IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

B.P.J., by her next friend and mother, HEATHER JACKSON

Plaintiff,

v.

WEST VIRGINIA STATE BOARD EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST **VIRGINIA** SECONDARY SCHOOL **ACTIVITIES** COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA

Defendants

Case No. 2:21-cv-00316

Hon. Joseph R. Goodwin

Oral Argument Requested

and

LAINEY ARMISTEAD

Defendant-Intervenor.

MEMORANDUM IN SUPPORT OF DEFENDANT-INTERVENOR AND THE STATE OF WEST VIRGINIA'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. DEANNA ADKINS

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INTRODUCTION

In 2021, West Virginia passed H.B. 3293, titled: "Clarifying participation for sports events to be based on biological sex of the athlete at birth" ("the Sports Act"). Plaintiff B.P.J. filed suit, claiming that the Sports Act violates Title IX and the Equal Protection Clause. The additional factual background and procedural history of this case are incorporated here from Defendant-Intervenor's Brief in Support of Summary Judgment.

B.P.J. proffers Dr. Deanna Adkins to provide purported expert testimony pursuant to Federal Rule of Evidence 702 on a wide range of topics including:

- that the term "biological sex" is imprecise;
- disorders of sexual development;
- that gender identity cannot be voluntarily changed;
- purported harm and risks because of sex-separated sports policies;
- treatment protocols for gender dysphoria;
- the safety of puberty-blockers and cross-sex hormones; and
- the fairness and reasonableness of the Sports Act.

As set out in this brief, however, Dr. Adkins' proffered testimony on each of these topics fails to satisfy the requirements of Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny, because Dr. Adkins' opinions are not relevant to any issue in the case, because her opinions amount to *ipse dixit* rather than science and are not reliable, and/or because she possesses no special expertise pertaining to her opinions. As a result, this Court should exclude her opinions and testimony on each of these topics.

LEGAL STANDARDS

The principles of *Daubert* flesh out the requirements of Rule 702 that to be admissible, expert testimony must pertain to "scientific, technical, or other

specialized knowledge"; must be based on sufficient facts and reliable methods; and must "help" or "assist" the trier of fact. Fed. R. Evid. 702; *Daubert*, 509 U.S. at 588.

The inquiry is a flexible rather than formalistic one, *Daubert*, 509 U.S. at 594, and courts have articulated and organized the requirements of Rule 702 in multiple ways. At the highest level, courts have usefully observed that the evidence must be both "helpful" and "reliable."

A. Expert evidence must be relevant and scientific.

The requirement that the evidence "assist" or be "helpful" "goes primarily to relevance." *Id.* at 591. But it goes further: to be "helpful" in the required sense, the evidence must be scientific in nature with "a valid scientific connection to the pertinent inquiry." *Id.* at 591–92.

B. Expert evidence must be reliable.

In order to be "reliable," the evidence must (1) be "based upon sufficient facts or data"; (2) be "the product of reliable principles and methods" which (3) "h[ave] been reliably applied to the facts of the case." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013) (cleaned up); *see* Fed. R. Evid. 702.

What evidence is required to establish "reliability" is highly context-specific. With that said, courts are able to articulate certain minimum requirements or red flags.

First, "[e]xpert opinion must be connected to data by something more than the "it is so because I say it is so" of the expert." Eghnayem v. Bos. Scientific Corp., 57 F. Supp. 3d 658, 701 (S.D.W.Va. 2014). "[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997). The expert may not "make[] sweeping statements without support." Eghnayem, 57 F. Supp. 3d at 680.

Even if an expert possesses "extensive [or] specialized experience," proffered opinions must still be "supported by appropriate [scientific] validation." *Id.* at 680. Mere assertion that such validation exists cannot satisfy the burden to establish admissibility: "Writ[ing] that [s]he 'considered the scientific literature' in forming [her] opinions" is not enough—"[s]he must still base h[er] opinions on a reliable, scientific method." *Id.* "Without information about which studies [the expert] relie[s] upon in forming each of her opinions in her report, [courts are] unable to conclude whether her opinions are based on a reliable method." *Id.* at 706.

Second, "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative." Tyger Const. Co. Inc., v. Pensacola Const. Co., 29 F.3d 137, 142 (4th Cir. 1994). Speculation cannot make up the deficiency where an expert "leave[s] a gap between analytical possibility and actual proof of occurrence." Belville v. Ford Motor Co., 919 F.3d 224, 299 (4th Cir. 2019).

Third, an expert's opinion is "unreliable" when "the expert does not acknowledge or account for" "evidence tending to refute the expert's theory" among "the relevant scientific literature." Eghnayem, 57 F. Supp. 3d at 676–77 (cleaned up). Similarly, it is a strong indicia of unreliability when an expert engages in "results driven" "cherry-picking," In re Lipitor, 892 F.3d 624, 634 (4th Cir. 2018), and "selectively chooses his support from the scientific landscape," Eghnayem, 57 F. Supp. 3d at 676 (cleaned up).

Fourth, an expert must "reliably appl[y] the principles and methods to the facts of the case." In re C.R. Bard, 948 F. Supp. 2d at 612. A "bold statement of the expert's qualifications, conclusions, and assurances of reliability are not enough to satisfy the Daubert standard." Id.

