

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

MAXWELL KADEL, *et al.*,

Plaintiffs,

v.

DALE FOLWELL, in his official capacity as
State Treasurer of North Carolina, *et al.*,

Defendants.

Case No. 1:19-cv-00272-LCB-LPA

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

TABLE OF CONTENTS

STATEMENT OF THE CASE AND FACTS 1

INTRODUCTION 1

LEGAL STANDARD 2

ARGUMENT 4

 I. Dr. Hruz is not qualified to offer an expert opinion on the diagnosis and treatment of gender dysphoria, or any issue in this case..... 4

 II. Dr. Hruz’s opinions and testimony are not relevant to this case. 8

 A. *Dr. Hruz’s opinions about desistance are irrelevant.* 9

 B. *Dr. Hruz’s opinions about supposed controversies in other countries are irrelevant.*..... 10

 C. *Dr. Hruz’s musings about the causes of gender dysphoria are irrelevant.* 11

 D. *The totality of Dr. Hruz’s opinions are irrelevant because they are based on hypotheticals and speculation.*..... 11

 III. Dr. Hruz’s opinions and testimony are unreliable. 12

 A. *Dr. Hruz’s opinions are unreliable because they are based on untested hypotheses and speculation.* 13

 B. *Dr. Hruz’s opinions are unreliable because they are misleading and therefore do not serve to enlighten the trier of fact.*..... 13

 C. *Dr. Hruz’s opinions are unreliable because they are not generally accepted in the scientific and medical community.*..... 17

 D. *Dr. Hruz’s opinions are unreliable because they have no support and are based on ipse dixit.* 19

 IV. Dr. Hruz’s opinions are so tainted by his personal bias as to render his opinions unreliable..... 19

 V. Dr. Hruz’s opinions lack probative value and are therefore inadmissible under Federal Rule of Evidence 403. 23

CONCLUSION 24

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

STATEMENT OF THE CASE AND FACTS

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

INTRODUCTION

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

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

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

LEGAL STANDARD

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

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

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

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

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

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

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

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

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

ARGUMENT

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

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

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

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

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

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

Dr. Hruz has never treated or diagnosed a transgender patient with gender dysphoria. Ex. A at 88:18-89:8, 89:17-25; Ex. C at 24:11-24:14, 25:20-25:23. Dr. Hruz has also not sat in on a meeting with a patient discussing the treatment options for gender dysphoria. *Id.* at 40:6-40:11. Nor has he conducted any original research about transgender people or gender dysphoria. Ex. A at 35:5-36:1; Ex. C at 62:25-63:9; Ex. D at 25:24-28:13. He has not published any scientific, peer-reviewed literature on gender dysphoria or transgender people either. Ex. A at 42:14-49:19; Ex. C at 61:17-64:7, 295:19-295:23.²

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

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

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

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

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

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

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

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

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

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

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

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

A. *Dr. Hruz’s opinions about “desistance” are irrelevant.*

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

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

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

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

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

Dr. Hruz’s opinions regarding “desistance” are thus irrelevant to this case.

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

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

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

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

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

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

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

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

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

* * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Dated this 2nd day of February, 2022.

/s/ Amy E. Richardson

Amy E. Richardson
(N.C. Bar No. 28768)
Lauren E. Snyder
(N.C. Bar No. 54150)
HARRIS, WILTSHIRE & GRANNIS LLP
1033 Wade Avenue, Suite 100
Raleigh, NC 27605-1155
Phone: 919-429-7386 | Fax: 202-730-1301
arichardson@hwglaw.com

Deepika H. Ravi*
Grace H. Wynn*
HARRIS, WILTSHIRE & GRANNIS LLP
1919 M Street N.W., 8th Floor,
Washington, D.C. 20036
Phone: 202-730-1300 | Fax: 202-730-1301
dravi@hwglaw.com

Michael W. Weaver*
Adam M. Safer*
MCDERMOTT WILL & EMERY
444 W. Lake St., Suite 4000
Chicago, IL 60606
Phone: 312-984-5820 | Fax: 312-984-7700
mweaver@mwe.com

Dmitriy G. Tishyevich*

Respectfully submitted,

/s/ Omar Gonzalez-Pagan

Omar Gonzalez-Pagan*
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
Telephone: 212-809-8585
Facsimile: 212-809-0055
ogonzalez-pagan@lambdalegal.org

Tara Borelli*
Carl S. Charles*
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
1 West Court Square, Ste. 105
Decatur, GA 30030
Telephone: 404-897-1880
Facsimile: 404-506-9320
tborelli@lambdalegal.org

David Brown*
Ezra Cukor*
TRANSGENDER LEGAL DEFENSE AND
EDUCATION FUND, INC.
520 8th Ave, Ste. 2204
New York, NY 10018
Telephone: 646-993-1680
Facsimile: 646-993-1686

Warren Haskel*
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
Phone: 212-547-5534 | Fax: 646-417-7668
dtishyevich@mwe.com

dbrown@transgenderlegal.org

Lauren H. Evans*
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
Phone: 202-756-8864 | Fax: 202-591-2900
levans@mwe.com

Counsel for Plaintiffs

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

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) 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

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan*
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
Telephone: 212-809-8585
Facsimile: 212-809-0055
ogonzalez-pagan@lambdalegal.org

CERTIFICATE OF SERVICE

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

Dated: February 2, 2022

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan*
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
Telephone: 212-809-8585
Facsimile: 212-809-0055
ogonzalez-pagan@lambdalegal.org