 (agreeing it does not "surprise [him] that the [ABS] does not allow doctors to represent that they are board-certified in surgery unless they have a current board certificate.").)

Setting aside these misrepresentations about his credentials, Dr. Lappert is also not qualified to give expert opinions about gender-affirming surgery for a more basic reason: he has never even performed a single such procedure. He admitted that he has "never

performed facial feminization surgery" or "facial masculinization surgery" for any transgender patient. (*Id.* at 167.) The same is true for "transfeminine top surgery" and "chest reconstruction surgery." (*Id.* at 167.) He has also never "performed a vaginoplasty" nor "metoidioplasty." (*Id.* at 167-68.) In short, Dr. Lappert has "***never*** performed ***any kind*** of gender-affirming surgery in transgender patients." (*Id.* at 168; *id.* at 151 ("I have never treated a patient with gender dysphoria surgically.").) He was also emphatic that he would never perform such surgeries, because he personally does not "see them as beneficial" and thinks that they are "incorrect treatments." (*Id.* at 150.)

Dr. Lappert has not published any research on gender-affirming surgery either. He agreed that he has "not published any original research in peer-reviewed literature within the ***last 23 years***" at all—and of the six total articles that he did publish a quarter-century ago, not one was on gender-affirming surgeries for patients with gender dysphoria. (*Id.* at 129; *see id.* at 130-134.)

As a substitute for first-hand experience, Dr. Lappert cites a handful of studies in his report about supposed complications from gender-affirming surgery. But reading studies does not make one an expert. That is just the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. *Martinez*, 2007 WL 2570362, at *2. As with the disqualified expert in *Lebron* who "reached his opinion . . . by relying on studies," reading literature is not enough. 772 F.3d at 1369.

It is also telling that the Code of Ethics of the American Society of Plastic Surgeons ("ASPS") prohibits members from giving this kind of unfounded testimony.[2] Section IV of that Code of Ethics says that "to help limit false, deceptive and/or misleading testimony, Members serving as expert witnesses ***must***: 1. Have ***recent and substantive experience*** (as defined in the Glossary of the Code) in the area in which they testify[.]" (Ex. 4 at 6.) The Glossary, in turn, defines "recent and substantive experience" to mean (among other requirements) that the member "has performed the specific procedure in question within three (3) years of the date of being retained as an expert witness." (*Id.* at 8.)

Dr. Lappert fails these requirements. Far from having actually performed any of the gender-affirming procedures that he criticizes in his report (*see* Ex. 1 at 29-39)—***ever***, let alone within the last three years—Dr. Lappert was emphatic that he would never perform such surgeries because he does not "see them as beneficial." (Ex. 2 at 150.) To be sure, the ASPS Code of Ethics is not a substitute for the Court's Rule 702 inquiry. But the fact that the ASPS prohibits members from providing these kinds of ill-informed expert opinions precisely to "help limit false, deceptive, and/or misleading [expert] testimony" from being offered in court (Ex. 4 at 6) should give the Court serious pause, to say the least, about allowing Dr. Lappert's testimony.

[2] Dr. Lappert resigned from ASPS around the time his board certification lapsed (Ex. 2 at 100-101), but he was a member from 1997 to 2017, and he agreed that ASPS is a "reputable organization" to which "93 or so percent of all plastic surgeons" in the country belong. (*Id.* at 102-103.)

B. Dr. Lappert Has No Basis to Offer Opinions on Topics Outside of Plastic Surgery.

Dr. Lappert also offers a grab-bag of opinions on topics far outside his field of plastic surgery—including endocrinology (*e.g.*, opining whether puberty-blocking agents and cross-sex hormones like testosterone are appropriate treatments for gender dysphoria), psychiatry (*e.g.*, criticizing how patients are diagnosed with gender dysphoria), and more.

Dr. Lappert has no qualifications or any other basis to give any of these opinions, and they all should be excluded. For example, he has no basis to opine about purported risks of puberty-blocking treatments, given that he agreed that he is "not an endocrinologist" and has "no specialized training or expertise in endocrinology." (Ex. 2 at 153, 204.) He also has "never prescribed any puberty-blocking drugs of any kind"; and indeed, he admitted: "I ***do not*** consider myself an expert in that area" and "that's not my area of expertise." (*Id.* at 201, 203.)

The same is true for Dr. Lappert's opinions on cross-sex hormone treatments—given that he admits that he has "never prescribed cross-sex hormones for treatment of gender dysphoria," and that he has "no firsthand experience with advising [his] patients about potential risks and benefits" of such treatment. (*Id.* at 214.) Here, again, Dr. Lappert conceded that he does not "hold [himself] out as an expert in endocrinology," and that he does not plan to offer "any expert opinions in endocrinology in this case because that's outside [his] scope of expertise." (*Id.* at 204.) All of his purported opinions related to endocrinology should be excluded accordingly.

Dr. Lappert also has no qualifications—or any other basis—to opine about diagnosis or treatment of mental conditions. He admits that he has "very limited psychiatric/psychological knowledge"; he is "not a psychiatrist" or "a licensed mental healthcare provider of any kind"; and in his "professional day-to-day practice," he "do[es] not diagnose mental health conditions of any kind." (*Id.* at 68, 153-54.)[3] Thus, as Dr. Lappert conceded, "for any patient that presents to [him] with a mental health condition," he would "send them to someone who is . . . trained in how to diagnose mental health conditions."). (*Id.* at 157.) And after all of these admissions, he also conceded that he "do[es] not hold [himself] out as an expert in ***diagnosing*** mental health conditions outside, potentially, of body dysmorphic disorder," and that he also does "not have special[ized] training or expertise in ***treating*** mental health conditions." (*Id.* at 75.)

In short, while Dr. Lappert does not even have the relevant expertise to opine about gender-affirming surgery, he certainly does not have the expertise to "waltz into the courtroom" and mislead a factfinder with purported expert testimony about endocrinology, psychiatry, or anything else. *See Clark*, 192 F.3d at 759 n.5. So at the very least, all of his opinions outside of plastic surgery should be excluded.

[3] Dr. Lappert said he feels qualified to identify a potential diagnosis of body dysmorphia, and to then "offer referral for psychiatric/psychological support and evaluation" to those patients. (Ex. 2 at 72.) Body dysmorphic disorder is a distinct condition from gender dysphoria, however, that "is primarily characterized by an excessive preoccupation with a perceived defect or flaw in appearance that others cannot see or would judge as slight in appearance." (Ex. 17 at 1; Ex. 2 at 71 ("They see a defect that you don't see.").)

II. Dr. Lappert's Opinions on Topics Outside of Gender-Affirming Surgery Do Not "Fit" the Disputed Issues, Are Unreliable, Or Both.

An expert's testimony should only be admitted if it is reliable. And "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018).

Even if the testimony is reliable, the court must still "satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis*, 10 F.4th at 282. "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F. Supp. 3d 837, 846 (W.D.N.C. 2016).

This case turns on whether Defendants' exclusion of coverage for gender-confirming health care treatments violates Plaintiffs' rights under the equal protection clause, Title VII, and Section 1557 of the Affordable Care Act. Many of Dr. Lappert's opinions are both unreliable and irrelevant to this inquiry, as described below.

A. Far from Being Generally Accepted, Dr. Lappert's Opinions Have Been Rejected by the Scientific Community.

General acceptance is a reliability factor, *Nease*, 848 F.3d at 229, and the fact that a particular theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Dr. Lappert asserts that gender-affirming surgical and hormonal treatments "have not been accepted by the relevant

scientific communities" (Ex. 1 at 40), but this is not true. In fact, it is Dr. Lappert's opinions that are on the scientific fringe, to say the least.

Another court found as much just last year in addressing a challenge to Arkansas' state-law ban on gender-affirming treatment for minors, where Dr. Lappert had offered virtually identical opinions to support that ban. *Brandt v. Rutledge*, 4:21-cv-450 (E.D. Ark.); Ex. 2 at 33-34; Ex. 5 (Lappert *Brandt* Declaration). In *Brandt*, Dr. Lappert asserted that "'[g]ender affirming' treatments are experimental," which he agreed was "basically the same opinion that [he] offered in this case." (Ex. 2 at 35.) Drs. Hruz and Levine had also submitted similar declarations in *Brandt* in support of the ban. (*See id.* at 33-34.)

The *Brandt* court preliminarily enjoined the ban on August 2, 2021 (Ex. 6), squarely rejecting these opinions. That court recognized that "the consensus recommendation of medical organizations is that the ***only*** effective treatment for . . . gender dysphoria is to provide gender-affirming care," citing briefs from organizations like the American Medical Association, American Academy of Pediatrics, and many more. (*Id.* at 6 n.3; Br. of Am. Med. Ass'n, et al. (ECF No. 131 (expressing same views in this case).) *Brandt* also found that "gender-affirming treatment is supported by medical evidence that has been subject to rigorous study," and that "***every*** major expert medical association recognizes that gender-affirming care for transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people." (Ex. 6 at 7-8.)

As Dr. Lappert admitted, *Brandt*'s findings were "contrary to the opinions that [he] offered." (Ex. 2 at 39.) And as he also agreed, "every major expert medical association

disagrees with [him] because they've all taken [the] position that this treatment is in fact medically necessary." (*Id.* at 40; *see also id.* (agreeing the same is true regarding Drs. Hruz and Levine).) In fact, Dr. Lappert admits that there are at least "18 different professional medical organizations" that "take[] the view that's contrary to the opinions that [he] and Dr. Hruz and Dr. Levine are offering" here, testifying that "there's a consensus of consensus on this, exactly." (*Id.* at 42.)

