UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

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

DEFENDANTS' MOTION TO EXCLUDE
SELECTED TESTIMONY OF DR. MORISSA LADINSKY

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

INTRODUCTION

Dr. Ladinsky treats minors who suffer from gender dysphoria. Defendants do not seek to preclude her from testifying about her personal observations, or about practices within the University of Alabama Birmingham pediatric gender clinic. In addition, much of Dr. Ladinsky's expert report simply recites what diagnostic or treatment steps the Endocrine Society or WPATH guidelines call for; Defendants do not seek to preclude such testimony, either, despite its doubtful utility to the Court.

However, two important aspects of Dr. Ladinsky's proffered testimony fall far short of the requirements of *Daubert*. *First*, Dr. Ladinsky proposes to testify that those guidelines are "evidence-based" and that the Endocrine Society Guidelines were developed through "rigorous" procedures. *Daubert*.DX1:3, 7 (Ladinsky Rep.).[1] But Dr. Ladinsky has no knowledge on this topic; she is just parroting what these two documents claim for themselves, without any investigation.

Second, Dr. Ladinsky told this Court at the preliminary injunction hearing, and proposes to testify again, that administering puberty blockers and cross-sex hormones to disrupt the natural maturation of healthy adolescent bodies is "safe." Doc. 104 at 105 (PI Tr.). But Dr. Ladinsky does not have professional experience that could support such a sweeping statement, and the scant references to the scientific literature that she provides do not reflect a meaningful scientific basis nor a reliable methodology for ascertaining what is currently known in medical science.

[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).

Dr. Ladinsky should testify about what she knows, whether from experience or thorough careful research. She should not be permitted to testify to glib party-line assertions for which she has provided no basis.

LEGAL STANDARD

Under Federal Rule of Evidence 702, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that":

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court held that Rule 702 "requires that trial courts act as 'gatekeepers' to ensure that speculative, unreliable expert testimony does not reach the jury." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citing 509 U.S. 579, 597 & n. 13 (1993)). As the Eleventh Circuit has explained, "[t]he importance of *Daubert*'s gatekeeping requirement cannot be overstated" given the leeway expert witnesses are given "to opine about a complicated matter without any firsthand knowledge of the facts in the case, and based upon otherwise inadmissible hearsay." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc).

"[I]n determining the admissibility of expert testimony under Rule 702," courts in the Eleventh Circuit "engage in a rigorous three-part inquiry." *Id.* "Trial courts must consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Id.* (citation omitted). "While there is inevitably some overlap among the basic requirements—qualification, reliability, and helpfulness—they remain distinct concepts and the courts must take care not to conflate them." *Id.*

"The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Id.* The proponent must meet its burden by a preponderance of the evidence. *Kilpatrick*, 613 F.3d at 1335.

A. Experts Must be Qualified.

"A witness is qualified as an expert if he is the type of person who should be testifying on the matter at hand." *Moore v. Intuitive Surgical, Inc.*, 995 F.3d 839, 852 (11th Cir. 2021). "[E]xperts may be qualified in various ways." *Frazier*, 387 F.3d at 1260-61. "[S]cientific training or education" that equips an expert to study and understand the peer-reviewed literature is one "possible means to qualify"; "experience in a field may offer another path to expert status." *Id.* Particularly when a witness's qualifications rely primarily on experience, "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., 2023 WL 1808348, at *2 (M.D. Ala. Feb. 7, 2023) (quoting Fed. R. Evid. 702, advisory committee's notes).

"[I]n determining whether a proffered expert is 'qualified' to offer an opinion, courts generally look to evidence of the witness's education and experience and ask whether the subject matter of the witness's proposed testimony is sufficiently within the expert's expertise." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1367 (M.D. Ga. 2010) (citing *Maiz v. Virani*, 253 F.3d 641, 665 (11th Cir. 2001)). "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).

B. Experts Must Use a Reliable Methodology.

"Reliability" is a "discrete, independent, and important" inquiry, distinct from expert qualification. *Frazier*, 387 F.3d at 1261. Even "an expert's overwhelming qualifications … are by no means a guarantor of reliability." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). Though an expert witness may be eminently qualified, he "cannot waltz into the courtroom and render opinions unless those opinions are based on some recognized scientific method." *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004). "Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. A judge asked to admit expert testimony "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) (citation omitted). "Courts are cautioned not to admit speculation, conjecture, or inference that cannot be supported by sound scientific principles." *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002).

