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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. KRISTOPHER KALIEBE

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Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Kristopher Kaliebe.¹

INTRODUCTION AND STATEMENT OF THE CASE

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. Kristopher Kaliebe, a child and adolescent psychiatrist, who has no experience regarding the treatment of gender dysphoria, nor has ever studied or written any literature—alone scientific, peer-reviewed literature—on gender identity or gender dysphoria. However, Dr. Kaliebe is not a qualified expert on gender dysphoria or its treatment, and his

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

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opinions and testimony are neither relevant nor reliable, under Federal Rule of Evidence 702 and the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny.

Accordingly, and for the reasons set forth below, the Court should exclude the expert report, opinions, and testimony of Dr. Kaliebe. At minimum, based on Dr. Kaliebe's lack of qualifications and the unreliability and unhelpfulness of his testimony and opinions, the Court should exclude any portions of the expert report, opinions, and testimony of Dr. Kaliebe that go beyond his experience regarding the diagnosis—not treatment—of gender dysphoria in children and adolescents.

LEGAL STANDARD

"The admission of expert evidence is governed by Federal Rule of Evidence 702, as explained by *Daubert* 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, 387 F.3d at 1260 (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). The Eleventh Circuit refers to these three considerations separately as "qualification," "reliability," and "helpfulness" and has emphasized they are "distinct concepts that courts and 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). "Rule 702 applies whether the trier of fact is a judge or a jury." *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832 (3d Cir. 2020). Even rigorous cross-examination is not a substitute for the court's gatekeeping role. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017). As such, 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*, 400 F.3d at 1294 (finding no abuse of discretion by the district court in 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) (granting motions to exclude in the context of summary judgment); *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").

Finally, because of the potentially misleading effect of expert evidence, *see Daubert*, 509 U.S. at 595, on occasion expert opinions that otherwise meet admissibility requirements may still be excluded under Fed. R. Evid. 403.

ARGUMENT

I. Qualification – Dr. Kaliebe is not qualified to offer expert opinions on the treatment or causes of gender dysphoria, nor on the development of clinical practice guidelines.

An expert witness may be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "Determining whether a witness is qualified to testify as an expert requires the trial court to examine the credentials of the proposed expert in light of the subject matter of the proposed testimony." *Banuchi v. City of Homestead*, 606 F.Supp.3d 1262, 1272 (S.D. Fla. 2022) (cleaned up). "Whether [an expert] is qualified is a threshold question, and vigorous cross-examination is no substitute." *Griffin v. Coffee Cnty.*, 608 F.Supp.3d 1363, 1373 (S.D. Ga. 2022),

objections overruled, 2022 WL 2805037 (S.D. Ga. July 18, 2022). If not qualified, the expert's testimony is unreliable. *See Reliastar Life Ins. Co. v. Laschkewitsch*, 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.*, 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.*, 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) ("Expertise in one field does not qualify a witness to testify about others."). "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.

This is particularly true in medicine where "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). For example, a clinical psychologist may not be necessarily qualified to testify about stress worsening a preexisting heart condition, and a pediatrician experienced as a children's accident preventionist may not be qualified to testify to the conduct of an adult driver. See Diviero v. Uniroyal Goodrich Tire Co., 919 F.Supp. 1353, 1355–56 (D. Ariz. 1996) (citing Kloepfer v. Honda Motor Co., 898 F.2d 1452, 1458–59 (10th Cir. 1990), and Edmonds v. Illinois Central Gulf Railroad, 910 F.2d 1284, 1287 (5th Cir. 1990), as examples).

Here, Dr. Kaliebe opines that: gender dysphoria has been rare until the last two decades; there is no consensus in the field regarding the treatment of gender dysphoria, nor is there an evidence-base sufficient to lead to any confident recommendations; the evidence for affirmative treatment is low-quality; spread of ideology combined with technologically induced contagion effects leading the recent increase in gender dysphoria; and on criticisms of medical associations as well as political criticisms. Ex. A, at \P 4. But Dr. Kaliebe, a child and adolescent psychiatrist, is not qualified to render most, if any, of the opinions he proffers.

Dr. Kaliebe (1) has never conducted any original, peer-reviewed research about gender identity, transgender people, or gender dysphoria, Ex. B, at 43:17-44:1; (2) has not published any literature, let alone scientific, peer-reviewed literature, on gender dysphoria or transgender people, Ex. B, at 25:5-14; (3) has never treated a patient for gender dysphoria, Ex. B, at 33:18-21 ("So you wouldn't be providing treatment for the dysphoria at Silver Clinic? A. I think we would not be directly addressing gender dysphoria in psychotherapy."); *id.* at 33:15-16 ("A. ... I don't know that we would say we were giving therapy for gender dysphoria"); *id.* at 138:24-139:1 ("Q. You do not provide medical treatment for gender dysphoria; is that right? A. Medicines, correct.");² and (4) is not an endocrinologist, pediatrician, adolescent medicine doctor, surgeon, or other kind of physician qualified to medically treat gender dysphoria. Ex. B, at 44:2-8; Curriculum vitae attached to Ex. A.

