UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
and	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Plaintiff-Intervenor,	)	
	)	
v.	)	No. 2:22-cv-00184-LCB-CWB
	)	Hon. Liles C. Burke
STEVE MARSHALL, in his official capacity as Attorney General of the State of Alabama, *et al.*,	)	**SUBMITTED UNDER SEAL**
	)	
Defendants.	)	

DEFENDANTS' MOTION TO EXCLUDE
SELECTED TESTIMONY OF DR. MEREDITHE McNAMARA

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

INTRODUCTION

Over the last two years, Dr. Meredithe McNamara has been on a PR campaign against those who—like the Alabama Legislature—question the safety of injecting children with hormones that disrupt the healthy maturation of their bodies. Dr. McNamara accuses those who raise such concerns of "science denialism," making "deceptive" and "false" claims, using "misinformation techniques," and spreading "scientific disinformation." *See Daubert*.DX4 (McNamara *Protecting Transgender Health*); *Daubert*.DX5 (McNamara *PBS Interview*); *Daubert*.DX6 (McNamara *Combatting Scientific Disinformation*).[1] Now, Plaintiffs want to bring that road show to this Court.

Dr. McNamara is wrong. The science cited by the Legislature is legitimate; the concerns for children's well-being that motivated the Legislature are shared by many respected voices; multiple European national health authorities have declared broad moratoria on the same hormonal interventions and surgeries in children that Alabama's law prohibits. These respected voices and national health authorities can no longer be dismissed as "transphobes" and "science deniers."

But Dr. McNamara is not just wrong; the central opinions to which she proposes to testify do not come close to meeting the threshold requirements of *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). Dr. McNamara is unqualified to offer expert testimony on those topics and does not provide anything like the

[1] Defendants use two main citations form in their *Daubert* briefing. The first—*Daubert*.DX#:##—refers to exhibits Defendants submit in support of their *Daubert* motions, where the first "#" refers to the exhibit number and the second "##" refers to the page numbers within that exhibit. The second citation form—SJ.DX#:##—refers to the exhibits Defendants submitted in support of their motion for summary judgment. *See* Docs. 557-60 (public exhibits) & 564 (sealed exhibits).

required scientific basis for the opinions she offers. The bulk of Dr. McNamara's proffered opinion testimony should not be admitted.

LEGAL STANDARD

To avoid duplication, Defendants respectfully refer the Court to the statement of governing legal principles contained in Defendants' Motion to Exclude Selected Testimony of Dr. Morissa Ladinsky. *See* Doc. 593 at 2-8.

ARGUMENT

I. Dr. McNamara Is Not Qualified To Offer Expert Opinions Regarding The Safety Or Efficacy Of Hormonal Interventions In Minors, Nor About The Actual Practices Of Clinics And Practitioners In The Field, Because Her Claim Of Experience In The Field Is False.

"While scientific training or education may provide possible means to qualify [as an expert], experience in a field may offer another path to expert status." *United States v. Frazier*, 387 F.3d 1244, 1260-61 (11th Cir. 2004) (en banc). But "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Ruberti v. Ethicon, Inc.*, No. 2:20-CV-874-WKW, 2023 WL 1808348, at *2 (M.D. Ala. Feb. 7, 2023) (quoting Fed. R. Evid. 702 advisory committee's note, 2000 amends.). "Expertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1368 (11th Cir. 2014).

Dr. McNamara claims "my experience treating patients" as the lead basis for her proffered opinions that "[t]he medications used for treatment of transgender

adolescents are safe and effective" and that "[a]dolescent patients with gender dysphoria who are treated consistent with the standard of care can thrive." *Daubert*.DX3:25 (McNamara Rep.). She tells the Court that "I provide full spectrum clinical care to youth aged 12-25 years, which includes youth experiencing gender dysphoria," *id.* at 2, and that "I have cared for many patients who have disclosed gender dysphoria to me in later adolescence or early adulthood," *id.* at 16. In an advocacy piece published in 2023, Dr. McNamara likewise assured the world that she and her co-authors "all … treat transgender youth." *Daubert*.DX6:2 (McNamara *Combatting Scientific Disinformation*).

At her deposition, however, Dr. McNamara revealed that none of this is true. Dr. McNamara has neither experience nor expertise in treating children or adolescents who suffer from gender dysphoria, has never prescribed or supervised any of the hormonal or surgical treatments prohibited by Alabama's law, and indeed has never in her ten years of practice had a *single* minor patient who has undergone any one of these treatments. Dr. McNamara's only relevant "expertise" turns out to be in publishing rhetoric-laden and overstated hit pieces.