Accordingly, courts must "conduct an exacting analysis of the proffered expert's methodology." *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002). They must assess both "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 593-94. Factors to consider in determining reliability include "(1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the technique has been subjected to peer review and publication; (3) the known and potential error rate of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community." *McDowell*, 392 F.3d at 1298 (citation omitted).

Courts may also consider "[w]hether the expert is proposing to testify about matters growing naturally and directly out of research he has conducted independent of the litigation, or whether he has developed his opinion expressly for purposes of testifying"; "[w]hether the expert has unjustifiably extrapolated from an accepted to an unfounded conclusion"; and "[w]hether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting." *Hall v. Thomas*, 753 F. Supp. 2d 1113, 1130 n.95 (N.D. Ala. 2010) (quoting Fed. R. Evid. 702, advisory committee's notes, 2000 amends.).

"[T]he reliability of an expert's opinion should be seriously questioned when it is shown that the expert formed his or her opinion prior to reviewing scientific evidence, and, thereafter, merely cherry-picked evidence favorable to that opinion." *In re Seroquel Prods. Liab. Litig.*, 2009 WL 3806434, at *5 (M.D. Fla. June 18, 2009) (citing *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985)). "Courts have excluded expert testimony where the expert selectively chose his support from the scientific landscape." *In re Rezulin Prod. Liabl. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005); *see Travelers Indemnity Co. v. Broan-Nutone, LLC*, 2008 WL 11381927, at *8 (N.D. Ala. Mar. 26, 2008) (testimony unreliable when expert "ignored pertinent data"); *In re Deepwater Horizon Belo Cases*, 2022 WL 17721595, at *22 (N.D. Fla. Dec. 15, 2022) ("cherry pick[ing]" studies "does not constitute a reliable method."). "[A] reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." *Rimbert v. Eli Lilly & Co.*, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009), *aff'd* 647 F.3d 1247 (10th Cir. 2011).

"A district court cannot simply accept that an opinion is reliable because the expert says that his methodology is sound." *United States v. Azmat*, 805 F.3d 1018, 1041 (11th Cir. 2015). When an expert's methodology falls short, "the judge is free to conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Chapman v. Proctor & Gamble Distrib., LLC*, 766 F.3d 1296, 1305-06 (11th Cir. 2014) (cleaned up) (quoting *Hendrix*, 609 F.3d at 1194). The court must exclude expert testimony unless it is "properly grounded, well-reasoned, and not speculative." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1293 (11th Cir. 2005).

C. Expert Testimony Must be Helpful and Relevant.

Daubert's third prong "is commonly called the 'helpfulness' inquiry." *Proper v. Martin*, 989 F.3d 1242, 1249 (11th Cir. 2021). "The touchstone of this inquiry is the concept of relevance." *Id.* (citing *Daubert*, 509 U.S. at 591). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. Testimony must be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Id.* And even when relevant, expert testimony is admissible only "if it concerns matters that are beyond the understanding of the average lay person." *Frazier*, 387 F.3d at 1262-63.

Under the governing legal standard, it's not clear that *any* of Plaintiffs' or the United States' experts' testimony would be helpful to the Court. This case is governed by rational-basis review. Doc. 564 at 1, 28-29; *see Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205, 1224-25, 1227 (11th Cir. 2023). Under that standard, "a legislative choice is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data." *Williams v. Pryor*, 240 F.3d 944, 948 (11th Cir. 2001) (quoting *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993)). Even taken together, Plaintiffs' and the United States' experts do not (and cannot) "negate every conceivable basis that might support" the Act. *Leib v. Hillsborough Cnty. Pub. Transp. Comm'n*, 558 F.3d 1301, 1306 (11th Cir. 2009) (cleaned up). That makes their proposed testimony irrelevant and, thus, unhelpful. Plaintiffs and the United States "may not procure invalidation of the legislation merely by tendering evidence in court that the legislature was mistaken." *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 464 (1981); *cf. Rothe Dev., Inc. v. Dep't*

of Def., 836 F.3d 57, 73 (D.C. Cir. 2016) (finding it "not necessary" to consider "expert witness testimony" when determining whether a law "is subject to and survives rational-basis review").

