

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 OF
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

and

LAINIEY ARMISTEAD

Defendant-Intervenor.

Case No. 2:21-cv-00316

Hon. Joseph R. Goodwin

Oral Argument Requested

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

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INTRODUCTION

In 2021, West Virginia passed HB 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. Joshua Safer to provide purported expert testimony pursuant to Fed. R. Evid. 702 on a wide range of topics including:

- the extent and success of transgender participation in girls’ and women’s scholastic athletic competition to date;
- whether males enjoy athletic advantages over females before puberty;
- whether suppression of testosterone after undergoing male puberty can eliminate male athletic advantages over females;
- the policies of organizations including the International Olympics Committee (“IOC”), World Athletics, and the NCAA concerning testosterone suppression and eligibility to compete in women’s athletics;
- what is or is not “fair”;
- the role of sports in education;
- the scientific validity of the category of “biological sex” invoked in the Act;
- disorders of sexual development;
- the supposed existence of an unidentified biological basis for transgender identification.

As set out in this brief, however, Dr. Safer’s proffered testimony on each of these topics fails to satisfy the requirements of Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and its progeny, because Dr. Safer’s proffered opinions are not relevant to any issue in the case, because his opinions amount to *ipse dixit* rather than science and are not reliable, and/or because he

possesses no special expertise pertaining to the opinions. As a result, this Court should exclude his opinions and testimony on each of these topics.

LEGAL STANDARD

The principles of *Daubert* flesh out the requirement 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(a).

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.” *Daubert*, 509 U.S. 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 592.

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) “ha[ve] 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); 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. Boston Scientific Corp.*, 57

F. Supp. 3d 658, 701 (S.D.W. Va. 2014) (citation omitted). “[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 677 (citation omitted).

Even if an expert possesses “extensive [or] specialized experience,” proffered opinions must still be “supported by appropriate validation.” *Id.* at 680 (cleaned up). Mere assertion that such validation exists cannot satisfy the burden to establish admissibility: “[W]rit[ing] that he ‘considered the scientific literature’ in forming his opinions” is not enough—“he must still base his opinions on a reliable, scientific method.” *Id.* “Without information about which studies [the expert] relie[s] upon in forming each of h[is] opinions in h[is] report, [courts are] unable to conclude whether h[is] 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 Constr. Co. Inc. v. Pensacola Constr. 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, 229 (4th Cir. 2019) (citation omitted).

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 “[r]esults-driven” “cherry-picking,” *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation*, 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.” Fed. R. Evid. 702(d). A “bold statement of the experts’ qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard.” *In re C.R. Bard*, 948 F. Supp. 2d at 612 (citation omitted).

C. The proponent of expert evidence bears a “burden of coming forward” with facts establishing admissibility.

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*. *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 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 (cleaned up); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (cleaned up). They left the trial court as the “gatekeeper” for policing the minimum requirements of helpfulness and reliability. *See, e.g., In re C.R. Bard*, 948 F. Supp. 2d at 601.

ARGUMENT

As detailed below, Dr. Safer fails to satisfy one or more of the minimum requirements of Rule 702 and *Daubert* for each of the opinions that he proffers. Accordingly, this Court should exclude his testimony. *Eghnayem*, 57 F. Supp. 3d at 676–77, 680; *Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 809, 821 (S.D.W. Va. 2018).

I. The Court should exclude Dr. Safer’s proffered opinions concerning transgender participation and advantage in female athletics because they are not reliable.

A. Dr. Safer’s opinions concerning transgender participation and success in female athletics are unreliable.

Dr. Safer opines that “transgender girls and women have been playing in NCAA and secondary school sports for at least the past 10 years.” 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.*”)¹ 206 (¶ 25), and that “[t]he occasional championships that have been widely publicized do not come close to constituting the rates one would expect if they won at rates that are proportional to their overall percentage of the population (which is approximately 1%).” *Daubert App.* 205 (¶ 22). Presumably, he intends to leave an impression that transgender athletes do not enjoy physiological advantages over biological females, and that their inclusion in female athletics will not meaningfully disadvantage those born female.