C. The proponent of expert evidence bears the "burden of coming forward."

The proponent of expert evidence does not (at the *Daubert* stage) bear the burden to "prove" that the proffered evidence is true, but it does bear "the burden to come forward with evidence from which the court can determine that the proffered testimony is properly admissible" within the boundaries demarked by *Daubert. Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (1998).

Further, this is not a requirement that can be patched up after the fact in briefing or argument. Rather, it dovetails with the requirement of Rule 26 that the expert's pre-trial written report must contain not only "a complete statement of all opinions the witness will express," but also "the basis and reasons for them" and "the facts or data considered by the witness in forming them" Fed. R. Civ. P. 26(a)(2)(B)(i)—(ii). Thus, information sufficient to meet that burden of coming forward must be "in [the expert's] report." *Eghnayem*, 57 F. Supp. 3d at 706.

Except where a motion challenges the expert qualification of the witness himself, the Rule 702 inquiry is an opinion-by-opinion one; each proffered opinion must meet all of the threshold requirements. *See, e.g., In re C.R. Bard*, 948 F. Supp. 2d at 603 and *Eghnayem*, 57 F. Supp. 3d at 671–727 (analyzing the reliability and relevance of each expert's testimony opinion-by-opinion under Rule 702 and *Daubert*).

The Supreme Court and subsequent courts have emphasized the potential for expert testimony to be "both powerful and quite misleading," *Daubert*, 509 U.S. at 595; see Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001), and the resulting importance of the trial court's "gatekeeper" function in policing the minimum requirements of helpfulness and reliability. See, e.g., In re C.R. Bard, 948 F. Supp. 2d at 601.

ARGUMENT

On point after point, expert opinions proffered by Dr. Adkins are irrelevant, unreliable due to nonexistent or cherry-picked scientific support, or both. The *ipse* dixit or "say-so" nature of her opinions is apparent on the face of her opening expert report, which—while propounding a number of distinct opinions—cites a grand total of 24 "scientific" publications. Def.-Intervenor and the State of W. Va.'s App. in Supp. of Mots. to Exclude Expert Testimony of Drs. Adkins, Fry, Janssen, and Safer ("Daubert App.")¹ 20–22. Seven of these publications only concern the wholly irrelevant topic of disorders of sexual development. Id. Four of them are committeedrafted organizational position and policy statements—advocacy documents rather than peer-reviewed scientific research publications. Id. She cites no data or peerreviewed publications at all to support most of the opinions she proffers. And Dr. Adkins claims no original clinical research of her own in support of any of her opinions. In contrast, the State's expert Dr. Stephen Levine of Case Western Reserve Medical Center, cited over 90 peer-reviewed scientific publications in support of the opinions he proffered. Def.-Intervenor's App. in Supp. of Mot. for Summ. J. ("App.") $276 - 383.^{2}$

Nor, in light of her disclosure obligations under Fed. R. Civ. P. 26(a)(2)(B)(i)—(ii)), is Dr. Adkins entitled to hide her cards in her opening report and attempt to cite supporting evidence to this Court at a later stage.

In short, each of the opinions Dr. Adkins proffers utterly fails to satisfy the "reliability" requirement of *Daubert*, and at least most are irrelevant to any issue properly before this Court in this case. All should be excluded.

¹ The Daubert Appendix was filed contemporaneously and attached to Defendant Intervenor and the State of West Virginia's Motion to Exclude Expert Testimony of Dr. Deanna Adkins.

² All citations to documents filed in this case are to the document's original or bates stamped page number.

I. This Court should exclude Dr. Adkins' proffered opinion that the term "biological sex" is "inherently flawed" or "imprecise" because it is not reliable.

Dr. Adkins opines that "the notion of a singular 'biological sex,' is inherently flawed," and that there is a "scientific consensus" that "the term 'biological sex' is imprecise and should be avoided." Daubert App. 14 (¶ 37), 38–39 (¶ 7). Presumably, the argument will be that the West Virginia Legislature could not rationally or reasonably use "biological sex" as a category in the Sports Act to promote the goals of fairness and safety in athletics for the half of the population in West Virginia schools and universities born female.

Universal human experience teaches that "biological sex" is a meaningful, useful, and indeed important category. But Dr. Adkins cites only a single committee position statement in support of her counterintuitive assertion. Daubert App. 15 (¶ 41). This one-line quote from the 2017 Endocrine Society guidelines—a committee-drafted position statement, rather than a peer-reviewed scientific study—that "the terms 'biological sex, biological male or female ... are imprecise and should be avoided." Daubert App. 529.

But Dr. Adkins cherry-picks her quote from this one document she cites, and simply ignores the deep well of scientific literature that asserts precisely the opposite. Those same Endocrine Society guidelines at one place define "[s]ex" as "refer[ring] to attributes that characterize *biological maleness or femaleness," id.* (emphasis added), and elsewhere refer to a "person's genetic/gonadal sex," *id.* at 523. Meanwhile, Dr. Adkins herself, the Endocrine Society, and other respected national and international authorities continue to use and refer to "biological sex" as a meaningful category right up to the present:

• In 2018, Dr. Adkins co-authored a "Clinician's Guide" to "Best Practices in Transgender Health" in which she and her co-authors wrote that sexual orientation changes "more commonly with individuals who are attracted to the opposite *biological sex* before transitioning." *Id.* at 579 (emphasis added).