ARGUMENT

Dr. Ladinsky's testimony should be limited pursuant to *Daubert*. Indeed, her proffered testimony offers a prime example of why the Court's gatekeeping functions under *Daubert* are so important: Dr. Ladinsky has demonstrated a striking willingness to speak (and sign) carelessly, representing as firm fact things she later recognizes to be untrue.

For example, Dr. Ladinsky told this Court at the PI hearing that no gender transition-related surgeries were "performed here in the state of Alabama on transgender minors." Doc. 104 at 114 (PI Tr.). As later document production revealed, that was false: UAB itself admitted that "the Gender Health Clinic has conducted one transitioning surgery on an 18-year-old." SJ.DX34:33 (UAB Responses and Objections). Dr. Ladinsky claimed not to know about this surgery, and testified that "I do not recall" whether she—as head of the UAB pediatric gender clinic—was consulted in connection with this minor patient. SJ.DX33:54-55 (Ladinsky Dep.).

Dr. Ladinsky also told this Court that "[t]he established guidelines recommend waiting until the age of legal majority for gender-related surgeries." Doc. 104 at 114 (PI Tr.). That was also untrue. At her deposition, Dr. Ladinsky admitted that the Endocrine Society guidelines expressly state that if significant breast development has occurred, clinicians "may … consider mastectomy … before the age of 18," Ladinsky Dep. 67, and that "the majority of girls who present at [the UAB]

clinic are candidates for mastectomy before age 18," *id.* at 68. Dr. Ladinsky also chose not to mention in her expert report that WPATH's updated Standards of Care dropped *all* minimum age limits for "gender-conforming" surgeries and cross-sex hormones. *See* SJ.DX187:300-302 (WPATH 14); SJ.DX21:293-95 (Coleman Dep.).

The point is not to attack Dr. Ladinsky's integrity (careless or uninformed inaccurate statements do not imply dishonesty), but to emphasize the importance of *Daubert*'s requirement of a demonstrated basis for proffered expert testimony. The "exacting analysis" of the basis of proffered expert testimony that the Eleventh Circuit demands, *McCorvey*, 298 F.3d at 1257, is an important safeguard for this Court's truth-finding function where complex scientific issues must be considered.

I. Dr. Ladinsky's Proffered Opinions Concerning The WPATH And Endocrine Society Guidelines Should Be Excluded For Lack Of Relevant Expertise And Reliable Basis.

Dr. Ladinsky asserts that the WPATH and Endocrine Society guidelines are "evidence-based" and reflect "considerable scientific and medical research." Ladinsky Rep. 5. She has no basis to say so.

Dr. Ladinsky did not participate in the development of either guideline. Ladinsky Dep. 12, 60. Nor does she claim to have done any review of the scientific literature to evaluate to what extent the guidelines do or do not fairly reflect the available science. Indeed, it is apparent that she did not do so. At the time of her deposition in 2023, Dr. Ladinsky had not even troubled herself to study *any* systematic review of the evidence concerning the safety and effectiveness of transitioning treatments for minors. *Id.* at 98, 130-31.

As for her claim that the WPATH and Endocrine Society guidelines are "evidence-based," Dr. Ladinsky does not even know what that means. Dr. Ladinsky is aware that there is "a whole field developed of evidence-based medicine," *id.* at 89, but she has never taken any course or attended any seminar covering principles of evidence-based medicine, *id.* at 95. She does not even understand how the term "evidence based medicine" is defined. *Id.* at 89. Her opinion as to whether the WPATH and Endocrine Society guidelines are "evidence-based" is without foundation.

