THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

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

v.

JASON WEIDA, et al.,

Defendants.

<u>PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF</u> <u>MICHAEL BIGGS, PH.D. AND SUPPORTING MEMORANDUM OF LAW</u>

TABLE OF CONTENTS

<u>Page</u>

INTRODUCTION	.1
ARGUMENT	.3
A. Legal Standard	.3
B. Biggs' Background and Experience.	.5
C. Biggs Is Not Qualified To Offer An Expert Opinion On Any Issue In This Case.	.7
D. Biggs' Report, Opinions, And Testimony Have No Relevance To This Case1	14
E. Biggs' Report, Opinions, And Testimony Are Unreliable1	19
a. Biggs' report, opinions, and testimony are based on guesswork and flawed methodology2	20
b. Biggs's opinions about the effectiveness of gender-affirming care are not generally accepted and are unreliable	26
F. Biggs's Report, Opinions, And Testimony Are Tainted By His Personal Bias	28
G. Biggs's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403	31
CONCLUSION	31
CERTIFICATE OF WORD COUNT	34
CERTIFICATE OF CONFERENCE PURSUANT TO LOCAL RULE 7.1(B)3	32

TABLE OF AUTHORITIES

Page(s)

Cases

Adams v. Lab. Corp. of Am., 760 F.3d 1322 (11th Cir. 2014)
<i>Allison v. McGhan Med. Corp.</i> , 184 F.3d 1300 (11th Cir. 1999)23
Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp., 582 F.3d 1227 (11th Cir.2009)14
Brandt v. Rutledge, 551 F. Supp. 3d 882 (E.D. Ark. 2021)27
City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548 (11th Cir. 1998), cert. denied, 528 U.S. 812 (1999)
Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)passin
Dura Automotive Systems of Indiana, Inc. v. CTS Corp., 285 F.3d 609 (7th Cir. 2002)
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997)14
Hendrix v. Evenflo Co., Inc., 255 F.R.D. 568 (N.D. Fla. 2009), aff'd sub nom. Hendrix ex rel. G.P. v. Evenflo Co., Inc., 609 F.3d 1183 (11th Cir. 2010)
Hull v. Merck & Co., Inc., 758 F.2d 1474 (11th Cir.1985)
<i>In re 3M Combat Arms Earplug Products Liab. Litig.</i> , 3:19MD2885, 2022 WL 1262203 (N.D. Fla. Apr. 28, 2022)19, 25
In re Abilify (Aripiprazole) Products Liab. Litig., 299 F. Supp. 3d 1291 (N.D. Fla. 2018)

Jones v. Otis Elevator Co., 861 F.2d 655 (11th Cir. 1988)
Kadel v. Folwell, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022)10, 11
<i>Lebron v. Sec'y of Fla. Dep't of Children & Families</i> , 772 F.3d 1352 (11th Cir. 2014)
<i>McClain v. Metabolife Intern., Inc.,</i> 401 F.3d 1233 (11th Cir. 2005)26
<i>McDowell v. Brown</i> , 392 F.3d 1283 (11th Cir. 2004)14, 26
<i>Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.</i> , 326 F.3d 1333 (11th Cir. 2003)4, 8, 24
<i>Rider v. Sandoz Pharm. Corp.</i> , 295 F.3d 1194 (11th Cir. 2002)19, 20
<i>Rink v. Cheminova, Inc.</i> , 400 F.3d 1286 (11th Cir. 2005)19
Sanchez v. Esso Standard Oil de Puerto Rico, Inc., No. CIV 08-2151, 2010 WL 3809990 (D.P.R. Sept. 29, 2010)28
<i>Tran v. Toyota Motor Corp.</i> , 420 F.3d 1310 (11th Cir. 2005)4
United States v. Frazier, 387 F.3d 1244 (11th Cir. 2004)3, 4, 6
United States v. Gaines, 979 F. Supp. 1429 (S.D. Fla. 1997)26
Rules and Regulations
Federal Rules of Evidence Rule 104

Rule 702.....passim

Iministrative Code	
PG-1.010	2
PG-1.050(7)passim	passim

Other Authorities

Zucker, Kenneth J., et al., Memo Outlining Evidence for Change for Gender	
Identity Disorder in the DSM-5, ARCHIVES OF SEXUAL BEHAVIOR	26

Pursuant to Federal Rules of Evidence 104, 403, and 702, Plaintiffs AUGUST DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents JANE and JOHN DOE; and K.F., a minor, by and through his parent and next friend JADE LADUE (collectively, "Plaintiffs"), move this Court to exclude the expert testimony of Michael Biggs, Ph.D ("Biggs"). As outlined below, Biggs is not a qualified expert and his opinions and testimony are neither relevant nor reliable and fail to comply with the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions are likewise inadmissible because any probative value is substantially outweighed by the danger of unfair prejudice, confusion, waste of time, undue delay, and are undeniably cumulative. *See* Fed. R. Evid. 403.

