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

AUGUST DEKKER *et al.,*

Plaintiffs,

v.

JASON WEIDA, *et al.,*

Defendants.

Case No. 4:22-cv-00325-RH MAF

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

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I. INTRODUCTION

Plaintiffs are transgender Medicaid beneficiaries who have been diagnosed with gender dysphoria. In August 2022, Defendants adopted a rule, Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"), prohibiting Medicaid coverage of services for the treatment of gender dysphoria. Defendants adopted the Challenged Exclusion after undergoing a process with a predetermined outcome that concluded that the provision of medical treatment for the treatment of gender dysphoria, including puberty blockers, hormone therapy, and surgery, "do not conform to GAPMS [("generally accepted professional medical standards")] and are experimental and investigational." Defendants thus deny equal treatment to Plaintiffs based on sex because they are transgender.

In response, Defendants have put forward an expert, Dr. Stephen Levine, a psychiatrist, whose opinions other federal courts have significantly narrowed, excluded in part, and in one case, dismissed altogether. The same is true here. Dr. Levine's opinions should be excluded because (1) many are unhelpful because they are not opposed to the relief Plaintiffs seek and (2) the remaining opinions are unreliable because they are not based on scientifically valid principles, reasoning, and methodology. The Court should therefore, with narrow exception, exclude Dr.

Levine's opinions.[1]

II. LEGAL STANDARD

The admission of expert testimony is governed by Federal Rule of Evidence 702, as explained by *Daubert* [v. *Merrell Dow Pharm*., *Inc*., 509 U.S. 579, 597 (1993)] and its progeny." *Rink* v. *Cheminova*, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005). "District courts are [thus] charged with [a] gatekeeping function." *Id*.; see also *United States* v. *Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) ("The importance of *Daubert*'s gatekeeping requirement cannot be overstated."). In conducting their gatekeeping function, courts must "engage in a rigorous three-part inquiry and determine whether:

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Frazier, at 1260; *see also City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998), *cert. denied*, 528 U.S. 812 (1999). The Eleventh Circuit refers to these three considerations separately as "qualification," "reliability," and "helpfulness" and has emphasized that they are "distinct concepts that courts and

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[1] Excerpts of the Expert Disclosure of Stephen B. Levine, M.D., signed February 16, 2023, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles ("Charles Decl.")

litigants must take care not to conflate." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). "The party offering the expert has the burden of satisfying each of these three elements by a preponderance of the evidence." *Rink*, 400 F.3d at 1292.

To be sure, "[i]mplementing Rule 702, *Daubert* requires district courts to ensure that any and all scientific testimony or evidence admitted is both relevant and reliable." *Claire v. Fla. Dep't of Mgmt. Servs.*, 2021 WL 5982330, at *1 (N.D. Fla. Oct. 20, 2021). "[T]he trial judge must determine [this] ***at the outset***." *Daubert*, 509 U.S. at 592 (emphasis added). The court's gatekeeping role and the test for admissibility of expert testimony are applicable even at a bench trial or at the summary judgment stage. *See, e.g.*, *Rink v. Cheminova*, 400 F.3d 1286 (11th Cir.) (granting motions to exclude in the context of summary judgment); *Kadel v. Folwell*, 2022 WL 3226731, at **5-17 (M.D.N.C. Aug. 10, 2022) (same); *Lo v. United States*, 2022 WL 1014902, at *12 (W.D. Wash. Apr. 5, 2022) (excluding unqualified expert evidence in the context of a bench trial); *cf. UGI Sunbury*, 949 F.3d at 833 (holding the district court abused its discretion in a bench trial when it "ignored rule [702]'s clear mandate" by "sidestepping Rule 702 altogether and declining to perform any assessment of [expert]'s testimony before trial").

It is axiomatic that "[a] witness may be qualified as an expert by virtue of his 'knowledge, skill, experience, training, or education." *Quiet Technology DC-8, Inc.*,

326 F.3d at 1342. However, credentials are not dispositive when determining qualification. In conducting the *Daubert* inquiry, each of the three analytical prongs is assessed in reference to the matter to which the expert seeks to testify—i.e., "to the task at hand." *Daubert*, 509 U.S. at 597. It is for that reason that "expertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1368 (11th Cir. 2014) (holding that a psychiatrist was properly prevented from opining on rates of drug use in an economically vulnerable population because he had never conducted research on the subject, and instead relied on studies to form his opinion). If a proposed expert witness does not "propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation," such an expert should be disqualified. *Lebron*, 772 F.3d at 1369 (quoting Fed. R. Evid. 702 (cleaned up)).

An expert's testimony should only be admitted if it is sufficiently reliable. "To meet the reliability requirement, an expert's opinion must be based on scientifically valid principles, reasoning, and methodology that are properly applied to the facts at issue." *In re 3M Combat Arms Earplug Products Liab. Litig.*, 3:19MD2885, 2022 WL 1262203, at *1 (N.D. Fla. Apr. 28, 2022). The requirement of reliability found in Rule 702 is "the centerpiece of any determination of admissibility." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). In making this determination the court can consider a variety of factors, including whether the

purported expert's theory has been tested, whether it has been subjected to peer review and publication, and whether the theory has been generally accepted in the scientific community. *See Daubert*, 509 U.S. at 593-94; *Rink*, 400 F.3d at 1291-92.[2] To be reliable the expert's testimony must always be based on "good grounds." *Daubert,* 509 U.S. at 590. Moreover, *Daubert* requires that reliable expert testimony be more than scientifically unsupported "leaps of faith." *Rider* v. *Sandoz Pharm*. *Corp*., 295 F.3d 1194, 1202 (11th Cir. 2002).