Dr. Ladinsky further proposes to testify that the WPATH and Endocrine Society "guidelines are recognized as the prevailing standard of care by the major associations of medical professionals, including the American Medical Association, American Academy of Pediatrics, and the Society for Adolescent Health and Medicine, to name a few." Ladinsky Rep. 5-6. But she provides no citation to any statement by these or any organization to support this supposed "recognition." Her say-so alone is insufficient for Plaintiffs to meet their burden of establishing the reliability of Dr. Ladinsky's proffered opinion by a preponderance of the evidence.

And in fact, evidence from WPATH shows that Dr. Ladinsky is wrong: The organizations she lists have *not* endorsed the WPATH Standards of Care. Dr. Eli Coleman, former WPATH President and Chair of both the SOC-7 and SOC-8 development projects, admitted in an internal email chain: "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 17). He testified that the American Academy of Pediatrics

has "never endorsed SOC-8," and 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.DX21:261-62 (Coleman Dep.). Indeed, the AMA's express *refusal* to endorse the WPATH SOC-8 made then-president of WPATH Dr. Walter Bouman "mad as hell"—so mad that he denounced the AMA national leadership as "some white cisgender heterosexual hillbillies from nowhere." SJ.DX189:13 (WPATH 16); *see* SJ.DX21:255-59 (Coleman Dep.). Safe to say, WPATH's leadership does not share Dr. Ladinsky's impression that the AMA has endorsed the WPATH Standards of Care. Dr. Ladinsky should not be permitted to testify concerning what medical organizations, if any, have "endorsed" or "accepted" or "recognized" the WPATH or Endocrine Society guidelines. She does not know.

II. Dr. Ladinsky's Proffered Testimony That Medicalized Transition Is "Safe" Must Be Excluded For Lack Of A Reliable Basis.

Dr. Ladinsky asserts repeatedly and in different ways that puberty blockers and cross-sex hormones are "safe." She flat-out says so. Ladinsky Rep. 17, 18, 23, 26, 29. She asserts that "[s]cience does not support" concerns about harm to development of the adolescent brain, *id.* at 29; that "we know" that bone-density "catch[es] up" after puberty blockers are stopped, *id.* at 27; and that "[p]uberty blockers do not impair long-term fertility," *id.* at 21.

Some of this is false. Some of it is unknown. For none of it does Dr. Ladinsky provide a reliable scientific basis, or arrive at her conclusion by means of a reliable methodology. Her opinion must be excluded.

A. Dr. Ladinsky's Testimony That "All Major Medical Professional Groups in the United States" Agree That Medicalized Transition of Minors is "Safe" Has No Basis Whatsoever, and Is False.

Dr. Ladinsky asserts that "all the major medical professional groups" "agree" that medicalized transition of minors is "safe," and lists three by name: "the American Academy of Pediatrics, the American Medical Association, and the American Academy of Child and Adolescent Psychiatry." Ladinsky Rep. 7. A footnote links to one article or press release issued by each of these three. *Id.* But when shown the three references she chose to cite, Dr. Ladinsky admitted that not one of them states that any of these treatments are "safe." Ladinsky Dep. 240 (AAP), 244 (AACAP), 246 (AMA). Indeed, the Endocrine Society guidelines themselves nowhere say that puberty blockers or cross-sex hormones are "safe." They instead caution that "we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols." SJ.DX115:3874 (Endocrine Society Guideline). So, Dr. Ladinsky fell back to arguing that "I certainly did not see in any of these guidelines a statement that this treatment is unsafe." Ladinsky Dep. 238. But translating silence into "agreement" that medicalized transition is "safe" is an abuse of basic logic. It is certainly not a "reliable basis" for Dr. Ladinsky's proffered testimony.

B. Dr. Ladinsky Provides No Reliable Basis For Her Opinions That Cross-Sex Hormones and Puberty Blockers Are Safe With Respect to Adolescent Brain Development.

Many respected voices have expressed concern that prolonged disruption of natural puberty may inflict lasting harm on the child's cognitive development. *E.g.*, SJ.DX84:104, 178 (Cass Review). A recent peer-reviewed survey of the research in this area reported published studies that observed significant decline in IQ in subjects

who received puberty blockers across multiple years of adolescence. It concluded that "[c]ompletely reversible neuropsychological effects would not be predicted given our current understanding of the 'windows of opportunity' model of neurodevelopment," and that "there is no evidence to date to support the oft cited assertion that the effects of puberty blockers are fully reversible." SJ.DX154:3, 9 (Baxendale).