- In 2021, four years after it published the 2017 "guidelines," the Endocrine Society published *Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Statement.* It states, "[s]ex is a biological concept"; "all mammals have 2 distinct sexes;" "sex is an essential part of vertebrate biology"; and "biological sex is ... a fundamental source of intraspecific variation in anatomy and physiology"; "Women and men differ in many physiological and psychological variables." *Id.* at 381 (emphasis added).
- A currently posted information sheet from the government's National Institute of Health Office of Research for Women's Health tells us that "sex is a biological classification, encoded in our DNA ... [s]ex makes us male or female." *Id.* at 627.
- The World Health Organization's currently posted website on "Gender and health" affirms that sex "refers to the different biological and physiological characteristics of females, males and intersex persons." *Id.* at 946. Adkins testified that the WHO is a reliable authority on medical matters. App. 777 (96:15–20).

Dr. Adkins thus "make[s] sweeping statements without support and cite[s] papers that do not provide the support [she] assert[s]." *Eghnayem*, 57 F. Supp. 3d at 677. She "selectively [chooses] [her] support" from one isolated statement while failing to "acknowledge or account for" "contrary" literature, *id.* at 676–77. That includes more recent affirmations of the category of "biological sex" from the Endocrine Society itself, the National Institute for Health, the World Health Organization, and her own publication. This "is a quintessential example of applying methodologies" based on "cherry-pick[ed]" statements to support the result she seeks. *In re Lipitor*, 892 F.3d at 634.

Further, Dr. Adkins repeatedly conceded the reality of the biological binary of sex during her deposition:

- Dr. Adkins testified that "Sex is a biological concept, yes." App. 772 (74:13–14).
- Dr. Adkins acknowledged that "the genetic sex of an infant is determined at the moment of conception" and is "not something that a doctor has any choice or could change at the time of birth." App. 763 (40:5–14).
- Dr. Adkins confirmed as true the "sixth grade biology" fact that, absent a "chromosomal abnormality," "an individual with two X chromosomes ... is

- female ... and an individual ... who has an X and a Y chromosome is male." *Id.* (40:16–24).
- Dr. Adkins admitted "that in humans, like all mammals, a gamete from a male and a gamete from a female are necessary to create a fertilized egg and a new individual." *Id.* (41:2–15).

In short, Dr. Adkins' proffered opinion that "biological sex" is a vague or scientifically useless category is not only unsupported, but unsupportable. *Daubert* teaches that she should not be permitted to present such an opinion to the finder of fact.

II. This Court should exclude Dr. Adkins' proffered opinions concerning disorders of sexual development and intersex conditions because they are not relevant.

Dr. Adkins devotes several pages of her opening opinion to a set of rare medical conditions referred to as "disorders of sexual development" ("DSDs") or "intersex conditions," attempting to use these rare genetic defects to cast doubt on the reality of the biological binary of sex, and to confuse this disorder with the phenomenon of transgender identity. Daubert App. 7, 14–19 (¶¶ 7, 39–48). Dr. Adkins' proffered opinions concerning disorders of sexual development should not be admitted because they will not be "helpful": they do not relate to any issue in this case.

First, disorders of sexual development have nothing to do with B.P.J. It is not alleged, and Dr. Adkins does not opine, that B.P.J. suffers from any DSD. App. 783 (119:23–120:4).

Second, DSDs have nothing to do with the challenged law. The Sports Act protects separate female athletics defined according to biological sex. It does not exclude anyone from any participation based on a DSD. As the Endocrine Society recently noted, the existence of a developmental disorder does not mean that the biological sex of the affected individual is indeterminate. Daubert App. 381–383. Instead, even in the presence of a disorder, "people who do not have either ovaries or testes are rare," and "tightly linked" biological traits including chromosomes and

gonads "are sufficient to classify most individuals as either biologically male or female." Daubert App. 381.

How courts might interpret the medical science and the Sports Act if the Act were ever applied to someone who suffers from a rare DSD so severe as to make biological sex classification uncertain ever seeks to participate in female athletics in a West Virginia school are likely to be highly fact-specific questions. Indeed, Dr. Adkins is "not aware of any case of an XY individual who suffered from a disorder of sexual development seeking to compete in female athletics in West Virginia." App. 783 (121:6–12). But this case and B.P.J. present no occasion to engage in a speculative analysis of this fact-specific hypothetical situation.

Third, DSDs have nothing to do with any legal theory advanced by B.P.J. B.P.J. contends that males who identify as female are similarly situated to females for purposes of sports participation regardless of their physiological characteristics. B.P.J. argues that gender identity alone must control. See Mem. in Supp. of Pl.'s Mot. for Summ. J. 12–14, ECF No. 291. According to B.P.J.'s theory, the fact that (to quote the Endocrine Society) "biological sex is ... a fundamental source of intraspecific variation in anatomy and physiology," and that "[w]omen and men differ in many physiological and psychological variables" should not justify separation of sport by biological sex. Daubert App. 388–89. Rare defects in the development of those sexbased "intraspecific variations," then, must be even less relevant to B.P.J.'s theory that biological sex should not guide sex-separated sports policies.