INTRODUCTION

The relevance of Biggs's testimony must be considered in the context of what is at issue in this case: whether gender-affirming care was banned without adherence to the Defendant Florida Agency for Healthcare Administration's ("AHCA" or the "Agency") established process and whether the care is medically necessary, "investigative" and/or "experimental."¹ As a result of the published GAPMS Memo,

¹ On June 2, 2022, AHCA published its report, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" (the "GAPMS Memo"). The GAPMS Memo was created in a hurried and sub-rosa fashion, outside the Agency's established procedures, by an

on August 21, 2022, AHCA adopted Fla. Admin. Code R. 59G-1.050(7) (the "Challenged Exclusion") prohibiting Medicaid coverage for medically necessary treatments for those diagnosed with gender dysphoria irrespective of age or any other factors.²

To support its flawed analysis, the Agency has offered the opinions of, among others, Biggs. It is immediately obvious upon reviewing his qualifications that Biggs is wholly untrained to offer any reliable opinion or testimony in this case. He is the quintessential "manufactured" expert for litigation, acting as an improper "mouthpiece" for subjects on which he is not competent. Further, the opinions Biggs offers are irrelevant and wildly unreliable. He is a sociologist, whose PhD was in

individual who was not part of the GAPMS process. The evidence at trial will show that AHCA relied only on the opinions of putative medical experts and others who, without question, fall into the category of transgender care deniers. After considering only the opinions of these "deniers", the GAPMS Memo concluded that gender-affirming medical treatments "do not conform to [generally accepted professional medical standards] and are experimental and investigational." The Agency's defense to this case is consistent with the GAPMS process, again only relying upon transgender "deniers" rather than a considered analysis of the medical literature.

² The Challenged Exclusion categorically excludes Medicaid coverage of treatment for gender dysphoria, specifically: (i) "puberty blockers;" (ii) "hormones and hormone antagonists;" (iii) "sex reassignment surgeries;" and (iv) "[a]ny other procedures that alter primary or secondary sexual characteristics." Rule 59G-1.050(7), Fla. Admin. Code. The Challenged Exclusion provides that these services "do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C." The same services are regularly used to treat other conditions and are covered by Florida Medicaid (and have been covered for many, many years including to children).

"The Rise and Decline of Mass Movement American Workers and Strike Wave of 1886."³ Biggs has no relevant expertise that will aide this Court in deciding the important issues before it and, therefore, his testimony should be excluded in its entirety.

ARGUMENT

A. Legal Standard.

Federal Rule of Evidence 702 governs the admissibility of expert testimony.

In *Daubert*, the Supreme Court, analyzing Rule 702, held that the district courts are to perform the critical "gatekeeping" function concerning the admissibility of expert scientific evidence. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *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 determining the admissibility of expert testimony under Rule 702, courts engage in a "rigorous" three-part inquiry to 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

³ A copy of Biggs's Expert Report is attached as Exhibit "A" ("Biggs Report"); a copy of his deposition transcript is attached as Exhibit "B." ("Biggs Dep."). Citation to Biggs Report will be referenced as "Biggs Report" followed by the page number. Citation to his deposition will be referenced as "Biggs Dep." followed by the page(s) and line(s).

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; *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 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 testimony has the "burden of establishing qualification, reliability, and helpfulness." *Frazier*, 387 F.3d at 1260. Biggs meets none of those standards and, accordingly, must be excluded.

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. Exclusion under Rule 403 is appropriate if the probative value of otherwise admissible expert testimony is substantially outweighed by its potential to confuse or mislead the jury, or 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, "the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises *more* control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595 (cleaned up).

B. Biggs' Background and Experience.

Biggs is a sociologist, Biggs Dep., p. 33:19-20, who has no medical training or experience whatsoever. *Id.* at 7:6-10; *see also* Curriculum Vitae of Biggs attached as Attachment "1" to his report. He does not treat or interact with transgender patients (Biggs Dep., p. 7:11-16), is not an ethicist, does not draft or promulgate health care policy and has no role in assessing patients with gender dysphoria. *Id.* at 26:1-25 through 27:1-8. Biggs was not involved, directly or indirectly, in the drafting of the GAPMS Memo or in the creation of the Challenged Exclusion, and he is not offering opinions about either in this case. Biggs Dep., p. 40:10-:15; *Id.* at 165:1-6. He likewise has no knowledge or opinion about the process used by AHCA in creating the GAPMS Memo or the Challenged Exclusion. Biggs Dep., p. 165:7-10.⁴ Biggs did not review the medical records of the Plaintiffs in this case, meet

⁴ As discussed below, despite his lack of credible experience and in keeping with the State of Florida's choice to rely on only "deniers" in formulating the policy at issue, Biggs was invited to espouse his unreliable opinions at Florida's Board of Medicine ("BOM") meeting on October 28, 2022 and other important meetings where healthcare policy was decided. The BOM relied on Biggs's and other "experts" opinions to ban qualified physicians from rendering gender affirming care after the Challenged Exclusion was passed.

with any of their medical providers and, although he opines on the same, he is not qualified to interpret the DSM-5. Biggs Dep., pp. 165:1-19 through 166:1-12.⁵

Despite having no relevant experience, Biggs offers a host of opinions, none of which are based on scientific study or analysis. Instead, after his interest was piqued by a few doctoral students, Biggs sought a freedom of information query in England directed to the Tavistock facility seeking to have that institution publish its results relating to the efficacy of services it provided to transgender individuals.⁶ Biggs credits himself with having this information published, the results of which he contends were not positive, even though he lacks "the scientific, technical, or specialized expertise, to understand the evidence." *Frazier*, 387 F.3d at 1260. On this basis, Biggs concludes–without having performed any independent research or study–that puberty delaying drugs should not be provided to adolescents under 16

⁵ Biggs' Ph.D. dissertation, "*The Rise and Decline of a Mass Movement American Workers and Strike Wave of 1886*," is wholly unrelated to gender dysphoria or the use of puberty delaying medications. Biggs Dep., p. 25:10-22. This notwithstanding and despite having no clinical experience or a medical degree, Biggs testified that his general "academic training" garners him with the ability to interpret the DSM-5. Biggs Dep., pp. 42:7-25 through 43:1-13.