Dr. Ladinsky brushes aside these widespread concerns by asserting that "I have not seen this in my practice," and that "science does not support" the concern that puberty blockers may "alter[] normal adolescent brain maturation," citing a single article. Ladinsky Rep. 29. Her assertion has no relationship to a scientific basis, nor to a reliable methodology for arriving at scientific opinions.

1. Dr. Ladinsky has disclaimed knowledge of the effect of puberty suppression on adolescent brain development.

To start, Dr. Ladinsky effectively disclaimed knowledge of the science and literature in this area. She admitted that she is not a neurologist or expert in cognitive development. Ladinsky Dep. 12, 13, 195. She considers it "outside my expertise to know" whether "the full consequences of suppressing endogenous puberty are not yet understood." *Id.* at 197. It is again "outside [her] expertise to comment on" whether "the effects of pubertal suppression [on brain structure] may not appear for several years." *Id.* at 205-206. While the Endocrine Society guidelines caution that "animal data suggest there may be effect of [puberty blockers] on cognitive function," SJ.DX115:3883, Dr. Ladinsky has "no knowledge" as to what animal studies may have found with respect to "the effect of blocking puberty on cognitive

function," Ladinsky Dep. 190-91. Dr. Ladinsky should not be permitted to offer expert testimony on a topic she expressly recognizes to be outside her expertise.

2. Dr. Ladinsky provides no meaningful analysis of the scientific literature that could support her assertion that "science does not support" concerns about harm to brain development.

Dr. Ladinsky cites a single study relating to the impact of puberty blockers on brain development—a "very small sample" study by Staphorsius et al. from 2015. Ladinsky Dep. 219; Ladinsky Rep. 29. At deposition, however, she admitted that the authors of the study reported that after puberty suppression of a "fairly standard" duration (Ladinsky Dep. 219-20), "the [puberty] suppressed male to females … had significantly lower accuracy scores [on the "Tower of London" neuropsychological test] than the control group" (*id.* at 222, 224), and that the "reaction time of the puberty suppressed boys was slower" than the control boys (*id.* at 228).

Meanwhile, Dr. Ladinsky neither acknowledges nor responds to the respected scientific voices that have expressed serious concern that there *is* scientific reason to fear that puberty blockers will cause lasting harm to cognitive development and the (small and early) studies beyond Staphorsius et al. that *do* report troubling signs of such harm. *See, e.g.*, SJ.DX2:91-93 (Cantor Rep.) (collecting studies). Indeed, she is apparently not even aware of those studies: "I am not aware of studies that may have measured [the effect of pubertal suppression on] cognitive development with neuropsychological tests." Ladinsky Dep. 190.

Because Dr. Ladinsky shows no sign of having made any thorough investigation of the peer-reviewed literature relating to the impact of blocking puberty on

neurological development, that wider scientific literature cannot provide a reliable basis for her proffered testimony asserting safety.

3. Dr. Ladinsky's personal professional experience provides no basis for her opinions concerning safety.

While personal research and clinical experience could hypothetically provide a basis for opinions, they cannot do so for Dr. Ladinsky's assertions about the "safety" of puberty blockers and cross-sex hormones.

As to harm to brain development, Dr. Ladinsky testified that she does not "make any tests of cognitive capability of [her] patients before and after treatment." Ladinsky Dep. 184. Since she hasn't looked, the fact that she hasn't "seen" neuro-developmental harm from puberty blockers "in my practice" (Ladinsky Rep. 29) is utterly uninformative.