Given the above, the district court's decision in *Kadel*, 2022 WL 3226731, at **5-17, is most instructive here. Like other experts in *Kadel*, Dr. Kaliebe "has never … treated gender dysphoria, … conducted any original research about gender dysphoria diagnosis or its causes, or published any *scientific*, *peer-reviewed*

² At most, Dr. Kaliebe can claim that he has supervised psychiatric residents (Ex. B, at 29:9-10) in overseeing the care of twelve (12) patients with gender dysphoria (Ex. B, at 28:15-20) for "comorbidities," like "depression or anxiety or trauma or personality disorders or whatever," by "trying to provide them skills and sort of basic coping mechanisms, self-regulation, all the standard things you provide to someone who has emotional dysregulation or behavioral problems or, you know, emotional problems, standard care." Ex. B, at 33:21-34:5. But as Dr. Kaliebe has acknowledged, "[p]roviding treatment for comorbidities doesn't necessarily address a patient's gender dysphoria." Ex. B, 35:10-16.

literature on gender dysphoria." Kadel, 2022 WL 3226731, at *9 (emphasis added). Dr. Kaliebe "is not an endocrinologist, nor has he ever treated a patient with hormone therapies." Id. at at *13; Ex. B, at 32:15-17 ("A. ... nor are we involved with providing hormones or those type of things."); id. at 138:24-139:4. In fact, Dr. Kaliebe had to consult his wife, an adult endocrinologist, ahead of his deposition in order to familiarize with the effects of puberty-delaying medications and hormone therapy. Ex. B, at 12:24-13:11, 139:5-8. Thus, Dr. Kaliebe "is not qualified to render opinions about ... the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for ... endocrinologists." Kadel, 2022 WL 3226731, at *13. Additionally, Dr. Kaliebe "is not a surgeon and has no experience with surgery for gender dysphoria and, therefore, is not qualified to testify to the risks associated with surgery or the standard of care used by surgeons for obtaining informed consent for surgery." Id. at *9.

Moreover, Dr. Kaliebe is not qualified to opine on the diagnosis and treatment of gender dysphoria in adults. During his deposition, Dr. Kaliebe acknowledged that he "definitely ha[s] more expertise and more experience in child psychiatry" and that "would be more where I'm comfortable." Ex. B, at 44:16-17, 45:1. While Dr. Kaliebe "was asked to review and opine generally," he "did [his] best to try to catch up on adult literature and know more about adult issues." Ex. B, at 44:21-22. But that is not enough. *See* Ex. B, at 86:1-2 ("And I will admit that I know less about and am less up to date everything about adult transgender care.").

Dr. Kaliebe "is also not qualified to opine on the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria." *Kadel*, 2022 WL 3226731, at *13; *see*, *e.g.*, Ex. A, at ¶¶ 47, 163, 164. "He is not a statistician or epidemiologist, and there is no evidence in his report or deposition that he has any experience, specialized training, or knowledge about crafting a research study, analyzing data, or conducting a clinical trial." *Id.* A psychiatrist "with little to no research experience is not qualified to opine on the veracity of statistical studies." *Id.*

In large part, Dr. Kaliebe bases his opinions on his review of other people's scholarship—in fact, on non-primary sources, those being non-peer reviewed reports about the scientific literature. But "[m]erely reading literature in a scientific field does not qualify a witness—even an educated witness—as an expert." *Kadel*, 2022 WL 3226731, at *9; *see also Dura Auto. Sys. of Ind., 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."). Indeed, this 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.

Nor can Dr. Kaliebe claim to be qualified based on his conversations with the twelve (12) transgender minor patients, to whom he has provided no treatment for gender dysphoria and only supervised others' psychotherapeutic care of the patients. Such "reliance on anecdotal evidence" is a "red flag[] that caution[s] against certifying an expert." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012).

Moreover, Dr. Kaliebe, who opines at length about the development of clinical practice guidelines by WPATH and the Endocrine Society (*see*, *e.g.*, Ex. A, at ¶¶ 62-63; Ex. C, at ¶¶ 19-26, 31-33), admits he is not an expert on the development of clinical practice guidelines. Ex. B, at 101:3-10; *see Solaia Tech. LLC v. ArvinMeritor, Inc.*, 361 F.Supp.2d 797, 813–14 (N.D. Ill. 2005) (finding expert was not qualified "to testify about areas in which he has admitted he has no expertise"); *accord Lifewise Master Funding v. Telebank*, 374 F.3d 917, 928 (10th Cir. 2004) (affirming trial court's ruling that purported expert could not testify where the court noted, inter alia, that witness admitted that he was not expert in areas pertinent to damages modeling). And Dr. Kaliebe does not profess any training or experience on the development of clinical practice guidelines.

The Court should find that Dr. Kaliebe is not qualified to testify about gender dysphoria and its treatment, the conduct and efficacy of scientific studies and the weighing of these, and the promulgation of clinical practice guidelines. At most, based on his purported experience diagnosing twelve (12) patients with gender dysphoria over his career, Dr. Kaliebe could testify to the diagnosis of gender dysphoria in children and adolescents.