⁶ Biggs has testified in only one case, in the form of a written declaration. The specific matter was in England, brought by Keira Bell against Tavistock and Portman NHS Foundation Trust. Although the court initially held that a minor under the age of 16 was not mature enough to provide informed consent to take puberty delaying medication, that ruling was reversed on appeal. The three high court judges held that "it was clinicians rather than the court to decide on competence [to consent]."

(but would be appropriate for adolescents ages 16 to 18). Biggs Dep., pp. 138:5-25 through 139:1-22. But Biggs has no qualifications to render such an opinion. This does not stop him from issuing a series of musings including that these medications negatively impact bone density (Biggs Report, p. 17-18), brain health (*Id.* at p. 15-16) and sexual function.⁷ *Id.* at p. 18. Biggs draws these unsupported conclusions despite his lack of medical training or experience and, as importantly, despite his acknowledgement that there is no clinical or scientific data on which he could do so. Biggs. Dep., p. 7:6-10.

C. Biggs Is Not Qualified To Offer An Expert Opinion On Any Issue In This Case.

Biggs's opinions and testimony lack any indicia of admissibility under *Daubert* and the Federal Rules of Evidence. Indeed, if this Court performs its traditional and rigorous gatekeeping role, *his testimony must be excluded in its*

⁷ There are a host of other anecdotal theories in his report that are irrelevant to the issues before this Court including that a certain percentage of transgender individuals may also be on the autism spectrum and that certain individuals who may initially be diagnosed with gender dysphoria may simply have same-sex attraction rather than being transgender. He provides no explanation for why, even if true, these matters have any bearing on the issues presented. Worse still, Biggs opines, without any evidential basis, that some individuals who have suicidal ideation do not really want to kill themselves, they're just "crying out for help". *See* Biggs Report, p. 11 (¶16). Biggs unsupported and unscientific rhetoric is precisely the type that has created the wide chasm in understanding gender dysphoria and transgenderism. His testimony would only prove to be confusing and misleading to the Court. Notably, as discussed below, Biggs also has a history of what could be construed as transphobic tweets. Biggs Dep., p. 219:4-9; *Id.* at 222:14-18. This type of discourse simply has no place in this proceeding.

entirety because he is not qualified to serve as an expert witness in this case. Biggs's opinions and testimony are neither reliable nor probative of any of the issues this Court must decide.

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, particularly where an expert offers testimony in areas outside of their knowledge, skill, experience, training, or education. In conducting the Daubert inquiry, each of the three analytical prongs (including qualifications) 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. To be clear, "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). "A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty." Id. (quoting Dura Automotive Systems of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002)). Thus, if an expert witness does not "propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation," such expert should be disqualified. *Lebron*, 772 F.3d at 1369 (quoting Fed. R. Evid. 702 (cleaned up)).

As noted above, Biggs is an Associate Professor of Sociology at the University of Oxford in Oxford, England, with no medical training or experience. Despite his clear lack of qualifications and the failure to have conducted any scientific research whatsoever, Biggs has been proffered as an expert witness "to summarize [his] knowledge and opinions on gender dysphoria in adolescents, focusing on the use of puberty blockers." Biggs Report, p. 2 (¶1). He has been asked by the Agency to render these opinions despite Biggs himself admitting that he has never treated patients who suffer from gender dysphoria. Biggs Dep., p. 7:11-16 ("Q. Have you ever treated anyone with gender dysphoria? A. No. Q. Have you ever prescribed treatment for anyone with gender dysphoria? A. No."). Indeed, Biggs is not a clinician who can speak knowledgeably about whether gender-affirming medical treatments, including puberty blockers, hormone therapy, and surgery, conform to the generally accepted professional medical standards that govern such care or the medical needs of any Medicaid beneficiary, let alone the Plaintiffs in this case. Biggs Dep., p. 7:3-10 ("Q. All right. So let's get started. So are you a medical doctor? A. No. Q. Have you gone to medical school? A. No. Q. Have you had any medical training whatsoever? A. No.").

What is clear from a review of his curriculum vitae and his deposition testimony is that Biggs is not qualified to opine on a patient's course of care. He "is not a psychiatrist, psychologist, or mental health professional, nor has he ever diagnosed a patient with gender dysphoria. He is not an endocrinologist, nor has he ever treated a patient with hormone therapies." *Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731, at *13 (M.D.N.C. Aug. 10, 2022). As such, he "is not qualified to render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists." *Id.*

He even agrees that a psychologist or an endocrinologist is properly qualified to determine the course of treatment for a person (child or adult) with gender dysphoria, not a sociologist like himself. Biggs Dep., pp. 105:20-25 through 106:1 ("Q. Who determines the course of treatment for a child with gender dysphoria? A. It would be a psychologist, perhaps with a endocrinologist as well. Q. You would agree with me it is not a sociologist, correct? A. Correct."); *see also Id.* at p. 26:3-15 ("Q. You are not a clinician of any kind, correct? A. Correct. Q. You are not a bioethicist, correct? A. Correct. Q. You are not an endocrinologist, correct? A. Correct. Q. You are not a psychologist, correct? A. Correct? A. Correct. Q. You are not a psychologist, correct? A. Correct. Psychologist, correct? A. Correct. Q. You are not a psychologist.