As to what Dr. Ladinsky has seen "in my practice" more generally, the entire UAB pediatric gender clinic has administered puberty blockers to only 17 patients across eight years—scarcely a large enough sample to draw firm conclusions about long-term safety, even if one attempted the study. And Dr. Ladinsky and UAB have *not* attempted that study: no one associated with UAB has ever undertaken any systematic study of outcomes of children treated at UAB with puberty blockers or cross-sex hormones. Ladinsky Dep. 49, 81, 104. Indeed, after injecting cross-sex hormones and puberty blockers that disrupt the healthy development of adolescents, Dr. Ladinsky and UAB make *no effort at all* to track the longer-term "health and well-being" of those patients "once our patients graduate from our space and go on into college or adulthood." *Id.* at 150; *see also id.* at 51. Dr. Ladinsky repeatedly

explained her ignorance of various matters relevant to the efficacy or safety of hormonal interventions by emphasizing that "I'm not a researcher." *Id.* at 76, 146, 152, 231, 232, 233, 300. She has thus never conducted or participated in *any* clinical research relating to gender dysphoria. *Id.* at 77-78. Given these multiple flat denials of any careful measurement or long-term follow-up of her patients, Dr. Ladinsky's clinical experience cannot provide the required reliable basis for opinion testimony concerning the long-term safety of puberty blockers or cross-sex hormones.

C. Dr. Ladinsky Provides No Reliable Basis For Her Opinions That Cross-Sex Hormones and Puberty Blockers Are Safe With Respect to Sterilization.

A drug that poses an acknowledged risk of irreversible sterilization is not "safe." Such is the case for puberty blockers and cross-sex hormones.

Start with cross-sex hormones. Dr. Ladinsky—like the UAB clinic in its informed consent form—acknowledges that administering cross-sex hormones to developing adolescents may permanently sterilize them. Ladinsky Rep. 12-13; SJ.DX36:209-21 (UAB Informed Consent Form) ("[T]his treatment may … make me permanently unable to make a woman pregnant"; "I have been told that I may or may not be able to get pregnant even if I stop taking testosterone"). And Dr. Ladinsky was unable to identify a single report in the literature of any male who had been able to impregnate a woman, or any woman who had been able to achieve a healthy pregnancy and birth, after prolonged exposure to cross-sex hormones. Ladinsky Dep. 266-269, 277. She thus retreated to arguing that the fact that "I cannot point you to such a study … does not mean it is nonexistent in the literature, the popular literature as well as the medical literature." Ladinsky Dep. 277-78. But

(again) the burden of establishing reliability is on the proponent, *Frazier*, 387 F.3d at 1260, and rank speculation that there might be such a report out there in "the popular literature" does not meet that burden.

As for puberty blockers, the UAB clinic provides no written disclosures to patients and parents concerning risks from the radical disruption of normal development. Ladinsky Dep. 284. But even the Endocrine Society guidelines caution that there is "no data" concerning development of healthy ovulation or spermatogenesis sufficient for fertility "following prolonged gonadotropin suppression" (puberty blockade) and call for "more rigorous evaluations of the … safety of endocrine … protocols," including specifically "the effects of prolonged delay of puberty in adolescents on … gonadal function." SJ.DX115: 3880, 3874 (Endocrine Society Guideline). Seminal researcher—and WPATH SOC-8 co-author—Dr. de Vries wrote in 2023 that potential benefits of "puberty suppression need to be weighed against possible adverse effects—for example, with regard to bone and brain development and fertility." SJ.DX35:193-94 (de Vries, *Growing Evidence*). Even Plaintiffs' expert Dr. Antommaria agreed that one of the risks of puberty blockers is "impaired fertility." SJ.DX43:231 (Antommaria Dep.).

Against these and many more warnings of potential harm, *see, e.g.*, SJ.DX10:25-62 (Thompson Rep.), Dr. Ladinsky proposes to testify that "puberty blockers *do not* impair long-term fertility," Ladinsky Rep. 21 (emphasis added). But she has no qualification to offer that opinion based on her own professional experience, and she has applied no reliable methodology that could enable her to offer such an opinion based on a careful review of the scientific literature.

As for direct experience, the UAB clinic has not had a single patient who, after being prescribed puberty blockers to prevent normal adolescent maturation, later went on to experience (or father) a healthy pregnancy: "Our clinic hasn't been around long enough for that to have taken place." Ladinsky Dep. 266-67.

And as for the literature, Dr. Ladinsky does not identify a reliable basis (or any basis) for her proposed "no harm to fertility" testimony. Indeed, she provides no cite whatsoever in support of that assertion in her expert report. Pressed at deposition, she did not repair the lack—and instead admitted that "the effects of sustained puberty suppression on fertility is unknown." *Id.* at 250.

