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 VIRGINIA EDUCATION, WEST 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.

Civil Action No. 2:21-cv-00316

Hon. Joseph R. Goodwin

PLAINTIFF'S OPPOSITION TO DEFENDANT-INTERVENOR AND DEFEDNANT STATE OF WEST VIRGINIA'S MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. JOSHUA D. SAFER

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Plaintiff B.P.J. respectfully submits this memorandum of law in opposition to the motion by Defendant-Intervenor and Defendant State of West Virginia (collectively "Defendants") to exclude the proffered expert testimony of Joshua D. Safer, MD, FACP, FACE from consideration at summary judgment or trial. (*See* Dkt. No. 314 (Defs.' Mot.).)

BACKGROUND

Plaintiff B.P.J. is a 12-year-old girl who is transgender. Because she is transgender, B.P.J. is categorically prohibited from participating with other girls on her middle school's cross-country or track and field teams as a result of H.B. 3293. B.P.J. brought this lawsuit to challenge this categorical exclusion as violating her right to be free from discrimination under Title IX of the Education Amendments of 1972 and the Equal Protection Clause.

In support of her claims, B.P.J. intends to offer expert testimony from Joshua D. Safer, MD, FACP, FACE. In his expert reports, Dr. Safer offers expert opinions on the following topics:

- (1) The relevant medical and scientific background regarding gender identity and the attempted regulation of transgender women playing women's sports, including the Endocrine Society's Guidelines for providing gender-affirming care to transgender people;
- (2) the policies of athletic organizations regarding the participation of transgender women in women's sports, the difficulties that have arisen when athletic associations have attempted to define a person's sex, and the relationship of these policies to the scholastic context; and
- (2) whether there is any medical justification for West Virginia's exclusion of transgender women and girls from school sports, including whether the available scientific evidence supports West Virginia's assertion that "classification of athletic teams according to" an "individual's reproductive biology and genetics at birth" "is necessary to promote equal athletic opportunities for the female sex."

(Dkt. No. 289-25 (Safer Rep.) ¶ 2.) In the course of discussing these topics, Dr. Safer also responds to the testimony of Defendants' proffered expert witnesses Dr. Brown and Dr. Carlson.

Dr. Safer's credentials and qualifications to testify as an expert as a general matter are not in dispute. To summarize: Dr. Safer is Staff Physician in the Endocrinology Division of the

Department of Medicine at the Mount Sinai Hospital and Mount Sinai Beth Israel Medical Center in New York, New York. (Dkt. No. 289-25 (Safer Rep.) ¶ 5.) He serves as Executive Director of the Center for Transgender Medicine and Surgery at Mount Sinai. (*Id.*) He also holds an academic appointment as Professor of Medicine in Mount Sinai's Icahn School of Medicine. (*Id.*) Dr. Safer has authored or coauthored over 100 peer-reviewed papers, including many critical reviews, textbook chapters, and case reports in endocrinology and transgender medicine. (*Id.* ¶ 9.) He has served in several roles in professional societies related to endocrinology and transgender health, including the Endocrine Society, the World Professional Association for Transgender Health, the U.S. Professional Association for Transgender Health, the Alliance of Academic Internal Medicine, the American College of Physicians Council of Subspecialty Societies, the American Board of Internal Medicine, the Association of Program Directors in Endocrinology and Metabolism, and the American Thyroid Association. (*Id.* ¶¶ 10-13.)

Of particular relevance to this case, Dr. Safer has served as a Transgender Medicine Guidelines Drafting Group Member for the International Olympic Committee ("IOC") since 2017. (*Id.* ¶ 14.) Since 2019, he has also served as a drafting group member for the transgender medical guidelines of World Athletics. (*Id.* ¶ 15.)

LEGAL STANDARD

"Under Federal Rule of Evidence 702, expert testimony is admissible if it will 'help the trier of fact to understand the evidence or to determine a fact in issue' and (1) is 'based upon sufficient facts or data' and (2) is 'the product of reliable principles and methods' which (3) has been reliably applied 'to the facts of the case." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220622, at *2 (S.D. W. Va. Sept. 5, 2018) (quoting Fed. R. Evid. 702). "A two-part test governs the admissibility of expert testimony. The evidence is admitted if it 'rests on a reliable foundation and is relevant." *Id.* (quoting *Daubert v. Merrell Dow*

Pharms., 509 U.S. 579, 597 (1993)). "The proponent of expert testimony does not have the burden to 'prove' anything. However, he or she must 'come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.* (quoting *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998)).