To satisfy the helpfulness requirement, the testimony must have a justified scientific relationship to the facts at issue. *Daubert*, 509 U.S. at 591. Thus, helpfulness, "goes primarily to relevance." *Id.* at 580. Relevant expert testimony "logically advances a material aspect of the proposing party's case" and "fits" the disputed facts. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004). "The relationship must be an appropriate 'fit' with respect to the offered opinion and the facts of the case." *Id.* Expert testimony does not "fit" when there is "too great an analytical gap" between the facts and the opinion offered. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997) (offering animal studies showing one type of cancer in mice to establish causation of another type of cancer in humans is "simply too great

[2] Other factors that may be relevant include (1) the nature of the field of claimed expertise, (2) the source of the expert's knowledge, (3) the expert's level of care in using the knowledge, and (4) the expert's consideration of alternative hypotheses. *Hendrix*, 255 F.R.D. at 578-79.

an analytical gap between the data and the opinion offered"); *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir.2009) ("if an expert opinion does not have a 'valid scientific connection to the pertinent inquiry' it should be excluded because there is no 'fit.'").

Finally, because of the potentially misleading effect of expert evidence, *see Daubert*, 509 U.S. at 595, expert opinions that otherwise meet admissibility requirements may still be excluded under Fed. R. Evid. 403. Exclusion under Rule 403 is appropriate if the testimony is cumulative or needlessly time consuming. *See, e.g., Hull v. Merck & Co., Inc.*, 758 F.2d 1474, 1477 (11th Cir.1985) (admission of speculative and "potentially confusing testimony is at odds with the purposes of expert testimony as envisioned in Fed. R. Evid. 702"); *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1316 (11th Cir. 2005) (affirming exclusion of expert testimony as cumulative). Consequently, because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it…[T]he 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 (cleaned up) (emphasis added).

III. ARGUMENT

As noted above, other federal courts have narrowed, excluded, and in one case, entirely dismissed Dr. Levine's opinions about transgender people and the

treatment of gender dysphoria.[3] This began several years ago with district court's holding in *Norsworthy v. Beard*, that "the Court gives very little weight to the opinions of Levine, whose report misrepresents the Standards of Care; overwhelmingly relies on generalizations about gender dysphoric prisoners, rather than an individualized assessment of Norsworthy; contains illogical inferences; and admittedly includes references to a fabricated anecdote." 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015). This holding was echoed in *Edmo v. Idaho Dep't of Corr*., 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (holding that Dr. Levine "is considered an outlier in the field of gender dysphoria" and gave "virtually no weight" to his opinions), *vacated in part on other grounds sub nom. in Edmo v. Corizon, Inc.*, 935 F.3d 757 (9th Cir. 2019). Dr. Levine's opinions were likewise excluded in *Hecox v. Little,* where the Court dismissed his opinion that "gender-affirming policies … are … harmful to transgender individuals," and instead "accept[ed] Plaintiffs' evidence regarding the harm forcing transgender individuals to deny their gender identity can cause." 479 F. Supp. 3d 930, 977 n.33 (D. Idaho 2020).

Of most relevance to this case, several of Dr. Levine's proposed opinions were

[3] Because of the numerical limitation on the parties depositions, Plaintiffs opted not to depose Dr. Levine and instead rely on his prior deposition and trial testimony in cases similar to this one, where his expert reports and proffered opinions have been nearly identical to his report submitted here. *See Brandt et al*., v. *Rutledge et al*. No. 4:21-cv-00450-JM (E.D. Ark., 2022); *Fain et al*., v. *Crouch et al*., No. CV 3:20-0740, 2022 WL 3051015 (S.D.W. Va. Aug. 2, 2022); *Kadel et al.,* v. *Folwell et al.*, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022).

excluded based on irrelevance and unreliable methodology by the U.S. District Court for the Middle District of North Carolina in *Kadel* v. *Folwell*, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022). Judge Loretta C. Biggs granted in part a motion to exclude Dr. Levine's testimony, noting that he would be limited to offering opinions primarily to the following matters: (1) identifying risks associated with prescribing medication and surgery to adolescents, (2) and criticizing the quality of the research on treatments for gender dysphoria.[4] At a minimum, Dr. Levine's proposed opinions in this matter should be so limited as well, with his remaining testimony, opinions and content of reports otherwise excluded.