Given this admission, and Dr. Ladinsky's failure to identify any scientific basis for her proffered testimony that "puberty blockers do not impair long-term fertility," the threshold requirements of *Daubert* dictate that Dr. Ladinsky should be precluded from muddying the record with that unreliable and unscientific testimony.

D. Dr. Ladinsky Provides No Reliable Basis For Her Opinions That Puberty Blockers Are Safe With Respect to Bone Health.

The same leading authors cited above recognize that puberty blockers pose a risk to long-term bone health that has not yet been adequately studied.[2] Dr. Ladinsky nevertheless wants to tell this Court that even after a multi-year suppression of natural pubertal development, "we know from excellent data that bone density catch-up ensures. This is well documented and matches our own clinical experience." Ladinsky Rep. 27. But the single article Dr. Ladinsky references for "excellent data"—

[2] The Endocrine Society calls for "more rigorous evaluations of the … safety of endocrine … procedures," including "the effects of prolonged delay of puberty in adolescents on bone health." SJ.DX115:3874 (Endocrine Society Guideline). Dr. de Vries warns of "possible adverse effects" of puberty blockers on "bone development." SJ.DX35:193-94 (De Vries *Growing Evidence*).

an article by van der Loos et al. (*see id.* at 27 n.20)—*provides no data on bone density at all*, much less data demonstrating "catch-up." *See Daubert*.DX2 (van der Loos 2021). Instead, the van der Loos authors present measurements of *bone geometry*. *Id.* For information on the effect on *bone density* of administering puberty blockers to prevent normal puberty, the authors refer readers to the very Klink et al. article that Defendants' endocrinology expert Dr. Hruz discusses (and that Dr. Ladinsky attempts to downplay in her report (at 27 n.21)). *See* DX5:¶¶74-75, 79 (Hruz Rep.). Like Dr. Hruz, the van der Loos at al. authors summarize the Klink study as reporting that bone density *decreased* in adolescents who were subjected to puberty blockers during the period of normal pubertal development when density should *increase*, and "did not reach pretreatment levels" even long after treatment with puberty blockers had ceased. *Daubert*.DX2:936 (van der Loos 2021).[3]

Given this, it seems all too likely that Dr. Ladinsky simply did not read the van der Loos article that she cites. Regardless, one article that provides no data whatsoever on bone density cannot provide a reliable basis for an opinion that "we know … that bone density catches up." Ladinsky Rep. 27.

As for Dr. Ladinsky's assertion that she also knows this from "our own clinical experience," *id.*, this is once again a fantasy. Dr. Ladinsky admitted that the UAB clinic does not routinely measure the bone density of the (only 17) children whom they have subjected to puberty blockade, either before or after, and that they have

[3] As their titles reveal, the only two other articles that Dr. Ladinsky cites in her discussion of harm to bone health (*see* Ladinsky Rep. 27 n.21 and 28 n.22) both addressed bone density when puberty blockers were used to treat precocious puberty—that is, to prevent a diseased state and cause puberty to occur at a normal, healthy age. They provide no data concerning the effect on bone health of *preventing* normal pubertal development.

not compiled any data about the bone density of their patients. Ladinsky Dep. 279. So once again, Dr. Ladinsky doesn't know, because she hasn't looked. Her clinical experience can provide no basis for an expert opinion about the safety of puberty blockers with respect to bone health. That opinion should be excluded.

CONCLUSION

Defendants do not ask this Court to exclude Dr. Ladinsky from testifying at all. To the extent she wishes to describe to the Court the actual practices and experience of the UAB pediatric gender clinic, or to tell the Court what the WPATH and Endocrine Society guidelines recommend, Defendants will deal with such testimony by cross-examination. But for the reasons set forth above, the Court should preclude Dr. Ladinsky from testifying about the following topics:

- The development of the WPATH and Endocrine Society guidelines, and the nature and quality of evidence on which they rest;
- The safety of puberty blockers or cross-sex hormones when administered to minors as a treatment of gender dysphoria, including safety with respect to brain development, future fertility, and bone health.

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