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

But at deposition, Dr. Safer conceded that these opinions are based on no factual data at all. He “cannot point to a specific instance” to support his opinion that “transgender athletes have been competing in the women’s division of NCAA or secondary school athletics . . . for many years.” Def.-Intervenor’s App. in Supp. of Mot. for Summ. J. (“App.”)² 657 (171:14–24).

Nor did he have any factual basis for his assertion that transgender athletes are not winning disproportionate numbers of “female” championships: Dr. Safer admitted that he did not base that opinion on any “percentages,” “survey[s],” or “statistics.” App. 642 (111:13–112:9). And he admitted that he does not “know whether the number of victories of championships that have been taken in the women's division by transgender competitors is higher or lower than the percentage of athletes in those divisions who are transgender.” *Id.* (111:21–112:7).

In short, Dr. Safer’s proffered opinions about transgender participation and victory in female sports are based on no facts or data whatsoever. As a result, those opinions cannot be the result of “reliable principles and methods,” *In re C.R. Bard*, 948 F. Supp. 2d at 601, and represent unalloyed *ipse dixit*. As was the case in *Eghnayem*, Dr. Safer has “provided no objective data to back up this assertion.” 57 F. Supp. 3d at 701. And a “reliable expert would not . . . make sweeping statements without support.” *Id.* at 677 (citation omitted). These opinions must be excluded as unreliable.

B. Dr. Safer’s opinions denying male athletic advantage before puberty are unreliable.

Dr. Safer concedes that “after puberty, non-transgender boys and men as a group have better average performance outcomes in most athletic competitions when compared to non-transgender girls and women as a group.” Daubert App. 151 (¶ 25).

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

But he opines that “[b]efore puberty, age-grade competitive sports records show minimal or no differences in athletic performance between non-transgender boys and non-transgender girls.” *Id.*

Dr. Safer provides no data or scientific articles to support his categorical denial of any pre-pubertal male advantage. And as Dr. Safer conceded at deposition, the actual data contained in the one article he cites later in the same paragraph of his expert report—Handelsman, et al. (2018)—shows just the opposite—that males enjoy significant performance advantages in several athletic metrics before puberty. Daubert App. 493, 495. And Dr. Safer altogether fails to “acknowledge or account for,” *Eghnayem*, 57 F. Supp. 3d at 676 (citation omitted), extensive peer-reviewed literature showing male advantage even before puberty and contradicting his opinion, even though he is aware of that literature. This opinion must therefore be excluded as unreliable and not based on data or reliable methodology.

At his deposition, Dr. Safer reviewed the data presented in Handelsman, et al. (2018) (Daubert App. 493, 495), and admitted that it showed that junior high boys (age 12, specifically) enjoyed a five percent performance advantage in running, and a “four to six percent advantage for boys” “in jumping.” App. 636–637 (89:6–90:24); App. 638 (94:18–95:3). And though he opined that boys enjoy minimal or no advantage over girls, he now claimed to be unable to answer whether a six percent advantage is “minimal.” App. 638 (95:6–11). And later, he disclaimed expert ability to say whether even a 16.6 percent advantage would be a “very large” advantage. App. 640 (103:4–10).

Defendants’ sports physiology expert, Dr. Gregory Brown, cited a more recent and very widely known article by Professors Hilton and Lundberg (2020) that, among other things, thoroughly reviewed the scientific literature and reported that:

[a]n extensive review of fitness data from over 85,000 Australian children . . . showed that, compared with 9-year-old females, 9-year-old

males were faster over short sprints (9.8%) and 1 mile (16.6%), could jump 9.5% further from a standing start (a test of explosive power), could complete 33% more push-ups in 30 s[econds] and had 13.8% stronger grip. Male advantage of a similar magnitude was detected in a study of Greek children, where, compared with 6-year-old females, 6-year-old males completed 16.6% more shuttle runs in a given time and could jump 9.7% further from a standing position. In terms of aerobic capacity, 6- to 7-year-old males have been shown to have a higher absolute and relative (to body mass) VO₂max than 6- to 7-year-old females.