A. Many Of Dr. Levine's Opinions Will Not Help the Trier of Fact Because They Support Plaintiffs' Position.

Many of Dr. Levine's opinions do not "logically advance a material aspect *of the proposing party's case*" and do not "fit" the disputed facts because his proposed opinions do not oppose the relief Plaintiffs seek. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004) (emphasis added). For that reason, Dr. Levine's opinions "fit" with the facts relevant to resolving this matter in favor of Plaintiffs' claims, not those of Defendants. *Id*. And even though several of Dr. Levine's opinions, and the clinical experience upon which they are based, do not stand in opposition to the relief

[4] The court in *Kadel* also found that Dr. Levine was permitted to testify as to his opinions of WPATH but for the reasons stated herein, infra, this Court should not so permit.

Plaintiffs seek, many do, and admitting this unreliable and unhelpful testimony wholesale would not meet the standard set forth by *Daubert* and its progeny.

Significantly, several of Dr. Levine's proposed opinions regarding gender-affirming medical care, and his clinical experience upon which those opinions are based, are not contrary to the relief Plaintiffs seek in this case: that Florida Medicaid beneficiaries diagnosed with gender dysphoria receive appropriate medical care. Charles Decl., Ex. A at ¶6. On November 28, 2022, Dr. Levine testified at length about his proposed opinions regarding gender-affirming care at the bench trial in *Brandt* v. *Rutledge,* No. 4:21-cv-00450-JM (E.D. Ark., 2022).[5] There, as here, Dr. Levine was Defendants' only expert witness to have ever treated patients for gender dysphoria, and he testified that removing gender affirming medical care from patients currently receiving it would have "shocking and devastating" psychological consequences. Charles Decl. Ex. B at 912:3-19. Dr. Levine testified there, as he does in his report in this matter, that "there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women." Charles Decl., Ex. A at ¶49; Charles Decl., Ex. B at 920:18-24. And to be sure, "broad opinions [that] are based solely on … anecdotal accounts, and speculation … are not reliable." *In re 3M Combat Arms Earplug Prod.*

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[5] The Plaintiffs in *Brandt* did move to exclude or limit Dr. Levine's testimony.

Liab. Litig., 2021 WL 684183, at *3. Dr. Levine also testified that reliance on self-report from the patients and information from parents is not unique to the diagnosis of gender dysphoria and is "ideally" how psychiatry works. Charles Decl. Ex. B at 894:24-895:6. He also testified that the use of medications to treat gender dysphoria is off-label—meaning not FDA approved for this specific indication—does not mean the drugs are experimental. Charles Decl. Ex B. at 930:14-17. And while Dr. Levine agreed that the "overwhelming majority" of his patients have been adults, he testified that he has written letters of authorization for hormone therapy for some patients under 18 and, going forward, would consider doing so on a case-by-case basis. Charles Decl. Ex. B at 886:13-18, 897:1-898:18, 900:21-902:15, 902:25-903:6.

Similarly, in *Fain* v. *Crouch*, No. CV 3:20-0740, 2022 WL 3051015 (S.D.W. Va. Aug. 2, 2022), where plaintiffs challenged a Medicaid coverage restriction of gender-affirming care in West Virginia, similar to the one at issue in this case, Dr. Levine testified at deposition that in the previous seven months he had provided several letters of approval for gender-affirming surgeries for transgender people incarcerated at Framingham, a correctional institution in Massachusetts. Charles Decl. Ex. C at 84:4-85:4. Dr. Levine has also previously testified that he has written similar letters for gender-affirming hormones and surgery in accordance with the medical community's widely accepted and authoritative guidance for transgender care, World Professional Association of Transgender Health ("WPATH") Standards

of Care ("SOC"). Charles Decl., Ex. C. at 139:14-19; Ex. D at 55:13-17; 56:2-5; 112:16-21; 176:8-16; Ex. E at 1-90:15-22. He also testified that he does not provide such letters unless he has sufficiently informed his patients of possible risks and received a reasonable assurance that they understand. Charles Decl., Ex. D at 176: 8-16; 225:24-226:17. For almost 50 years, Dr. Levine's clinical practice has generally adhered to the WPATH SOC. Charles Decl. Ex. C at 136:8-11. And, as WPATH's former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the SOC, recognized his own writing in Version 7, and asked if he could help draft the recently published Version 8. Charles Decl., Ex. A at ¶5; Ex. C at 147:12-149:18. He testified at deposition in *Fain*, and under oath previously, that he "is not advocating denying endocrine treatment or surgical treatment" to transgender people, a position he described as "draconian."[6]

Finally, Dr. Levine testified at deposition in *Fain* and that he was not offering

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[6] Charles Decl., Ex. C at 88:10-13; Ex. D at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …."); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: Do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").

any opinions about whether Defendants should have an exclusion in their Medicaid program for coverage of gender-affirming medical care. Charles Decl. Ex. C at 86:25-87:19. He also testified that he does not feel his "expertise extends to how the insurance industry works and how governments and legislatives work," nor "does he consider himself an expert" on whether the West Virginia Medicaid exclusion should exist. Charles Decl., Ex. C at 87:14-22. Nevertheless, Dr. Levine has testified that he is "an agent of the patient, I want what's best for the patient, and especially if the patient couldn't otherwise afford it, I would wish for my patient to have it, yes." Charles Decl., Ex. F at 157:7.