That consensus also includes Dr. Lappert's own former association, the ASPS. While he says that gender-affirming surgery is experimental, the ASPS said the exact opposite in a February 2021 statement—stating that it "***firmly believes*** that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be," and promising to "continue its efforts to advocate across state legislatures for full access to medically necessary transition care." (Ex. 8 at 3.) So as Dr. Lappert admitted, the ASPS also "does not agree with [his] opinions that gender-affirming surgery is experimental." (Ex. 2 at 112-13.)

And it is not just professional medical associations either. ***Every major insurer*** in the country also says that gender-affirming surgical and hormonal treatments are medically necessary, as Dr. Lappert also admitted. (Ex. 2 at 334-38 & Ex. 9 at 2 (BCBS North Carolina policy, stating that "[s]ervices for gender affirming surgery and hormone therapy may be considered medically necessary when the criteria below are met"); Ex. 2 at 427-28 & Ex. 10 at 1 (similar for Aetna); Ex. 2 at 430-33 & Ex. 11 (similar for Cigna); Ex. 2 at 434-39 & Ex. 12 (similar for UnitedHealthCare).)

In short, this overwhelming consensus confirms that far from being generally accepted, Dr. Lappert's opinions are fringe and unreliable.

B. Dr. Lappert's Critiques of WPATH, Endocrine Society Guidelines, DSM-V, and Other Organizations' Positions Are Unreliable.

Aware that his views are contrary to those of every major medical society and professional organization, Dr. Lappert tries to dismiss every single one of them as partisan—part of the same supposed "Transgender Treatment Industry" that he crusades against. For example, he contends that the "WPATH, APA, AAP," and "AMA" all supposedly rely on a "non-scientific" methodology, and that the guidelines and position statements issued by every one of those organizations are "political" and are "not the product of a reliable scientific method." (Ex. 1 at 10-11.)

These opinions are—again—not generally accepted, to put it mildly. Just recently, the Fourth Circuit confirmed that the WPATH guidelines in particular "represent the consensus approach of the medical and mental health community" and "have been recognized by various courts, including [the Fourth Circuit], as the authoritative standards of care." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020). "There are ***no*** other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups," in fact. *Id.* at 595-596.

Dr. Lappert's deposition further confirmed that his critiques are baseless *ipse dixit* because he admitted that he has no idea how any of these standards of care were actually developed, and on what scientific basis. Take WPATH SOC Version 7 ("WPATH7"), for example. Dr. Lappert admits that he has "not been involved with the development" of

WPATH7; he does not "know what kind of scientific literature [review] the WPATH conducted as part of drafting" WPATH7; he does not know what kind of "peer review" or "outside experts" or "public comments" the WPATH may have relied on in developing WPATH7, or how many "different drafts" the WPATH7 went through, or "what may have gone on during [WPATH] meetings or conferences" to discuss the development of WPATH7. (Ex. 2 at 184-87.) And after these admissions, Dr. Lappert unsurprisingly conceded that he is "***not an expert*** in how Version 7 of the WPATH was developed." (*Id.* at 188.) The same is true for WPATH SOC Version 8. (*Id.* at 189 (agreeing he does not "hold [himself] out as an expert on how Version 8" is being developed).)

The same is also true with respect to Dr. Lappert's critiques of other standards of care and position statements:

- Endocrine Society Guidelines for Treatment of Gender Dysphoria: Dr. Lappert does not know when these guidelines "were initially published" or "last revised"; he was "not involved with the[ir] development"; he does not know "what kind of scientific literature review" went into that development; thus, he agrees he is "***not an expert*** in how the Endocrine Society developed the original 2009 guidelines" or "the 2017 updates" (Ex. 2 at 195-200);

- DSM-5: Dr. Lappert has "not been involved with the development of DSM-5"; does not know "what kind of scientific literature review was done" during that development; does not know what went on during "different meetings or conferences" to "discuss that development"; thus, he "do[es] ***not*** have expert firsthand knowledge of how the DSM-5 was developed" (*id.* at 190-93);

- AMA Position Statement on Gender-Affirming Treatment: Dr. Lappert "do[es] not know how the AMA came to issue this consensus statement" and has "no personal knowledge what scientific literature they reviewed"; thus, he has "***no idea*** . . . how the AMA came to reach this consensus statement" (*id.* at 47-48);

- American Academy of Pediatrics Position Statement on Gender-Affirming Treatment: has no "personal knowledge" of how the AAP adopted this statement (*id.* at 48).

In the end, Dr. Lappert agreed more broadly that he does "not have firsthand knowledge of how ***any*** of those organizations came to reach these positions," and that he "do[es] not know what scientific literature they relied on." (*Id.* at 49-50.) He should not be allowed to mislead a factfinder with these unfounded *ipse dixit* critiques. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

C. Dr. Lappert's Opinions About the Need for Randomized Clinical Trials Are Unreliable.

A key component of Dr. Lappert's opinions is that surgical and hormone gender-affirming treatments are supposedly experimental because they are unsupported by results from randomized clinical trials ("RCTs"). (*See, e.g.*, Ex. 1 at 5 (arguing that "properly conducted [RCTs] and long-term treatment outcome studies" are necessary to make "experimental procedures actual, proven treatments"). But his deposition confirmed that these critiques are baseless because he agreed that: (1) it is common for surgeons to perform procedures unsupported by RCT results; and (2) in any event, it is not possible to conduct RCTs for hormonal or surgical gender-affirming treatments.

First, RCTs in surgery are exceedingly rare. The ASPS's Plastics and Reconstructive Surgery Journal—which Dr. Lappert agreed is the "premier peer-reviewed source for current information on reconstructive and cosmetic surgery" (Ex. 2 at 296)—confirms as much. As a 2019 study found, in 2018, "only ***2.1 percent*** of all publications" in the ASPS Journal "were level 1 [*i.e.*, RCT] evidence"; "in 2008 and 2013, those

percentages were ***0.3*** and ***1.7 percent*** respectively," as he also agreed. (*Id.* at 299, 302; Ex. 7 (Sugrue study)). Given this paucity of RCTs, Dr. Lappert unsurprisingly conceded that surgeons in the real world do not actually wait for RCT results before deciding that a particular procedure is non-experimental. (Ex. 2 at 294-95 (agreeing it is "not uncommon for plastic surgeons to perform procedures that are not supported by results from an RCT").) In fact, he ***himself*** does not even "think it's necessary for a surgical procedure to be supported by results from a[n] . . . RCT before it can be considered effective." (*Id.* at 285.) Rule 702 demands that experts apply "the same level of intellectual rigor [in the courtroom] that characterizes the practice of an expert in the relevant field." *Cooper*, 259 F.3d at 200. Here, though, Dr. Lappert tries to impose an impossible RCT-based standard that he concedes surgeons in the real world—including himself—do not actually apply.

Second, it is not possible to perform RCTs for gender-affirming surgery or hormonal treatment. Dr. Lappert conceded this too: he agreed "it is not possible to perform RCTs for some surgical procedures because you can't blind the patient or the investigator to what the procedure is" (meaning, it is impossible to do the surgery without the patient and the investigator knowing that it was done)—including for "phalloplasty," "metoidioplasty," and more generally for all types of what is "colloquially known as bottom surgery." (Ex. 2 at 315-16.) He also agreed the same is true for "puberty-blocking hormones," since they cause "observable physical effects"; thus, "it's not possible to do an RCT for puberty-blocking hormones" either. (*Id.* at 316-18.) And he also conceded that the same is true for

cross-sex hormones, because those also cause "physical effects" and thus "it's not possible to design a double-blind RCT" for those treatments. (*Id.* at 318-19.)

Given all this, Dr. Lappert should not be permitted to offer his misleading opinion that gender-affirming surgery and hormone treatments are experimental in the absence of RCT support.

D. Dr. Lappert's Speculation About "Detransitioners," "Regret" and "Social Contagion" Is Unreliable.

Dr. Lappert also opines that some patients will "drop out of transitioning or reverse the process" (so-called "detransitioners"); others will experience "regret" after surgery; and yet others supposedly develop gender dysphoria as a result of "social contagion" like "peer group, social media, [and] YouTube role modeling." (Ex. 1 at 21-22, 40.)

None of this passes *Daubert* muster. To start, none of these opinions are even remotely connected to Dr. Lappert's experience as a plastic surgeon, given that he studiously avoids performing gender-affirming surgical procedures due to his personal beliefs, and has "never treated a single patient for gender dysphoria." (Ex. 2 at 150-51; *SAS Inst., Inc.*, 125 F. Supp. 3d at 589 (when an expert relies on experience, he must show how his "experience leads to the conclusion reached" and "why that experience is a sufficient basis for the opinion").)

Next, Dr. Lappert's own report makes clear that these are all speculative hypotheses at best. For instance, he admits that the extent of "social contagion" is unknown, writing: "a currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by . . . social contagion and social pressure processes." (Ex. 1 at 40

(underlining in original).) He also wrote the same thing about "desistance" and "regret," stating that these phenomena have "to my knowledge ***not been quantified or well-studied***." (*Id.* at 21 (emphasis in original).)

Dr. Lappert's deposition confirmed that these opinions are pure guesswork. He conceded that he is "not aware of any peer-reviewed studies that quantifies the number of people" affected by social contagion, and that "we don't know the numbers." (Ex. 2 at 367-38; *id.* at 373 ("At present, we're ***hypothesizing*** about the actual cause.").) The same was true for his "regret" opinions. (*Id.* at 329 (agreeing "there's no data available on the percentage of people" treated for "gender dysphoria who experience regret.").

But "the courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *accord, e.g.*, *Small v. WellDyne, Inc.*, 927 F.3d 169, 176-77 (4th Cir. 2019) (expert testimony "must not be based on belief or speculation"). Dr. Lappert's speculation about regret, de-transitioning, and social contagion should be excluded accordingly.