ARGUMENT

H.B. 3293 is a sweeping, categorical exclusion of all transgender girls from all girls' sports teams, under all circumstances. To support this legislation, Defendants and their proffered experts have made sweeping, categorical claims based on speculation, unsupported inferences, or blatant misrepresentations of the documents they purport to summarize. Plaintiff has provided a detailed accounting of those misrepresentations and misleading assertions as part of her *Daubert* motions to exclude Defendants' witnesses. (*See* Dkt. Nos. 315, 316, 327.)

Defendants now seek to exclude Dr. Safer's testimony because he disagrees with Defendants' unsupported claims and provides a sober assessment of the scientific literature and a measured assessment of what inferences the current data do—and do not—support. Defendants accuse Dr. Safer of "ignor[ing]" studies that allegedly conflict with his expert opinions. (Dkt. No. 314 (Defs.' Mot.) at 8.) But Dr. Safer does no such thing. He clearly and directly explains why the studies Defendants cite do not support Defendants' conclusions. That is not "cherry-picking." (*Id.* at 17.) It is explaining why Defendants are wrong.

For these reasons, and for the reasons discussed below, Defendants' motion to exclude Dr. Safer's testimony should be denied.

I. Dr. Safer's Testimony About The Scientific Literature Regarding The Participation Of Transgender Women Is Relevant, Accurate, And Reliable.

Dr. Safer explains in his expert reports that the primary known biological cause of average differences in athletic performance between non-transgender men as a group and non-transgender

women as a group is circulating testosterone—not "reproductive biology and genetics at birth," the only two factors on which H.B. 3293 conditions participation on girls' sports teams. (Dkt. Nos. 289-25 (Safer Rep.) ¶ 49; 289-26 (Safer Rebuttal) ¶¶ 4b, 8.); W. Va. Code § 18-2-25d(b)(1). He further explains why there is no reason to expect that transgender girls and women who receive puberty-delaying medication followed by gender-affirming hormones would have any innate physiological advantages over cisgender girls and women. (Dkt. No. 289-25 (Safer Rep.) ¶¶ 49-50.) And Dr. Safer explains that the available evidence regarding the athletic performance of transgender women who suppress testosterone after endogenous puberty does not support H.B. 3293's sweeping and categorical ban. (*Id.* ¶¶ 51-58.) Because Dr. Safer's testimony is relevant, accurate, and reliable, Defendants' motion to exclude it should be denied.

A. Dr. Safer's Testimony Regarding Prepubertal Children Is Relevant, Accurate, And Reliable.

Dr. Safer explains in his report:

[A]ge-grade competitive sports records show minimal or no differences in athletic performance between non-transgender boys and non-transgender girls before puberty. But 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. Based on current research comparing non-transgender boys and men with non-transgender girls and women before, during, and after puberty, the primary known biological driver of these average group differences is testosterone starting at puberty, and not reproductive biology or genetics. See Handelsman DJ, et al., *Circulating testosterone as the hormonal basis of sex differences in athletic performance*. Endocrine Reviews 2018; 39:803–829, (p. 820) (summarizing evidence rejecting hypothesis that physiological characteristics are driven by Y chromosome).

(Dkt. No. 289-25 (Safer Rep.) ¶ 25.)

Misrepresenting Dr. Safer's testimony, Defendants accuse him of issuing "a categorical denial of any prepubertal male advantage" and of ignoring data from Handelsman 2018 showing that 12-year-old boys, on average, outperformed 12-year-old girls by 5% in running and 4-6% in jumping. (Dkt. No. 314 (Defs.' Mot.) at 7.) But Dr. Safer did no such thing. Dr. Safer stated there

were "minimal or no difference[s]," which is not "a categorical denial" of differences, and is exactly the same language used in the Handelsman 2018 article itself: "Age-grade competitive sports records show minimal or no female disadvantage prior to puberty." (Dkt. No. 289-27, Ex. 4 (Handelsman 2018) at 812.) As explained in Plaintiff's motion to exclude the testimony of Dr. Brown, the scientific literature routinely describes average differences in the athletic range of 0 to 6% as "minimal" or nonexistent. (*See* Dkt. No. 316 (Brown *Daubert* Mot.) at 9.)

Defendants also falsely accuse Dr. Safer of "ignor[ing] contrary data," (Dkt. No. 314 (Defs.' Mot.) at 8), but the articles they point to are not "contrary" and Dr. Safer did not "ignore" them. Defendants do not identify any contrary articles measuring differences in athletic performance in age-grade competitive sports. Rather, Defendants point to articles summarizing the results of physical fitness surveys of the population at large, without undertaking any analysis of the causes of those results. (Dkt. No. 314 (Defs.' Mot.) at 7-8 (discussing Hilton & Lundberg 2020).) In his rebuttal report and at his deposition, Dr. Safer specifically addressed these articles and explained why they do not support Defendants' arguments that prepubertal boys have an innate physiological advantage over prepubertal girls. Dr. Safer explained in his rebuttal report:

Dr. Brown relies primarily on demographic data from physical fitness tests or athletics in which prepubertal cisgender boys have outperformed prepubertal cisgender girls. But there is no reliable basis for Dr. Brown to attribute those differences to biology instead of social factors such as greater societal encouragement of athleticism in boys, greater opportunities for boys to play sports, or different preferences of the boys and girls surveyed.