Daubert App. 560. Dr. Safer testified that he is “familiar” with this article and that “[He has] read it with some care.” App. 639 (99:8–22). He testified that he had no reason to “expect[] that [the authors of these studies are] fabricating that data.” App. 639–640 (101:22–102:9). Yet Dr. Safer nowhere cited or mentioned this important article in his expert or rebuttal report. Nor did he cite, discuss, or account for the several additional peer-reviewed articles referenced in the Hilton & Lundberg (2020) paper which provide data showing pre-pubertal male athletic advantages, or the still more on-point papers reviewed by Professor Brown. *See* App. 145–156 (¶¶ 71–108). Instead, Dr. Safer chose to ignore contrary data.

After cherry-picking his support, Dr. Safer then moves on to rampant, explicit speculation, tossing out the possibility that even if boys in general *do* have athletic advantages over girls before puberty, perhaps boys who identify as female do not. “[I]t cannot be assumed,” he says, “that the physiological characteristics of cisgender boys and men will automatically apply to transgender girls and women.” Daubert App. 200–201 (¶ 12).

On the contrary, given that males who identify as female are “normal males” in their biology (there is no contention that B.P.J. or any transgender athlete in West Virginia suffers from any disorder of sexual development), it would be entirely reasonable for a legislature to “assume” that they possess normal male athletic capabilities. *Id.* In fact, Dr. Safer nowhere offers even a *hypothesis* as to how gender *identity* could affect physiology and physical ability, and indeed he asserts that he is

not offering any opinion that males who identify as female are any less athletically capable than males generally: “I’m not offering an opinion between those two groups. *I’m simply raising the possibility . . .*” App. 641 (107:18–21) (emphasis added). He “did not ‘reference any articles’ in making his opinion”; he “performed no tests or experiments to come to his conclusions nor has he submitted any relevant work to peer review”; and he “provided no objective data to back up this assertion.” *Eghnayem*, 57 F. Supp. 3d at 701; *see* App. 640–641 (104:10–106:12); App. 641 (107:7–21). He testified, “I don’t know that. It only might be true.” App. 641 (106:12).

But Dr. Safer is attempting to flip the burden: *he* must provide a basis from which this Court can conclude that the opinions he offers are reliable. It is not the State’s burden to demonstrate that his opinions could not possibly be true. And Dr. Safer does not even pretend to have met his burden.

This Court should thus preclude Dr. Safer from offering any opinion evidence concerning the relative athletic capabilities or advantages of prepubertal boys, girls, and boys who identify as girls.

C. Dr. Safer’s opinions concerning the effect of testosterone suppression on athletic performance are irrelevant and unreliable.

As with his opinions on the prepubertal athletic advantage enjoyed by biological males, Dr. Safer attempts to shift the burden rather than offer and substantiate a meaningful opinion on the effects of suppressing testosterone on athletic performance. He does not opine that testosterone suppression can eliminate the undisputed post-puberty male advantage, but rather he claims that no published study “proves there are meaningful athletic advantages for transgender women after receiving gender-affirming hormone therapy [i.e., testosterone suppression].” Daubert App. 161 (¶ 57). But Dr. Safer’s “we just don’t know” opinion is irrelevant, unreliable, and simply wrong—it has been rejected by responsible voices around the world.

It is irrelevant to the case now before this Court, because nothing in the Sports Act turns on whether a male individual has suppressed testosterone, and B.P.J. does not claim to have suppressed testosterone.

Dr. Safer's opinion is unreliable because he misstates one of the only two papers he cites on this topic. On the contrary, one of those two studies—a recent, careful, and widely-cited study performed on Air Force members undergoing gender transition—reports that after at least two years of testosterone suppression, the male-to-female study group still ran 12% faster than the Air Force female average. Daubert App. 694.