E. Dr. Lappert's Opinions About Risks Communicated to Plaintiffs Are Unreliable.

Dr. Lappert also purports to opine about what risks were or were not communicated to individual Plaintiffs before they started gender dysphoria treatment. (*See, e.g.*, Ex. 1 at 50 (for C.B., asserting there is no evidence that "the parents were counseled concerning" risks of "off-label use of puberty blocker"); *id.* (opining there was a "failure to obtain proper informed consent" for Plaintiff "CT-F").)

There is no basis for these opinions either. Dr. Lappert "did not meet with any of the plaintiffs" and has "never spoken" with any of them about what risks their doctors discussed. (Ex. 2 at 417-18.) He was "not present in any meetings that any of these plaintiffs may have had with their mental health professionals," or their "endocrinologists," or their "surgeons"; thus, outside of reviewing medical records, he has no idea "what was said or not said during those meetings." (*Id.* at 418-19.) With no reliable basis to say what was or was not communicated during these meetings, Dr. Lappert should not be permitted to create confusion with this speculation. *See, e.g.*, *Small*, 927 F.3d at 176-77.

III. Dr. Lappert's Opinions Are Based on His Personal Beliefs Rather than Science.

Reliability is a flexible inquiry, under which "courts must ensure that an expert's opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281. There is ample evidence that Dr. Lappert's opinions are so tainted by his strong personal views against gender-affirming care as to make those opinions unreliable. To be clear, Plaintiffs do not seek to impugn whatever moral or religious views Dr. Lappert may hold. But because those views plainly inform the opinions that he offers here—indeed, they seem to be the main driver of those opinions—they are something the Court should consider in assessing their reliability.

Dr. Lappert readily admits that he has "strong personal opinions on whether doctors should be providing gender-affirming treatment to minors." (Ex. 2 at 79.) That's putting it mildly. He has urged state legislatures in Utah, Arkansas, Alabama, and Texas (at least) to pass laws that would ban doctors from being able to provide this medical care for

adolescents. (*Id.* at 57, 61-62; *id.* at 54-55 (agreeing he has "actively lobbied to get these kinds of bans passed").) For example, he spoke in favor of the ban before the Alabama legislature and "publish[ed] an op-ed" that urged the legislature to protect what he called "gender-confused children." (Ex. 2 at 77, 64, 76 & Ex. 14.) He likewise threw his support behind a similar proposed ban in Utah—arguing to the legislature that "you can't change a person's sex," and that "all that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex." (Ex. 13 at 5).

Dr. Lappert was unapologetic about these opinions at his deposition. He testified that he "absolutely" stands by them, and that he "absolutely" considers "gender reassignment surgery to be an intentional mutilation." (Ex. 2 at 60.) What's more, he also wants doctors who perform these gender-affirming surgeries to be "criminally prosecute[d]"—agreeing that he thinks "that's a good idea." (*Id.* at 52.)

And even though Dr. Lappert was understandably more careful in how he phrased his expert report—avoiding inflammatory language that he uses outside of litigation, like calling gender-affirming care "intentional mutilation"—sometimes the mask slips. For instance, his report accuses every single doctor and organization who oppose his views of being part of some made-up "Transgender Treatment Industry." That is obviously not "a commonly used term in the field of treatment and diagnosis of gender dysphoria," as he admitted; instead, it is "idiosyncratic" to his report. (*Id.* at 21-22.)

Dr. Lappert has also worked closely with the Alliance Defending Freedom ("ADF"), an organization he agreed has "moral objections" to gender-affirming healthcare. (*Id.* at

83, 82.) Among other things, he attended an ADF conference that discussed the "poverty of [experts] who are willing to testify" about these anti-gender-affirming treatments. (*Id.* at 90-91.) Attendees at that conference "were asked whether they would be willing as participate as expert witnesses"; not coincidentally, Dr. Lappert became an expert witness for the first time after attending that conference. (*Id.* at 91.)

Dr. Lappert's report also unapologetically misgenders individual Plaintiffs—"referring to [them] in a way that doesn't align with their gender"—because in Dr. Lappert's view, he is "obliged to honor objective biological realities" (*id.* at 447), which is to say that he does not believe that a person's birth-assigned sex can ever be changed. (*See also id.* at 448 ("I think it's essential that we stick to the biological reality that . . . biological sex is ***immutable***.").)

And then there are Dr. Lappert's many public interviews and presentations where he crusades against gender-affirming care. These include, for example, his views that the religious conception of "the human person" "defines the 'end' of medical and surgical care." (Ex. 2 at 459.) They also include his opinions that "changing a person's sex is a lie and also a moral violation for a physician," and that gender-affirming surgery is "diabolical in every sense of the word." (*Id.* at 464 & Ex. 16 at 1, 7; Ex. 2 at 465 (agreeing that he "hold[s] those views"). And finally, these also include his inflammatory views that parents who "discuss[] gender identity issues with children" are "sexualizing them" (Ex. 2 at 462), and that these conversations are "grooming a generation" for abuse. (*Id.* at 461 & Ex. 15 (Dr. Lappert's presentation titled "Transgender Surgery & Christian Anthropology") at 23;

see also Ex. 16 at 1, 2 (another interview with Dr. Lappert titled "Plastic surgeon: sex-change operation 'utterly unacceptable' and a form of 'child abuse'"; reporting that "regarding children, Lappert said, sexualizing them at a young age with these ideas is grooming them for later abuse.").)

These are obviously not neutral, well-reasoned scientific opinions by a dispassionate expert. It is moral opprobrium masquerading as science, and it should be excluded as such.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Lappert's opinions in full.

Dated: February 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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

Dated: February 2, 2022

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CERTIFICATE OF SERVICE

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

Dated: February 2, 2022

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EXHIBIT O

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF F WASHINGTON

AT TACOMA

C.P., by and through his parents, Patricia Pritchard and Nolle Pritchard and PATRICIA PRITCHARD, Plaintiffs,	)	
vs.	)	No. 3:20-cv-06145-RJB
BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendant.	)	

ZOOM VIDEO DEPOSITION UPON ORAL EXAMINATION

OF

MICHAEL LAIDLAW

9:00 a.m.

September 2, 2022

REPORTED BY: Pat Lessard, CCR #2104

A P P E A R A N C E S

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ALSO PRESENT:

MR. PATRICK NORTON, Videographer

MICHAEL LAIDLAW, being duly sworn, testified upon oath, as follows:

E X A M I N A T I O N

BY MR. GONZALEZ-PAGAN:

Q. All right. I think we're good to proceed. Good morning, Dr. Laidlaw, thank you for joining us today. It's afternoon for me; I'm in New York.

A. Okay.

Q. Are you in California today?

A. Correct.

Q. Okay. So as you might have heard, I represent the plaintiffs in this matter and I will be asking you some questions about your opinions in this case.

A. Okay.

Q. First I just want to go over some ground rules for the deposition which will make it easier for everyone and most importantly for our court reporter. You understand that you're under oath today, is that correct?

A. Yes.

Q. We cannot speak at the same time because the court reporter needs to be able to take down what each of us says.

where a researcher, say a medical doctor, is a researcher, there are patients that collect data, say temperature and blood tests, and then draw up a journal article and have it published with all of their observations and those sorts of thing.

If we could call that primary research, as opposed to, say, a meta-analysis where there are a number of different studies that have already been done -- if you want to call those primary research -- and then someone comes up with a conclusion based on those other studies.

Q. (By Mr. Gonzalez-Pagan) Thank you. That's very helpful.

So what I'm trying to do is for us to have an understanding of what we're talking about so that --

A. Sure.

Q. -- so we can have some questioning about it.

A. Yes.

Q. So I'm trying to establish a distinction between original research, okay, where there's collection of data, right --

A. Yes.

Q. -- and the observations being done by the researcher, versus secondary research which is based

on existing publications and preexisting data.

I think that's the distinction that you were drawing in your answer as well, is that correct?

A. Yes.

Q. So would you be comfortable with that understanding, that shared understanding of -- do you know what I mean by primary research?

A. Yes, I understand your meaning.

Q. Have you performed any primary research?

A. Yes.

Q. On what? On what matters?

A. There were two studies. One was a magnesium study that had to -- we're looking for an association of low magnesium leading to osteoporosis.

And the other study was regarding thyroid cancer where we were looking at thyroid globulin tumor markers and how they correlated with ultrasound findings of the neck.

Q. And when did you perform this research?

A. This was during my -- it may have begun during my -- I think it began during my residency and then I continued into fellowship.

Q. Have you performed any primary research regarding gender dysphoria?

A. No.

Q. Have you performed any primary research relating to transgender people?
A. No.
Q. Have you performed any primary research relating to gender identity?
A. No.
Q. Do you have any peer-reviewed publications?
A. Yes.
Q. Do you have a copy of your CV with you?
A. No.
Q. I will show you what's been marked as Exhibit 2.
A. Okay.
Q. And this is a copy of your CV, right?
Well, it's not showing yet. This is a copy of your CV, right?
A. Yes. It's the one we looked at earlier.
Q. And you have here a section titled "Research, Publications, and Expert Witness Work," is that right?
A. Yes.
Q. And we can scroll through it but just go area by area.
Can you tell me which the -- within the screen showing right now which of these publications

THE VIDEOGRAPHER: We're going off the record at 10:00 a.m.

(Recess.)

THE VIDEOGRAPHER: We're back on the record at 10:07 a.m.

Q. (By Mr. Gonzalez-Pagan) We left off discussing your publications. Do you recall that, Dr. Laidlaw?

A. Yes, I do.

Q. Just to sum up, none of your publications pertaining to gender dysphoria are based on original primary research, is that correct?

A. That's correct.

Q. And with the exception of the piece in the Journal of Bioethics none of your publications pertaining to gender dysphoria are peer-reviewed?

A. Well, a number are published in peer-reduced journals.

Q. Sorry. The Letters to the Editor, is that right?

A. The Letters to the Editors are in peer-reviewed journals, yes.

Q. We've established that you have a private practice dedicated to endocrinology, is that correct?

A. That's correct.

you're providing him to align his body with his sex assigned at birth to be treatment for gender dysphoria?