Dr. McNamara highlights her affiliation with the Yale School of Medicine. Yale does have a pediatric gender clinic … but Dr. McNamara is not part of that clinic, and has never been on the staff of any gender clinic anywhere. SJ.DX59: 17:4-11 (McNamara Dep.). Indeed, she testified that she has never been responsible for diagnosing pediatric gender dysphoria in any patient, *id.* at 17:19-25, has never had primary responsibility for treating any minor for gender dysphoria, and has never

prescribed any medical treatment for gender dysphoria for a minor, *id.* at 16:18-21; 18:16-20; 133:1-3 ("I don't make those treatment decisions.").

Across her ten years of practice as a general pediatrician, Dr. McNamara has had a grand total of *two* minor patients whom she referred to the experts at the Yale pediatric gender clinic for diagnosis for potential gender dysphoria. Neither has been prescribed any medical intervention. *Id.* at 21:5-17; 22:3-18. Indeed, because the two girls she referred for evaluation had already "completed puberty," Dr. McNamara testified that she has "not yet encountered a patient" who was even *potentially* eligible to receive puberty blockers. *Id.* at 90:22-91:15. In short, Dr. McNamara has never treated minors for gender dysphoria and has literally no relevant experience—a serious problem since it is her purported real-world experience treating gender dysphoric pediatric patients that Dr. McNamara says makes her an expert in this field.

Nor does Dr. McNamara make up for her lack of experience by other means. Rather, during her deposition she repeatedly disclaimed relevant expertise. Although she is a pediatrician who proposes to opine to this Court about treating children, Dr. McNamara admitted that she has never even read the chapter of the WPATH Standards of Care devoted to treating gender dysphoria in children. *Id.* at 195:15-24 ("excuse me, I haven't looked at the Children chapter"). She testified that she does not "consider myself an expert in … the endocrinologic processes of pausing puberty," *id.* at105:9-11; has not "done an in-depth analysis" of potential harm to brain development from blocking puberty, *id.* at 114:1-5; has no opinion as to whether puberty blockade has "negative long-term effects on brain development, *id.* at 82:1-7; and considers it "outside my scope of expertise" to comment on the assertion by

prominent authors that such harm to brain development is "likely to be observed over the long term, rather than immediately," *id.* at 88:8-19.

Similarly, Dr. McNamara testified that "[i]mportantly, I have not done an in-depth analysis on the literature on fertility," *id.* at 141:2-6; that she has no opinion about whether cross-sex hormones permanently sterilize some percentage of adolescents who are subjected to that "treatment" ("because I haven't done the type of literature search that would be required to answer that question," *id.* at 146:12–147:7); and that she likewise has no opinion as to whether prolonged exposure to puberty blockers can result in permanent sterilization, *id.* at 135:11-18 ("It's not a topic I have endeavored to do a thorough literature search on").

In sum, when asked about whether she herself disclosed to minor patients the risk of harm to brain development that is widely recognized in the literature, Dr. McNamara dodged responsibility by testifying that she would "not … perform counseling on medications I myself would not be prescribing or managing," *id.* at 91:13-15—i.e., puberty blockers and cross-sex hormones. So be it. But if Dr. McNamara would not presume to advise patients about these radical hormonal interventions, she should not be permitted to advise this Court about the risks and benefits based on her false claim of "experience" and expertise. Because Dr. McNamara has no relevant experience or expertise, she is not qualified to offer expert opinions as to the safety or efficacy of puberty blockers, cross-sex hormones, or surgery as a treatment for gender dysphoria in minors. Nor—having never practiced in the field or in the state—is Dr. McNamara qualified to offer opinion (or fact) evidence to this Court as to the actual practices of doctors and gender clinics in Alabama or elsewhere.

II. Key Aspects Of Dr. McNamara's Proffered Testimony Must Be Excluded Because They Are Not Reliable.

Key portions of Dr. McNamara's proffered evidence are also inadmissible because they are unreliable. "Reliability" is distinct from "expertise." "[O]ne may be considered an expert but still offer unreliable testimony." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341-42 (11th Cir. 2003). "Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. The trial judge asked to admit expert testimony evidence "must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1306 (11th Cir. 2014). The court should not admit opinion testimony that is "connected to existing data only by the *ipse dixit* of the expert." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1194 (11th Cir. 2010) (quotation omitted). The trial court is tasked "to conduct an exacting analysis of the proffered expert's methodology." *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002). Key opinions proffered by Dr. McNamara lack even a pretext of "good grounds" or sound "methodology."