Fourth, DSDs have little or nothing to do with transgender identity. They are simply different phenomena. Across all her years of practice, and all the 500 (according to her estimate) young people who have come to her with gender dysphoria or transgender identity, Dr. Adkins could recall only a *single* patient who also suffered from any DSD. App. 781 (111:7–112:12). And she confirmed that "[m]any

individuals who experience transgender identity do not suffer from any identified disorders of sexual development." App. 783 (118:10–120:4).

In sum, Dr. Adkins' proffered opinions about DSDs and intersex conditions do not relate to the "pertinent inquiry" in this case: whether the Sports Act is consistent with Equal Protection or Title IX. *In re C.R. Bard*, 948 F. Supp. 2d at 602. Accordingly, this Court should exclude Dr. Adkins' testimony on disorders of sexual development and intersex conditions.

III. The Court should exclude Dr. Adkins proffered opinion that gender identity is "fixed" and unchangeable because it is both unreliable and irrelevant.

Dr. Adkins opines that "[a] person's gender identity ... cannot be voluntarily changed," and contends in her rebuttal report that the fact that some individuals assert a transgender identity at one time but later "realize that they are not transgender ... does not mean their gender identity is not 'fixed' but rather that their understanding of it evolved." Daubert App. 9 (¶ 18); Daubert App. 41 (¶ 11).

Dr. Adkins' proffered opinion that gender identity is fixed or unchangeable is a declaration of personal faith not based on science or any methodology. She cites no article, no study, and no personal clinical research in support of this opinion. *See* Daubert App. 6; Daubert App. 037.

On the contrary, Dr. Adkins fails to account for multiple scientific sources that assert gender identity is *not* fixed or unchanging. The Endocrine Society 2017 Guidelines (which she cites when convenient) accurately summarize the uniform findings of multiple peer-reviewed and published studies when it states, "the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain [gender dysphoric]/gender incongruent in adolescence" and also cites "reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity." Daubert App. 533, 527.

Dr. Adkins simply professed ignorance of a recent and widely publicized peer-reviewed study of 100 individuals who experienced and lived in a transgender identity for a period of years and then "desisted"—claiming a gender identity congruent with their biological sex—as adults. App. 808 (220:6–18); see Daubert App. 591–607. In his expert report, Defendants' expert Dr. Levine cites multiple, recent, peer-reviewed publications all reporting "rising number[s] of detransitioners." App. 322–24. In her rebuttal report, Dr. Adkins' response to this heavy weight of science against the immutability of gender identity consists of mis-citing a single source and incoherent semantic games.

Dr. Adkins cites a single book chapter to attempt to deny the reality of the phenomenon of change in gender identity, asserting:

It is also not the case that there are high numbers of people who 'desist' in their transgender identity once they reach puberty. Adolescents with persistent gender dysphoria after reaching Tanner Stage 2 [i.e., the very earliest visible signs of puberty] almost always persist in their gender identity in the long-term ... ,

Daubert App. 41 (¶ 11). But she admitted at deposition that this chapter actually said *nothing* about at what stage of puberty (puberty is classically broken down into five "Tanner stages"³) transgender identity was observed to be relatively unchanging. App. 817–18 (256:2–259:8). In fact, Dr. Adkins could not identify a single study showing that "those who desist from childhood gender dysphoria do so no later than the time they first reach Tanner stage two." App. 818 (259:10–260:5). Dr. Adkins cherry-picked one source to support her assertion of immutability and misstated what that source says. This "does not reflect scientific knowledge" and is just not "good science." *In re Lipitor*, 892 F.3d at 634.

³ See, e.g., World Health Organization, Annex H, Sexual Maturity Rating (Tanner Staging) In Adolescents, in Antiretroviral Therapy for HIV Infection in Infants and Children: Towards Universal Access: Recommendations for a Public Health Approach: 2010 Revision, https://www.ncbi.nlm.nih.gov/books/NBK138588/ (last accessed May 3, 2022) (explaining the five Tanner stages).

Eghnayem illustrates the requirement that an expert's opinions be based on an accurate reading and portrayal of scientific sources relied on. There, an expert proposed to testify that "the infection rate of polypropylene mesh is up to 100%." Eghnayem, 57 F. Supp. 3d at 678. But the study that the expert cited only measured the presence of bacteria on mesh systems, and the authors of the study expressly disclaimed any conclusion equating "bacteria contamination ... to infection." Id. (emphasis added). As a result, the court found the study was not "directly applicable," that the expert's portrayal of the study did not "support the [proffered] opinion," and the should be excluded. Id. In the same way, Dr. Adkins' cited source on gender identity is not "directly applicable," and her portrayal of this single book chapter does not "support" her proffered opinion. Id.