(Dkt. No. 289-26 (Safer Rebuttal) ¶ 9.) Dr. Safer further explained during his deposition, "the larger these groups—these cross-sectional studies get the more confounded they get by access and other social explanations for why there are boys participating to a greater degree." (Dkt. No. 289-27 (Safer Dep. Tr.) at 101:16-20.) In other words, because these surveys consider the population at large rather than individuals who choose to participate in school athletics, and because they do

not control for social factors, there is no reliable basis to attribute any differences in physical fitness surveys to innate physiology.

Finally, Defendants take issue with Dr. Safer's statement that "[t]here is also no basis to confidently predict that patterns about the athletic performance of prepubertal cisgender boys will be the same for prepubertal transgender girls." (Dkt. Nos. 289-26 (Safer Rebuttal) ¶ 11; 314 (Defs.' Mot.) at 8-9.) As Dr. Safer explains:

To the extent that differences in performance are influenced by social influences, biases, or preferences, the experience of transgender girls might be more similar to the experience of cisgender girls than to cisgender boys. And to the extent that differences in performance are shown to have some connection to epigenetics or exposure to sex hormones in utero or infancy, we do not know whether those biological factors are always equally true for transgender girls in light of scientific studies documenting potential biological underpinnings of gender identity.

(Dkt. No. 289-26 (Safer Rebuttal) ¶ 11.) Defendants falsely assert that Dr. Safer "did not 'reference any articles' in making his opinion." (Dkt. No. 314 (Defs.' Mot.) at 9.) To the contrary, Dr. Safer's report substantiates his opinion by reference to peer-reviewed research:

For example, studies have shown that even before initiating hormone therapy transgender women tend to have lower bone density than cisgender men. Van Caenegem E, Taes Y, Wierckx K, Vandewalle S, Toye K, Kaufman JM, et al. *Low Bone Mass is Prevalent in Male-to-Female Transsexual Persons Before the Start of Cross-Sex Hormonal Therapy and Gonadectomy*. Bone 2013; 54(1):92–7. We do not know whether those differences are explained by social factors or biological ones. But regardless of the cause, it cannot be assumed that the physiological characteristic of cisgender boys and men will automatically apply to transgender girls and women even in the absence of gender affirming hormones.

(Dkt. No. 289-26 (Safer Rebuttal) ¶ 12.) Dr. Safer's opinion that any generalizable trends in athletic performance among prepubertal cisgender boys cannot be automatically and equally extrapolated to prepubertal transgender girls is not unique to Dr. Safer. Many of the articles Dr. Brown cites make the same observation (which Defendants simply choose to ignore). One of the sources Dr. Brown cites specifically observed that, even before receiving puberty-blocking

medication, a cohort of transgender girls already had a percentage of body fat that was more similar to cisgender girls than to cisgender boys. (*See* Dkt. No. 317-15 (Block Decl. Ex. O (Klaver 2018) at 251–60.) Other articles Dr. Brown cites also expressly caution that "hormone-naïve transwomen may not, on average, have the same athletic attributes as cisgender men" and state that "[t]he need to move beyond simple comparisons of cisgender men and women to assess the sporting capabilities of transwomen is imperative." (*See* Dkt. No. 317-6 (Block Decl. Ex. F (Harper 2021) at 7.)

Dr. Brown has presented a novel theory that "prepubertal male children perform better in almost all sports than . . . prepubertal female children because of their inherent physiological advantages," and that transgender girls who receive puberty-delaying medication have a "pre-existing athletic advantage" over cisgender girls "in almost all athletic events." (Dkt. No. 289-30 (Brown Rep.) at 4.) In explaining why Dr. Brown's theory is not supported by existing data, Dr. Safer is not trying to "flip the burden." (Dkt. No. 314 (Defs.' Mot.) at 9.) Dr. Safer is simply—and correctly—pointing out that the evidence does not support Dr. Brown's broad assertions.

Defendants' motion to exclude Dr. Safer's testimony about prepubertal children should be denied.