A. Dr. McNamara's Opinions That Puberty Blockers and Cross-Sex Hormones Are "Safe" and That Puberty Blockers Act Only as a Reversible "Pause" Are Not Reliable Because They Ignore Widely Recognized Risks and Do Not Rest on any Legitimate Methodology.

Dr. McNamara repeatedly opines that puberty blockers and cross-sex hormones are "safe," McNamara Rep. 2, 12, 25, and that puberty blockers act only as a reversible "pause," *id.* at 12, impairing fertility only "while in use," *id.* at 13. In her recent advocacy pieces, she makes the same assertions, declaring that "the effects

[of puberty blockers] are fully reversible" (*Daubert*.DX7:2 (McNamara *Scientific Misinformation and Gender Affirming Care*)), and that "[m]edical evidence establishes that … GAC [medical transition] is safe" (*Daubert*.DX6:1 (McNamara *Combatting Scientific Disinformation*). In addition to her lack of relevant expertise, these opinions are inadmissible because they do not reflect acceptable methodology. Notably, Dr. McNamara quotes not a single scientific article that declares puberty blockers, cross-sex hormones, or surgeries as treatments for gender dysphoria in minors to be "safe," nor any scientific source that declares puberty blockers to be "fully reversible." But opinion supported by mere say-so or *ipse dixit* is inadmissible. *Hendrix*, 609 F.3d at 1194.

1. Respected sources include risk of harm to brain development and risk of sterilization among real, important, and inadequately studied risks from puberty blockers and cross-sex hormones.

As a starting point, it is obvious that inflicting lasting damage to a child's brain development or permanently sterilizing a child would be grave harms—the polar opposite of "safe." And repeatedly, respected scientific voices list precisely these harms among the leading recognized but inadequately studied risks of administering puberty blockers or cross-sex hormones to children or adolescents.

In 2017, the Endocrine Society admitted that "we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols … [including] the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on … the brain (including effects on cognitive, emotional, social, and sexual development)." SI.DX115:7 (Endocrine Society Guideline). In

2020, a large team of experts in neurology and psychology from leading research institutions recognized that "pubertal suppression may prevent key aspects of development during a sensitive period of brain organization. Neurodevelopmental impacts might emerge over time…." SJ.DX62:4 (Chen *Consensus Parameter*). In 2023, Dr. Annelou de Vries, seminal researcher in the field and co-chair of the WPATH SOC-8 chapter on Adolescents, wrote that "benefits of early medical intervention, including puberty suppression, need to be weighed against possible adverse effects—for example, with regard to bone and brain development and fertility." SJ.DX62:29 (de Vries *Growing Evidence*). In 2024, Dr. Hilary Cass, the past president of the U.K. Royal College of Paediatrics and Children's Health and who was commissioned by the English National Health Service to conduct a thorough review of the causes and treatment of gender dysphoria in minors, concluded that administration of puberty blockers "could have a range of unintended and as yet unidentified consequences" for the adolescent's brain development. SJ.DX84:178 (Cass Review). Also in 2024, neurologist Dr. Sally Baxendale of the University College London published a review of the (very limited) available literature relevant to the impact of puberty blockers on brain development and noted that two small studies had observed a significant decline in IQ in subjects who received puberty blockers across multiple years of adolescence. SJ.DX154 (Baxendale *Neuropsychological Function*). She concluded that "[c]ompletely reversible neuropsychological effects would not be predicted given our current understanding of the 'windows of opportunity' model of neurodevelopment," *id.* at 3, and that "there is no evidence to date to support the oft cited assertion that the effects of puberty blockers are fully reversible," *id.* at 9.