A. No. This is a treatment for testosterone deficiency.

Q. How long have you been seeing this person?

A. I think I first saw him in May.

Q. So then let me reask the prior question now that we have some further clarification.

A. Yes.

Q. Beyond the patient for whom you provided that one prescription of estrogen, have you provided any patient with care as treatment for their gender dysphoria?

A. No.

Q. Have you monitored any patient undergoing gender affirming medical treatment?

A. When you say "monitor," do you mean monitor specifically for effects of that treatment?

Q. Yes. Or worked with, like a patient that is undergoing medical care and you're overseeing in some way their laboratories, their care.

A. I've had patients with gender dysphoria that I'm seeing for other reasons that I'm monitoring their laboratory or imaging, stuff like that.

Q. But you're not treating them yourself for gender dysphoria, is that right?

A. Correct.

Q. Have you ever conducted a review of medical necessity as an insurance company employee or as an external reviewer?

A. No.

Q. All right. Let's talk a little bit about your report.

A. Okay.

Q. And by "a little," I mean the bulk of the next conversation.

A. Okay. I kind of figured.

Q. What did you do to prepare your report?

A. To prepare my report?

Q. Yes.

A. Let's see. I reviewed -- I reviewed the materials from paragraph ten.

I looked at -- spent a lot of time with medical records and the clinical visit notes and laboratories and so forth of Dr. Hatfield and Dr. Kyllo.

Yeah, I read through the expert declarations and looked to build my report based on those items.

Q. Does the report we have, your report which

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D.

I, Loren Schechter, pursuant to 28 U.S.C. §1746, declare as follows:

1. I have been retained by counsel for the Plaintiffs as an expert in the above-captioned lawsuit. I previously submitted an expert witness declaration [Dkt. No. 11-4] ("Schechter Dec.") in connection with Plaintiffs' motion for a preliminary injunction in this case.

2. I submit this declaration to respond to points raised in the declaration of Patrick W. Lappert, M.D. [Dkt. No. 49-1 App. 557-90] ("Lappert Dec."), which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

3. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration. In preparing this declaration, I was provided with and reviewed the following additional case-specific materials: Expert Declaration of Patrick W. Lappert, MD, with attachments.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I note that since I submitted my prior declaration, WPATH has published version 8 of the Standards of Care.[1] While version 8 does contain important updates with respect to gender-affirming surgery, it does not change the substance of any of the opinions I expressed in my previous declaration.

6. Dr. Lappert continues to misunderstand that gender dysphoria is a valid medical diagnosis. *See* Schechter Dec. ¶ 37. Because he does not accept gender dysphoria as a diagnosis, it is no surprise that Dr. Lappert disagrees that surgery is an appropriate reconstructive treatment. But his views on the appropriateness of surgery and other medical interventions to treat gender dysphoria fall far outside of the medical mainstream.

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

American Plastic Surgery Society Levels of Evidence

7. Dr. Lappert discusses the American Society of Plastic Surgeons Levels of Evidence extensively, suggesting that because there are Level IV and V studies supporting gender-affirming surgical procedures, these surgeries are not established as safe, effective, or accepted. Lappert Dec. ¶¶ 25-27, 55. As I described in my prior declaration, there are practical and ethical limitations on conducting studies in clinical medicine, especially in surgery. Schechter Dec. ¶¶ 54-56. That does not mean that studies with lower levels of evidence are not useful to inform clinical decision making.

8. In fact, Dr. Lappert ignores that the quality of the evidence supporting gender-affirming surgeries is similar to that supporting many common plastic surgeries. For example, Dr. Lappert points to his experience performing surgery to treat cleft palate and craniofacial differences. Lappert Dec. ¶¶ 8, 10. However, there are only a small number of studies providing Level 1 evidence for that treatment.[2] Scientific ratings of evidence generally employ extremely high standards that are not satisfied for many commonly-

[2] *See, e.g.*, Jonathan M. Bekisz, *A Review of Randomized Controlled Trials in Cleft and Craniofacial Surgery*, 29 J. of Craniofacial Surgery 219 (2018).

prescribed treatments and procedures.[3] Such ratings do not mean that the treatment is unsupported in the literature and clinical practice, or that it is not medically necessary. The level of evidence does not always speak to the quality of the research, including because conducting prospective, randomized, double-blind, placebo-controlled studies is not always the optimal or appropriate choice for a particular research question, and in some areas, is not feasible or ethical. *See* Schechter Dec. ¶¶ 54-56.

9. Dr. Lappert is also wrong to suggest that studies are the only way for surgeons to determine the appropriate course of treatment for a particular condition. Critical review of the scientific literature is certainly an important component as to how surgeons evaluate whether a particular procedure is generally safe and effective and whether it is appropriate or recommended for an individual patient. But in addition to considering the literature en masse, we must also account for our own clinical experience and that of our colleagues, as well as our patients' experiences and input. Here, the existing literature, taken as a whole, combined with my own experience and that of many colleagues,

[3] *See, e.g.*, Bernard T. Lee, et al., *Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps*, Plastic and Reconstructive Surgery, 140(5):651e-664e (Nov. 2017); doi: 10.1097/PRS.0000000000003768.

indicates that gender affirming surgery is a safe and effective treatment for individuals with gender dysphoria.

10. In fact, since I submitted my prior declaration, a higher level study has been published showing that in transgender and nonbinary adolescents and young adults, top surgery is associated with low complication rates and improved chest dysphoria, gender congruence, and body image satisfaction.[4] That study adds to the body of evidence supporting the use of gender affirming surgery in patients with gender dysphoria.

Surgery, Like All Medicine, Is An Evolving Field

11. Dr. Lappert focuses on the evolution of treatment for gastric ulcers to support his claims that using Level 4 and 5 evidence to support surgical treatment "can result in grave missteps." Lappert Dec. ¶ 27. But as Dr. Lappert notes, once Level 1 and 2 studies demonstrated that gastric ulcers could be treated with medications, the standard of care changed. This is common in medicine. As the research and clinical evidence evolves, treatment evolves in turn.[5] For example, we previously counseled patients that the only way to lose weight was through dietary changes. Now, we use surgical interventions, such

[4] *See* Mon Ascha et al., Top Surgery and Chest Dysphria Among Transmasculine and Nonbinary Adolescents and Young Adults, JAMA Pediatrics (Sept. 26, 2022), doi:10.1001/jamapediatrics.2022.3424 .
[5] *See, e.g.*, Conor M. Sugrue et al., *Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years?,* 7 Plast. Reconstruct. Surg. Global Open e2408 (2019).

as bariatric surgery, to treat obesity in certain situations. Notably, Dr. Lappert does not – and cannot – point to any research showing that treatment other than gender-affirming care is effective for gender dysphoria.

Reconstructive Surgeries

12. Dr. Lappert misconstrues the distinction between reconstructive and cosmetic surgery. He suggests that a mastectomy performed to treat gender dysphoria is cosmetic because it "will produce a degradation or loss of two essential human functions, namely: sexual arousal, and breast feeding." Lappert Dec. ¶¶ 42. Here, he makes at least two incorrect assumptions. First, research, as well as my clinical experience, shows that gender-affirming mastectomy is associated with an increase in sexual satisfaction.[6] Second, not all patients view breastfeeding as a desirable function. What is more, Dr. Lappert ignores that a mastectomy performed to treat breast cancer will likewise result in the inability to breast feed. So, his assertion that any procedure that causes a loss of function is cosmetic cannot be correct.

13. Dr. Lappert later suggests that the difference between reconstructive surgery (which he states that insurance will cover) and cosmetic

[6] *See, e.g.*, Cori A. Agarwal et al., *Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test*, 71 Journal of Plastic, Reconstructive & Aesthetic Surgery 651-657 (2018).

surgery (which he states that insurance will not) turns on pathology reports, using breast reduction surgery and surgery to treat gynecomastia as examples. Lappert Dec. ¶¶ 47-48. But, for both of those procedures, the American Society of Plastic Surgeons states that symptomatology – not pathology reports – is the important determinant for insurance coverage.[7]

14. As I described in my prior declaration, it is the underlying diagnosis that distinguishes a reconstructive procedure from a cosmetic one. Schechter Dec. ¶¶ 33-37. Gender-affirming surgery is considered medically necessary, reconstructive surgery when performed in accordance with the WPATH Standards of Care because it is clinically indicated to treat the underlying diagnosis of gender dysphoria. Schechter Dec. ¶¶ 34-35.

15. Ultimately, Dr. Lappert classifies gender-affirming procedures as cosmetic because he does not believe that gender dysphoria is a valid diagnosis for which surgery is necessary, pointing to the lack of "objective" tests for the condition. Lappert ¶¶ 31, 42, 47-48. *See also* Lappert ¶ 51 (stating that the condition of a cancer patient "is far more grievous" than the condition of a

[7] *See* American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Reduction Mammaplasty (2021), https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021-reduction-mammaplasty.pdf; American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Gynecomastia, https://www.plasticsurgery.org/documents/Health-Policy/Positions/Gynecomastia_ICC.pdf.

person with gender dysphoria). That belief conflicts with the consensus of the medical community. Schechter Dec. ¶¶ 22, 28.

16. In addition, his reliance on "objective" tests is misplaced. What he considers to be objective tests – an x-ray, pathology report, or lab value – are open to interpretation. It is not uncommon to have conflicting opinions regarding an x-ray or a pathology report. In addition, while various tests may be considered in regards to establishing a diagnosis, the tests are usually interpreted within the clinical context. For example, x-ray reports typically include the phrase "clinical correlation is recommended." Finally, Dr. Lappert ignores that once a diagnosis is established, treatment then depends on a discussion with the patient. That discussion includes information from the literature, but also includes other clinical considerations, such as the patient's values, preferences, choices, and autonomy, which Dr. Lappert disregards. For example, while Dr. Lappert references complex oropharyngeal reconstruction, *see* Lappert Dec. ¶ 51, he fails to acknowledge that there are other methods for treating and/or reconstructing this complex defect, as there are other techniques for reconstructing genitalia to treat gender dysphoria. Thus, while Dr. Lappert may be describing his preferred approach to patient care, that approach does not reflect the clinical reality of medicine in 2022.