B. Dr. Safer's Testimony Regarding Suppression Of Testosterone After Puberty Is Relevant, Accurate, And Reliable.

Dr. Safer also presented testimony regarding the current scientific literature on how suppressing testosterone affects the athletic performance of transgender women after puberty. Defendants make the puzzling assertion that Dr. Safer's testimony is "irrelevant to the case now before this Court, because . . . B.P.J. does not claim to have suppressed testosterone." (Dkt. No. 314 (Defs.' Mot.) at 10.) Plaintiff agrees that this case is an as-applied challenge by B.P.J. who has not—and will not—go through endogenous puberty, and that the Court therefore need not

consider whether any alleged athletic advantage that remains after testosterone suppression supplies an exceedingly persuasive justification for H.B. 3293's categorical exclusion. But Defendants have chosen to defend H.B. 3293 by focusing extensively on transgender women who have completed endogenous puberty. Dr. Safer's testimony is relevant to rebut those assertions.

Defendants' assertions that Dr. Safer's testimony is "unreliable" is equally puzzling. (Dkt. No. 314 (Defs.' Mot.) at 10.) Dr. Safer's testimony is that there is not sufficient scientific evidence to support Defendants' assertion that transgender women who suppress circulating testosterone after puberty have an athletic advantage over cisgender women in almost all sports. As Dr. Safer explained:

There have been only two studies that examined the effects of gender-affirming hormone therapy on the athletic performance of transgender female athletes. (Safer Rep. ¶¶ 55-57). The first is a small study of eight long-distance runners who are transgender women. The study showed that after undergoing gender-affirming medical intervention, which included lowering their testosterone levels, the athletes' performance was reduced so that their performance when compared to non-transgender women was proportionally the same as their performance had been before treatment relative to non-transgender men. See Harper J. Race times for transgender athletes. Journal of Sporting Cultures and Identities 2015; 6:1–9.

A more recent study retrospectively reviewed the military fitness test results of 46 transgender women in the U.S. Air Force before and after receiving gender-affirming hormone therapy. These authors found that any advantage transgender women had over non-transgender women in performing push-ups and sit-ups was negated after 2 years. The study also found that before beginning gender affirming hormone therapy, transgender women completed the 1.5 mile run 21% faster on average than non-transgender women; and after 2 years of gender-affirming hormone therapy, transgender women completed the 1.5 mile run 12% faster on average than non-transgender women. See Roberts TA, Smalley J, Ahrendt D. Effect of gender affirming hormones on athletic performance in transwomen and transmen: implications for sporting organisations and legislators. Br J Sports Med. 2020.

Neither of these limited studies proves there are meaningful athletic advantages for transgender women after receiving gender-affirming hormone therapy, which could only be shown by longitudinal transgender athlete case-comparison studies that control for variations in hormonal exposure and involve numerous indices of performance. Moreover, the ability to perform push-ups and sit-ups or to run 1.5 miles does not necessarily translate into an athletic advantage in any particular

athletic event. Because different sports require different types of physical performance, the studies suggest that the existence and extent of a performance advantage may vary from sport to sport and should not be subject to a categorical across-the-board rule.

(Dkt. No. 289-26 (Safer Rebuttal) at 9-10.)

Defendants assert that Dr. Safer "misstates" the Roberts 2020 study's finding "that after at least two years of testosterone suppression, the male-to-female study group still ran 12% faster than the Air Force female." (Dkt. No. 314 (Defs.' Mot.) at 10.) But—as reflected in the second paragraph quoted above—Dr. Safer clearly reports that finding. (Dkt. No. 289-26 (Safer Rep.) ¶ 56.)

Defendants go on to claim that Dr. Safer "is wrong" because "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." (Dkt. No. 314 (Defs.' Mot.) at 10.) But Dr. Safer squarely addresses those studies in his rebuttal report as well, explaining that those individual metrics do not necessarily translate into an advantage in athletic performance:

Dr. Brown cites to a variety of studies of transgender women measuring discrete physiological characteristics such as muscle size or grip strength. (Brown Rep. ¶¶ 153-56). Dr. Brown predicts that if puberty-influenced characteristics like bone and muscle size are not completely reversed by testosterone suppression, then those characteristics will continue to provide an advantage for transgender women. But because changes in testosterone affect different parts of the body in different ways, we do not have enough information to confidently predict whether the combined effect of the changes will be an advantage or a disadvantage.

The study about military fitness tests (Roberts 2020) illustrates the point. Roberts TA, et al. *Br J Sports Med*. 2020; 0:1–7. After two years of suppressing testosterone any advantage that the transgender women had in performing push-ups or sit-ups was eliminated. But because the transgender women in the study weighed more than the cisgender women even after suppressing testosterone, the transgender women had to use more muscle strength to perform the same number of push-ups. In other words, the transgender women may have had more muscle strength, but that greater strength did not translate into an athletic advantage in a push-up contest.

Because different sports require different types of physical performance, the existence and extent of any performance advantage based on grip strength or leg-muscle size may vary from sport to sport and cannot support a categorical across-the-board rule.