As the quotes above reflect, the Endocrine Society and Dr. de Vries have also warned about the possible effects of hormonal interventions on an adolescent's future fertility. Plaintiffs' expert Dr. Antommaria acknowledged during the preliminary injunction hearing that "[t]here is a risk of impaired fertility" from both puberty blockers and cross-sex hormones. Doc. 105 at 231 (PI Tr.). The UAB Pediatric Gender Clinic itself requires adolescent female patients to acknowledge that "the effects of [cross-sex] testosterone on fertility are unknown" and that "I may or may not be able to get pregnant even if I stop taking testosterone." SJ.DX36:218 (UAB Consent Form). And based on a thorough review of the scientific literature, Dr. Cass concluded that due to the limited and poor quality of that evidence, "[n]o conclusions can be drawn about the effect [of cross-sex hormones] on gender dysphoria," "cognitive development, or fertility." SJ.DX84:185 (Cass Review).

Notably, Dr. McNamara was unwilling to dismiss Dr. de Vries or Dr. Chen as a "science denier" or deployer of "scare tactics" or "false and deceptive claims." McNamara Dep. 79:4–80:14, 93:8-24. But Dr. McNamara nevertheless wants to tell this Court that—essentially—"puberty blockers and cross-sex hormones are safe for adolescents … except that I haven't investigated and can't say anything about whether they cause brain damage and sterility." Of course, opinions about safety or reversibility that ignore brain damage and sterilization are meaningless and are not remotely based on "good grounds, based on what is known." *Daubert*, 509 U.S. at 590. Nor can such opinions be said to be the result of any legitimate "methodology." *McCorvey*, 298 F.3d at 1257. They should be excluded.

2. Dr. McNamara disclaims expertise in neurodevelopment, denies having researched the literature on impacts of hormonal interventions on brain development, and denies even having opinions on key questions concerning safety with respect to brain development.

With respect to damage to brain development, Dr. McNamara strongly denied having the expertise necessary to evaluate that risk. She testified that she is "not a neurologist." McNamara Dep. 5:24-25. And she was clear about what that meant: "I do not consider myself an expert in … the endocrinologic process of pausing puberty," *id.* at 105:3-14; "I consider cognitive development in the setting of pubertal blockade to be something that is outside the scope of my expertise," *id.* at 73:2-6. Dr. McNamara repeatedly declined to answer questions about the potential impact of puberty blockers or cross-sex hormones on adolescent brain development because it was "outside the scope of my expertise." *Id.* at 88:12-19, 54:2-20, 104:2–105:14.

In fact, Dr. McNamara not only disclaimed expertise but denied even researching the topic. She repeatedly stated that she was unable to answer questions about harms to cognitive development due to her lack of research: "I would have needed to do an in-depth analysis of the literature on that question, and I haven't done so," *id.* at 114:20-23; "I would not have reason to be aware having not done an in-depth look at the literature," *id.* at 74:11-13; "I have not done an in-depth analysis of the literature to try to find such studies," *id.* at 89:4-6; "puberty-blocking medications and cognitive functioning is not something I have done an in-depth analysis on in preparing any reports," *id.* at 113:25–114:5. Even as to relevant studies of which she *was* aware, Dr. McNamara testified that "I did not review them extensively for any of my reports." *Id.* at 81:13-19.

Indeed, Dr. McNamara testified that she had formed no opinions as to whether it has been demonstrated that puberty blockers do not harm brain development, *id.* at 81:25–82:6, or whether it would be expected that any adverse impact from puberty blockers on adolescent brain development would be fully reversible, *id.* at 104:5–105:2. Safe to say, if she has not researched these questions and has no opinion about them, her testimony about these issues would not be useful or reliable.

3. Dr. McNamara disclaims expertise in fertility, denies having researched the literature on impacts of hormonal interventions on fertility, and denies even having opinions on key questions concerning safety with respect to sterilization.

The story is similar with respect to harm to fertility. Dr. McNamara is "not an endocrinologist." *Id.* at 8:4. And again, she denies having done an in-depth review of the relevant literature on the topic. Dr. McNamara stated that the question whether adolescent girls who are subjected to a prolonged course of puberty blockers "will ever achieve healthy levels of fertility" is "not a topic that I have endeavored to do a thorough literature search on." *Id.* at 135:11-18. Asked about the UAB clinic's warning to male patients that estrogen might make them permanently sterile, Dr. McNamara stated: "I have not done an in-depth analysis on the literature on fertility to be able to render an expert opinion on this statement." *Id.* at 140:15–141:6. And again, Dr. McNamara testified that she has no expert opinion on whether cross-sex hormones permanently sterilize some percentage of adolescents to whom they are administered: "I am unable to opine either way. I haven't done the type of literature search that would be required to answer that question sufficiently." *Id.* at 146:1–147:7.