Indeed, Joanna Harper—a transgender athlete and the author of the one other, earlier (2015) study which Safer deigns to cite—agrees with this reading, writing in a more recent paper that Roberts' data shows that “transwomen ran significantly faster during the 1.5 mile fitness test than ciswomen,” and that this result is “consistent with the findings [in Harper's recent paper]” that even 30 months of testosterone suppression does not eliminate all male advantages “associated with muscle endurance and performance.” Daubert App. 521. And Handelsman, whom Safer cites when it fits his theories, recently wrote that “transwomen treated with estrogens after completing male puberty experienced only minimal declines in physical performance over 12 months, substantially surpassing average female performance for up to 8 years.” Daubert App. 510.

And Dr. Safer's opinion is unreliable because he is wrong that the Roberts (2020) and Harper (2015) studies “are the sum of the world literature on the subject.” App. 648 (135:23–136:18). On the contrary, numerous scientific teams have published peer-reviewed studies of the effect of testosterone suppression on male strength and other physiological metrics including muscle mass, muscle cross-section, hand strength, and knee strength, and routinely treat these as meaningful proxies for

athletic capability. Dr. Carlson, in his expert report, cites and reviews 15 such studies. App. 249–257 (¶¶ 83–97).

Indeed, the United Kingdom’s Sports Councils’ Equity Group for Transgender Inclusion in Domestic Sport, as part of a recent comprehensive review of the relevant scientific literature, *relied* on studies analyzing the effects of testosterone suppression on bone density, muscle mass, strength, speed, endurance to evaluate the athletic performance of biological males identifying as female. Daubert App. 885–913. And it concluded in 2021 that “[the] evidence suggests that parity in physical performance in relation to gender-affected sport cannot be achieved for transgender people in female sport through testosterone suppression,” Daubert App. 910, and that “[f]rom the synthesis of current research, the understanding is that testosterone suppression for the mandated one year before competition will result in little or no change to the anatomical differences between the sexes.” Daubert App. 907.

As always, Safer simply “fails to account for”—ignores—all of this available research “tending to refute [his] theory,” *Eghnayem*, 57 F. Supp. 3d at 676–77 (cleaned up), and which published researchers in the field, and sport governing bodies, find not only relevant, but decisive. The Court should exclude Safer’s opinions concerning the effects of testosterone suppression for these reasons.

D. This Court should exclude Dr. Safer’s proffered opinions concerning the policies of World Athletics, the IOC, and the NCAA because they are not relevant.

For reasons that are unclear, Dr. Safer proffers testimony concerning past and newer policies of World Athletics, the International Olympics Committee, and the NCAA regarding minimum requirements for testosterone suppression in biological males as a prerequisite for eligibility to compete in women’s sports. Daubert App. 152–156 (¶¶ 27–39). Among other details, he recites how the IOC set a 10 nm/ml maximum threshold in 2015, then in 2021 adopted a new policy leaving it to the

governing bodies of individual sports to set sport-specific eligibility requirements for transgender participation in women's sport. And he similarly reviews how the NCAA in 2011 adopted a policy requiring one year of testosterone suppression, but in 2021 adopted a policy that similarly asked sport-specific governing bodies to set sport-specific eligibility requirements. *Daubert* App. 155 (¶38).³ Dr. Safer does *not* cite or account for the multiple sporting organizations and scientific voices that have now adopted policies or expressed the conclusion based on extensive scientific literature and data that *no* degree of testosterone suppression can solve the safety and fairness problems. App. 171–175 (¶¶ 169–177).

Dr. Safer does not explain any relevance of this testimony, and there is none. Eligibility under the Sports Act does not turn on testosterone suppression or testosterone levels, and neither Dr. Safer nor B.P.J. contend that, fairness, Due Process, or Title IX require that it should. Therefore, there is no “valid scientific connection to the pertinent inquiry.” *Daubert*, 509 U.S. at 591–92, and Dr. Safer's testimony on how these groups regulate testosterone in women's sports will not “help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a). On the contrary, the situation is comparable to that faced by this Court in *Eghnayem*, where the court excluded testimony about FDCA and FDA regulations that were not at issue due to concern that “expert testimony about the requirements

³ As an example, pursuant to the new NCAA rule, and in light of recent science and experience, USA Swimming, the relevant national governing body of competitive swimming, adopted new eligibility rules that require at least three years of testosterone suppression, and additionally 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, *USA Swimming Releases Athlete Inclusion, Competitive Equity and Eligibility Policy*, USA Swimming News (Feb. 1, 2022), <https://www.usaswimming.org/news/2022/02/01/usa-swimming-releases-athlete-inclusion-competitive-equity-and-eligibility-policy>.

of the FDCA, which are not at issue in this case, could lead to more confusion” in this case. 57 F. Supp. 3d at 697.