It appears that rather than do, Biggs reads. He reads the works of others and then summarizes his views on the same. This does not qualify him to render the opinions he has offered in this case, however. Assuredly, he is not an expert on puberty delaying medications or anything else relating to the medical treatment of those suffering from gender dysphoria. Important here, he has not conducted any independent research about gender dysphoria or the use of puberty delaying medications.⁸ "Merely reading literature in a scientific field does not qualify a witness—even an educated witness—as an expert." *Kadel v. Folwell*, 1:19CV272, 2022 WL 3226731, at *9 (M.D.N.C. Aug. 10, 2022); *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002)) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.").

⁸ Biggs Dep., pp. 137:14-25 through 138:1-4 ("Q. Prior to your statement at the Florida Board of Medicine meeting, had you performed any independent research with regard to gender dysphoria that you were asked to speak about at the meeting? A. No. Q. And, again, I'm not asking you to repeat anything we've talked about on the record. But you didn't perform any independent research on gender dysphoria for your statements that you made at the Florida Board of Medicine meeting, did you? A. Correct. Q. And all of your research is merely reviewing the research of others and then opining on it, isn't that correct, other than we'll get back to your suicidality report and your bone density, correct? A. Correct."); *Id.* at p. 104:10-13 ("Q. Have you -- have you performed any independent research whatsoever with regard to providing puberty blockers to children with precocious puberty? A. No.").

Despite having performed none of the clinical work or studies that bear relevance to this case, Biggs fashions himself a self-proclaimed expert on puberty delaying medications due to his freedom of information act query that led to Tavistock making certain data public. After reviewing the data (which he acknowledges was compiled by others based on medical care also rendered by others), Biggs concludes that because puberty delaying medications did not result in positive outcomes for those receiving care at Tavistock, these medications should not be prescribed until there are randomized clinical trials. Biggs Dep., p. 138:6-14. Of course, Biggs did not provide any of the underlying diagnoses or treatments, establish any of the protocols applied to the data he reviewed, he did not interview patients at that facility himself or otherwise participate in any way in establishing the measures utilized by Tavistock to analyze the data that it ultimately made public. See Biggs Dep., pp. 175:22-25 through 177:1-5. For these reasons, not only are his opinions unreliable, but they are also dangerous.

To illustrate, Biggs makes grandiose statements about suicidal ideation in transgender patients with the intent of minimizing the suicidal risk to this population. Without any citation to authority or evidence whatsoever he claims that a study showed that 41% of transgender students reported having attempted suicide (compared to 14% amongst all students) should not really be a concern because "Respondents who report suicide attempts are not necessarily indicating an intent to

die..." Biggs Report, pp. 10-11 (¶ 16). His conclusions about the impact of puberty delaying medications on brain health are similarly devoid of evidential support.⁹ It is precisely these types of "opinion" that *Daubert* requires be excluded.

Notably, Biggs has not published any peer-reviewed literature based on original research pertaining to the relevant subjects presented here. His opinion on a study of cross-sex hormones, in the form of a comment, was rejected.¹⁰ Biggs Dep., p. 47:2-23. Additionally, a paper related to transgender surgeries was likewise rejected by the Archives of Sexual Behavior and has since failed to be published.¹¹ Biggs Dep., p. 48:3-22. Instead, Biggs relies solely on his review of the studies or analyses of others for his expert opinions, most of which are not supported by any proof whatsoever. As with the disqualified expert in *Lebron* who "reached his opinion instead by relying on studies," he is a textbook example of an individual who is not sufficiently qualified to serve as an expert witness. *Lebron*, 772 F.3d at 1369.

Put simply, Biggs has no foundation of specialized knowledge, skill, or experience necessary to serve as an expert on the controlling questions in this case.

⁹Not only is Biggs unqualified to provide any testimony in this case, his opinions are wholly unreliable as they are not "methods and procedures of science" but rather are grounded in his "subjective belief or unsupported speculation." *In re Abilify* (*Aripiprazole*) *Products Liab. Litig.*, 299 F. Supp. 3d 1291, 1311 (N.D. Fla. 2018).

¹⁰ It is important to note that Biggs nor Defendants ever produced this comment.

¹¹ This paper also was never produced to Plaintiffs.

He is "not qualified by background, training, or expertise to opine" about whether the care at issue is medically necessary or otherwise experimental. *Lebron*, 772 F.3d at 1369. Nor does Biggs have any information or experience to testify about the process used by the Agency to implement the Challenged Exclusion. Accordingly, his opinions fail to meet the first prong in *Daubert* and should be excluded on that basis alone.

D. Biggs' Report, Opinions, And Testimony Have No Relevance To This Case.

To satisfy the helpfulness requirement, the testimony must have a justified scientific relationship to the facts at issue. *Daubert*, 509 U.S. at 591. 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 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.'").¹²

As highlighted above, the primary issues at trial, among others, will be ascertaining (1) whether gender-affirming medical care is experimental and, if not, whether it was inappropriately excluded from Medicaid coverage; and (2) whether the process Florida underwent to exclude coverage of such care in its Medicaid was reasonable. Biggs has no ability to provide relevant opinions on either of these issues.