II. Reliability – Dr. Kaliebe's opinions and testimony are unreliable.

An expert's testimony should only be admitted if it is sufficiently reliable. 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). "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). It must be based on "good grounds," *Daubert*, 509 U.S. at 590, and cannot be based on "leaps of faith." *Rider*, 295 F.3d at 1202.

Thus, when determining the reliability of proposed expert testimony, courts "consider, to the extent possible: (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4)

whether the technique is generally accepted in the scientific community." *Quiet Tech.*, 326 F.3d at 1341. Other factors which 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. *See Hendrix v. Evenflo Co., Inc.*, 255 F.R.D. 568, 578-79 (N.D. Fla. 2009), *aff'd sub nom. Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183 (11th Cir. 2010).

"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." *Id.* at 578. 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. Kaliebe's report, testimony, and opinions fail all indicia of reliability. Dr. Kaliebe's proffered opinions are based on nothing more than speculation, "untested" theories, uncorroborated anecdotes, and assumptions that are obsolete, flawed, unethical, or expressed opinions based upon "unsettled science." What is more, some of his opinions are patently false. A. <u>Dr. Kaliebe's opinions are unreliable because they are based on</u> <u>unsupported premises, untested hypotheses, and speculation.</u>

"While 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. "Where an expert's opinion testimony is founded on an unsupported premise, it gives rise to an inference that is based on speculation and has no evidentiary value." *Walker v. Blitz USA, Inc.*, 663 F.Supp.2d 1344, 1364 (N.D. Ga. 2009).

Here, several of Dr. Kaliebe's opinions are based on speculation, unsupported premises, or mere guesswork. Take the following examples:

One. Dr. Kaliebe opines that "Significant evidence points to a spread of ideology combined with technologically induced contagion effects leading the recent increase in gender dysphoria." Ex. A, at \P 4(e); *id.* at $\P\P$ 30, 39-41. But Dr.

Kaliebe admits there is no evidence to support this opinion,³ rather, in his words, "We are all *hypothesizing*, obviously." Ex. B, at 58:23-59:3 (emphasis added).⁴

Two. Dr. Kaliebe repeatedly opines about a purported failure of the scientific and medical community to study what he calls "body affirmation" as a psychotherapeutic approach to treatment. Ex. A, at ¶ 66(a) ("SOC 8 makes no analysis of privileging gender affirmation over body affirmation."); Ex. C, at ¶ 12 ("Body positivity and body acceptance are laudable goals and should be compared against the use of hormones and surgeries in order to determine which is a more effective and humane treatment."), *id.* at \P 13 ("Further research may well find psychotherapies or mind-body approaches with better results than gender affirmation through hormones and surgery."). However, Dr. Kaliebe cites no literature—none—in support this hypothetical treatment modality he repeatedly proposes. In fact, he concedes there is no literature at all to support this hypothetical approach to therapy. Ex. B, at 111:20-21; Ex. C, at ¶ 13. In other words, it is a hypothesis built upon unsupported premises.

³ For example, the literature to which Dr. Kaliebe cites to support his opinion does not relate to gender dysphoria, Ex. B, at 58:8-11, and the Littman article to which he cites "actually doesn't reach any conclusions as to social contagions," but rather "at best ... raises hypotheses," Ex. B, at 71:15-18.

⁴ To the extent Dr. Kaliebe points to two unscientific polls of the attendees to two conference panel sessions and a single personal anecdote, such evidence has no indicia of reliability. *See* Section II.C, *infra*.

Upon questioning, Dr. Kaliebe clarified that what he refers to as "body affirmation" has nothing to do with treating gender dysphoria or resolving a person's incongruence. At his deposition, Dr. Kaliebe explained that what he terms "body affirmation" "is purely about [a person] being comfortable with their body," such that "somebody that identifies as female" would be "completely comfortable with their stereotypically male body, notwithstanding that they identify as female." Ex. B, at 111:11-17. However, upon questioning Dr. Kaliebe admits that "part of somebody's gender dysphoria [is] the distress associated with that incongruence due in part to how they are perceived by others in the world." Ex. B, at 113:1-5. It is thus unclear how his hypothetical approach would treat gender dysphoria.

Indeed, Dr. Kaliebe posits that "if we could help people become more comfortable in the body that they are in, you know, perhaps, that would mean that they could be somewhat more comfortable and *maybe the gender dysphoria never goes away*, but we might be able to help them with their depression or anxiety or self-harm or other things." Ex. B, at 113:6-11 (emphasis added). But again, Dr. Kaliebe cites to nothing in support of this hypothetical, and until now unheard of, approach to treating gender dysphoria.