At bottom, Dr. Levine has repeatedly and consistently testified in federal court that he does not support banning the provision or coverage of gender-affirming medical care, that for 50 years he has and continues to provide letters of authorization for gender affirming medical treatments for adult and minor patients, and that he is not an expert about insurance coverage of gender-affirming medical care. *See* e.g. Charles Decl., Ex. D at 86:1-8. Many of his opinions do not "logically advance a material aspect *of the proposing party's case*," do not "fit" the disputed facts, and will ultimately not assist the trier of fact because his proposed opinions do not oppose the relief Plaintiffs seek. *McDowell*, 392 F.3d at 1298-99 (emphasis added).

B. Dr. Levine's Opinions That Do Not Support Plaintiffs' Position Are Methodologically Unreliable and Scientifically Unsupported.

An expert's opinion should only be admitted if it is based on scientifically

valid methodology that is properly applied to the facts. *In re 3M*, 2022 WL 1262203, *at *1*. Dr. Levine's opinions fall far short of the reliability standard, a reality he has admitted to as recently as November 2022. Dr. Levine admits in his report submitted here, at trial in *Brandt*, and at deposition in *Fain* and other recent cases, that theories upon which he relies lack *any* scientific support and have not been tested or subjected to peer review or publication. Charles Decl., Ex. A at ¶49; Ex. B 797:8-19, 887:19-888:25, 921:21-922:7, 924:12-25, 949:24-954:22; Ex. C at 140:12-143:2, 145:19-25; Ex. D at 109:20-25; 116:4-7, 122:8-124:22, 200:11-201:25.

Even putting that aside, although Dr. Levine claims many times that his "experience" is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied to the facts here. Afterall, "At this stage, the court must undertake an independent analysis of each step in the logic leading to the expert's conclusions; if the analysis is deemed unreliable at any step the expert's entire opinion must be excluded." *Hendrix v. Evenflo Co., Inc*., 255 F.R.D. 568, 578 (N.D. Fla. 2009), *aff'd sub nom. Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183 (11th Cir. 2010).

1. Dr. Levine's Assertion that the WPATH SOC Version 8 Is Not the Widely Accepted and Authoritative Protocol for the Treatment of Gender Dysphoria Is Misleading and Unreliable Because It Is Demonstrably False.

Chief among Dr. Levine's many unreliable opinions is his assertion that the

widely-accepted and utilized WPATH SOC are not widely-accepted and considered to be authoritative treatment protocols for gender dysphoria. Contradicting himself, Dr. Levine has repeatedly testified that he generally adheres to the WPATH SOC in his own clinical practice. Charles Decl., Ex. C at 136:8-11; Ex. D at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. F at 29:10-18; 37:2-13; 47:22-49:3; 103:11-19. Nevertheless, Dr. Levine's attempt to undermine the WPATH SOC fail because he lacks evidence to support his assertions, contradicts his assertions with other binding testimony, misrepresents sources in his report, and fails to include relevant information that is contrary to his assertion—ultimately undermining the reliability and overall admissibility of his opinions.

First, Dr. Levine alleges that "reviews" of the 7th Version of the SOC ("SOC 7") "published in 2021 by Dahlen et al [sic] and Sapir in 2022 have clarified the low reliability and bias inherent in its recommendations. (Dahlen et al 2022)." The Dahlen et al. 2021 article does not characterize the SOC 7 as having "low reliability" or "inherent bias." Charles Decl., Ex. A at ¶69; Ex. G. The article does state that the SOC 7 are due for an update and acknowledges that evaluations of clinical practice guidelines in other medical areas including cancer, diabetes, pregnancy, and depression "tend to show room for improvement," and that "finding poor quality CPGs is not confined to this area of healthcare." Charles Decl., Ex. G at 8. Again, without evidence, Dr. Levine claims the 8th Version of the SOC ("SOC 8") has "not

gained additional confidence in its scientific merit." Charles Decl., Ex. A ¶69. He also claims that the presence of transgender participants at WPATH meetings "makes it difficult for professionals to raise their concerns." Charles Decl., Ex. A ¶69. But Dr. Levine admits he has not been a member of WPATH for more than 20 years and does not provide evidence to support these claims. *Id*. at ¶66.[7] The reality is that no one, not transgender people or other health professionals (whether transgender or cisgender), are preventing Dr. Levine from "raising his concerns." As Dr. Levine testified, he presented alongside other panelists with dissenting views, without interruption, at an American Psychiatric Association conference in 2022. Charles Decl., Ex. B at 925:16-926:23, 927:10-17.