As a threshold matter, he cannot provide an opinion on the GAPMS Memo (or how it was created) or on the Challenged Exclusion in this case. Biggs Dep., 165:1-6 ("Q. You are not providing an opinion in this case on the GAPMS report, are you? A. No. Q. You are not providing an opinion on the rule in this case, correct? A. No. Correct."). He also admits that he will not be providing an opinion about the process that AHCA followed when deciding to exclude gender-affirming care. *Id.* at

¹² As will be a theme with each of Defendants' experts, Biggs openly admits that he has no opinion on puberty blockers, cross-sex hormones, or surgical procedures as it pertains to adults. Biggs Dep., p. 69:12-22. Telling is the fact that the Challenged Exclusion blocks all gender-affirming medical care, whether to an adolescent or an adult. But not one of Defendants' experts (or the GAPMS Memo) addresses whether such care as administered to adults is "experimental" or "investigative", or whether it is medically necessary. This fact alone shows that AHCA's intended purpose was not to protect those who are transgender, but, rather, to further a political agenda. But medical care is neither political nor religious. Medical decisions should be made by clinicians, and clinicians alone.

p. 165:7-10.¹³ Because Biggs has no ability to opine on any pertinent facts or issue in this case, his testimony should be excluded.

Biggs's report includes irrelevant and generalized opinions regarding the association of gender dysphoria with same sex attraction and autism spectrum conditions; and the risk of suicide for children suffering from gender dysphoria (without regard to whether they are receiving gender affirming care). See generally Biggs Report. But as he must acknowledge, none of his opinions on the subject are based on his own clinical research, (Biggs Dep., p. 29:3-5; Id. at 47:2-5), nor do they fall within his area of expertise to even be reading the analyses of others. Further, none of his putative "opinions" have a relationship to the actual issues being tried, whether gender-affirming medical treatments, including puberty delaying medications, hormone therapy, and surgery are medically necessary or whether the Defendant reasonably reached this conclusion given that AHCA failed to consider the opinions of any medical expert who had an opinion outside those of who are transgender deniers. Instead, AHCA relied solely on medical outliers, who do not support the provision of such care, without ever considering those who have direct

¹³ Similarly, Biggs will not be providing an opinion on the diagnosis of the Plaintiffs (Biggs Dep. p. 165:11-14), and he acknowledges that he could not because he has no opinion about the proper medical treatment for the Plaintiffs; he has never even reviewed any of their medical records. *Id.* at p. 165:15-21 ("You don't have an opinion about the proper medical treatment for the plaintiffs in this case, correct? A. Correct. Q. You haven't reviewed their medical records, correct? A. Correct.").

experience in the area. As the Court will learn, none of the "experts" relied upon by Defendants actually treat transgender individuals other than Dr. Levine.

To be clear, Biggs' "opinion" and testimony that there is little risk of suicide for children suffering from gender dysphoria is not simply unscientific and irrelevant, it is reckless. Biggs Dep., pp. 198:12-25 through 199:1-21; Biggs Report, p. 10 (¶15-22). The implication to this Court that we should ignore vulnerable individuals with suicidal ideation because an unqualified sociologist believes that they don't *really* want to hurt themselves is as ridiculous as it is irresponsible. Even Biggs was forced to acknowledge that "the claim that puberty suppression reduces suicidality in children suffering from gender dysphoria is not implausible." Biggs Report, p. 13 (¶20). To the extent that there are psychiatrists and other experts testifying on this point, their testimony would be relevant, but Biggs is not qualified to do so.

Biggs proffers that gender dysphoria is associated with same sex attraction and with autism spectrum conditions, seemingly implying that this negates the needed care, but even he concedes that the two are not mutually exclusive. Biggs Dep., p. 192:9-12 ("Q. Sir, you would agree with me that being transgender and being on the spectrum are not mutually exclusive, correct? A. Correct.").

His opinions simply have no relationship to the issues this Court will consider as they have no bearing on whether the treatments at issue are medically necessary or whether AHCA's determination was reasonable. Instead, as with the balance of his Report, Biggs uses smoke and mirrors to distract from the important issues this Court must consider, using fear tactics and unsupported innuendo to further the political agenda of AHCA. The administration of medical care and the efficacy of the same should be left between a patient, in the case of a minor his/her parents and medical professionals, not unqualified individuals. ¹⁴ Medical care should not be subject to the vagaries of politics or religion.

Biggs' opinions are based on nothing more than the "subjective belief or unsupported speculation" found insufficient in *Daubert*. *Daubert*, 509 U.S. at 589-590. He indisputably 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). For these reasons, Biggs' opinions regarding the medical treatment for gender dysphoria generally, let alone for the Plaintiffs, are irrelevant to this case and they should be excluded in their entirety. *See, e.g.*, Biggs Dep., p. 165:7-21.

¹⁴ Biggs concedes that the decision of whether to administer gender-affirming care should be made between a patient, in the case of a minor, their parents and medical professionals, not someone unqualified. *See* Biggs Dep., pp. 120:19-25 through 121:1 ("Q. No. You told me the percentages of people that you believe will go on to cross-sex hormones. You didn't answer my question, which was, the decision of whether or not to take puberty blockers and the decision whether or not to take cross-sex hormones is not one for you to make. It is between a patient, their physician, and their parents; isn't that correct? A. Correct.").