If Dr. Safer’s proffered testimony about the shifting policies of various collegiate and international sporting bodies is intended to carry an implication that West Virginia’s Sports Act *should* make an exception for biological males who suppress testosterone to some one of these competing levels, then that “implied opinion” lacks all indicia of reliability. If anything, the disagreeing and shifting policies that Dr. Safer reviews highlight the lack of consensus as to how or whether biological males participating in women’s athletics can be reconciled with safety, fairness, and equal opportunities.

And Dr. Safer cites no scientific data, nor proposes a methodology justifying any one of these conflicting policies. On the contrary, taking one such policy as an example, Dr. Safer testified that it was arbitrary. He was asked about the reasoning for World Athletics placing the testosterone level at “five [nm/ml] instead of six.” App. 684 (279:2–6). Safer answered: “there needed to be a line so that there’s ability to enforce something. There needed to be a rule.” *Id.* That is pragmatics and compromise, not science. Dr. Safer does not purport to possess any specialized expertise in pragmatics or compromise.

Because Dr. Safer’s opinion is neither relevant nor reliable and it creates an unnecessary risk of confusing the fact-finder, this Court should preclude Dr. Safer from testifying on the rules of the IOC, World Athletics, or the NCAA governing eligibility of biological males to compete in women’s athletics.

II. The Court should exclude Dr. Safer’s proffered opinions concerning “fairness” and the role of sports in education.

A. The Court should exclude Dr. Safer’s proffered opinions concerning fairness because he is not an expert and his opinions are unreliable.

In his Report, Dr. Safer appears to proffer an opinion about what constitutes fair or unfair competition in sport, asserting that “there is no inherent reason why transgender women’s physiological characteristics related to athletic performance should be treated as any more of an ‘*unfair*’ advantage than the advantages that already exist[] among different women athletes.” Daubert App. 162 (¶ 60) (emphasis added).

However, Dr. Safer expressly admitted that he has no special expertise in defining “fairness.” On the contrary, he testified that “the question of fairness” “is outside my expertise,” that “I’m not rendering an opinion as an expert on what is fair,” App. 622 (31:7–21); App. 625 (43:3–8), and that “how to balance [the science] with other considerations of fairness, of inclusion,” is “not my expertise.” App. 621 (27:23–28:3). He repeatedly declined to answer questions about fairness. App. 621–625 (27:1–43:17). He similarly disclaimed any expertise in ethics—a field which might provide some insight into fairness. App. 623 (34:15–17).

Dr. Safer disclaims any expertise in fairness. He cites no authorities in support of any position as to what is or is not fair. He applies no identifiable methodology to arrive at any conclusion regarding fairness. He declined to answer questions about what is or is not fair or ethical. In short, he thoroughly disqualified himself in this area. This Court should preclude Dr. Safer from making any statements concerning fairness. *See In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation*, 174 F. Supp. 3d 911, 933 (D.S.C. 2016) (excluding testimony on epidemiology where the witness “readily admit[ted] that she is not an expert in epidemiology”).

B. This Court should exclude Dr. Safer’s proffered opinions concerning the role of sports in education because he is not an expert and his opinions are unreliable.