And in any case, a general observation by authors of one book chapter about persistence in a particular age group does not contradict the existence of the widespread phenomenon of desistence (gender-identity change) reported by the many studies cited in the Endocrine Society Guidelines and by Dr. Levine. Dr. Adkins' opinion simply "does not acknowledge or account for" these scientific reports and is thus unreliable. *Eghnayem*, 57 F. Supp. 3d at 676–77.

Dr. Adkins' real response to the extensive data of gender-identity change is to dive into epistemological mysticism. Gender identity, she asserts (without citation) is "not changeable"; it "is what it is." App. 810 (226:2–3, 9–10). As to what that unchangeable gender identity is, we must believe the individual: "Everyone's gender identity is how they explain it," and it "is something that can only be explained by a person because it is their knowledge of themselves." App. 810 (227:13–228:3).

We must believe them, that is, *unless* they report that their gender identity has changed. Then, Dr. Adkins asserts (without citation) that they are mistaken, that their "is what it is" gender identity has *not* really changed—merely their

"understanding" of their gender identity has changed. App. 810 (226:11; 227:8–9; 228:3–4); App. 811 (230:12–15). Dr. Adkins "explained":

[j]ust because I say I don't like strawberries when I'm eight and I do like strawberries now doesn't mean I never liked strawberries to begin with. It means I finally had a good strawberry.

Id. at 810 (228:2–7).

This is all utterly unsubstantiated, and it is not science. Science, the Supreme Court in *Daubert* explains, consists of forming hypotheses and then "testing them to see if they can be falsified." *Daubert*, 509 U.S. at 593.⁴ But Dr. Adkins asks us to believe individuals' claims about their gender identity that suit her theories, then dismiss those claims as mere (mis)"understanding" when they do not suit her theories. App. 810 (226:10–11). She has thus abandoned testable or falsifiable hypotheses, and she is in the realm of dogma, not science.

Happily, though, we need not spend too long pondering epistemology and self-understanding, because whether gender identity changes or not is irrelevant to any issue in this case. Nothing in the Sports Act turns on gender identity, whether fixed or not. Dr. Adkins, for her part, contends that the only reasonable policy would allow students who (e.g.) "experienc[e] ... alternation between a male and female gender identity" to "do what works for them based on their gender identity," App. 794 (165:7–166:5), and their "feeling" about that identity, *id.* (164:8), "on a particular day," *id.* (163:23)—regardless of whether that "alternation" reflects a "change in gender identity" or merely a "change in understanding of gender identity." *Id.* at 810–11 (226:11; 227:8–9; 228:3–4; 230:12–15). The proffered opinions that gender identity is "fixed" are irrelevant. Daubert App. 41 (¶ 11).

⁴ See also "criterion of falsifiability," Encyclopedia Britannica (Feb. 24, 2016), https://www.britannica.com/topic/criterion-of-falsifiability (last visited May 10, 2022).

IV. This Court should exclude Dr. Adkins' opinions that sex-separated sports will cause "extreme harm" and suicide because they are not reliable.

Dr. Adkins proposes to testify that unless West Virginia permits biologically male students who identify as female to participate in female athletics, this will be "extremely harmful" to those individuals and result in heightened rates of suicidal ideation. Daubert App. 9–12 (¶¶ 20–28). This, she opines, is true even as to those males who have not (yet) suppressed testosterone: "I think it is unreasonable for them to be taken out of their sport. I think it causes harm. We see evidence that it causes harm with regard to depression, anxiety, suicidality." App. 790 (147:18–148:7).

We should note at the outset that Dr. Adkins is careful to refer to "suicidality" rather than "suicide." The former includes merely thinking about the possibility of suicide and is far more common than and very weakly correlated with actual suicide. App. 333–34 (¶ 152). But even after lowering the hurdle in this way, Dr. Adkins provides no scientific basis for these opinions whatsoever. She cites literally no papers to support her opinions that a requirement to participate in athletics based on biological sex rather than gender identity does or will inflict "extreme harm" or increase suicidality. Daubert App. 11–12 (¶¶ 21, 27, 28).

And she cites nothing to support the hypothesis that a student will suffer "extreme harm" or any harm if "affirmed" in a transgender identity in name, dress, and other respects, but required to participate in sport according to their biological sex. *Id.* She did not testify that a single one of her patients experienced heightened suicide risk or ideation, or attempted or completed suicide, as a result of sex-separated sports policies—much less reference any scientific publications documenting any such impact. App. 785–86 (129:19–130:10). All of these opinions are the merest "*ipse dixit*," and therefore must be excluded as unreliable. *General Electric*, 522 U.S. at 146.

The absence of any proof of harm resulting from not participating in female athletics is particularly striking given that from 2011 through 2021, the NCAA had in place a policy excluding males who identify as females from participation in female athletics until they complete a full year of testosterone suppression. Daubert App. 155 (¶ 38).⁵ As noted above, Dr. Adkins gave her opinion that such a policy "causes harm" including "depression, anxiety, suicidality." App. 790 (147:18–148:7). Despite a decade-long opportunity to test that hypothesis, she cites no evidence that it ever did cause such harm.