Three. Dr. Kaliebe repeatedly makes broad assertions that "in private, but not in public, most psychiatrists will acknowledge their doubts regarding affirmative care," Ex. A, at ¶ 123; "[m]ost psychiatrists are willing to admit we don't have

enough research to really know how to proceed," *id.*; and "[m]ost physicians have doubts about a gender medicine," Ex. C, at ¶ 36. However, Dr. Kaliebe fails to cite to any study, literature, or evidence in support of such broad assertions in every instance in which he makes them. Instead, Dr. Kaliebe bases these opinions on a few conversations he has had and then extrapolates them to the population of physicians and psychiatrists at large. *See*, *e.g.*, Ex. B, at 60:17-61:6, 63:19-64:4, 127:8-10, 146:10-25. But when Dr. Kaliebe's opinions are based on a select few anecdotes, it is a circumstance where "there is simply too great an analytical gap between the data and the opinion proffered," such that the expert testimony must be excluded. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997).

Four. Dr. Kaliebe suggests that cognitive behavioral therapy (CBT) or yoga could be effective modes of psychotherapy for gender dysphoria. Ex. A, at ¶¶ 136, 142. But he admits he does not know if CBT could be effective to treat gender dysphoria (it cannot), because according to him it has not been studied. Ex. B, 152:7-22. Likewise, Dr. Kaliebe admits there are no studies on yoga as treatment of any mental health conditions, let alone gender dysphoria. Ex. B, at 164:21-165:9, 166:5-11. Such speculative opinions are wholly unreliable.

Similarly, Dr. Kaliebe suggests that "more specific and nuanced approaches for gender dysphoria exist," such as gender exploratory therapy. Ex. A, at \P 137 (citing to https://genderexploratory.com/). However, not only does he not cite to any

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literature in support for this modality of treatment, but he admits that there is no evidence that gender exploratory therapy is safe or effective. Ex. B, at 159:2-4. Again, his opinion about gender exploratory therapy is speculative, at best.⁵

Five. Dr. Kaliebe opines in his rebuttal report that "[i]n childhood, most gender dysphoria spontaneously resolves without treatment." Ex. C, at \P 16. He provides no citation or evidence for this opinion, making it an unsupported premise that should be excluded as unreliable.

Six. Dr. Kaliebe opines that "it is clear the SOC 8 guidelines are at odds with the stated policies of most countries." Ex. C, at \P 6. He provides no citation or support for this extremely broad statement. What is more, he concedes he has no awareness "of which countries have adopted SOC 8." *Id.* The Court should reject this wholly unsupported opinion as unreliable.

Seven. Dr. Kaliebe's opinions about the innerworkings of WPATH or the motivations and opinions of its membership is wholly speculative and unreliable. See, e.g., Ex. C, at $\P\P$ 3-4. The same holds true for his criticisms of the Endocrine

⁵ "Whereas gender-affirmative approaches follow the client's lead when it comes to gender, gender-exploratory therapy discourages gender affirmation in favor of exploring through talk therapy the potential pathological roots of youths' trans identities or gender dysphoria." Ex. D, at 472. "The surge of gender-exploratory therapy coincides with ongoing attempts to criminalize gender-affirming care for trans youths, sometimes masquerading as a compromise between gender-affirmative care and conversion practices and at other times functioning as the intellectual arm of political movements calling for the criminalization of gender-affirming care." *Id.* at 473.

Society. *E.g.*, Ex. A, at ¶ 105 ("While I have little direct experience with the Endocrine Society, my assessment is that many endocrinologists, and perhaps most, also believe their professional organization is also too strongly influenced by activist physicians."). Dr. Kaliebe has no experience with these organizations upon which to base his criticisms. "He is therefore not qualified to testify about the credibility of those organizations." *Kadel*, 2022 WL 3226731, at *10. Indeed, Dr. Kaliebe can "not offer[] any reliable testimony on this subject that will help the trier of fact." *Id.*

* * *

Dr. Kaliebe 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). Indeed, much of Dr. Kaliebe's testimony and opinions "appears to be based more on supposition than science." *O'Neill v. Windshire-Copeland Assocs.*, 372 F.3d 281, 285 (4th Cir. 2004). And opinions based on "subjective belief or unsupported speculation" should be rejected. *Daubert*, 509 U.S. at 589-590.

B. <u>Dr. Kaliebe's opinions are unreliable because they are misleading, employ</u> flawed methodologies, and do not serve to enlighten the trier of fact.

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

One. Dr. Kaliebe spends much ink criticizing the development of the WPATH Standards of Care, Version 7 and Version 8. Dr. Kaliebe does so by quoting

and repeating criticisms made by others. *See*, *e.g.*, Ex. A, at $\P\P$ 62-63; Ex. C, at $\P\P$ 19-26, 31-33. But these criticisms are unreliable for, at least, two independent reasons.

First, Dr. Kaliebe admits that he is not an expert in the development of clinical practice guidelines. Ex. B, at 101:3-10. And an expert, "however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Auto. Sys.*, 285 F.3d at 614. Indeed, because Dr. Kaliebe is not qualified "to testify about areas in which he has admitted he has no expertise," such testimony is unreliable. *Solaia Tech.*, 361 F.Supp.2d at 813–14.