Informed Consent and Mental Health

17. It is not uncommon for patients needing surgery for a wide variety of conditions to have been diagnosed with mental health conditions; this includes transgender patients. Dr. Lappert claims that surgery of any kind is inappropriate for someone with a behavioral health condition such as autism, depression, or anxiety. Lappert Dec. ¶¶ 43. But patients with these and other mental health conditions regularly and appropriately consent (and assent, as described below) to surgical care. Generally, these conditions do not prevent patients from understanding the procedure, the risks and complications of the procedure, and the benefits that they can reasonably expect to achieve from surgery. Rather, in some cases, surgeons and their colleagues will work with patients in a capacity referred to as "prehabilitation" to address mental health conditions and psychosocial considerations that could impact surgical results.[8] The WPATH Standards of Care are consistent with that approach. *See* Schechter Dec. ¶ 31.

18. Dr. Lappert also misunderstands the informed consent process for minors, claiming they "by definition are not competent to consent." Lappert Dec. ¶ 43. When individuals under age 18 seek any surgery, including gender

[8] *See* James Durrand et al., *Prehabilitation*, 19 Clin. Med. 458-64 (2019).

affirming surgery, it is their parent or guardian that must provide informed consent. Of course, the adolescent must also assent to gender confirming surgery.

19. In sum, not all people with gender dysphoria need, want or are candidates for surgery. However, in appropriately-selected and prepared people, surgery is safe, effective, and medically necessary. *See* Schechter Dec. ¶ 26-28.

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

Executed this 6th day of October, 2022.

Loren S. Schechter, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF
DR. DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have personal knowledge of the matters stated in this supplemental declaration.

3. I submit this declaration to respond to points raised in the declarations of Dr. Andre Van Mol, Dr. Michael K. Laidlaw, Dr. James Cantor, Dr. G. Kevin Donovan, Dr. Geeta Nangia, and Dr. Kristopher Kaliebe, which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I previously submitted an expert witness declaration [Dkt. 11-3] in support of Plaintiffs' motion for a preliminary injunction in this case.

6. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration.

7. Since I submitted my prior declaration, WPATH has published version 8 of the *Standards of Care for the Health of Transgender and Gender Diverse People* ("WPATH SOC-8").[1]

8. The SOC-8 is based upon a more rigorous and methodological evidence-based approach than previous versions. (Coleman, et al., 2022). This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Its recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

9. While SOC-8 includes important updates, it does not change the substance of any of the opinions I expressed in my previous declaration. Indeed, SOC-8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as medically appropriate and necessary treatments for gender dysphoria, based on an individual patient's needs.

REBUTTAL TESTIMONY

10. The opinions expressed and critiques outlined in my original declaration apply to the various new declarations submitted in support of defendants' response to the motion for a preliminary injunction. Below, I outline some additional critiques based on my review of these declarations.

Rebuttal to Dr. Van Mol

11. In his declaration, Dr. Van Mol sets up a straw man of "self-diagnosis" and "affirmation on demand." Dr. Van Mol states that WPATH supports "self-diagnosis" and "treatment on demand." In fact, WPATH Standards of Care 8 requires a diagnosis when used in local contexts, which in the United States is

Gender Dysphoria under the DSM 5-TR. Diagnoses for care are made by clinicians caring for patients.

12. Dr. Van Mol provides no evidence of "affirmation on demand" leading to poor outcomes, citing instead papers in which patients with gender dysphoria were given DSM diagnoses by clinicians.

13. Dr. Van Mol mentions the *interim* report by Dr. Hillary Cass in the United Kingdom and the closure of the Tavistock clinic in the UK. He fails to mention that the report recommends more access to care, based on a regional rather than single centralized model for the entire country, and that two clinics will be opened to replace Tavistock, with more to come, with the intent of expanding access to care for transgender youth.

14. Dr. Van Mol's efforts to separate UK policy from WPATH SOC-8 recommendations are incorrect. SOC-8 benefitted from the leadership of several UK-based clinicians and academicians, like Dr. Jon Arcelus, MD, co-editor of SOC-8, Dr. Christina Richards, PhD, chapter lead of the Assessment chapter, and Dr. Walter Bouman, MD, who oversaw the SOC 8 process as WPATH president.

15. Dr. Van Mol cites an opinion in Bell v. Tavistock that was overturned on appeal regarding the legal capacity of minors to consent for medical treatment in the UK. In Florida and most other states, however, it is parents or legal guardians

who consent for minors' care. WPATH SOC-8 provides guidance on clinicians assessing the cognitive maturity for minors to assent for care, but consent is by parents or adult guardian.

16. Dr. Van Mol cites Dhejne, et al. (2011), for the proposition that suicide rates were higher in the 324 patients who received gender affirming surgery from 1973-2003, than in the general population. However, Dr. Dhejne herself notes that the study does not compare those that had surgery with those that did not, so it really does not measure the effectiveness of care. In the last 15 years of the 30-year study, there was no statistical difference in suicide rates, and the total number of suicides over 30 years were 10 in trans people versus 5 in general population control.

17. Dr. Van Mol relies heavily on statements by others who oppose gender-affirming care, rather than on data and studies themselves. These provide no counter to the many studies that provide evidence of the benefits of gender-affirming care, including those discussed or cited in my original declaration.

Rebuttal to Dr. Laidlaw

18. Dr. Laidlaw states that Gender Dysphoria was a rare condition in children and adolescents. There is little data on the frequency of those meeting the Gender Dysphoria in Children criteria over time as the diagnosis has only existed in its current criteria since 2013. The current diagnosis of Gender Dysphoria in

Children was preceded by the diagnosis of Gender Identity Disorder of Childhood contained in prior versions of the DSM, like the DSM-IV, which included a broader population of gender diverse children.

19. Moreover, population surveys asking adolescents their gender identity are a recent phenomenon, and include larger numbers, but not evidence of substantial change when the same population has been surveyed over time. As WPATH SOC-8 notes, the Littman study of social contagion has significant limitations—only parents, not gender-dysphoric youth were surveyed, and recruited from websites concerned about social contagion, and the results have not been replicated.

20. Dr. Laidlaw also uses old studies of desistance in pre-pubertal youth to argue against treatment of youth in adolescence. The newest cited study (Singh 2012) includes data from youth in the Toronto clinic from as far back as the 1970s. These older studies included pre-pubertal gender diverse youth who only met broader, obsolete diagnostic criteria that did not require the youth to have a transgender identity, and included some youth who had no diagnosis at all. In any event, in the same clinics following these youth in Toronto and in Amsterdam, if gender dysphoria was present in adolescence, it was treated with puberty blockers and hormones.

21. Regarding sexual functioning in those given puberty blockers early in development, van der Meulen, et al. (2022) reported that from long-term follow up of the Dutch cohort who received puberty blockers at Tanner stages 2 and 3, when surveyed as adults after gender affirming surgery, 81% of trans women were able to orgasm, a higher percentage than those who received gender-affirming treatment that started later in adolescence. Thus, from available data, the use of puberty blockers early in adolescence did not harm sexual functioning.

22. Regarding fertility, effects of gender-affirming care on fertility are discussed with parents and the adolescent before starting gender-affirming care. Some youth and their parents choose to preserve fertility through sperm or ova and have financial resources to do so. This is part of the equation of weighing risks and benefits. Moreover, many trans people retain reproductive capacity and some bear children. While fertility concerns are taken seriously by youth, their parents, and treatment providers, these deeply personal decisions are made by families and their doctors, not the state.

23. Lastly, Dr. Laidlaw purports to review the clinical cases of the plaintiffs, without having met or examined them. He attempts to make clinical recommendations, based on partial records, that they should not receive gender-affirming care. Dr. Laidlaw lacks the training and experience in transgender care or

mental health to make these recommendations. This is compounded by his making clinical recommendations for those who are not his patients and whom he has not examined, and by making false assumptions in each case. Making these clinical recommendations is highly speculative and inappropriate.

Rebuttal to Dr. Cantor

24. Dr. Cantor attempts to counter the statement in my declaration that the sole contemporary American longitudinal study, by Olson, et al. (2022) shows very low desistance rates. He uses a study by Singh, et al. (2021) to claim there is recent evidence of high desistance. In fact, though Singh was recently published, it is a study of feminine boys from as far back as 1975, with a mean year of evaluation of 1989. This overlaps with other reports of these feminine boys from the same Toronto clinic, who received the now obsolete Gender Identity Disorder of Childhood, if they received any diagnosis. While the feminine prepubertal boys in this study predominately identified as gay and bisexual men as adults, patients in the same clinic who had gender dysphoria continuing into adolescence were treated with puberty blockers and hormones.

25. Dr. Cantor disputes my statement that transgender identity is not a paraphilic disorder. Transgender identity is not a paraphilic disorder nor itself a mental disorder. The American Psychiatric Association, in its list of mental

disorders, states that the Gender Dysphoria diagnosis is based on "distress, not identity per se." (DSM-5, APA 2013). DSM-5 further states in the Paraphilic Disorders chapter that those with a paraphilic disorder "Do not report an incongruence between their experienced gender and assigned gender nor a desire to be of the other gender."