In her expert report, Dr. Adkins asserts, "I know from experience ... that it can be extremely harmful for transgender youth to be excluded from the team consistent with their gender identity." Daubert App. 12 (¶ 28).

When pressed for examples, however, she had almost nothing to offer. One patient, she said, "didn't feel comfortable ... they chose not to participate." App. 785 (127:2–21). Pressed further, she asserted, "I have had patients who have no longer participated in sports, gained weight, become obese, and developed type two diabetes. I have seen that around --- I can think of at least two examples." App. 785 (129:19–23). But this is not science. Two patients (no details given) are a tiny fraction (less than one half of one percent) of her 500 patients. Over 40% of American adults are

⁵ In 2021, the NCAA adopted a revised policy that invited individual sport governing bodies to adopt sport-specific eligibility standards for male participation in female sports. In 2022, the intercollegiate competitive swimming governing body, USA Swimming, adopted a substantially more restrictive policy that requires at least *three* years of testosterone suppression, and puts the burden on the male athlete who seeks eligibility to demonstrate that "prior physical development of the athlete as a male, as mitigated by any medical intervention, does not give the athlete a competitive advantage over the athlete's cisgender female competitors." "USA Swimming Releases Athletic Inclusion, Competitive Equity and Eligibility Policy," USA Swimming (Feb. 1, 2022), https://www.usaswimming.org/news/2022/02/01/usa-swimming-releases-athlete-inclusion-competitive-equity-and-eligibility-policy.

obese.⁶ Over 10% of Americans develop diabetes.⁷ Any inference that a sex-separated sports policy *caused* two out of Adkins' claimed 500 patients to develop diabetes—absent a carefully designed study that could test for causation—is the merest speculation, nowhere close to the scientific methodology *Daubert* requires.

Eghnayem is again instructive. 57 F. Supp. 3d at 701. There, an expert "concede[d] that he did not 'reference any articles' in making his opinion [on causation and harm] because his testimony [was] based on 'knowledge and opinion he ha[d] accumulated over the last several years." Id. The expert "performed no tests or experiments to come to his conclusions nor ha[d] he submitted any relevant work to peer review." Id. And the court noted the expert "provided no objective data to back up this assertion and instead simply relied on memory." Id. The court held that this say-so foundation "does not survive Daubert's scrutiny." Id. All of these discrediting factors apply with equal or greater force to Dr. Adkins' opinions on harm and suicidality.

And her failure to provide any scientific connection between the health issues allegedly observed in two of her patients and any sex-separated sports policies leaps over the "line where assumptions open to cross-examination become assumptions that are so far removed from fact that they render an expert's opinion unreliable." *Bygum v. City of Montgomery*, No. 2:19-cv-00456, 2021 WL4487610, at *4 (S.D.W.Va. Sept. 30, 2021); *see Eghnayem*, 57 F. Supp. 3d at 680.

⁶ Adult Obesity Facts, Center for Disease Control and Prevention, https://www.cdc.gov/obesity/data/adult.html (last visited May 10, 2022).

⁷ Statistics About Diabetes, American Diabetes Association, https://www.diabetes.org/about-us/statistics/about-diabetes (last visited May 10, 2022).

V. This Court should exclude Dr. Adkins' opinion that her preferred protocol for addressing gender dysphoria is "the only treatment," because it is both irrelevant and unreliable.

Dr. Adkins proposes to opine that "[t]he only treatment [for gender dysphoria] to avoid ... serious harm is to ... follow appropriate treatment protocols to *affirm* gender identity" Daubert App. 10 (¶ 22) (emphasis added).

A. Dr. Adkins' opinions about preferred treatment protocols are not relevant.

At the threshold, Dr. Adkins' opinion concerning treatments for gender dysphoria is irrelevant to any issue in this case. The Sports Act does not regulate or prohibit any treatment protocol for gender dysphoria. Under the Sports Act, the right to participate in female athletics turns on biological sex, not on what treatment protocol a student may be undergoing.

Dr. Adkins confirmed that the Sports Act "doesn't restrict the use of puberty blockers" and "doesn't exclude anyone for participation on any team based on the use of puberty blockers." App. 822 (277:14–24). Indeed, in rebuttal she expressly affirms that the Act "does not have any effect on" decisions about "appropriate behavioral and medical care for minors with gender dysphoria." Daubert App. 42–43 (¶ 14). Nor can B.P.J. point to any precedent holding that Equal Protection (or Title IX) requires States to tailor otherwise legitimate laws to avoid any burden on the physician-prescribed "treatment" of any individual. Contested opinions about what is or is not the best or most widely accepted treatment protocol for minors who suffer from gender dysphoria are thus irrelevant to any issue which this Court must decide.

B. Dr. Adkins' opinions about preferred treatment protocols are not reliable.

Moving to substance, Dr. Adkins' opinion that "affirmation" is the "only treatment" that avoids "serious harm" is absolute *ipse dixit*. She cites no authority for that bold assertion. The two sources she does cite in adjacent discussions simply

do not endorse the position she asserts. And she ignores rather than "acknowledg[es] or account[s] for" the many respected voices to the contrary. She cites no scientific source that even asserts—much less offers evidence to support—that inclusion in opposite sex athletics is an essential part of any "treatment." *Eghnayem*, 57 F. Supp. 3d at 676–77; Daubert App. 12 (¶ 28). It is all speculation, smoke, and mirrors.