In his report, Dr. Safer appears to attempt to belittle the importance of fair competition for girls and women in the school and collegiate setting by asserting that “unlike elite international competitions, schools and colleges often provide athletic competition as part of a broader educational mission.” Daubert App. 158 (¶ 45). So, “institutions may adopt policies designed to ... provide the most athletic opportunities to the greatest number of people.” *Id.*

But here also, Dr. Safer denied possessing any expertise when questioned at his deposition, confessing that “how sports are used as part of educational systems” “[is]not my expertise.” App. 681 (269:20–24). Indeed, he declined to defend the quoted assertion in his report, stating that “I don’t think I’m even expressing an opinion in paragraph 45, expert or otherwise.” App. 682 (271:24–272:2). As with his proffered opinions relating to fairness, this Court should preclude Dr. Safer from providing opinion testimony regarding the role of sports in education, because he disclaims any expertise, and his proffered (and retracted) opinion in this area is not accompanied by any indicia of reliability required by *Daubert* and its progeny.

III. This Court should exclude Dr. Safer’s proffered opinions concerning the supposed ambiguity of “biological sex,” disorders of sexual development, and any speculative “biological basis” for gender identity, because they are irrelevant and/or unreliable.

A. Dr. Safer’s opinions casting doubt on the scientific validity of the category “biological sex” are unreliable.

The Sports Act establishes eligibility for girls’ and women’s sports based on “biological sex,” and defines biological sex based on “an individual's physical form as a male or female based solely on the individual's reproductive biology and genetics at birth.” W. Va. Code § 18-2-25d(b)(1). Dr. Safer cannot help but “agree” with Dr. Brown’s expert opinion that “sex is rooted in biology,” Daubert App. 198 (¶ 6), but he

nevertheless opines that the Sports Act’s reference to “reproductive biology and genetics” “do[] not reflect any medical understanding of” “biological sex,” Daubert App. 158 (¶ 48), and that “[t]he phrase ‘biological sex’ is an imprecise term that can cause confusion.” Daubert App. 150 (¶ 23).

This is nonsense. It is Dr. Safer who is attempting to “cause confusion” about one of the most basic realities of mammalian biology. He cites only a single article in defense of this counter-factual opinion . . . and it is one he wrote himself. Daubert App. 150 (¶ 23); Daubert App. 158 (¶ 48).

Meanwhile, Dr. Safer ignores—“fails to account for”—the *widespread* usage of the term “biological sex” in the relevant scientific literature, up to the very present. *Eghnayem*, 57 F. Supp. 3d at 676–77. The 2017 Endocrine Society Guidelines—which Dr. Safer co-authored and on which he repeatedly relies—refer on page one to a “person’s genetic/gonadal sex” (i.e., “genetics” and “reproductive anatomy”) as defining whether male or female hormones are “endogenous” (i.e., natural) to that individual. Daubert App. 523. The 2018 article by Dr. Handelsman, et al., concerning the effect of testosterone on athletic performance on which Dr. Safer relies, Daubert App. 151 (¶ 25); Daubert App. 159 (¶ 50), uses the term “biological sex” to refer to the basic male/female reproductive dichotomy of the human species, and even informs us that “*all* facets of *biological sex* are *almost always* aligned” with exceptions due to severe developmental disorders being “rare.” Daubert App. 484 (emphasis added). And Dr. Safer ignores the even more recent (2021) official “Scientific Statement” of the Endocrine Society on “Sex as a Biological Variable.” That Statement:

- contains a whole section headed “Biological Sex: The Definition of Male and Female;”
- uses the term “biological sex” throughout;
- distinguishes the “2 sexes” on the basis that “females have ovaries and make larger female gametes (eggs), whereas males have testes and make

smaller male gametes (sperm),” while “[t]he type of gonads is controlled by the presence of XX or XY chromosomes”;

- tells us that “numerous” sexual traits “that typically differ in males and females are tightly linked to each other”;
- and explains that even in individuals who suffer from extreme disorders of sexual development, “these clusters of traits are sufficient to classify most individuals as either biologically male or female.”

Daubert App. 381.

In other words, biological sex is functionally, adequately, and reliably defined by gonads (“reproductive biology”) and chromosomes (“genetics”). Other recent statements from respected United States and international health organizations confirming the continuing validity and indeed importance to science and health-care of the category and term “biological sex” are referenced in Defendants’ accompanying Memorandum in Support of Motion to Exclude Expert Testimony of Dr. Deanna Adkins at 5–7.