(Dkt. No. 289-26 (Safer Rebuttal) ¶¶ 10-11.)

Finally, Defendants falsely assert that other "published researchers in the field, and sport governing bodies, find" studies measuring discrete characteristics to be "not only relevant, but decisive." (Dkt. No. 314 (Defs.' Mot.) at 11.) To the contrary, other published researchers in the field agree with Dr. Safer that the existing evidence is insufficient to justify an across-the-board rule. The Hilton & Lundberg 2020 article touted by Defendants states that "it is clear that different sports differ vastly in terms of physiological determinants of success, which may create safety considerations and may alter the importance of retained performance advantages. Thus, we argue against universal guidelines for transgender athletes in sport and instead propose that each individual sports federation evaluate their own conditions for inclusivity, fairness and safety." (*Id.* at 211.) The article also specifically notes that given testosterone suppression's effects in endurance-based sports, "the balance between inclusion and fairness is likely closer to equilibrium in weight-bearing endurance-based sports compared with strength-based sports." (*Id.* at 209.)

In an attempt to contradict Dr. Safer, Defendants point to a report from the United Kingdom's Sports Councils' Equity Group for Transgender Inclusion in Domestic Sport, which relied on studies about discrete physical characteristics to conclude that suppressing testosterone cannot create parity between transgender female athletes and cisgender female athletes. (Dkt. No. 314 (Defs.' Mot.) at 11.) But the Sports Council specifically disclaimed a "one-size fits all approach," and emphasized that sports bodies should work to "accommodate transgender inclusion, fairness, and safety in their sport." (Dkt. No. 332-6 (Stark Supp. Decl. Ex. 50 (UK

Sports, Guidance for Transgender Inclusion in Domestic Sport).) A "frequently asked questions" document accompanying the UK Sport recommendations explained that the organization was not "giving definitive advice" because "[t]his is a complex area and what is right for one sport may not be right for another" and "[n]one of the Sports Councils are regulators." (Dkt. No. 332-7 (Stark Supp. Decl. Ex. 51 (UK Sports, Frequently Asked Questions).)

Defendants' motion to exclude Dr. Safer's testimony regarding transgender women who suppress circulating testosterone after puberty should be denied.

C. Dr. Safer's Testimony Regarding The Policies of NCAA, World Athletics, And The International Olympic Committee Are Relevant.

In his expert report and declaration, Dr. Safer provides background regarding the policies that the NCAA, World Athletics, and the IOC have adopted allowing transgender women to participate in women's sporting events. As Dr. Safer explains, H.B. 3293 is also "dramatically out of step with even the most stringent policies of elite international athletic competitions for girls and women who are transgender and who have gone through endogenous puberty." (Dkt. No. 289-25 (Safer Rep.) ¶ 13.) Unlike the policies of the IOC, World Athletics, or the NCAA, H.B. 3293 excludes girls and women who are transgender from participating on girls' and women's sports teams even if they have never gone through endogenous puberty or suppressed their circulating levels of testosterone through gender-affirming hormone therapy.

Repeating the same argument they made to challenge Dr. Safer's testimony regarding testosterone suppression, Defendants contend that Dr. Safer's testimony regarding the policies of the NCAA, World Athletics, or the IOC are not relevant because "[e]ligibility under the Sports Act does not turn on testosterone suppression or testosterone levels." (Dkt. No. 314 (Defs.' Mot.) at 12.) That is precisely the problem. By prohibiting even consideration of circulating testosterone,

H.B. 3293 is "dramatically out of step with even the most stringent policies of elite international athletic competition." (Dkt. No. 289-25 (Safer Rep.) ¶ 15.)¹

Defendants' motion to exclude Dr. Safer's testimony regarding the policies of the NCAA World Athletics, and the IOC should be denied.

II. Dr. Safer's Testimony Regarding The Biological Elements Of Sex And Gender Identity Is Relevant, Accurate, And Reliable.

H.B. 3293 defines "biological sex" exclusively as "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). In his expert reports, Dr. Safer explains why that definition of "biological sex"—which focuses solely on two discrete biological components of sex while ignoring other biological components—does not reflect the accepted medical and scientific meaning of the term. Because his testimony is relevant, accurate, and reliable, Defendants' motion to exclude it should be rejected.

A. Dr. Safer's Testimony Regarding The Biological Components Of Sex Is Reliable.

In his expert reports, Dr. Safer explains that:

"the phrase 'biological sex' is an imprecise term that can cause confusion, especially in the context of transgender people and people with intersex characteristics. A person's sex encompasses the sum of several different biological attributes, including sex chromosomes, certain genes, gonads, sex hormone levels, internal and external genitalia, other secondary sex characteristics, and the biological underpinnings of gender identity. Those attributes are not always aligned in the same direction."