Rebuttal to Dr. Donovan

26. Dr. Donovan replies to my ethical concerns about forced detransition by cutting off the current care received by transgender people on Medicaid by stating that gender-affirming care should include provisions for detransitioners. In fact, WPATH provides training on working with detransitioners, and has included detransition in SOC-8. However, this volitional detransition by choice, an uncommon occurrence that should be taken seriously by health professionals, is a very different ethical concern than forcing large numbers of poor and disabled people off care involuntarily. I am surprised that Dr. Donovan seems unable to distinguish between these very different circumstances.

Rebuttal to Dr. Nangia

27. Dr. Nangia, who has practiced in State College, Pennsylvania and Greenville South Carolina, reports to have seen over a thousand youth with gender dysphoria or transgender identity in her 15 years of practice. These high numbers

are very suspect and are not typical for a general psychiatric practice. By comparison, the UCSF Child and Adolescent Gender Center, a specialty clinic providing gender-affirming medical care which attracts referrals from across the country and around the world, has only seen approximately 2,000 gender diverse and transgender youth in its 10 years of existence, and treated approximately 1,200 with puberty blockers and hormones. For Dr. Nangia to have cared for over 1,000 transgender and gender dysphoric youth, she would have to had one of the largest psychiatric practices caring for trans youth in the United States, and yet has not previously reported on this cohort. Notwithstanding her claim, I was unfamiliar with Dr. Nangia prior to reading her declaration and I have practiced as a psychiatrist in this field for over 30 years.[2]

28. Without elaboration, Dr. Nangia claims her patients have not benefitted from gender-affirming care. Four of the largest gender clinics, UCSF, Children's Hospital of Los Angeles, Northwestern, and Boston Children's first reported at the WPATH Biennial Symposium in Montreal on a cohort of 315 transgender

[2] According to the Williams Institute, the estimated population of transgender youth (ages 13-17) is only 3,200 in South Carolina and 10,000 in Pennsylvania. (Herman, et al., 2022). Pennsylvania has well-established and recognized multidisciplinary gender clinics like the ones at Children's Hospital of Philadelphia and UPMC Children's Hospital of Pittsburgh. Similarly, South Carolina has a multidisciplinary pediatric transgender clinic at MUSC Children's Health.

adolescents that were followed for two years after starting gender-affirming hormones, who showed improvement on mental health measures and on body congruence. Again, without elaboration, Dr. Nangia reports that her patients have regretted gender-affirming medical treatment. A study of 209 gender-affirming mastectomies in transmasculine adolescents under 18, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Tang, et al., 2022).

29. Dr. Nangia mentions a doubling of estimates of the number of transgender youth by the Williams institute. This increase is in large part because of a change in methodology, from just using the Behavior Risk Factor Surveillance System (BRFSS) to using both the BRFSS and the Youth Risk Behavior Survey (YRBS). The YRBS is a survey of high school students that includes large urban school systems, including the San Francisco Unified School District. It has higher estimates than the BRFSS, which has been relatively stable over time.

CONCLUSION

30. There is a large and growing body of evidence, as well as a consensus of experts in the just published WPATH Standards of Care Version 8, that demonstrate the benefits and medical necessity of gender affirming care to people with gender dysphoria.

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

Executed this 6th day of October 2022.

Dan H. Karasic, M.D.

EXHIBIT A

Supplemental Bibliography

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REBUTTAL DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. My background and credentials are detailed in my previous declaration submitted September 11, 2022 (ECF 11-5). My CV is attached as Exhibit A of that declaration.

3. I submit this rebuttal declaration to address aspects of Dr. Andre Van Mol's declaration submitted by Defendants in support of their opposition to Plaintiffs' Motion for Preliminary Injunction (ECF 49, Appendix Attachment 6).[1] Because there are many issues with Dr. Van Mol's declaration, I do not address

[1] I will refer to Dr. Van Mol's declaration with parenthetical citations in the text to page numbers in the appendix filed by Defendants at ECF 49-1.

every point he makes or every study or article that he cites. Instead, I focus on his declaration's major shortcomings: Dr. Van Mol's lack of experience in gender-affirming medical care or bioethics, his persistent mischaracterization of the evidence for gender-affirming medical care, and his erroneous statements regarding the ethics of clinical research and informed consent. I reserve the right to supplement my opinions as the case proceeds.

4. To begin, Dr. Van Mol is not an expert on the topics involved in this litigation, specifically gender-affirming medical care and the treatment of gender dysphoria in adolescents and adults. He does not report any formal training in bioethics beyond what he would have received as a medical student and resident, nor does he report any employment as a bioethicist. He is a board-certified family physician in full-time practice. This makes Dr. Van Mol one of over 100,000 board-certified family physicians in the United States.[2] Dr. Van Mol does not indicate that he previously provided or currently provides medical care to individuals with gender dysphoria in his clinical practice. He does not have any academic appointments and reports only "six peer-reviewed commentaries and letters." He is, in fact, the author of only a single peer reviewed article whose topic, health-care reform, [3] is not

[2] About the American Board of Family Medicine. American Board of Family Medicine. Accessed October 5, 2022. Available at https://www.theabfm.org/about.
[3] Van Mol A. Health-care reform's great expectations and physician reality. *Ann Pharmacother*. 2010;44(9):1492-5.

germane to gender-affirming medical care or the treatment of gender dysphoria. His other five publications are letters to the editor.[4] While major medical journals perform peer-review of submitted manuscripts, they do not generally peer review letters to the editor. Dr. Van Mol does not offer any evidence to that his letters were "peer-reviewed" in the common meaning of this term. His characterization of these letters is, therefore, misleading. Finally, rather than stating his own opinions in his declaration, Dr. Van Mol quotes extensively from others, including another expert witness retained by the Defendants, Dr. James Cantor.

5. Many of Dr. Van Mol's responses to my initial declaration fail to address the issues that I raised, and instead attempt to misdirect the reader. For example, instead of responding directly to my pointing out that there are other common medical diagnoses that do not require confirmatory laboratory or radiographic studies, Dr. Van Mol instead asserts alleged risks of gender-affirming

[4] Van Mol A. Premature termination of life is not palliative care. *Chest*. 2013;143(1):279; Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline". *J Clin Endocrinol Metab*. 2019;104(3):686-687; Van Mol A, Laidlaw MK, Grossman M, McHugh PR. Gender-affirmation surgery conclusion lacks evidence. *Am J Psychiatry*. 2020;177(8):765-766; Rosik CH, Sullins DP, Schumm WR, Van Mol A. Sexual orientation change efforts, adverse childhood experiences, and suicidality. *Am J Public Health*. 2021;111(4):e19-e20; Laidlaw MK, Van Mol A, Van Meter Q, Hansen JE. Letter to the Editor From Laidlaw et al: "Erythrocytosis in a large cohort of transgender men using testosterone: A long-term follow-up study on prevalence, determinants, and exposure years." *J Clin Endocrinol Metab*. 2021;106(12):e5275-e5276.

medical care (App. 527) and instead of responding to my point that observational studies may be sufficient evidence upon which to base recommendations, Dr. Van Mol asserts that gender dysphoria is not a disease (App. 542). Furthermore, rather than attempt to refute my opinion that it is health care providers who make the diagnosis of gender dysphoria, Dr. Van Mol asserts, "The problem is that proper, extensive psychological evaluation and support of the gender dysphoric patient and family both is not assured or even consistent (App. 524)."

6. Contrary to Dr. Van Mol's unsupported assertion, clinical practice guidelines for the treatment of gender dysphoria are clear regarding the evaluation which should be performed prior to initiating gender-affirming medical care. The Endocrine Society's criteria for gender-affirming hormone therapy for adolescents include "A qualified [mental health professional] has confirmed that: the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria" and "any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."[5] It is not new or surprising that medical providers feel pressure from themselves, patients, families, and society to alleviate patients' pain

[5] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

and suffering whether it is caused by gender dysphoria or another medical condition. It is, however, providers' responsibility, as professionals, to make sound treatment recommendations.

7. Dr. Van Mol's sole empirical evidence for his claims that evaluation and support of patients diagnosed with gender dysphoria is not "assured or consistent" comes from only two clinics, one in London, England and the other in New South Wales, Australia (App. n. 3, 6). Without conceding that there is significant nonadherence to clinical practice guidelines in these two clinics, there are other, more appropriate ways to address such alleged concerns, rather than withdrawing funding for gender-affirming medical care. Dr. Van Mol does not point to evidence of nonadherence in Florida or provide arguments that withdrawing funding is the appropriate response to alleged nonadherence.

8. With respect to my opinion that "off-label" uses of medications to treat gender dysphoria, like gonadotropin releasing hormone (GnRH) analogs, estrogen, and testosterone, does not mean they are experimental, untested, or unsafe, Dr. Van Mol again misrepresents my opinion by responding that "Safe and effective for a given approved indication should not be assumed to mean safe and effective for any other (App. 532)." The Defendants maintain that because these medications are being used off label, they are experimental and not safe and effective, which is false. GAPMS Memo at 8, 14, 16, 19, 21; Attachment G at 4. In my declaration, I cite

independent evidence of the safety and efficacy of the use of medications "off-label" to treat gender dysphoria (ECF 11-5, at ¶¶ 22, 33-34).

9. Dr. Van Mol claims that, because additional research is purportedly needed regarding gender-affirming medical care, such care should be denied to Florida Medicaid beneficiaries. It is not possible for clinicians to tell their patients with gender dysphoria, or any other clinical condition whose treatment is currently based on a similar level of evidence, to come back later when more evidence is available. Clinicians must make treatment recommendations based on the best, currently available evidence. For example, clinical trials frequently have restrictive inclusion and exclusion criteria to improve their methodological rigor. Clinicians must subsequently determine whether to recommend the intervention to a patient with the same condition who would not have been eligible for the clinical trial. An example is fetal surgery for spina bifida in a pregnant person with a body mass index greater than 35 kg/m^2. Additional research would be beneficial for most medical conditions.