Second, while an expert may properly rely on the opinion of another expert, an expert cannot simply repeat or adopt the findings of other experts without investigating them. *See In re Polypropylene Carpet Antitrust Litig.*, 93 F.Supp.2d 1348, 1357 (N.D. Ga. 2000) (citing *In re TMI Litig.*, 193 F.3d 613, 715–16 (3d Cir. 1999) (finding blind reliance by expert on other expert opinions demonstrates flawed methodology under *Daubert*); *TK–7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732– 33 (10th Cir. 1993) (excluding expert opinion relying on another expert's report because witness failed to demonstrate a basis for concluding report was reliable and showed no familiarity with methods and reasons underlying the hearsay report)).

Two. Dr. Kaliebe opines throughout his reports on the efficacy of genderaffirming medical treatment. However, Dr. Kaliebe does not discuss any single original, peer-reviewed study in detail and in fact, only cites four original studies in the references for his original report. *See* Ex. B, at 88:2-22; Ex. A, at 69-75. Specifically, he cites to four studies Branstrom, et al. (2020), Chen, et al. (2023), Dhejne, et al. (2011), and Kaltiala, et al. (2020). However, the universe of original peer-review research looking into the safety and effectiveness of gender-affirming medical treatments is orders of magnitude larger.

For example, a systematic literature review of peer-reviewed studies published in English between 1991 and 2017 looked at 56 original peer-reviewed studies into whether gender transition, including medical treatments such as hormone therapy and surgeries, improves the overall well-being of transgender adults. *See* Exs. E and F.⁶ Similarly, a review from 1998 looked at data from 80 studies spanning 30 years. Ex. G (Expert Report of Johanna Olson-Kennedy, M.D., M.S.), at ¶ 44. In other words, *a meta-analysis review from 25 years looked at 20 times the number of studies that Dr. Kaliebe reviewed for his report*. There is likewise a multitude of original peer-reviewed studies looking into the effect of gender-affirming medical treatment on the mental health and well-being of transgender adolescents with gender dysphoria. *See, e.g.*, Ex. G, at ¶¶ 25-30, 33-39,

⁶ Though not relevant for purposes of this Motion to Exclude, it is worth noting that this systematic literature review "found a robust international consensus in the peer-reviewed literature that gender transition, including medical treatments such as hormone therapy and surgeries, improves the overall well-being of transgender individuals." Ex. E.

46 (discussing over 13 original peer-reviewed studies looking specifically at transgender adolescents); Ex. H (Expert Report of Daniel Shumer), at ¶¶ 82, 86 (discussing over 15 original peer-reviewed studies looking specifically at transgender adolescents); Ex. I (discussing 16 original peer-reviewed studies examining the impacts of gender-affirming medical care for transgender adolescents).

Plaintiffs do not point to the aforementioned vast expanse of scientific literature to argue the merits of Dr. Kaliebe's opinions (as wrong as they are), but to illustrate the lack of reliability of Dr. Kaliebe's opinions based on his methodology (or lack thereof). Dr. Kaliebe is unfamiliar with and does not reference—let alone, discuss—the original peer-reviewed studies that he criticizes. Rather, Dr. Kaliebe parrots the criticisms of others. His references are primarily opinion pieces and literature reviews by others, not original peer-reviewed studies. *See generally* Ex. A, at 69-75. But Dr. Kaliebe cannot serve as a mouthpiece for others. His criticisms of the scientific evidence supporting gender-affirming medical care must be based on his own review of that evidence. The fact that Dr. Kaliebe is unfamiliar with the expansive universe of literature at issue here demonstrates the lack of reliability for his opinions about the effectiveness of gender-affirming medical care.

Three. Dr. Kaliebe disputes that gender identity has a biological basis. He cites to an article by Marianowicz-Szczygiel (2022) outlining an apparent rise of

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people presenting to gender clinics and an article by Littman (2018) discussing the perceptions of the non-affirming parents of transgender adolescents. Ex. C, at ¶ 10. But neither article disputes there is a biological basis for gender identity. For example, Dr. Kaliebe conceded that "the fact that more people have been showing up at clinics could be explained by the fact that, A, the care is more available; and, B, more people feel comfortable seeking the care." Ex. B, at 54:5-10. And Dr. Kaliebe conceded that the Littman article, given its multiple limitations, could not reach any conclusions regarding social contagion and, at most, raised hypotheses. Ex. B, at 71:16-18. What is more, scientific, peer-reviewed literature that Dr. Kaliebe has encountered shows the opposite, namely, that "there is empirical evidence that there is a biological basis for a person's gender identity." Ex. J; *see also* Ex. B, at 150:17 ("A. I've seen it cited.").

Dr. Kaliebe's opinions about whether there is a biological basis for gender identity are unreliable because (a) he employed a flawed methodology that omitted discussion of existing, on point peer-reviewed scientific literature, and (b) his opinions are based on unproven hypotheses and not any data. 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

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here where Dr. Kaliebe omits key information, or worse, misrepresents facts that if properly disclosed would contradict his opinions and undermine their foundation.