¹ Furthermore, the State's assertion that the policies of these sports organizations are not relevant contradicts the State's own repeated reliance on the World Rugby policy, as can be seen in its motion for summary judgment and in its opposition motion. (*See* Dkt. No. 287 (State MSJ) at 17; Dkt. No. 305 (State MSJ Opp.) at 15-16, 23.)

(Dkt. No. 289-26 (Safer Rebuttal) ¶ 5.) For example, Dr. Safer cites to the Endocrine Society Guidelines for Treatment of Gender Dysphoria/Gender Incongruent persons, which provide the following definition of sex: "This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics." (Dkt. No. 289-24, Ex. 4 (Hembree WC, et al., *Endocrine Treatment of Gender-Dysphoria/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline*. J Clin Endocrinol Metab 2017; 102:3869–3903 ("Endocrine Society Guidelines") at 3875.) The Endocrine Society Guidelines also provide the following definitions of "[b]iological sex, biological male or female": "These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided." (*Id.*)

Defendants contend that Dr. Safer's testimony and the sources he cites are unreliable because they reflect a more complicated understanding of sex than what defense counsel was taught "in sixth grade biology" class. (Dkt. No. 314 (Defs.' Mot.) at 18.) But Defendants do not cite any authority that contradicts Dr. Safer's testimony and cited literature, much less an authority that Dr. Safer "fail[ed] to account for." (*Id.* at 16.) Defendants note that the Endocrine Society Guidelines use the term "genetic/gonadal sex," (*id.*), but that is of no moment. When referring specifically to genetics and gonads, the Endocrine Society uses the phrase "genetic/gonadal sex." The Endocrine Society Guidelines do not purport to *define* "biological sex" based exclusively on genetics and gonads.

Defendants also cited to articles noting that the various biological components of sex "are almost always aligned." *Id.* But the critical point is that they are not *always* aligned. Specifically, although those sex-related components are aligned for cisgender people, who represent the vast majority of the population, they are not aligned for people with intersex characteristics and for people who are transgender. Thus, the term "biological sex" is imprecise, as Dr. Safer has repeatedly stated.

Finally, Defendants cite to an Endocrine Society Statement on "Sex as a Biological Variable." (Dkt. No. 314 (Defs.' Mot.) at 16.) But the Endocrine Society Statement fully supports Dr. Safer's testimony. (*See* Dkt. No. 289-26 (Safer Rebuttal) ¶¶ 6-7 (citing the same Endocrine Society Statement).) The Endocrine Society Statement does not say that biological sex is determined by genetics and reproductive biology at birth. To the contrary, the article explains that "[s]ex differences are caused by 3 major factors—sex hormones, genes, and environment." (Dkt. No. 317-4 (Block Decl. Ex. D (Bhargava 2021) at 220.) The article has a few subsections describing the role of chromosome kayrotypes, while cautioning that "karyotypic analysis may be misleading, as there are well-described 46,XX males" and "46,XY females." (*Id.* at 221.) The article then goes on to explain how physical sexual differentiation occurs when genes interact with hormones and environmental factors in utero and during puberty.²

See

² See id. at 222 (discussing "Sexual Differentiation Caused by Gonadal and Non-Gonadal Hormones); id. at 223 (discussing "Influence of Gonadal Steroid Hormones and Nongonadal Hormones in Brain Development"); id. at 225 ("Given that the critical and sensitive periods for sexual differentiation are defined by the production and response to gonadal steroids, it is not surprising that steroids are the primary drivers of developmental origins of sex differences in brain (and probably other tissues) and behavior."); id. at 227 (discussing "Hormonal Versus Sex Chromosome Effects" and explaining that "[s]ex differences are caused by 3 major factors—sex hormones, genes on sex chromosomes/autosomes, and environment").

Defendants' motion to exclude Dr. Safer's testimony about the biological components of sex should be denied.

B. Dr. Safer's Testimony Regarding The Biological Underpinnings Of Gender Identity Is Relevant And Reliable.

Dr. Safer explains in his report that "although the precise biological causes of gender identity are unknown, gender identity itself has biological underpinnings, possibly as a result of variations in prenatal exposure to sex hormones, gene sequences, epigenetics, or a combination of factors." (Dkt. No. 289-26 (Safer Rebuttal) ¶ 7.) His testimony is plainly relevant because it demonstrates that H.B. 3293's definition of "biological sex" is not scientifically accurate and it refutes Defendants' repeated assertions that gender identity is *not* biologically based. (*See e.g.*, Dkt. No. 305 at 12 (asserting that "the biological differences between males and females (not self-identified gender identities) are 'enduring.'"); *id.* (asserting that "transgender identity is not biologically based").)