10. As I detailed in my declaration, clinical practice guidelines for medical conditions other than gender dysphoria are also frequently based on similar, "low-quality" evidence. Other clinical practice guidelines also include qualifications, e.g., the guideline does not establish a standard of care. This simply indicates that clinicians must use their best clinical judgment in applying the guideline to

individual patients. Defendants are not, however, withdrawing coverage from all conditions whose clinical practice guidelines are based on a similar level of evidence or that make similar qualifications.

11. There are prospective observational trials that support the safety and efficacy of gender-affirming medical care. Immediately after the publication of these studies, providers and potential participants could still have had the clinical equipoise necessary to ethically conduct a randomized, placebo-controlled trail, e.g, they may have had genuine uncertainty about whether or not to use puberty blockers in adolescents. The reason why a randomized, placebo-controlled trial was not performed at that time is multifactorial including the lack of government or industry funding. With additional clinical experience, many potential investigators and participants no longer have equipoise. Other types of randomized, controlled trials may nonetheless be beneficial, such as trials comparing different dosing regimens.[6] Prospective observational studies, e.g., studies of the incidence of side-effects, may also contribute to patient care.

12. It is important to reiterate that even if a randomized, placebo-controlled trial of puberty blockers had been performed, it would not have provided "high quality" evidence in the way that Dr. Van Mol inaccurately suggests. Although

[6] Burinkul S, Panyakhamlerd K, Suwan A, Tuntiviriyapun P, Wainipitapong S. Anti-androgenic effects comparison between cyproterone acetate and spironolactone in transgender women: A randomized controlled trial. *J Sex Med*. 2021;18(7):1299-1307.

randomized trials are initially assigned the grade "high," this initial grade is decreased to "moderate" if there are serious limitations in the study's quality, and to "low" if there are very serious limitations. Criteria for quality include the adequacy of allocation, concealment, blinding, and follow up.[7] In the case of placebo-controlled trials of gender-affirming medical care, it is not possible to prevent the investigators or the participants from knowing whether a participant has been assigned to the intervention or the control group. Participants and investigators would know based on whether the participant develops secondary sexual characteristics or what type of characteristics the participant develops. Dr. Van Mol insists on a type of evidence that is neither ethically nor methodologically possible.

13. It is surprising that while Dr. Van Mol asserts additional research is necessary, he is critical of the ongoing, prospective observational study of gender-affirming medical care of adolescents in the United States (U.S.). Funding for The Impact of Early Medical Treatment in Transgender Youth study was approved on a competitive basis by the Eunice Kennedy Shriver National Institute of Child Health & Human Development and the study protocol was approved by the Institutional Review Boards at the four participating hospitals.[8]

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[7] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. Jun 19 2004;328(7454):1490.

[8] Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the Longitudinal, Observational Trans Youth Care study. *JMIR Res Protoc.* 2019;8(7):e14434.

14. With respect to informed consent, Dr. Van Mol quotes European authors incorrectly implying that minors, rather than their parents or legal guardians, provide informed consent for gender-affirming medical care in the U.S. (App. 549-550). Dr. Van Mol also mischaracterizes a legal case from the United Kingdom (U.K.), Bell vs. The Tavistock and Portman NHS Foundation Trust, in support of his claims regarding informed consent (App. 550). In England and Wales, individuals 16- years-old and older are presumed to have the capacity to consent to medical treatment and those under 16 can consent if they possess sufficient understanding and intelligence to understand fully what is proposed. Although the court questioned the capacity of adolescents under age 16 to consent for gender-affirming medical care and suggested a role for the court in authorizing care for older adolescents, this ruling was later overturned by the Court of Appeal, [9] a fact that Dr. Van Mol conveniently fails to mention.

15. Dr. Van Mol, again quoting others, asserts that there is no established standard for informed consent and that practice varies considerably (App. 549). There are, in fact, well established standards of informed consent. Although states differ in the standard they utilize to determine if the disclosure of potential benefits and risks is adequate (the professional practice or the rational person standard), the

[9] Thornton J. Court upholds Gillick competence in puberty blockers case. *Lancet*. 2021; 398(10307):1205-1206.

standard is well established within individual states.[10] Again, Dr. Van Mol provides no empirical evidence of practice variation in Florida and, even if he were to, there are preferable ways to address such variation, were it to exist, other than completely withdrawing coverage for one type of medical care.

16. With respect to Dr. Van Mol's assertion that the Florida Medicaid Rule is non-discriminatory, the references that he cites do not support his claim (App. 553-54). As stated in above, the U.K. High Court's opinion in Bell v. Tavistock was overturned on appeal and therefore cannot be used for support as Dr. Van Mol attempts to do. The National Institute of Health and Care Excellence (NICE) reviews of puberty blockers and cross-sex hormones are systematic reviews of the literature[11] and, while they grade the quality of the evidence, they do not make treatment recommendations. The Swedish Agency of Health Technology Assessment and Assessment of Social Services report is a scoping review (a review which identifies knowledge gaps or the scope of a body of literature, clarifies concepts, or investigates research conduct)[12] and again does not make treatment recommendations. Instead of banning or defunding gender-affirming medical care,

[10] Murray B. Informed consent: What must a physician disclose to a patient? *Virtual Mentor*. 2012;14(7):563-6.
[11] Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med*. 1997;127(3):210-6.
[12] Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.

the U.K. and Sweden are reorganizing the delivery of gender-affirming medical care into regional interdisciplinary clinics and supporting research on gender-affirming medical care. For example, in her interim report, Dr. Hilary Cass recommends, "regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway."[13] To the best of my knowledge, neither the U.K., Sweden, Finland, nor France is banning or defunding gender-affirming medical care.

17. Dr. Van Mol fails to reference any evidence for his claim that "There are alternative treatments of mental health natures which are at least as effective. And without the harms of hormonal and surgical interventions (App. 555)." Such claims are based on case reports or anecdotes[14] which represent a lower level of evidence than prospective observational studies. Recall that Dr. Van Mol asserts

[13] Cass H. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed October 5, 2022. Available at https://cass.independent-review.uk/publications/interim-report/.

[14] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One size does not fit all: In support of psychotherapy for gender dysphoria. *Arch Sex Behav*. 2021;50(1):12; Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300; Schwartz D. Clinical and ethical considerations in the treatment of gender dysphoric children and adolescents: When doing less is helping more. *J Infant Child Adolesc Psychother.* 2021;20(4):439-449; Zucker KJ. The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-confirming children" by Temple Newhook et al. (2018). *Int J Transgenderism.* 2018;19(2):238-9.

prospective observational studies, let alone case reports or anecdotes, are an unacceptable level of evidence to support gender-affirming medical treatments.

18. Dr. Van Mol's declaration provides no substantive reasons for me to alter my conclusions that treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. I remain of the opinion that there is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

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

Executed on October 7, 2022

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF
DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have personal knowledge of the matters stated in this supplemental declaration.

3. I submit this declaration to respond to points raised in the declarations of Dr. Michael M. Laidlaw, M.D., Dr. Andrew Van Mol, M.D., and Dr. James Cantor (attachments 4, 6, and 11 to Defendants' Appendix), which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I previously submitted an expert witness declaration [Dkt. 11-2] in support of Plaintiffs' motion for a preliminary injunction in this case.

6. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration.

7. Since I submitted my prior declaration, WPATH has published version 8 of the *Standards of Care for the Health of Transgender and Gender Diverse People* ("SOC8").[1] Importantly, SOC8 is based on the best available science and expert professional consensus in transgender health; its recommendation statements were developed based on data derived from independent systematic literature reviews, background reviews, and expert opinions; and its grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability of these.

8. While SOC8 contains important updates with respect to gender-affirming surgery, it does not change the substance of any of the opinions I expressed

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

in my previous declaration. Indeed, SOC8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery as treatment for gender dysphoria, based on an individual patient's needs.

9. In preparing this supplemental declaration, I relied on my training and years of research and clinical experience, as set out in my curriculum vitae attached to my original declaration, and on the materials listed therein; the materials referenced in my original declaration and listed in the bibliography attached thereto; and on the materials referenced herein and the supplemental bibliography attached as Exhibit A. reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

REBUTTAL TESTIMONY

Rebuttal to Dr. Laidlaw

10. Dr. Laidlaw utilizes many of the same arguments against gender affirmation that are presented in the reports that were attached to GAPMS Memo and which I have addressed in my original declaration. These include his arguments about the high desistence rates of children, the inability of adolescents and their parents to make informed decisions, social contagion theory, lack of good quality

data, blockers and social transition as gateways to gender affirming medical treatment and an overemphasis on the secondary sex characteristics as reproductive tools.

11. Dr. Laidlaw does not include the most recent study examining persistence, that also has the largest sample size: Kristina R. Olson, Lily Durwood, Rachel Horton, Natalie M. Gallagher, Aaron Devor; Gender Identity 5 Years After Social Transition, Pediatrics, August 2022; 150 (2): e2021056082. 10.1542/peds.2021-056082. This study demonstrated that 94% of the transgender youth in this study continued to have a transgender identity five years after enrollment.

12. From his declaration, it is evident that Dr. Laidlaw does not work with transgender youth, nor does he have a good understanding of the care, as illustrated by the points below.

13. In many places throughout his report, Dr. Laidlaw references the use of "high dose" hormones. Nowhere does he provide a definition of "high dose."

14. Dr. Laidlaw writes: "There are also serious concerns regarding liver dysfunction: "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may

rupture] —all potentially life-threatening complications" (Actavis Pharma, 2018). (Laidlaw Dec. at 20.) The source document Dr. Laidlaw relies on describes these side effects of liver dysfunction as related to the use of 17alpha-AAS, Methyltestosterone, Oxandrolone, Oxymetholone and Stanozolol. These are not medications routinely used in gender-affirming care. Masculinization is achieved with testosterone esters, most commonly, testosterone cypionate. Someone who practices this medicine would know this.