* * *

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. Kaliebe has employed flawed methodologies and misrepresented or omitted information that goes to the heart of his opinions, all of which calls into question the reliability of his opinions. In such circumstances, the "potential to mislead" rather "than to enlighten" is too great. *In re Lipitor*, 892 F.3d at 632.

C. <u>Dr. Kaliebe's opinions are unreliable because they are based on facts or</u> <u>data not typically relied on by physician or scientists.</u>

Rule 703 requires that "[t]he facts or data ... upon which an expert bases an opinion or inference" must be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed. R. Evid. 703.

One. Based on his alleged "review of the research," Dr. Kaliebe opines "that the evidence base for gender dysphoria treatment is mixed and generally low quality." Ex. A, at ¶ 45. However, Dr. Kaliebe bases his opinions on his review of reports of government entities in Finland, Sweden, and the United Kingdom, as well as the GAPMS Report. Ex. B, at 86:25-87:8. But, as Dr. Kaliebe acknowledges, none of those are published, peer-reviewed literature. *Id.*; *see also* Ex. B, at 99:17-25. And

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such unpublished, non-peer-reviewed reports *are not* the types of materials reasonably relied upon by experts in any field of medicine. When asked what actual peer-reviewed, original studies he reviewed, he could not identify any and his original report cites to only four (4) original studies (none of which relate to the provision of puberty-delaying medications as treatment for an adolescent's gender dysphoria). Ex. B, at 86:21-88:22.

Two. As noted above, Dr. Kaliebe *hypothesizes* that "direct social influences and online and social media contagion" are "major contributors" to a rise in gender dysphoria. *E.g.*, Ex. A, at ¶ 30; *see also id.* at ¶¶ 40, 41. However, he points to no *reliable* evidence to support his *hypothesis* (which itself is an unreliable basis for an expert opinion, *see* Section II.A, *supra*). For example, Dr. Kaliebe points to a single case anecdote in support for his hypothesis. Ex. B, 59:13-16. But such "anecdotal information ... is scientifically unreliable and not supported by any ... scientifically reliable studies." *Soldo v. Sandoz Pharms. Corp.*, 244 F.Supp.2d 434, 571 (W.D. Pa. 2003);⁷ *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252, 1253-54 (11th Cir. 2005).

In addition, Dr. Kaliebe relies on two non-published, non-peer-reviewed, unscientific polls of the attendees of two conference panel sessions to support his

⁷ In *Soldo*, the excluded expert's testimony was based on anecdotal evidence contained *in published case reports*. Here, Dr. Kaliebe has not even attempted to publish his anecdotal evidence as a case report.

opinion that "Psychiatrists also believe social media has significantly contributed to the rise in gender dysphoria." Ex. A, at ¶ 41; *see also id.* at ¶¶ 42-43. Dr. Kaliebe admits that he did not do any regression or statistical significance analysis regarding these polls, Ex. B, at 66:15-19, and that all the polls tell us "is the views of the attendees of that particular seminar." Ex. B, at 67:1-4. Indeed, there are about 45,000 psychiatrists in the United States, Ex. B, at 63:15-18, and as Dr. Kaliebe admits his "conversations are not a representative sample of all childhood adolescent psychiatrists." Ex. B, at 64:8-11.

Dr. Kaliebe also cites as a support a *press release* from the French Academies, Ex. A, at ¶ 40, but admits that "a press release is not peer-reviewed or scientific literature." Ex. B, at 68:7-13.

Of course, it should be noted that, as Dr. Kaliebe admits, "it is not shocking that teens find like-minded teens online and they speak to each other about their similar experiences," and "that, in particular, small populations that tend to be isolated and/or discrete tend to turn to social media actually as a way to connect and find one another." Ex. B, at 67:21-68:6.

In sum, none of the sources upon which Dr. Kaliebe relies for his opinions are of reliable or of the type upon which any serious physician or scientist would rely on.

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Three. Dr. Kaliebe also spends much ink discussing the apparent politicized nature of conversations surrounding the treatment of gender dysphoria and hypothesizes that such politicization and moralization has led to the silencing of contrary views. See, e.g., Ex. A, at ¶¶ 71-89 (discussing apparent "lack of consensus"); id. at ¶¶ 90-124 (discussing "breakdown in scholarly dialogue"). Dr. Kaliebe bases these opinions on conjecture and anecdotes he has purportedly collected based on a few conversations. However, neither of these are the type of "facts or data" other experts in psychiatry or medicine "would reasonably rely on ... in forming an opinion in the subject." Fed. R. Evid. 703. Indeed, "broad opinions [that] are based solely on ... generalized views, anecdotal accounts, and speculation ... are not reliable." In re 3M, 2021 WL 684183, at *3 (N.D. Fla. Feb. 11, 2021). Similarly, 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).

What is more, in some instances, some of these opinions are demonstrably false. For example, Dr. Kaliebe states that "skeptical voices have been difficult to find within any of the journals of the Endocrine Society, American Academy of Pediatrics, American Psychiatric Association or American Academy of Child and Adolescent Psychiatry" and that he "ha[s] not found a single skeptical or even ideologically balanced article in any of these journals." Ex. A, at ¶ 82. But

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notwithstanding that Dr Kaliebe was aware of two letters to the editor published in the *Journal of the Endocrine Society* that were critical of gender-affirming medical care, he still made the false statement.⁸ *See* Ex. B, at 131:15-132:13.