4. In the absence of expertise and careful reviews of the literature, Dr. McNamara's proffered opinions concerning harm to brain development, harm to fertility, and safety lack scientific basis and cannot be "useful" to the Court.

Despite her express disclaimers of relevant expertise and her emphatic denials that she made any attempt to review the relevant literature, Dr. McNamara nevertheless opines that puberty blockers and cross-sex hormones are "safe," McNamara Rep. 1, 25; *see also id.* at 13-15, while making scattered assertions to obscure (without actually denying) the risk of harms to brain development or fertility. But "safe except for brain damage and sterilization" is not safe, and such unsystematic assertions of safety and reversibility, together with citations to cherry-picked literature, do not add up to application of the "scientific method" or any legitimate "methodology." *Daubert*, 509 U.S. at 570. Because Dr. McNamara's opinions concerning the safety of hormonal interventions and the reversibility of puberty blockers ignore recognized risks and contrary data, and do not rest on any coherent methodology, they must be excluded. This is all the more essential when (as here) the witness has repeatedly dodged inconvenient questions by outright *disclaiming* expertise and denying any thorough search of the relevant literature.

B. Dr. McNamara's Opinion That There Is an "International Consensus" In Favor of Medicalized Transition of Minors Is Baseless and Must Be Excluded.

Dr. McNamara proffers opinions that "[i]nternational … medical consensus … recommends use of standards of care from WPATH and … the Endocrine Society." McNamara Rep. 2. She continues, asserting that WPATH SOC-8 "is viewed as authoritative in the medical community," *id.*, and that "[t]he WPATH

Standards of Care and Endocrine Society [guideline] are based on the best available science and expert professional consensus," *id.* at 5. She concludes: "Other medical organizations such as the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry have endorsed these standards of care." *Id.*.

This is all utterly lacking in basis, and is in fact false. False, baseless opinions cannot be reliable or useful to this Court.

As to whether there is any "international consensus," it is obvious that there is not. The actions taken by multiple European health authorities over the last two years to ban or severely restrict administration of puberty blockers and cross-sex hormones to adolescents—including in England, Scotland, Finland, and Sweden—is a truth so inconvenient that Dr. McNamara simply pretends it isn't so. *See* SJ.DX84-96 (Cass Review and accompanying literature reviews); SJ.DX97-98 (England's National Health Services policies on puberty blockers and cross-sex hormones); SJ.DX103-106 (Sweden's policies and literature review); SJ.DX107-08 (Finland's policy and review); SJ.DX111 (Scotland's policy).

While claiming "international consensus," Dr. McNamara admitted that "I did not cite statements from other countries in any of my reports," McNamara Dep. 206:4-7, and declared that she has no idea "whether any country's nationalized health system has endorsed WPATH's standards of care in any version, or any other guidelines for any other medical organization," *id.* at 179:14–180:2. Dr. McNamara does not even acknowledge the existence of the hugely important and globally impactful reports of Dr. Hilary Cass in either her initial or supplemental expert reports;

does not discuss the policies adopted by European health authorities restricting the treatments prohibited by Alabama; and stated that she saw but did not bother to read the recent (4-page-long) Policy Statement from the English National Health Service that explains the reason for that nation's new restrictive policy. *Id.* at 207:5-8.

And when confronted with a 2021 evaluation of the quality of various "guidelines" for treatment of gender dysphoria, performed by a team from the respected King's College London applying the same "AGREE II" criteria recommended by Plaintiffs' expert Dr. Lightdale, Dr. McNamara resorted to bare denial of the facts in front of her eyes. That review by Dahlen et al. rated both the WPATH Standards of Care and the Endocrine Society Guideline as "Do Not Use." *Daubert*.DX8:7 (Dahlen *Systematic Review and Quality Assessment*). Dr. McNamara inexplicably asserts that "[t]he cited systematic review … does not conclude that the WPATH and Endocrine Society guidelines should not be used." McNamara Rep. 4. Actually, it does, as Plaintiffs' expert in the development of clinical practice guidelines, Dr. Lightdale, acknowledged: asked to explain the meaning of a "No" response by an evaluator to the prompt "I would recommend this guideline for use" in the AGREE II evaluation form, Dr. Lightdale explained, "it would mean that in … [the rater's] opinion that the guideline shouldn't be recommended for use." SJ.DX69:50:23-51:17 (Lightdale Dep.).