15. Similarly, Dr. Laidlaw writes: "Moreover, "[s]tudies ... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms." (Laidlaw Dec. at 22.) Again, if he was familiar with the care, he would be aware that testosterone doses for masculinization are not even close to the "medium" dosing described above. In fact, most commonly patients are being prescribed 60-100 mg a week.

16. Dr. Laidlaw repeatedly presents irrelevant data in order to create confusion and incite fear. He presents source data with very few subjects, or quotes studies with statistics that sound alarming, but does not accurately represent the

absolute risk of potential side effects. Additionally, he fails to mention the positive medical side effects of hormones.

17. For example, Dr. Laidlaw writes that "Breast cancer is a relatively uncommon problem of the male. However the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen." (Laidlaw Dec. at 23.) The source document he relies on says on its first page that "The absolute risk of breast cancer in transgender people remains low, and therefore following breast cancer screening guidelines for cisgender people seems sufficient for transgender people using hormone treatment."

18. Breast cancer risk is higher among transgender women compared to cisgender males, but lower than cisgender women. The fact that transgender individuals adopt a similar health risk profile to their cisgender counterparts is not surprising. Accordingly, transgender men have a lower risk of breast cancer than cisgender men.

19. Neither a practitioner in gender care, nor a researcher, Dr. Laidlaw further demonstrates his lack of understanding about transgender adolescent development when he writes about the apparent "impairment of sexual function" by relying on an episode of the TLC reality show "I am Jazz," where the protagonist of the show, Jazz, visited a surgeon and discussed sexual function. (Laidlaw Dec. at

16). If Dr. Laidlaw had experiencing caring for transgender youth, he would not distill the experiences of all transgender girls treated with puberty-delaying medication in early puberty to two sentences from a reality TV show on TLC. Many transgender girls have difficulty with masturbation because of a disconnection between themselves and their genitals. It takes conversation and education to help patients develop comfort with self-pleasure. Many patients do get over this discomfort and have both sexual sensation and orgasm.

20. Dr. Laidlaw further asserts that the psychosocial development of transgender youth treated with puberty blockers "will be necessarily stunted as they are not developing with their peers" and that "[t]his is a permanent harm as the time cannot be regained." (Laidlaw Dec. at 17.) This assertion completely discounts the understanding that pubertal trajectories vary between individuals.

21. Pubertal development has a wide variation among individuals. Puberty in people assigned male at birth typically begins anywhere from age 9 to age 14, and sometimes does not complete until past 18. For people assigned female at birth, puberty typically ranges from age 8 to age 17.

22. If a 13-year-old cisgender female had not yet started puberty, we would not give them exogenous hormones so that they were peer concordant with the

majority of their peers simply because they are on the later side of the normal range for puberty commencement.

23. Protocols used for the treatment of transgender youth tend to put the start of puberty using exogenous hormones in the latter third of typical puberty for the sex consistent with their identity, but nothing outside of the typica range.

24. Dr. Laidlaw also asserts that "there are unknown, but likely negative consequences to blocking normal puberty with respect to brain development." Dr. Laidlaw's assertion based on pure supposition. What is known is that untreated gender dysphoria has a tremendously negative impact on the quality of life and functioning of adolescents.

25. Finally, it should be noted that Dr. Laidlaw's commentary regarding the specific course of care of the plaintiffs is not reliable and highly suspect. It is inappropriate for Dr. Laidlaw to offer a recommendation about the specific course of care for plaintiffs when he has neither met nor treated these patients and is basing his recommendations on an incomplete and partial view of their medical history. Moreover, Dr. Laidlaw does not appear to be experienced in the provision of gender-affirming care and does not offer any recommendation for the treatment of people's gender dysphoria, including plaintiffs.

26. More specifically, in his comments about plaintiffs, Dr. Laidlaw makes references to doses of testosterone but only mentions the concentration of the suspension (200 mg/mL) not the *actual* dose. Dr. Laidlaw also repeatedly points out the coexistence of mental health concerns, including anxiety, depression, and ADHD. These are very common diagnoses in adolescents at large, and it is well-documented that youth with gender dysphoria have even higher rates of anxiety and depression likely *as a result of* their gender dysphoria. Moreover, there is no reason that youth with coexisting anxiety, depression and ADHD should be denied care related to gender dysphoria.

27. Dr. Laidlaw also unabashedly declares professionals "unfit" to provide both diagnoses of gender dysphoria and medical treatment of gender dysphoria. This is not only an appalling display of unprofessionalism, it demonstrates his lack of understanding about how multidisciplinary teams function in the care of transgender youth. He has no personal knowledge of these providers' training and leans on his own "hierarchy of professionals" that places medical doctors at the top to deem whether or not people are qualified to be doing the work they are doing. This declaration from a provider who clearly does not practice in this field of medicine is unprecedented.

28. Dr. Laidlaw's suggestion that medical services related to gender dysphoria for plaintiffs, who he has not met nor treated, should be discontinued is misinformed and dangerous.

29. Dr. Laidlaw is not an expert in the care of transgender youth, nor is he an investigator in transgender care or any other topic. His CV consists largely of letters to the editor, speeches advocating against transgender youth care, and providing unsubstantiated "expert testimony" in cases such as these.

Rebuttal to Dr. Van Mol

30. Much of Dr. Van Mol's declarations draws upon the existing testimony from others, such as Dr. Stephen Levine and Dr. James Cantor. Dr. Van Mol does not care for transgender patients, and has a clear bias given his listed credentials.

31. The American College of Pediatricians, the Council on Adolescent Sexuality and the Christian Medical & Dental Associations and the Alliance Defending Freedom have historically opposed transgender rights, including access to gender-affirming care, and LGBTQ rights more broadly.

32. Dr. Van Mol refers to the closing of the Tavistock Clinic in the United Kingdom as a justification for denying care to youth with gender dysphoria in Florida. But the closure is not intended to end the provision of gender-affirming care (as Dr. Van Mol and Dr. Laidlaw) would have one believe. It was based on

issues such as long waitlists that were documented by Dr. Hillary Cass's "independent review of gender identity services for children and young people" in the United Kingdom.

33. To the contrary, the closure is based on a recommendation by Dr. Hillary Cass to move to a "regionalised service delivery model," that is meant to "*improve access*, networked care, research capacity and workforce development." Simply put, gender-affirming care for youth with gender dysphoria is not being discontinued. Indeed, England's National Health Service has stated that, "The aim is to close the Tavistock clinic [the Gender and Identity Development Service (Gids)] by spring 2023, moving to the new provider model through specialist children hospitals" and noted that the youth "being seen by the Tavistock (and those on waiting lists) will be transferred to a new provider over the course of that time."

34. Dr. Van Mol also repeats the assertion that the use of psychological treatment for patients with gender dysphoria is not proven to be inferior to medical interventions, which is outlandish given the decades of research, scientific study, and clinical experience we now have. In 1966, Harry Benjamin noted in "The Transsexual Phenomenon" that while transsexualism is primarily considered a psychiatric disorder, it is refractory to psychiatric intervention. Over the past 50 years, mental health professionals who have attempted to treat gender dysphoria with

psychological interventions that have been unsuccessful. (Olson-Kennedy Dec. at ¶¶ 110-11.)

35. Dr. Van Mol also presents the same arguments about gender-affirming care, particularly for youth, is purportedly experimental and that there is no good quality evidence because of the lack of an untreated control group. I have addressed these concerns in my original declaration. (Olson-Kennedy Dec. at ¶¶ 68-88.) Dr. Van Mol's assertion here is based on the belief that the control group would have access to psychological interventions. But as, as stated above, this is not true and has proven to be unsuccessful. Additionally, participants would have to choose to be in a study in which they could receive no medical intervention. There are distinct issues that I have outlined in my previous testimony regarding the feasibility of RCTs in this context.

36. Finally, Dr. Van Mol omits the importance of clinician experience and patient values in the construct of evidence-based medicine, as noted in my original declaration (Olson-Kennedy Dec. at ¶¶ 85-88).

Rebuttal to Dr. Cantor

37. In my original declaration, I discussed at length the challenges of using a grading system to identify research as "high quality" and of the importance of clinical experience and patient values in the practice of evidence-based medicine. I

am not disputing that the research discussed by Dr. Cantor does not reach a grading of high quality, but that RCTs (the "gold standard" of high-quality evidence) are not feasible based on the challenges posed in adolescent gender care research.

38. Dr. Cantor reasserts that mental health therapy alone can improve the mental health of patients with gender dysphoria. (Cantor Dec. ¶ 33.) But gender dysphoria is characterized by the clinically significant distress that results from the incongruence between a person's gender identity and sex assigned at birth. No study has demonstrated that mental health therapy alone is a successful mechanism to manage gender dysphoria.

39. Dr. Cantor also takes issue with my discussion of Harry Benjamin's work based on the fact that the seminal text *The Transsexual Phenomenon* does not mention children. But the Rule at issue in this case prohibits coverage of gender-affirming care for adults and minors alike. Moreover, while I did not represent the quote was referring to children, in fact, Harry Benjamin did care for adolescents. (Dear Doctor Benjamin; Letters from Transsexual Youth, International Journal of Transgenderism Vol 10, 2008) There is no reference to whether or not youth are included in his sentiment, but given that he did care for adolescents, it is likely that he includes them in this sentiment.

CONCLUSION

40. The testimony of Dr. Van Mol and Dr. Laidlaw exposes that neither of these defendants have experience in the care of transgender adolescents.

41. While it is true that the field of transgender youth care is a growing field, there is ample clinical experience and data to demonstrate the positive impact of medical interventions in the care of youth with gender dysphoria, and to cut off access to this care would have a detrimental impact on a very vulnerable population.

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

Executed this 7th day of October 2022.

Johanna Olson-Kennedy, M.D., M.S.

EXHIBIT A

Supplemental Bibliography

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