Second, Dr. Levine makes inaccurate statements about other countries' treatment protocols for gender dysphoria in youth to support his claim that "opinions

[7] Dr. Levine claims in his report that "Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with 'There are none. This is how it is done.'" Charles Decl. Ex. A at ¶68. But Dr. Levine fails to name these groups he works with, the people who attended the WPATH sessions, the dates, times and other identifying information about the alleged sessions, or the people who supposedly "quickly dismissed" questions. This assertion is mere conjecture, and methodologically unreliable. Not only is such "reliance on anecdotal evidence" a "red flag[] that caution[s] against certifying an expert," *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012), but the Court should not countenance Dr. Levine testifying "based on limited personal accounts and information relayed to [him] by an unspecified number of third parties," as doing so "would be to sanction [his] use as a vehicle for introducing hearsay testimony." *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 684183, at *2.

and practices vary widely with respect to puberty blockers and hormones" and as evidence that the WPATH SOC 8 are not authoritative. Charles Decl., Ex. A at ¶82. However, Dr. Levine admitted in his *Brandt* trial testimony that in Finland, gender affirming medical care is provided to adolescents with gender dysphoria when indicated under their guidelines. Charles Decl., Ex. B at 938:16-939:3. He also testified that France does not have a prohibition on minors receiving gender affirming medical care, nor does Canada. Charles Decl., Ex. B at 939:23-940:9, 944:2-5. And Dr. Levine conceded he does not know how the provision of gender affirming care for minors works in Sweden but agreed that the Swedish National Board of Health stated puberty blockers and cross sex hormones may be given in exceptional cases in accordance with their guidelines criteria. Charles Decl., Ex. B at 960:1-17, 961:11-962:1. Dr. Levine has admitted these facts when asked at deposition in *Fain*. Ex. C at 106:4-108:8. Dr. Levine also acknowledged that the United Kingdom's Cass Review, which is still underway and not final, begins from the premise that some youth experience gender dysphoria and will need clinical support and medical interventions and that such care is not prohibited in their health system. Charles Decl., Ex H; Ex. C at 191:20-192:16.

Dr. Levine's own testimony at trial and at deposition contradict the opinions offered by his expert report here, which underscores serious flaws in his methodology and demonstrates that his opinions about the WPATH SOC do not

meet the reliability burden under *Daubert* or related standards for admissibility of expert testimony.

2. Dr. Levine's Opinions That Gender-Affirming Medical Care Is Experimental, Is Provided Without Mental Health Assessments or Sufficiently Informed Consent and Is Without Lasting Benefit are Inaccurate and Unsupported.

Dr. Levine opines that gender-affirming medical care is experimental, is provided without mental health assessments or sufficiently informed consent and is without lasting benefit. Charles Decl., Ex. A at VIII, X, ¶73, ¶176. But Dr. Levine has, and continues to, write letters authorizing gender affirming medical care for his patients, including for hormone therapy for some patients under 18 and, going forward, would consider doing so on a case-by-case basis. Charles Decl., Ex. B at 897:1-898:18, 900:21-902:15, 902:25-903:6. The *Kadel* court cites to an opinion that Dr. Levine has identically asserted here: that it is impossible "to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues." Charles Decl., Ex. A at ¶61. As a result, the *Kadel* court observed, "Notably, Levine does not testify that medical or surgical care for gender dysphoria is categorically inappropriate." *Kadel*, 2022 WL 322673, at *15. And when asked if based on his publication from March 2022 "Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults," he claimed that "gender affirming medical care, specifically hormone therapy or

blockers or surgeries, should be categorically prohibited for minors," he replied "No, I don't." Charles Decl., Ex. B at 905:11-16. Dr. Levine is "not motivated to prohibit care." *Id*. at 906:11-14.

Dr. Levine asserts repeatedly that gender-affirming medical care is provided by doctors who encourage patients to identify as transgender and provide hormones without assessing patients and addressing other mental health conditions or without informing patients and their parents of the risks and limitations of the evidence regarding treatments. Charles Decl. Ex. A at ¶¶50, 64, 74, 83. As an initial matter, Dr. Levine admits in his report that he cannot confirm if any practitioners engage in this "affirmation care/therapy model" he describes. Charles Decl. Ex. A at ¶53. And he confirmed his lack of support for this assertion during his testimony in *Brandt*, when on cross-examination, he admitted that he does not know how common it is for doctors to provide care the way he described, which is contrary to WPATH SOC 8 and Endocrine Society clinical guideline, both of which require comprehensive psychological assessments prior to initiation of any medical treatment for adolescents. Charles Decl., Ex. B at 887:19-888:21, 890:24, 933:2-7; Charles Decl. Ex. I at 3870, 3876-3878; Charles Decl., Ex. J at S48-51.

Finally, the *Kadel* court also recognized that Dr. Levine's assertions that healthcare providers are prescribing treatment without due caution or informed consent were not admissible:

> Fourth, as discussed, it does not appear that he offers any categorical opinion as to the medical necessity of medical and surgical treatments of gender dysphoria, nor does he testify that healthcare providers are prescribing such treatment without due caution and informed consent beyond his anecdotal "experience." To the extent that Defendants seek to introduce testimony from Levine to that effect, he has not provided the Court with any data or methodology from which such claims could be made. Levine has conducted no research to identify which physicians are proceeding as he does, and which do not, rendering any broader opinion about the practice of such healthcare providers pure speculation.

Kadel, 2022 WL 322673, at *17. This is no less true here.