E. Biggs' Report, Opinions, And Testimony Are Unreliable.

As a rule, 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. Littig.*, 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). "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).

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 v*.

Cheminova, Inc., 400 F.3d 1286, 1291-92 (11th Cir. 2005).¹⁵ To be reliable the expert's testimony must always be based on "good grounds." *Daubert*, 509 U.S. at 590. *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).

a. Biggs' report, opinions, and testimony are based on guesswork and flawed methodology.

Here, Biggs' testimony and opinions are based on nothing more than rank speculation, untested theories, unsubstantiated anecdotes, assumptions that are obsolete, flawed, unethical, and unsettled science. Biggs has not performed any scientific or clinical studies, nor employed any methodology that could be considered or tested, instead relying on his untrained review of other people's writings. His opinions lack the markers of reliability necessary to be admitted as expert testimony.

Biggs's report includes generalized opinions regarding the effect of puberty suppression on mental health; the effect of puberty suppression on bone density; and the effect of puberty suppression on sexual function; and as noted above, the risk of

¹⁵ 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.

suicide for children suffering from gender dysphoria (without regard to whether they are receiving gender affirming care). *See generally* Biggs Report. To the point:

One. Biggs is not qualified to render an opinion about the effect of puberty suppression on bone density. Although Biggs asserts that patients *could* "end with a decreased bone density, which is associated with a high risk of osteoporosis", Biggs Report, p. 17 (¶26), he has no medical training to support this conclusion. Such conjecture from a non-medical person is not reliable testimony in this context. His testimony is also internally inconsistent rendering it unreliable. Indeed, although Biggs emphatically states that bone density is a side effect of puberty delaying medications, he admits that even if true, it is not a reason to ban gender affirming care. For this reason, the fact that the treatment could impact bone density does not support the Challenged Exclusion. Biggs Dep., pp. 211:2-25 through 213:1-18.

Biggs likewise concedes that low bone density in adolescents treated with puberty delaying medications can be the result of unrelated factors such as "the high prevalence of eating disorders" (Biggs Report, p. 17 (\P 26)) or a genetic predisposition. *Id.* at p. 111:18-25. Moreover, even if the medications impacted bone density, that is merely a reason to monitor the care and its effects, not ban it, as is done with virtually every medication because prescription drugs frequently have side

effects.¹⁶ Regardless, Biggs is not qualified to read bone density scans or administer such tests and so he has no place providing opinions on these issues. Biggs Dep., pp. 16:19-25 through 17:1-20. Given his dearth of experience, Biggs's "conclusions" do not provide any information that will aide this Court in determining whether the care is experimental or investigational (as opposed to whether, if administered, there may be medical side effects as with any mediation, which is why they should be monitored by a qualified professional).¹⁷

Biggs also accepts that he is not qualified to render an opinion on any medical side effects of puberty delaying medications, but nonetheless has submitted a report suggesting to the contrary. *See* Biggs Dep., p. 99:11-18 ("Q. And you are not qualified, sir, to render any opinion on whether there are any medical side effects to puberty blockers, are you? A. No. Q. And as you sit here today, you have no medical

¹⁶ Presumably it will not be AHCA's position at trial that all medications that have side-effects should be banned. This would essentially mean that no medications would be reimbursable by Medicaid given that virtually all medications—even aspirin—have potential side-effects.

¹⁷ Biggs concedes that the decision of whether to administer gender-affirming care should be made between a patient, in the case of a minor, their parents and medical professionals, not someone unqualified. *See* Biggs Dep., pp. 120:19-25 through 121:1 ("Q. No. You told me the percentages of people that you believe will go on to cross-sex hormones. You didn't answer my question, which was, the decision of whether or not to take puberty blockers and the decision whether or not to take cross-sex hormones is not one for you to make. It is between a patient, their physician, and their parents; isn't that correct? A. Correct.").

training or experience that would qualify you to render any such opinions; isn't that right? A. Correct.").

Two. In discussing outcomes from a longitudinal study of a cohort of 70 children treated with puberty delaying medications, Biggs improperly claims that one teenager died as "a consequence of puberty suppression." Biggs Report, p.5 (¶9). This "opinion" is misleading and factually inaccurate. The teenager's untimely death was a direct result of "necrotizing fasciitis during vaginoplasty", meaning due to a *surgical procedure* that she had at eighteen (18), not the fact that the individual was prescribed puberty delaying medications. *Id.* Notably, there is risk in every surgery; again, the use of fear mongering in such an irresponsible way speaks volumes about Biggs's qualifications and reliability to aide this Court in analyzing the issues presented. This Court's analysis should be free of unsupported hyperbole, focusing instead on the opinions of qualified individuals that will aide in issuing a just outcome in this case.

Unsurprisingly, Biggs admits to forming his opinion without reviewing the surgical notes from the case, relevant medical records, or discussing the case with the teen's doctors. Biggs Dep., pp., 77:23-25 through 79:1-3. Despite never speaking with any surgeon who specializes in vaginoplasty to determine what impact, if any, puberty delaying medications have on their ability to provide such surgery, (*Id.* at p. 79:4-8), Biggs brazenly encourages this Court to rely on his

23

Case 4:22-cv-00325-RH-MAF Document 128 Filed 04/07/23 Page 29 of 39

subjective untrained opinion. There is no basis to consider such unreliable and unsupported testimony. *See Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1319 (11th Cir. 1999) (affirming exclusion of expert testimony where the proffered testimony was "based more on personal opinion than on scientific knowledge"). Biggs is not a medical doctor, (*Id.* at p. 7:3-10), and he lacks the "knowledge, skill, experience, training, or education" necessary to determine the teen's cause of death. *Quiet Technology DC-8, Inc.*, 326 F.3d at 1342.