In adjacent discussions, Dr. Adkins cites the WPATH self-anointed "standards of care," and the Endocrine Society 2017 Guidelines. The Endocrine Society makes no recommendation at all about social transition except that "decisions regarding the social transition of prepubertal youths with GD/gender incongruence [should be] made with the assistance of an MHP [Mental Health Professional] or another experienced professional." Daubert App. 524, 533. Indeed, the Endocrine Society Guidelines caution that while most children who experience gender dysphoria will desist from that dysphoria in the course of adolescence, "social transition ... has been found to contribute to the likelihood of persistence." Daubert App. 533.

The WPATH Standards of Care similarly does not recommend social transition for children, instead recognizing that "[t]his is a controversial issue, and divergent views are held by health professionals," and that social transition is fraught with risk because "[a] change back to the original gender role can be highly distressing," and recommending that mental health professionals "should counsel and support" families as the families "work through the options and implications" which may include "not allow[ing] their young child to make a gender-role transition." Daubert App. 969.

And even as to these two sources, Dr. Adkins nowhere claims that they represent universally accepted or ethically binding standards in any sense. She testified that "the Endocrine Society guidelines are guidelines. All of us who use guidelines do vary some from those guidelines when it's appropriate for the particular

patient." App. 829 (305:2–5). And she testified that she has "reservations" about the Endocrine Society guidelines that she discusses with other practitioners. App. 829 (305:12–14). Yet these are the very sources that Dr. Adkins cites to support her opinions here.

In contrast, Drs. Levine and Cantor identify and discuss a number of respected and prominent voices that Dr. Adkins *omits* and that disagree sharply with her assertion that affirmation is the "only" accepted therapeutic path, or even a prudent path. Daubert App. 51–52 (¶ 28); App. 297–313 (¶¶ 42–89); App. at 409–430 (¶¶ 54–103); App. at 433–440 (111–138). These include multiple European national health services which have recently announced policies *against* administration of puberty blockers (which Dr. Adkins presents as an integral part of an "affirming" course of treatment) on the grounds that the benefits of this dramatic intervention in normal development are unproven by any reliable science, while the risks are substantial. Daubert App. 10–11 (¶ 25); *See* App. 311 (¶ 82).

To illustrate, the Royal Australian and New Zealand College of Psychiatrists just last year published a statement recognizing that "[t]here are polarized views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people." App. 302–303 (¶ 57). Likewise, prominent psychologist and former board member of WPATH Erica Anderson—a transgender woman—has publicly expressed grave concern that children and adolescents are being too hastily encouraged to socially transition, in the absence of reliable evidence that transition improves wellbeing. App. 305 (¶ 64).

Dr. Adkins may disagree with all of these respected voices, but the requirements of *Daubert* do not permit her simply to ignore them while asserting a contrary view unsupported by any citation.

VI. This Court should exclude Dr. Adkins' proffered opinions concerning the safety of certain treatment protocols because they are irrelevant and unreliable.

In her declaration at the preliminary injunction stage, Dr. Adkins flatly asserted that administration of puberty blockers to prevent ordinary pubertal development at the ordinary time in children is "safe." Adkins Decl. in Supp. of Pl.'s Mot. for Prelim. Inj. ¶ 34. In her opening expert report, though, she asserts that administering not only puberty blockers, but also cross-sex hormones to take sex-linked hormone levels in an adolescent's body to the levels characteristic to the opposite sex, is "safe." Daubert App. 13 (¶ 34). She repeats the same opinions in varying words in multiple places. Daubert App. 46–49 (¶¶ 21, 24).

These opinions are not relevant. The Sports Act does not regulate, prohibit, or mandate any form of hormonal treatment of young people. No provision in the Sports Act turns on whether hormones or hormone blockers have been administered to a child. App. 822 (277:21–24). Indeed, Dr. Adkins opined that she would *not want* to see a law on the books that created incentives for children to begin puberty blockers by making participation by biological males in female athletics contingent on suppressing puberty. App. 823 (279:16–280:4). There is thus no "fit" or logical connection at all between Dr. Adkins' safety opinions and any issue in this case. *In re C.R. Bard*, 948 F. Supp. 2d at 602.

The opinions also represent *ipse dixit* lacking all indicia of reliability. "Safe" is a very big word when it comes to what are indisputably radical hormonal interventions in normal human development and hormone levels. It is remarkable that Dr. Adkins makes this bold and absolute assertion of safety without citing to a single source in the scientific literature. *See, e.g.*, Daubert App. 13 (¶ 34).

Remarkable, but indicative of the underlying reality. While Dr. Adkins proposes to tell this court that hormone blockers and cross-sex hormones are "safe," she does not tell patients and parents that they are "safe." When pressed repeatedly

at deposition as to whether she "tell[s] parents that puberty blockers are safe," Dr. Adkins refused to answer "yes," but rather said "I review the effects and the side effects." App. 820 (267:24–268:1).