The bottom line is that everything you learned about the two biological sexes in sixth grade biology is true. The West Virginia Legislature was on extraordinarily firm ground in identifying “biological sex” as a clear category, and as a category overwhelmingly relevant to athletic performance and advantage. Dr. Safer’s self-citing opinion to the contrary represents an extreme case of “cherry-picking” and failing to “acknowledge or account for” “evidence tending to refute [his] theory” among “the relevant scientific literature.” *Eghnayem*, 57 F. Supp. 3d at 676–77 (cleaned up); *In re Lipitor*, 892 F.3d at 634.

B. Dr. Safer’s opinions about disorders of sexual development and intersex conditions are not relevant to any issue in this case.

Apparently in aide of his effort to confuse the well-defined category of “biological sex,” Dr. Safer proffers opinions relating to what are variously referred to as disorders of sexual development (“DSD”) and intersex conditions. Daubert App.

151–152 (¶ 26), Daubert App. 158 (¶ 48), Daubert App. 159 (¶ 50); Daubert App. 197–198 (¶ 5). He discusses “a group of conditions where individuals have XY chromosomes but are born with typically female external genitalia and assigned a female sex at birth.” Daubert App. 151 (¶ 26). And he opines, “it is not clear how West Virginia would define the ‘biological sex’ of children with ‘46,XY DSDs,’ who have XY chromosomes but typically female external reproductive anatomy.” Daubert App. 158 (¶ 48). He argues, “girls and women who are transgender and who do not go through endogenous puberty are *somewhat* similarly situated to women with XY chromosomes who have complete androgen insensitivity syndrome.” Daubert App. 159 (¶ 50) (emphasis added).

This is all irrelevant; these opinions do not relate to the “pertinent inquiry” in this case: whether the Sports Act violates Equal Protection and Title IX. *In re C.R. Bard*, 948 F. Supp. 2d at 602. Dr. Safer confirmed that “the *overwhelming* majority of transgender individuals do not suffer from any current identifiable, physical ... irregularity [disorders of sexual development or intersex conditions].” App. 669 (219:10–220:15) (emphasis added). B.P.J. does not allege, and Dr. Safer does not opine, that B.P.J. suffers from any DSD. App. 659–660 (181:18–182:19). Indeed, Dr. Safer is not aware of a single instance in which “*any* child with XY chromosomes who suffers from a DSD has *ever* sought to compete in female athletics in West Virginia.” Daubert App. 660 (182:20–183:15) (emphasis added). DSDs have nothing to do with the *facts* presented by the present case.

Nor do DSDs have anything to do with B.P.J.’s *legal theories* presented in this case. B.P.J. contends that males who identify as female must be permitted to compete in female sports *regardless* of their physiological characteristics. *See* Mem. in Supp. of Pl.’s Mot. for Summ. J. 12–14, ECF No. 291. B.P.J. argues that gender identity alone must control. The existence of developmental disorders affecting ordinary male

genital development in a tiny percentage of genetically male individuals is irrelevant to this theory.

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 and who seeks to participate in female athletics in a West Virginia school are likely to be highly fact-specific questions. But this case and B.P.J. present no occasion to engage in a speculative analysis of this fact-specific hypothetical situation.

This Court should thus exclude all of Dr. Safer's proffered testimony regarding disorders of sexual development and intersex conditions because they are not relevant.

C. Dr. Safer's opinions asserting an unknown biologic cause of transgender identity are irrelevant and unreliable.

At the same time that Dr. Safer tries to disparage the very concrete categories of "biological sex" as vague and unsophisticated, he tries to lend biological concreteness to the concept of gender identity—even though gender identity is widely defined in strictly subjective terms, for example as a "deeply held sense of gender." Daubert App. 529. Dr. Safer opines that "gender identity" "is an internal and largely biological phenomenon," Daubert App. 150 (¶ 21), and that "although the precise biological causes of gender identity are unknown, gender identity itself has biological underpinnings." Daubert App. 198 (¶ 7). *See also* Daubert App. 149 (¶18).