Biggs then employs quantum leaps of logic predicated on his unfounded assertion regarding the cause of death to urge that "[i]n a cohort of healthy teenagers, a death rate exceeding 1% is alarming." Biggs Report, p. 5 (¶ 9). Using pretzel logic tethered to his false statement that the death was associated with puberty blockers, he claims that there is a 1% death rate because the one individual died from an unrelated surgical complication. The statement is wildly irrational and irresponsible. While mechanically dividing 1 by 70 results in the numeric calculation he recites, it is completely unmoored to reality otherwise. He begins with a false premise and ends with the same. This is simply junk science offered despite acknowledging that he conducted no research as to the health of the cohort in the relevant study.¹⁸ Put simply, Biggs claims that the teenager's death was caused by puberty delaying medications and, as a result, there was a death rate exceeding 1% in a "healthy" cohort are void of any "scientifically valid principles, reasoning, [or] methodology." *In re 3M Combat Arms Earplug Products Liab. Litig.*, 3:19MD2885, 2022 WL 1262203, at *1.

Three. Biggs improperly opines, based on his "suspicion," "that at least some of these children [diagnosed with GID] could have grown up to be typical gays and lesbians, without requiring lifetime medical treatment and without loss of fertility and sexual function." Biggs Report ¶ 13. The implication from Biggs is that by delaying puberty in transgender adolescents, people are preventing these adolescents from growing out of being transgender to simply being gay or lesbian. Not only is "suspicion" an unreliable basis for expert testimony, but Biggs's suspicions are marred by a myriad of flaws. For one, Biggs assumes without any evidence that a person cannot be gay or lesbian and transgender. But sexual orientation and gender identity are distinct, and one does not negate the other. For another, his flawed

¹⁸ "Q. Okay. So other than reading those two articles, my question is, have you done any study or analysis to determine whether or not any of the individuals in that 70person study suffered from comorbidity? A. No. Q. Have you done any analysis whatsoever in either of those studies to determine whether any of those individuals had -- had other health issues or concerns? A. No." Biggs Dep., pp. 88:16-25 and 89:1

suspicion has no foundation on facts or data. Biggs relies on desistance studies that speak only to (1) *preadolescent/prepubertal* youth not *adolescents after the onset of puberty* and who were diagnosed with *gender identity disorder* under the DSM-III or the DSM-IV not *gender dysphoria* under the DSM-5. Indeed, the changes from the DSM-IV diagnosis of gender identity disorder to the DSM-5 diagnosis of gender dysphoria in 2013 changes in the diagnostic criteria that made "the diagnosis more restrictive and conservative" to reduce "false positives." *See* Kenneth J. Zucker, et. al., *Memo Outlining Evidence for Change for Gender Identity Disorder in the DSM-5*, ARCHIVES OF SEXUAL BEHAVIOR, at 904-05 attached as Exhibit "C."

The unreliability of Biggs' testimony is also evidenced by his history of rejected articles and papers. Biggs Dep., p. 47:8-16.; *Id.* at 48:2-25. His theories are based on "more of a guess than scientific theory" and this does not meet the requirements of Rule 702 or *Daubert. See, e.g., McDowell v. Brown*, 392 F.3d 1283, 1301 (11th Cir. 2004) ("A mere guess that earlier treatment would either have improved McDowell's condition or rendered it the same simply fails the tests for expert opinion").

b. Biggs's opinions about the effectiveness of gender-affirming care are not generally accepted and are unreliable.

It bears mentioning that Biggs's opinions are rejected by the vast majority of the scientific and medical community. General acceptance in the relevant community is "an important factor to be considered" during the reliability inquiry. *United States v. Gaines*, 979 F. Supp. 1429, 1437 (S.D. Fla. 1997); *see also McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1251 (11th Cir. 2005) ("General acceptance of [a] theory would offer important support for the reliability of [the] opinion."). Moreover, the fact that a known theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594.

Indeed, his opinions about the effectiveness, side effects and necessity of gender-affirming care are far outside the mainstream of medical and scientific opinion and have been explicitly rejected by every relevant scientific and medical community. He, himself, acknowledges that his opinions are contrary to standards of care established and followed by many of the world's foremost authorities on the treatment of gender dysphoria, including the World Professional Association for Transgender Health, the American Medical Association, the American Academy of Pediatrics, and the Endocrine Society Guidelines. Biggs Dep., pp. 200:18-25 through 201:1-4. He of course concedes, as he must, that his opinions are contrary to the standards of care for gender-affirming care in the United States generally. Biggs

Dep., p. 201:5-9.¹⁹

Biggs' opinions in this case are decidedly unscientific and represent guess work unbacked by science or reliable methodology. Thus, this Court should exclude his testimony given its role as the gatekeeper even though it is a bench trial. His untried conclusions add nothing to the matters being presented and are wildly unreliable.