Dr. Levine's opinions that gender-affirming medical care is without lasting benefit also fail the reliability test because he ignores studies contrary to his personal belief or distorts studies' findings beyond the authors' explicit intentions, conclusion, or study design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. K at ¶55. A plethora of studies show that transgender people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine omits any reference to that evidence and instead suggests that "long-term life in a transgender identity, however, correlates with very high rates of completed suicide," and goes on to discuss four studies that reviewed the rate of suicide among transgender adults who received gender-affirming medical care. Charles Decl., Ex. A at ¶¶166-171. While Dr. Levine admits, as he must, that "None of the studies demonstrated the hormonal or surgical intervention *caused* [sic]

suicide," he goes on in the same paragraph to assert a different unsupported conclusion, that "what these studies demonstrate" is that transgender people "are in need of extensive psychological care they don't receive," and that "neither hormonal nor surgical transition and 'affirmation' resolve their underlying problems and put them on the path to a stable and healthy life." *Id.* at ¶172. This is unreliable methodology at its finest. First, none of the four studies purport to analyze the efficacy of "hormonal or surgical transition," or whether gender-affirming medical care "resolves underlying problems" or "puts [people] on a path to a stable and healthy life." As least one of the studies' authors, Cecilia Dhejne, has explicitly said as much, both in the study itself (it is not designed to "address whether sex reassignment is an effective treatment or not.") and in direct response to Dr. Levine's misuse of her work. Charles Decl., Ex. L at 2; Charles Decl., Ex. M at 65. Another major flaw in Dr. Levine's methodology is that three of the studies' control groups were comprised of the general Dutch population, not of other transgender people with gender dysphoria who did not receiving any gender-affirming medical care. In other words, it is comparing apples to oranges. But Dr. Levine has acknowledged that the Dhejne study does not lend the study to be used to draw any conclusions about the efficacy of gender-affirming care. Charles Decl., Ex. D at 156:7-11. Finally, Dr. Levine's description of the Hall et al. 2021 study obscures the study's actual rate of suicide for the cohort by, without explanation but presumably to

support his description of a "rather shocking result," focusing on the number of transgender women in the group who died by suicide, rather than the total number of deaths by suicide for the entire cohort—which was 3 out of 175 participants, or 1.7%. Charles Decl., Ex. A at ¶171.

Furthermore, as the *Kadel* court observed, Dr. Levine himself has conceded that:

> he does not know how often medical or surgical care helps alleviate symptoms of gender dysphoria and does not offer an opinion as to the portion of these procedures that are necessary and unnecessary. (*Id.* at 67:24–68:3 ("It is not our [clinic's] knowledge base to know who's going to do better and who's going to do worse and who is not going to have any difference at all with hormones or with surgery.").)

Kadel, 2022 WL 322673, at *15.

Ultimately, Dr. Levine fails to cite any literature or clinical experience of his own to support this opinion, and regardless, he has testified that studies like these should not prevent youth and adults with gender dysphoria from receiving gender affirming care. When asked recently if he believes that because a study showed that some people committed suicide *no patient* should be able to access gender-affirming surgery, Dr. Levine responded, "that would be illogical." Charles Decl., Ex. D at 151:25-152:6. And when asked if his concerns justify denying medical interventions to all people with gender dysphoria, he responded "I'm not advocating denying endocrine treatment or surgical treatment." *Id*. at 85:4-11.

At bottom, Dr. Levine's report and the opinions contained therein are wildly

inconsistent with his oral testimony, making both unreliable.

3. Dr. Levine's Opinions About Gender Dysphoria "Naturally Resolving" in Children and Adolescents Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that "the large majority" of *prepubertal* children diagnosed with gender dysphoria will, absent intervention, cease to be transgender (or "desist") through puberty. Charles Decl., Ex. A at ¶¶109-111, 113-114. Putting aside that Dr. Levine has almost no clinical experience with children during his 50-year career treating patients with gender dysphoria to support this opinion, it is unreliable and methodologically unsound for other reasons.

First, Dr. Levine has conceded that some children are and will continue to be transgender and that as they progress into adolescence and adulthood, they would need medical care that he has, and would, authorize. Charles Decl., Ex. D. at 173:7-15, 137:14-23, 173:22-174:5, 53:2-10. Second, as the scholarly basis for this opinion, Dr. Levine cites three articles that share the same core characteristic that reveals the methodological flaw in Dr. Levine's analysis: they rely on previous studies whose underlying data included gender non-conforming children who never identified as a sex different from their birth-assigned sex in the first place. In other words, they included children who were never transgender. That is because the diagnosis at the time these studies were conducted— "Gender Identity Disorder in

Children" —did not include a cross-gender identification or clinically significant distress requirement for the diagnosis. *See*, *e.g.*, Diagnostic Statistical Manuals ("DSM") III, III-R, IV, and IV-R. Under these outdated diagnostic criteria, most of the children diagnosed with "Gender Identity Disorder in Children" were not actually transgender but were gender non-conforming boys who grew up to be gay or bisexual. Because the years of initial visits in the study samples were from 1952-2008, none of these children were diagnosed under the current, and relevant to the case at hand, diagnostic criteria for "Gender Dysphoria in Children," in the DSM 5, published in 2013, which requires for diagnosis "a strong desire to be of the other gender or an insistence that one is the other sex" and "clinically significant distress or impairment in social, school, or other important areas of functioning."[8] Charles Decl., Ex. N at 452. Dr. Levine confirmed this fact as to these and others of the "11 studies," at his deposition in *Fain*. Charles Decl., Ex. C at 221:2-229:14. Therefore, the "desistance rates" from the studies upon which Dr. Levine bases his opinion reflect children who, while they exhibited gender non-conforming behaviors, were