Dr. Safer's testimony is also reliable. The evidence supporting a biological basis for gender identity is recounted in the Endocrine Society Guidelines, (*see* Endocrine Society Guidelines at 3874-75, 3888-89), the articles collected in one of Dr. Safer's pieces published in the Annals of Internal Medicine, (Safer JD, Tangpricha V. Care of the Transgender Patient. Ann Intern Med 2019; 171: ITC1-ITC16 ("Ann Intern Med 2019") at nn.17-23), and in an Endocrine Society Statement cited in Defendants' own brief, (Dkt. No. 314 (Defs.' Mot.) at 16 (citing Bhargava 2021 at 227)). To summarize that evidence: "Investigators report an inability to manipulate gender identity by external means. Twin studies indicate that identical twins have greater concordance with regard to transgender identity than fraternal twins. Further, evidence shows increased rates of male gender identity among some persons with congenital adrenal hyperplasia who were exposed to excess androgen in utero, whereas those with complete androgen insensitivity syndrome have

female gender identity." (Ann Intern Med 2019 at 2-3 (footnotes omitted).) Together, these "compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development." (Endocrine Society Guidelines at 3875.)

Defendants assert that Dr. Safer's testimony should be excluded because a specific biological causal mechanism has not yet been definitively proven. (Dkt. No. 314 (Defs.' Mot.) at 20.) But "absolute certainty is not a prerequisite for expert testimony." *United States v. Houdersheldt*, No. 19 Cr. 239, 2020 WL 1521805, at *2 (S.D. W. Va. Mar. 30, 2020); *accord Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct."). Dr. Safer describes the evidence supporting the inferences that biological factors play a role in the formation of gender identity, while at the same time being "careful not to overstate his conclusions." *Carter v. United States*, No. 15 Civ. 04984, 2019 WL 5700774, at *4 (S.D. W. Va. Nov. 4, 2019). His acknowledgment of the strength and limitations of the evidence makes his testimony more reliable, not less.

Defendants' motion to exclude Dr. Safer's testimony regarding the biological underpinnings of gender identity should be denied.

C. Dr. Safer's Testimony Regarding Women With DSDs And Intersex Characteristics Is Relevant.

In his expert report, Dr. Safer explains that "[s]ome elite female athletes have '46,XY DSDs,' a group of conditions where individuals have XY chromosomes but are born with typically female external genitalia and assigned a female sex at birth. Among individuals with 46,XY DSD some may have inactive testosterone receptors (a syndrome called "complete androgen insensitivity syndrome, CAIS") which means they don't respond to testosterone despite very high

levels. Usually, these individuals have female gender identity and have external genitalia." (Dkt. No. 289-25 (Safer Rep.) ¶ 26(b).) Dr. Safer further explains that because women with CAIS do not experience physiological changes resulting from a typically male puberty," [i]t has long-been recognized that women with CAIS have no athletic advantage simply by virtue of having XY chromosomes." (*Id.* ¶ 50.)

Despite Defendants' assertions to the contrary (*see* Dkt. No. 314 (Defs.' Mot.) at 17), Dr. Safer's undisputed testimony about DSDs is highly relevant to this case because it demonstrates that average sex-based differences in athletic performance are not determined by chromosomes. Rather, those differences are determined by the body's response to testosterone during puberty. The transgender participation policies adopted by World Athletics and the IOC were based on the knowledge and experience gained from working with athletes with DSDs. *See* (Dkt. No. 289-25 (Safer Rep.) ¶ 27-29, 33); Rogol AD, Pieper LP. *The interconnected histories of endocrinology and eligibility in women's sports*. Horm Res Paediatr 2018; 90:213–20 (cited in Safer Rep. bibliography).

Defendants' motion to exclude Dr. Safer's testimony about women with DSDs and intersex characteristics should be denied.

III. Defendants' Other Challenges Are Meritless.

Defendants' remaining arguments do not attack the reliability of Dr. Safer's actual testimony. Instead, Defendants distort Dr. Safer's testimony and then accuse him of lacking support for opinions he never offered in the first place. Because Defendants do not accurately characterize the testimony at issue, Defendants' motion to exclude Dr. Safer's testimony should be denied.

A. Dr. Safer Did Not Offer Opinions Comparing The Percentage Of Victories To The Percentage Of Transgender Athletes.

Defendants take issue with the following statement from Dr. Safer:

Dr. Brown also refers to widely publicized anecdotes about isolated cases of transgender girls and women winning state championships in high school sports or NCAA championships in college. But transgender athletes and women have been competing in NCAA and secondary school athletics for many years at this point, and they remain dramatically underrepresented amongst champions. The 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%).