Inescapable evidence now negates the existence of any "international" medical consensus in favor of transitioning treatments for minors. Her proffered opinion lacks any basis in fact, much less in scientific method or an appropriate use of peer-reviewed science. It should be excluded.

Dr. McNamara's assertion that "[o]ther medical organizations such as the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry have endorsed [the WPATH SOC-8] standards of care," McNamara Rep. 5, is equally devoid of basis, and indeed counterfactual. Notably, while claiming a number of "endorsements," Dr. McNamara provides citations to none. That alone falls short of the most basic evidentiary standards and should suffice to exclude her opinion. When pressed at deposition, Dr. McNamara was unable to point to a single actual endorsement of the WPATH SOC by any medical organization, instead redefining terms to claim that a mere *citation* to the SOC in any statement from a medical organization amounts to formal endorsement. McNamara Dep. 180:20–182:3. That claim is insupportable, as anyone who reads legal opinions or scientific articles will recognize.

Meanwhile, those who actually know, know that it is *false* that these organizations have endorsed the WPATH SOC. Former WPATH President and Chair of both the SOC-7 and SOC-8 development projects Dr. Eli Coleman admitted: "I have no idea how it was ever said that so many medical organizations have endorsed SOC7. This statement is made in many legal briefs and court proceedings. But is it true? … My suspicion is that these organizations have never formally endorsed but have referenced SOC7." SJ.DX190:7 (WPATH Ex. 17). He testified that the American Academy of Pediatrics has "never endorsed SOC-8," and indeed that no medical organizations other than the (far from major) "World Association for Sexual Health" and the "International Society for Sexual Medicine" have endorsed SOC-8. SJ.DX21:261:5-262:8 (Coleman Dep.). Dr. Coleman did testify that he "assumed"

the "many endorsements" mantra was true because "[i]t's written over and over again and stated in even legal, you know, documents"—but he is aware of no factual basis for that claim. *Id.* at 264:12-16.

Cites to legal briefs are not science. Citations are not endorsements. Dr. McNamara's opinion that the WPATH SOC has been "endorsed" by other medical organizations is based on no facts and no methodology. It should be excluded.

C. Dr. McNamara's Opinion That WPATH and the Endocrine Society Guidelines are "Evidence-Based" Should Be Excluded.

Dr. McNamara repeatedly claims that the WPATH and Endocrine Society guidelines are "evidence-based" or "based on the best available evidence." McNamara Rep. 2. Once again, she provides (and has) no meaningful basis for that opinion. Dr. McNamara played no role in the development of either guideline; she was not invited to review or comment on drafts; and she does not know the qualifications of those who were involved. McNamara Dep. 7:8–8:21. In fact, she has never participated in the development of any clinical practice guideline on any topic. *Id.* at 7:2-4. Dr. McNamara wants to tell the Court about rigorous procedures for guideline development, McNamara Rep. 3, but she has no knowledge as to whether WPATH or the Endocrine Society followed those procedures. Nor does Dr. McNamara claim to have undertaken a review of the evidence relied on by the guidelines. Reading procedures for how to create clinical guidelines and simply *assuming* that WPATH and the Endocrine Society followed those procedures is not a methodology. Dr. McNamara's opinions on these topics should be excluded.

D. Dr. McNamara's Opinion That Controlled Experiments to Determine the Efficacy and Safety of Medicalized Treatments of Minors Cannot Ethically Be Conducted Should Be Excluded.

Dr. McNamara would tell the Court that controlled experiments that could prove or disprove the efficacy and safety of medicalized treatments of minors cannot be done ethically. McNamara Rep. 20-21. Given that she does not "consider [her]self to be an expert in medical ethics," McNamara Dep. 6:7-10, has never "participated in the conduct of any clinical trial on any topic," *id.* at 7:2-4, and has not undertaken any effort to review the literature concerning risks of harm to brain development and fertility (which would be essential to any informed opinion as to whether scientific knowledge concerning potential risks and benefits of hormonal interventions are currently in "equipoise"), *see supra* 10-11, these opinions must count as mere "*ipse dixit*" lacking both appropriate expertise and any scientific basis.

E. Dr. McNamara's Opinions As to How Treatment is Actually Conducted in Clinics (Including in Alabama) Should Be Excluded for Lack of Factual Basis and Reliable Methodology.