Yet again, Dr. Safer's speculations concerning a biological basis for transgender identity are irrelevant to any issue before this Court. Nothing turns on this question. The State draws no lines based on gender identity, whether biologically based or not, and B.P.J. insists that sport must be separated based *exclusively* on gender identity (not sex)—whether biologically based or not.

Nor would anything follow as a matter of legal doctrine if transgender identity were shown to have some biological basis. There is no dispute at all that there is a “biological basis” for sex—the category relied on by the Legislature to protect equal athletic opportunities and safety for girls and women. As noted above, Dr. Safer concurs that “sex is rooted in biology.” Daubert App. 198 (¶ 6). B.P.J. also does not dispute the basic fact exhaustively documented by Dr. Brown: biological males have a large average athletic advantage over biological females, by many metrics. Even if a biological basis exists for other categories one might draw (height; speed; transgender identity), that in no way negates the reality and legitimacy of the category and dividing line that the Legislature chose to use.

But transgender identity has *not* been shown to have a biological basis. Dr. Safer’s broad statements to the contrary are *ipse dixit* unsupported by any science, and indeed unsupported by his own testimony. In his rebuttal, Dr. Safer referred only to “potential biological underpinnings” of transgender identification. Daubert App. 200 (¶ 11). In his deposition, he hedged by saying that various hypotheses “might be” or “could be” “part of the explanation for some people.” App. 670 (222:16–17; 223:21–24). Could be . . . but so far as science has yet determined, *is not*. That is, Dr. Safer unambiguously admitted that no measurable biological differences or characteristics that correlate *to any significant degree* with transgender identity have been found. No biological difference detectable by chromosome scan, by brain scan, by blood test, or by any test. In a paper that Dr. Safer published in 2015, he detailed that multiple attempts to identify potential genetic bases for transgender identity found “no statistically significant association”; returned “contradictory” results; or “found no association.” Daubert App. 1070. In sum, Dr. Safer testified that “there are no tests to identify somebody who is transgender.” App. 669 (220:23–221:1).

But biological factors are physical, and by definition, measurable. With modern technology and gene-scanning technology, they are measurable to an astonishing

degree of precision. And the reality is not that merely the *precise* biological causes of gender identity are unknown, but that *no* biological cause of gender identity has been demonstrated with any statistical validity *in the least*, whether general or precise, by any researcher anywhere in the world.

Science, the Supreme Court in *Daubert* reminded us, consists of forming hypotheses and then “testing them to see if they can be falsified.” *Daubert*, 509 U.S. at 593 (citation omitted). Saying, “we can’t prove it, but we know it is true,” is not science. *See In re C.R. Bard*, 948 F. Supp. 2d at 601 (explaining that “whether the particular scientific theory ‘can be (and has been) tested’” is one of the factors *Daubert* offers to assess reliability of an expert’s opinion/theory (cleaned up)). If there are no biological measurements (tests) that can identify someone as transgender; if trial after trial has found “no statistically significant association” between a hypothesized biological basis and transgender identification; that means Dr. Safer’s hypothesis of a biological basis has been *repeatedly* tested . . . and so far as science has yet been able to measure, is *false*. In asserting otherwise, Dr. Safer is substituting speculation and *ipse dixit* for science. But “proposed testimony must be supported by appropriate validation—*i.e.*, ‘good grounds’ based on *what is known*.” *Eghnayem*, 57 F. Supp. 3d at 680 (emphasis added) (citation omitted). Sweeping claims of “consensus,” *Daubert* App. 149 (¶ 18), cannot make up the lack.

CONCLUSION

For the reasons set forth above, this Court should preclude Dr. Safer from presenting the opinions reviewed above to the trier of fact, because they cannot satisfy the relevance and reliability requirements of Fed. R. Evid. 702.

Respectfully submitted this 12th day of May, 2022.

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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 OF
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,

and

LAINY 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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