In sum, none of Dr. Kaliebe's "opinions" about the politicized nature of the debate surrounding transgender issues and the treatment of gender dysphoria are medical or scientific opinions. They do not require "the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Frazier*, 387 F.3d at 1260. To the contrary, they are at best personal opinions and gripes with those with whom he disagrees. They are both unreliable and irrelevant, and at times, outright false. Allowing Dr. Kaliebe to testify "based on limited personal accounts and information relayed to [him] by an unspecified number of third parties would be to sanction [his] use as a vehicle for introducing hearsay testimony." *In re 3M*, 2021 WL 684183, at *2.

* * *

Dr. Kaliebe's opinions are thus "unsupported by reliable principles and methods and lack[s] hallmarks of scientific rigor: peer-reviewed research, studies, or experiments in support of his opinions." *United States v. Geanakos*, 2017 WL 4883294, at *3 (E.D. Cal. Oct. 30, 2017).

⁸ To be sure, neither of these two letters were based on original research or were peer-reviewed.

D. Dr. Kaliebe'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. Kaliebe's opinions are outside the mainstream of medical and scientific opinion and have been explicitly rejected by these relevant communities.

The provision of gender-affirming medical 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; and the National Academies of Science, Engineering, and Medicine. *See* Ex. K at 361.

In fact, 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*, 551 F.Supp.3d 882 (E.D. Ark. 2021), *aff'd*, 47 F.4th 661 (8th Cir. 2022). 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 891 (emphasis added). The *Brandt* court's findings stand as a stark repudiation of Dr. Kaliebe's opinion that the provision of gender-affirming medical care to adolescents with gender dysphoria is an "experiment," for which "there is clearly no consensus of opinion." Ex. A, at ¶¶ 11, 21-22.

* * *

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

III. Helpfulness – Dr. Kaliebe's opinions and testimony are not relevant to this case.

Helpfulness "goes primarily to relevance." *Daubert*, 509 U.S. at 580; *see also Prosper v. Martin*, 989 F.3d 1242, 1249 (11th Cir. 2021) ("The touchstone of this inquiry is the concept of relevance."). Under the helpfulness prong, the "court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 282 (4th Cir. 2021) (cleaned up). 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). Thus, "expert testimony which does not relate to any issue in the case is not relevant and nonhelpful." 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. *Simmons v. Augusta Aviation, Inc.*, 596 F.Supp.3d 1363, 1374 (S.D. Ga. 2022) "To satisfy this requirement, the testimony must concern matters beyond the understanding of the average lay person and logically advance a material aspect of the proponent's case." *Id.* Testimony that "offers nothing more than what lawyers for the parties can argue in closing arguments" or that consists of "subjective portrayals of factual information" "generally will not help the trier of fact." *Giusto v. Int'l Paper Co.*, 2021 WL 3603374, at *4 (N.D. Ga. Aug. 13, 2021).

This case is about whether Defendants' exclusion of coverage for medical treatments for gender dysphoria violates Plaintiffs' rights under the equal protection clause, Section 1557 of the Affordable Care Act, and the Medicaid Act. Dr. Kaliebe'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. 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. Kaliebe's opinions about "desistance" are irrelevant.

Dr. Kaliebe's opinion that "[i]n childhood, most gender dysphoria spontaneously resolves without treatment" is wholly irrelevant. Ex. C, ¶ 16. But no

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medical or surgical treatment is recommended or provided to *prepubertal* children. And this case is about the coverage for medical treatment for gender dysphoria. Dr. Kaliebe's (unsupported) opinions about "spontaneous desistance" are thus irrelevant to this case.⁹

B. <u>Dr. Kaliebe's opinions about supposed controversies in other countries</u> <u>are irrelevant.</u>

Likewise, Dr. Kaliebe's opinions about "controversies" regarding the provision of medical treatment for gender dysphoria in other countries, such as Finland, Sweden, and the United Kingdom, are both misleading and wholly irrelevant. *See*, *e.g.*, Ex. A, at ¶¶ 49-60, 160, 161. Dr. Kaliebe failed to disclose that each of these countries *provides and covers* gender-affirming hormonal and surgical treatment for gender dysphoria for adolescents in certain circumstances and adults, without any restriction, whereas Defendants exclude coverage for treatments for both these populations categorically. *See*, *e.g.*, Ex. B, at 100:17-101:2; Ex. L; *see also Brandt*, 47 F.4th at 671; *Eknes-Tucker v. Marshall*, 603 F.Supp.3d 1131, 1146 (M.D. Ala. 2022) ("According to Dr. Cantor, Defendants' own expert witness, no state or country in the entire world has enacted a blanket ban of these medications other than Alabama.").

⁹ These opinions are methodologically flawed and unreliable because Dr. Kaliebe cites to no authority and provides no basis for his opinion.