Dr. McNamara seems to proffer a great deal of testimony as to what those who treat gender dysphoria in this nation actually do. She assures the Court that treatment is provided only after thorough psychological analysis; after "careful" counseling on the possibility of impairments to fertility, McNamara Rep. 15; after the patient has "worked with a mental health provider to ensure that the youth has the psychological maturity to understand the impacts of these treatments," *id.* at 13; after physicians have obtained informed consent, *id.* at 5-6; and more.

But Dr. McNamara wouldn't know what is actually done in the field. She has never treated gender dysphoria in minors, McNamara Dep. 18:16-20, and is not on

staff with any gender clinic, *id.* at 17:4-25. She has never had a single minor patient who went on to be treated with hormones or surgery by any gender clinic. *Id.* at 21:5–22:18. She does not know basic information about actual practices even in her local clinic at Yale, such as what proportion of those referred to the clinic are prescribed puberty blockers or cross-sex hormones. *Id.* at 23:10-25. She has not tried to learn about the "actual practices in the gender clinic at the University of Alabama Birmingham Gender Clinic," *id.* at 19:20-24, and did not bother to read that clinic's consent disclosures to form an opinion as to whether they are adequate, *id.* at 20:21–21:1. She expressly testified that she does not know whether gender clinics in Alabama, prior to the enactment of the law at issue in this litigation, "consistently followed SOC-7 guidelines or the Endocrine Society Guidelines." *Id.* at 183:7-16.

The sum total of Dr. McNamara's knowledge about practice in the field comes from "listserv" exchanges with colleagues and conversations with (unidentified) doctors "about their practices." *Id.* at 117:10–118:3. Those anonymous colleagues are apparently unrepresentative and uninformed. Dr. McNamara is blissfully unaware of what WPATH insiders discuss among themselves and consider to be a very large problem. In 2021, for instance, Dr. Erica Anderson (former USPATH president), and Dr. Laura Edwards-Leeper (an author of SOC-8) published an op-ed in which they decried the reality of widespread "sloppy, dangerous care." SJ.DX136:2 (Edwards-Leeper & Anderson *Failing Trans Kids*). They noted that many clinics "do not require psychological assessment before initiating puberty blockers or hormones" and warned that "many youths are being rushed toward the medical model." *Id.* Other WPATH insiders warned (internally) of a "wave of treatment-on-demand

clinics," "opportunistic … medicine in the U.S.," and "ill-informed profiteers taking advantage of troubled youth." SJ.DX179:12 (WPATH Ex. 6).

As one high-level WPATH leader wrote in 2021 in an internal email: "The first step in solving a problem is admitting that you have one. Everyone, we have a problem." *Id.* But Dr. McNamara knows none of this, because she doesn't actually practice in the area. Asked whether she shares the concern of WPATH leaders that providers are engaging in "sloppy, dangerous care" for minors suffering from gender dysphoria, Dr. McNamara answered: "I only have knowledge of the opposite; careful, measured, thoughtful care." McNamara Dep. 187:6-11. Actually, her testimony has revealed that she has no real knowledge one way or the other. *Id.* at 187:12-19.

Dr. McNamara does not practice in the field of treating gender dysphoria, does not claim to be an expert in such treatments, and took no steps to investigate actual practice in Alabama. She has neither qualification nor any sound basis for opinions as to what is done in actual practice in gender clinics in America, much less in Alabama. Her opinions on such topics are mere speculation, do not satisfy *Daubert*, and should be excluded.

The same is true of informed consent in particular. Dr. McNamara's testimony revealed that she has no knowledge as to either the content of the disclosure forms or the actual practices with respect to obtaining informed consent in clinics in Alabama (or anywhere else). *Supra* p.18. More, she testified that she has never participated in an evaluation of whether an adolescent had the capability to give informed consent and does not have "the expertise necessary to make that determination." McNamara Dep. 124:15–125:8. In short, she does not know what information is

disclosed, whether adolescents are able to understand it, and when or how supposed informed consent is obtained. Her testimony with respect to informed consent is entirely speculation, assumption, and say-so; it should be excluded.