She acknowledged that puberty blockers have never undergone clinical trials to evaluate safety when used to delay puberty from its naturally occurring time in children who do not suffer from precocious puberty (the only FDA-approved indication), App. 822 (276:3–24), and she did not know whether administration of cross-sex testosterone to natal females had ever been tested for safety "to a level of rigor that could satisfy FDA requirements," App. 802 (197:10–17).

The Endocrine Society Guidelines that Dr. Adkins cites for other purposes make no sweeping assertion that puberty blockers and cross-sex hormones are safe. Rather, as Dr. Adkins acknowledged, the Guidelines flag a long list of cautions, warning that:

[I]n the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols ... includ[ing] the careful assessment of ... the effect[] ... on bone health, gonadal function and the brain, including effects on cognitive, emotional ... social and sexual development.

App. 824 (283:4–19). And the Endocrine Society specifically "recommend[s]" that practitioners counsel all patients concerning "options for fertility preservation" before initiating either puberty blockers or cross-sex hormones—precisely because of the risk to future fertility. Daubert App. 533.

Equally, risk to brain development if puberty is suppressed cannot be casually dismissed because—as Dr. Adkins concedes—it is well recognized that "hormonal changes associated with puberty do drive important developmental stages in the human brain." App. 828 (299:18–23). In fact, the single study she does cite as showing no negative effects on brain development reports just the opposite: biological males not on puberty blockers ("control boys") "had *significantly higher IQ scores* than" biological males subjected to puberty blockers. Daubert App. 718 (emphasis added).

Likewise, biological males on puberty blockers "had *significantly lower accuracy* scores than the control groups" in various tests. *Id.* (emphasis added). And Dr. Adkins herself has done no "study of ... the role of puberty hormones in promoting [brain] development," nor of the "effects of blocking puberty" on the development of "the thinking part of the brain." App. 826 (290:10–24).

Dr. Adkins' true opinion about "safety" is revealed by the fact that in her own practice (where the risk of personal liability hovers), she has an aide read some 20 minutes' worth of disclosures about "risk[s]" and "unknowns" to the patient and family—including risks to future fertility—before she will prescribe cross-sex hormones. App. 801 (190:10–193:13); Daubert App. 663–64. But she wants to opine to this Court that it is all "safe." Daubert App. 13 (¶ 34).

As the expert reports of Drs. Levine and Cantor detail with extensive citations to the literature, the risks or known harms associated with the administration of puberty blockers and cross-sex hormones are real, extensive, and well-documented. See App. 328–335 (¶¶ 135–159); App. 407–415 (¶¶ 46–68). But the critical point here is that Dr. Adkins has not in her expert report even begun to carry her "burden of coming forward" with evidence sufficient to permit the Court to conclude that her proffered opinions about safety satisfy the "reliability" requirements of *Daubert* and its progeny.

VII. This Court should exclude Dr. Adkins' proffered opinions concerning whether the Sports Act is "fair" or "reasonable" because she has no relevant expertise, and her opinions are unreliable.

At her deposition, Dr. Adkins testified that she is offering an opinion that the Sports Act is unreasonable "to the extent it prevents even a single transgender youth from playing in the division consistent with their gender identity." App. 784 (124:8–13). Likewise, she opines that "the West Virginia Law is not a reasonable measure to

ensure fair and safe competition for females in schools and colleges in West Virginia." App. 784 (125:16–23).

These opinions should be excluded because Dr. Adkins possesses no relevant expertise. She testified that she has no expertise in "the concept of fairness" except as a layperson: "I can recognize fairness and have a concept that would be appropriate for someone of my age." App. 758–759 (21:24–22:5). But that describes common sense and lay experience, not expertise. And she denied ever having done any research related to sports physiology, as would be necessary to opine on safety. In Dr. Adkins' own words, "Yeah. I don't study sports." App. 791 (151:12–13). But she did acknowledge scientific literature showing that females "have been reported to have more frequent knee injuries." App. 776 (92:1–10).

Dr. Adkins' opinions concerning what is fair or reasonable with regards to a sex-separated sports policy for eligibility in female athletics must also be excluded because she cites no scientific sources, and she applies no identifiable methodology, in arriving at those conclusions. Quite simply, these are nothing more than personal *ipse dixit* opinions.

CONCLUSION

For the reasons set forth above, the Court should preclude Dr. Adkins from offering opinion testimony on each of the topics detailed above.

Respectfully submitted this 12th day of May, 2022.

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/s/ Brandon S. Steele

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IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

B.P.J., by her next friend and mother, HEATHER JACKSON

Plaintiff.

v.

WEST VIRGINIA STATE **BOARD** EDUCATION, HARRISON COUNTY BOARD EDUCATION. WEST **VIRGINIA** OF SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA

Defendants.

and

LAINEY ARMISTEAD

Defendant-Intervenor.

Case No. 2:21-cv-00316

Hon. Joseph R. Goodwin

CERTIFICATE OF SERVICE

I, Brandon Steele, hereby certify that on May 12, 2022, I electronically filed a true and exact copy of the forgoing with the Clerk of Court and all parties using the CM/ECF system.

/s/ Brandon S. Steele

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