[8] Based on Dr. Levine's failure to identify at deposition in *Kadel* any of the underlying "11 studies" upon which this opinion is based, the court found his methodology to be unreliable and therefore inadmissible: "Levine's testimony regarding desistance rates does not appear to be based on reliable methodology. During deposition, Levine was unable to recall many of the studies that purportedly support his conclusion. (ECF No. 213-3 at 191:20-192:14.)" *Kadel*, 2022 WL 322673, at *16.

not transgender, or suffering from gender dysphoria.

4. Dr. Levine's Assertion that "Rapid Onset Gender Dysphoria," as a Cause of Gender Dysphoria or the Concept of "Detransition" Justifies Denying Treatment to Florida Medicaid Beneficiaries Is Unsupported By Scientific Evidence.

A stark example of one of Dr. Levine's opinions failing to meet methodological reliability is the assertion that "rapid onset gender dysphoria" is a credible phenomenon caused by "social influences through friend groups or through the internet." Charles Decl., Ex. A at II(1)(f), ¶38, ¶96, ¶114. Dr. Levine admitted at the *Brandt* trial, just six months ago, that such a conclusion is based on speculation, not science. Ex. B at 797:8-19. Furthermore, "rapid onset gender dysphoria" ("ROGD") is a scientifically unsupported hypothesis and the only article Dr. Levine routinely cites or discusses regarding ROGD was withdrawn and republished with a significant correction. Dr. Levine testified at deposition in *Kadel* he had not read the correction. Charles Decl., Ex. D at 116:22-117:9. Had he done so, Dr. Levine would be forced to acknowledge the correction's explicit disclaimers that "rapid onset gender dysphoria is not a formal mental health diagnosis," "the report did not collect data from adolescents and young adults or clinicians and therefore does not validate the phenomenon," and "the use of the term, 'rapid onset gender dysphoria' should be used cautiously by clinicians and parents to describe youth." Charles Decl., Ex. O at 1. Despite this, at deposition in *Fain*, Dr. Levine attempted to conflate an

increased number of transgender young people presenting to clinics for care with the theory of "rapid onset gender dysphoria" and asserted, without evidence, it is not a hypothesis but "a fact," that he "assumes everyone understands [this] is true." Charles Decl. Ex. C at 151:18-152:6, 152:22-153:5. When pressed to provide peer-reviewed articles, sources, or studies as scientific support he referenced presentations without title or date, admitted he could not remember the names of "authors from Europe" but asserted it had been documented by "DiAngelo and Clayton in Australia." To date, the only peer-reviewed study that interrogates this hypothesis using adolescent clinical data "did not support the ROGD hypothesis." Charles Decl., Ex. P at 1.

Similarly, Dr. Levine's opinions that there is "a growing number of detransitioners [sic]," or that the number of detransitioners is "accelerating," are also methodologically unreliable, largely because he lacks any evidence to support this belief. Charles Decl., Ex. A at ¶120. The three papers he cites for support of this assertion, "Entwistle 2020, Littman 2021, and Vandenbussche 2021," are purely descriptive, not statistical, or quantitative studies. These, respectively, include a description of anecdotal experiences of "detransitioners," describe the results of "a survey of 100 detransitioners," and report on responses from an online survey about the needs and support for people who detransition. None of the three articles purports to establish that the rate of detransition is growing or accelerating, a fact

Dr. Levine admitted as to two of the studies at deposition in *Fain*. Charles Decl., Ex. C at 155:8-163:24. Indeed, Dr. Levine's own clinical experience is contrary to this assertion—in 50 years of seeing patients with gender dysphoria, he is aware of only two patients who detransitioned. Charles Decl., Ex. B at 920:25-921:5. Nevertheless, Dr. Levine doubles down in his expert rebuttal report, relying on a reference to a "detransition subreddit" with 16,000 members as evidence that "the assumption that [detransition] was a rare occurrence began to lose traction." Ex. Q at ¶30. When confronted about this so-called evidence at deposition in *Kadel*, Dr. Levine admitted he had no evidence that *even one* of the 16,000 members of the subreddit had actually "detransitioned." Charles Decl., Ex. D at 200:6-201:25. Unsurprisingly, the *Kadel* court found such testimony lacking:

> His anecdotal testimony concerning adults and adolescents who regret their transitions appears to be based on a misreading of an article that reviewed entries on the website Reddit. (See ECF No. 215-1 ¶¶ 35, 56, 98.) He admitted during deposition that the article referred to 16,000 entries—not 60,000, as he repeatedly stated in his report—and that he had no knowledge of the content of those entries or whether any of the authors actually de-transitioned or regret their transitions. (Id. at 196:3-7, 201:12-25).

Kadel, 2022 WL 3226731, at *16.