CONCLUSION

Defendants do not ask this Court to exclude Dr. McNamara from testifying at all. To the extent she wishes to offer her interpretation of specific scientific studies, Defendants will deal with such testimony by cross-examination. But for the reasons set forth above, the Court should preclude Dr. McNamara from testifying about the following topics:

- the safety or efficacy of puberty blockers, cross-sex hormones, or surgery as treatments for gender dysphoria in minors;
- the existence of any "consensus" or "endorsements" in support of either the WPATH or Endocrine Society guidelines;
- assertions that the WPATH or Endocrine Society guidelines are "evidence-based" or based on the "best available scientific evidence";
- questions of medical ethics including whether controlled experiments to probe the safety and efficacy of hormonal interventions in minors could be performed ethically;
- any aspect of what clinicians in Alabama or elsewhere actually do in connection with the diagnosis and treatment of gender dysphoria in minors, including with respect to the obtaining of informed consent.

Dated: June 24, 2024

Respectfully submitted,

Steve Marshall
Attorney General

Edmund G. LaCour Jr. (ASB-9182-U81L)
Solicitor General

s/
A. Barrett Bowdre (ASB-2087-K29V)
Principal Deputy Solicitor General

James W. Davis (ASB-4063-I58J)
Deputy Attorney General

Benjamin M. Seiss (ASB-2110-O00W)
Charles A. McKay (ASB-7256-K18K)
Assistant Attorneys General

OFFICE OF THE ATTORNEY GENERAL
STATE OF ALABAMA
501 Washington Avenue
Post Office Box 300152
Montgomery, Alabama 36130-0152
Telephone: (334) 242-7300
Facsimile: (334) 353-8400
Edmund.LaCour@AlabamaAG.gov
Barrett.Bowdre@AlabamaAG.gov
Jim.Davis@AlabamaAG.gov
Ben.Seiss@AlabamaAG.gov
Charles.McKay@AlabamaAG.gov

Counsel for Defendants

Christopher Mills (*pro hac vice*)
SPERO LAW LLC
557 East Bay Street, #22251
Charleston, SC 29413
(843) 606-0640
CMills@Spero.law

David H. Thompson (*pro hac vice*)
Peter A. Patterson (*pro hac vice*)
Brian W. Barnes (*pro hac vice*)
John D. Ramer (*pro hac vice*)
COOPER & KIRK, PLLC
1523 New Hampshire Ave., NW
Washington, D.C. 20036
(202) 220-9600
dthompson@cooperkirk.com
ppatterson@cooperkirk.com
bbarnes@cooperkirk.com
jramer@cooperkirk.com

Roger G. Brooks (*pro hac vice*)
Henry W. Frampton, IV (*pro hac vice*)
Philip A. Sechler (*pro hac vice*)
ALLIANCE DEFENDING FREEDOM
15100 N. 90th Street
Scottsdale, AZ 85260
(480) 444-0200
rbrooks@adflegal.org
hframpton@adflegal.org
psechler@adflegal.org

CERTIFICATE OF SERVICE

I certify that I have, on this 24th day of June, hand-filed this document under seal with the Clerk of Court and that copies of the document and exhibits have been emailed to the following counsel of record at the email addresses below:

Melody H. Eagan - meagan@lightfootlaw.com;
Jeffrey P. Doss - jdoss@lightfootlaw.com;
Amie A. Vague - avague@lightfootlaw.com;
J. Andrew Pratt - Apratt@kslaw.com;
Adam Reinke - Areinke@kslaw.com;
Brent Ray - Bray@kslaw.com;
Abby Parsons - aparsons@kslaw.com
Sarah Warbelow - Sarah.Warbelow@hrc.org;
Cynthia Weaver - cynthia.Weaver@hrc.org;
Jennifer Levi - Jlevi@glad.org;
Jessica L. Stone - Jessica.stone@splcenter.org;
Christopher Stoll - cstoll@nclrights.org;
Amy Whelan - awhelan@nclrights.org;
Rachel H. Berg - rberg@nclrights.org;
Scott McCoy - Scott.Mccoy@splcenter.org;
Diego A. Soto - diego.soto@splcenter.org

Counsel for Private Plaintiffs

Jason Cheek - Jason.Cheek@usdoj.gov;
Margaret Marshall - Margaret.Marshall@usdoj.gov;
Coty Montag - Coty.Montag@usdoj.gov;
Kaitlin Toyama - Kaitlin.Toyama@usdoj.gov;
Renee Williams - Renee.Williams3@usdoj.gov;
James Fletcher - james.fletcher@usdoj.gov;

Counsel for Plaintiff-Intervenor United States of America

s/ A. Barrett Bowdre
Counsel for Defendants