Moreover, each of the reports and reviews of the provision of genderaffirming care in these three countries pertained to medical care for minors and not adults, unlike the Challenged Exclusion. Ex. B, at 100:1-16.

In the end, how care is provided and covered in countries with nationalized health care systems is not relevant to whether coverage of gender-affirming medical care should be provided by Medicaid in Florida.¹⁰

C. <u>Dr. Kaliebe's musings about the causes of gender dysphoria are</u> <u>irrelevant.</u>

As noted above, Dr. Kaliebe *hypothesizes*, without any evidence, that gender dysphoria *may be* caused by social contagion and social pressure. But whether gender dysphoria is caused by social contagion is both wholly unsupported, as described above, and irrelevant to the case at hand. It is undisputed that gender dysphoria is a recognized medical condition that necessitates treatment. *See, e.g.*, Ex. B, at 34:9-11 ("Q. ... Would you agree with me that gender dysphoria is a very real condition? A. Yes."); *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594-95 (4th Cir. 2020); *Eknes-Tucker*, 603 F.Supp.3d at 1138 ("Gender dysphoria is a clinically diagnosed incongruence between one's gender identity and assigned gender. If untreated, gender dysphoria may cause or lead to anxiety,

¹⁰ 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*, <u>https://www.socialstyrelsen.se/en/about-us/</u> (accessed Apr. 7, 2023) (noting that standards are based on legislation).

depression, eating disorders, substance abuse, self-harm, and suicide." (citations omitted)).

* * *

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

IV. Dr. Kaliebe's opinions lack probative value and are therefore inadmissible under Rule 403.

Finally, the Court should exclude Dr. Kaliebe's opinions because their introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Dr. Kaliebe offers no opinions relevant to the issues in this case, and, in any event, the opinions he offers are unfounded, 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. Kaliebe's report, opinions, and testimony. More specifically, at minimum, the Court should limit Dr. Kaliebe's opinions and testimony solely to those regarding the diagnosis of gender dysphoria in children and adolescents, and otherwise exclude Dr. Kaliebe's report, opinions, and testimony in full.

Dated this 7th day of April 2023.

PILLSBURY WINTHROP SHAW PITTMAN, LLP

Jennifer Altman (Fl. Bar No. 881384) Shani Rivaux (Fl. Bar No. 42095) 600 Brickell Avenue, Suite 3100 Miami, FL 33131 (786) 913-4900 jennifer.altman@pillsbury.com shani.rivaux@pillsbury.com

William C. Miller* Gary J. Shaw* 1200 17th Street N.W. Washington, D.C. 20036 (202) 663-8000 william.c.miller@pillsburylaw.com

Joe Little* 500 Capitol Mall, Suite 1800 Sacramento, CA 95814 (916) 329-4700 joe.little@pillsburylaw.com

NATIONAL HEALTH LAW PROGRAM

Abigail Coursolle* 3701 Wilshire Boulevard, Suite 315 Los Angeles, CA 90010

(310) 736-1652 coursolle@healthlaw.org

Catherine McKee*

1512 E. Franklin Street, Suite 110 Chapel Hill, NC 27541 (919) 968-6308 mckee@healthlaw.org Respectfully Submitted,

/s/ Omar Gonzalez-Pagan

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.

Omar Gonzalez-Pagan* 120 Wall Street, 19th Floor New York, NY 10005

(212) 809-8585 ogonzalez-pagan@lambdalegal.org

Carl S. Charles* 1 West Court Square, Suite 105 Decatur, GA 30030 (404) 897-1880 <u>ccharles@lambdalegal.org</u>

SOUTHERN LEGAL COUNSEL, INC.

Simone Chriss (Fl. Bar No. 124062) Chelsea Dunn (Fl. Bar No. 1013541) 1229 NW 12th Avenue Gainesville, FL 32601 (352) 271-8890 Simone.Chriss@southernlegal.org Chelsea.Dunn@southernlegal.org

FLORIDA HEALTH JUSTICE PROJECT

Katy DeBriere (Fl. Bar No. 58506) 3900 Richmond Street Jacksonville, FL 32205 (352) 278-6059 debriere@floridahealthjustice.org

* Admitted pro hac vice

Counsel for Plaintiffs

LOCAL RULE 7.1(B) CERTIFICATION

The undersigned certifies that he attempted in good faith to resolve the issues raised in this motion through a meaningful conference with Defendants' counsel, including through a meet and confer Zoom conference on April 6, 2023.

<u>/s/ Omar Gonzalez-Pagan</u> Omar Gonzalez-Pagan Counsel for Plaintiffs

LOCAL RULE 7.1(F) WORD COUNT CERTIFICATION

As required by Local Rule 7.1(F), I certify that this Opposition contains 7,948 words.

<u>/s/ Omar Gonzalez-Pagan</u> Omar Gonzalez-Pagan Counsel for Plaintiffs

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.

<u>/s/ Omar Gonzalez-Pagan</u> Omar Gonzalez-Pagan Counsel for Plaintiffs