F. Biggs's Report, Opinions, And Testimony Are Tainted By His Personal Bias.

While Plaintiffs are cognizant that bias in an expert witness's testimony is usually an issue for the jury, *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1332 (11th Cir. 2014), this case is a bench trial. Here, there is ample evidence that Biggs' testimony is permeated and tainted by his unscientific views and personal bias. *See Sanchez v. Esso Standard Oil de Puerto Rico, Inc.*, No. CIV 08-2151, 2010 WL 3809990, at *4 (D.P.R. Sept. 29, 2010).

Ignoring his lack of experience, Biggs possesses bias that impacts his ability to credibly offer opinions in this case. It has been written that he is responsible for

¹⁹ In a recent case addressing a challenge to Arkansas' state-law ban on genderaffirming treatment for minors, the *Brandt* court recognized that "the consensus recommendation of medical organizations is that the only effective treatment for . . gender dysphoria is to provide gender-affirming care," citing briefs from the aforementioned organizations that Biggs' opinions are admittedly contrary to, and many more. *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 890 n.3 (E.D. Ark. 2021).

transmitting transphobic tweets under the pseudonym "Henry Wimbush." Biggs Dep., p. 217:9-12. For example, he tweeted that "Transphobia is a word created by fascists and used by cowards to manipulates morons." Biggs Dep., p. 219:4-9. Biggs has gone as far as tweeting that "transitioning makes you LESS attractive." Biggs Dep., p. 222:14-18. Much to his chagrin, these transphobic tweets were exposed and unsurprisingly met with backlash from his student body in the form of an article in the Oxford Student.²⁰ Biggs Dep., pp. 218:23-25 through 219:1-2. This type of discourse simply has no place in this proceeding. Biggs's tweets reveal that his opposition to gender-affirming medical care and treatment of transgender youth is firmly established and rooted in his personal views not credible science.

The bias illuminated by Biggs's testimony is further confirmed by the nature of his presentations on this issue. Biggs's participation as a panelist on this topic, as recently as October 28, 2022, was before the Florida BOM. Biggs Dep., p. 52:10-17. Although Biggs agrees that his attendance at this meeting would be a relevant disclosure, he conveniently failed to do so. Biggs Dep., p. 52:10-17 ("Q. Now, sir, in your report, you don't – you also don't mention that you participated in a panel before the Florida Board of Medicine, do you? A. No, I did not. I did not think that was relevant. Q. Right. You didn't include it on your CV either, right? A. Possibly

²⁰ A copy of The Oxford Student article exposing Biggs' transphobic tweets is attached as Exhibit "D."

not."); Biggs Dep., pp. 52:25 through 53:1-7 ("But you would agree with me that it -- it's relevant because it's the very issue for which we're here today; isn't that correct? ... THE WITNESS: Correct."). Biggs also failed to disclose his participation in answering questions before the Florida Health and Human Services Committee ("HHS Committee").²¹ Biggs Dep., p. 54:4-11. Biggs admits that the presentations were hosted by organizations that are aligned with the Defendants' goals in this case and, again, should have been disclosed. Biggs Dep., p. 55:3-9.²²

The foregoing, coupled with Biggs's gross departure with generally accepted medical and scientific standards, demonstrates that his purported expert testimony lacks any indicia of reliability. The record evidence demonstrates a clear bias by

²¹ Notably, Biggs admits that no one spoke about gender-affirming medical care in a positive light at the HHS Committee. Biggs Dep., p. 69:4-7. Instead, the panel of speakers was comprised exclusively of outspoken deniers of transgenderism including two other unreliable and wholly unqualified purported experts proffered by Defendants in this case: Dr. Laidlaw and Dr. Levine. Biggs Dep., pp. 67:25 and 68:1-8.

²² "Q. And you would agree with me that both the board of medicine meeting that I referred to and the committee meeting relating to the Health and Human Services, they're aligned with the defendants in this case in terms of the work that they are trying to do, correct? A. Yes, correct."

Biggs' against transgender people generally, which infects his reliability as a purported expert witness in this case.

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

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Biggs offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his histrionic testimony would merely waste time and create confusion. There will be medical professionals introduced by both sides, but the opinions of Biggs in this case are unsupported and prejudicial; his musings do nothing other than sow confusion and introduce unsupported conjecture by a sociologist who is not qualified to render opinions on these subjects. The testimony would likewise be cumulative given that there will be numerous other witnesses by Defendants, who they intend to offer on the issue of puberty blockers. Using any standard, Biggs' testimony fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

CONCLUSION

Based on the foregoing, Plaintiff respectfully requests that the Court grant the instant motion and exclude Biggs's purported expert testimony because it does not

31

meet any of the indicia for admissibility under *Daubert* and the Federal Rules of Evidence. Accordingly, the Court should exclude his report, opinions, and testimony in full.

CERTIFICATE OF CONFERENCE PURSUANT TO LOCAL RULE 7.1(B)

Pursuant to 7.1(B) of the Local Rules of the Northern District of Florida, the undersigned certifies that she has conferred with the attorneys representing Defendant regarding the relief requested in the motion. The parties were unable to reach a resolution and Defendants' counsel does not consent to the relief requested.

Respectfully submitted this <u>7th</u> day of April, 2023.

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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.

CERTIFICATE OF WORD COUNT

According to Microsoft Word, the word-processing system used to prepare this Motion and Memorandum, there are 7,922 total words.

/s/ Jennifer Altman

Jennifer Altman ATTORNEY FOR PLAINTIFFS