Similarly, when asked in *Fain* about his opinion that there is "evidence that *a growing number* of young people regret transition and wish to reverse it," Dr. Levine admitted he lacked any scientific support for such an opinion. Charles Decl., Ex. C at 158:8-159:2; 160:25-161:9; 163:9-24. Dr. Levine did not point to his own

experience as a basis for this opinion and conceded three times that the sources he cited in his report did not provide relevant evidence. *Id*.

Given that these hypotheses about "rapid onset gender dysphoria" and ideas about "detransition" are unverified or unsupported, Dr. Levine cannot claim the use of reliable methodology. His reliance on his own *ipse dixit* fails to establish a basis upon which to assert these opinions. Indeed, case law establishes that "broad opinions [that] are based solely on … generalized views, anecdotal accounts, and speculation … are not reliable." *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 684183, at *3 (N.D. Fla. Feb. 11, 2021). And that opinions "based on mere conjecture, assumption, credibility calls, and amounting to no more than ipse dixit" are "neither reliable nor helpful." *Day v. Edenfield*, 2022 WL 972430, at *10 (N.D. Fla. Mar. 31, 2022).

C. Dr. Levine Is Not Qualified To Offer Opinions About Puberty-Delaying Treatment or the Treatment of Prepubertal Children Generally.

Dr. Levine has repeatedly admitted, most recently at the *Brandt* trial six months ago, and at depositions for the last several years, that he has virtually no experience administering psychiatric treatment to prepubertal children and no experience performing research or publishing studies about them. Charles Decl., Ex. A at ¶5; Ex. B at 887:5-8; Ex. C at 26:10-13; Ex. D at 23:1-8. When asked whether he has treated any children with gender dysphoria, he admitted, "I have only on rare

occasion personally treated or directly or indirectly treated a child." Charles Decl. Ex. C at 28:23-29:6; 62:6-14. Dr. Levine also confirmed his testimony from March 30, 2022, that over the course of his nearly 50-year career, he had only seen an estimated six prepubertal children, and not for more than one visit. Charles Decl., Ex. B at 887:5-8; Ex. R at 87:1-7. When asked if he had helped to develop guidelines for the treatment of prepubertal children or adolescents with gender identity issues he responded "the answer is no." Charles Decl., Ex. C at 51:10-16. Dr. Levine is not recognized as an expert in providing treatment to prepubertal children by his private employer who by his own admission does not refer children to him as patients, nor by the University Hospitals' LGBTQ and Gender Care Program--the Cleveland hospital affiliated with Case Western Reserve University Medical School where Dr. Levine is a clinical professor—which he previously admitted did not consult with him as part of its formation or their ongoing work. Charles Decl., Ex. R at 113:19-114:4. Nor does he write or research about providing treatment to prepubertal children or deliver any psychiatric care to them in his day-to-day practice.[9]

While lacking a reliable methodology for his proposed opinions about the

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[9] Notably, the *Kadel* court held that "Levine's opinions on mental health approaches to social transition are irrelevant as well, as Defendants maintain that the Plan's exclusion of coverage for mental health treatments of gender dysphoria has never been given effect and is no longer part of the Plan. (*See* ECF Nos. 137 n.2; 137-4 ¶ 27.)" *Kadel,* 2022 WL 3226731, at *16. Dr. Levine has also testified that he has counseled some parents to support their minor child's social transition. Charles Decl., Ex. B at 896:23-25.

treatment of prepubertal children, Dr. Levine does not hesitate to offer his personal beliefs about their care. Dr. Levine would "consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist." Charles Decl., Ex. D at 186:20-25. But Dr. Levine acknowledges the unscientific nature of this opinion, admitting he does not know where it comes from or "to what extent it's from my politics, or from my being a parent or a doctor, I don't know." Charles Decl., Ex. D at 187:20-24.

In short, given his proposed testimony and experience, Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of prepubertal children, and he cannot use his personal beliefs as reliable evidence. Nor is any of this testimony relevant. This case concerns coverage of gender-affirming medical care, and no clinical practice guideline recommends the provision of medical treatments, like puberty delaying medications or hormones, until after the onset of puberty.[10]

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

Finally, the Court should exclude Dr. Levine's opinions because their

[10] The *Kadel* court also found that Dr. Levine's criticism of medical or surgical treatment of gender dysphoria in prepubescent children was not relevant because "Plaintiffs conceded that such treatments are not medically necessary until the onset of puberty. *See* Section II.B, *supra*." *Kadel*, 2022 WL 322673, at *16.

introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Most of Dr. Levine's opinions are unreliable and unhelpful. 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 treatment they have been undergoing for years—issues unrelated to whether the Florida Medicaid Program can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request the Court grant the instant motion and limit Dr. Levine's opinions and testimony, at a minimum, to his opinions (1) identifying risks associated with prescribing medication and surgery to adolescents, and (2) criticizing the quality of the research on treatments for gender dysphoria and that Dr. Levine's report, opinions, and his testimony be otherwise excluded in full.

Dated this 7th day of April 2023.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of April 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Carl S. Charles
Carl S. Charles
Counsel for Plaintiffs

CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Memorandum contains 7,636 words.

/s/ Carl S. Charles
Carl S. Charles
Counsel for Plaintiffs