(Dkt. No. 314 (Defs.' Mot.) at 5 (citing Dkt. No. 289 (Safer Rebuttal) at 22).) Defendants do not—and cannot—dispute the accuracy of Dr. Safer's statement that the number of reported championships won by transgender girls and women is not proportional to their percentage of the population. Instead, accusing Dr. Safer of making a statement he never made, Defendants assert that Dr. Safer lacks any data to determine "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. at 6 (emphasis added).) Dr. Safer specifically referred to the percentage of the population who are transgender, not the percentage of high school and NCAA athletes who are transgender.

To the extent that Defendants take issue with Dr. Safer's statement that transgender women "have been participating in NCAA and secondary school athletics for many years at this point," (Dkt. No. 289 (Safer Rebuttal) ¶ 22), Defendants are playing games with the record. Defendants' own expert witness Dr. Carlson states in his report that "biologically male transgender athletes have competed in a wide range of high school, collegiate, and professional girls' or women's sports, including, at least, basketball, soccer, volleyball, softball, lacrosse, and even women's tackle football." (Dkt. No. 289-32 (Carlson Rep.) at 1 (footnotes omitted).) Using an ellipsis to remove critical words from the transcript, Defendants assert that Dr. Safer stated at his deposition

that 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." (Dkt. No. 314 (Defs.' Mot.) at 6 (quoting Dkt. No. 289-27 (Safer Dep.) 171:14-24).) The transcript reflects that Dr. Safer was asked, "Do you have any information as to whether transgender athletes have been competing in the women's division of NCAA or secondary school athletics *in contact or collision sports* for many years?" (Dkt. No. 289-27 (Safer Dep.) at 171:14-18 (emphasis added).) It is difficult to conceive of a legitimate reason for Defendants to replace those words with ellipses.

Defendants' motion to exclude the testimony should be denied.

B. Dr. Safer Did Not Offer Opinions On How Questions Of Fairness Should Be Resolved.

Dr. Safer explains in his expert report and declaration that "[e]ven if evidence were eventually to show that on average transgender women have some level of advantage compared to average non-transgender women, those findings would have to be placed in context of all the other intra-sex genetic variations among athletes that can enhance athletic performance among different women or different men." (Dkt. No. 289-25 (Safer Rep.) ¶ 8.) Dr. Safer noted that "As the IOC's 2021 framework recognizes, 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. The 2021 framework instructs that, even at the most elite level of competition, sporting organizations should base eligibility restrictions on whether there exists 'a consistent, unfair, and disproportionate competitive advantage' when viewed within the broader context of all the other intra-sex variations that may give a comparative athletic advantage to a particular athlete." (Id. ¶ 60.)

Defendants assert that Dr. Safer has no expertise to offer an opinion about what is fair or unfair. But Dr. Safer never offered such an opinion. He instead simply noted that when sporting organizations determine what is fair or unfair, they take into account the broader picture that athletes also have a variety of other inherent physiological advantages. Defendants' motion to exclude that testimony should be denied.

C. Dr. Safer Did Not Offer Opinions On How Sports Are Used As Part Of The Educational Process.

Defendants contend that Dr. Safer lacks expertise to discuss how sports are used as part of the educational process. (Dkt. No. 314 (Defs.' Mot.) at 15.) Dr. Safer never claimed he has such expertise. He merely explained that when elite international sporting organizations—unlike educational institutions—formulate policies, they do not have to consider how those policies may or may not interact with other educational goals (whatever those educational goals may be). (*See* (Dkt. No. 289-25 (Safer Rep.) ¶¶ 40 ("The policies developed by World Athletics and the IOC for transgender athletes were based on the particular context of elite international competition. Not all of the same considerations apply in scholastic contexts."), 45 (noting that "unlike elite international competitions, schools and colleges often provide athletic competition as part of a broader educational mission. In that context, when scholastic athletics are a component of the educational process, institutions may adopt policies designed to emphasize inclusion and to provide the most athletic opportunities to the greatest number of people.").) Defendants' motion to exclude that testimony should be denied as well.

CONCLUSION

For all these reasons, Defendants' motion to exclude Dr. Safer's testimony should be denied in its entirety.

Dated: May 26, 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

LAINEY ARMISTEAD,

Defendant-Intervenor.

Civil Action No. 2:21-cv-00316

Hon. Joseph R. Goodwin

CERTIFICATE OF SERVICE

I, Loree Stark, do hereby certify that on this 26th day of May, 2022, I electronically filed a true and exact copy of *Plaintiff's Opposition to Defendant-Intervenor and Defendant State of West Virginia's Motion to Exclude the Expert Testimony of Dr. Joshua D. Safer* with the Clerk of Court and all parties using the CM/ECF System.

/s/ Loree Stark
Loree Stark

West Virginia Bar No. 12936