

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, and DORA STUTLER in her official capacity as Harrison County Superintendent,

Defendants.

Civil Action No.

Hon.

**DECLARATION OF
JOSHUA D. SAFER, MD, FACP, FACE**

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
2. The purpose of this declaration is to offer my expert opinion on: (1) the Endocrine Society’s Guidelines for providing gender-affirming care to transgender people; (2) the difficulties that have arisen when athletic associations have attempted to define a person’s sex for purposes of competing in elite women’s sports; (3) the current policy of elite athletic organizations in limiting eligibility to compete in women’s sports based on serum testosterone levels; (4) 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 sex” “is necessary to promote equal athletic opportunities for the female sex.”
3. I have knowledge of the matters stated in this declaration and have collected and cite to relevant literature concerning the issues that arise in this litigation in the body of this declaration and in the attached bibliography.

4. In preparing this declaration, I relied on my scientific education and training, my research experience, and my knowledge of the scientific literature in the pertinent fields. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

PROFESSIONAL BACKGROUND

5. I am a 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, NY. I serve as Executive Director of the Center for Transgender Medicine and Surgery at Mount Sinai. I also hold an academic appointment as Professor of Medicine in Mount Sinai's Icahn School of Medicine. A true and correct copy of my CV is attached hereto as Exhibit A.

6. I have been Board Certified in Endocrinology, Diabetes and Metabolism by the American Board of Internal Medicine since 1997.

7. I graduated from the University of Wisconsin in Madison with a Bachelor of Science degree in 1986. I earned my Doctor of Medicine degree from the University of Wisconsin in 1990. I completed intern and resident training at Mount Sinai School of Medicine, Beth Israel Medical Center in New York, New York from 1990 to 1993. From 1993 to 1994, I was a Clinical Fellow in Endocrinology at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston, Massachusetts. I stayed at the same institution, serving as a Clinical and Research Fellow in Endocrinology under Fredric Wondisford, from 1994 to 1996.

8. Since 1997, I have evaluated and treated patients along with conducting research in endocrinology. Since 2004, my patient care and research has been focused on the

medicine/science specific to transgender people. I have led several other programs either in transgender medicine or in general endocrinology. In particular, I served as the Medical Director of the Center for Transgender Medicine and Surgery, Boston Medical Center, Boston, MA (2016-2018); as the Director of Medical Education, Endocrinology Section, Boston University School of Medicine, Boston, MA (2007-2018); as the Program Director for Endocrinology Fellowship Training, Boston University Medical Center, Boston, MA (2007-2018); and as Director of the Thyroid Clinic, Boston Medical Center, Boston, MA (1999-2003).

9. I have authored or coauthored over 100 peer-reviewed papers including many critical reviews; textbook chapters; and case reports in endocrinology and transgender medicine.

10. Among my publications are the latest review of transgender medicine in the *New England Journal of Medicine* and the latest review of transgender medicine in the *Annals of Internal Medicine*. See Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460; Safer JD, Tangpricha V. Care of the transgender patient. *Ann Intern Med* 2019; 171:ITC1-ITC16. I am also a co-author of the sections of UpToDate that relate to gender-affirming hormone treatment for transgender people. UpToDate is an evidence-based, physician authored, on-line medical guide and is currently the most widely used such guide among medical providers.

11. I was the inaugural President of the United States Professional Association for Transgender Health (“USPATH”). I am also Secretary and Co-Chair of the Steering Committee of TransNet, the International Consortium for Transgender Medicine and Health Research. I have served in several other leadership roles in professional societies related to endocrinology and transgender health. These societies include 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.

12. Since 2014, I have held various roles as a member of the World Professional Association for Transgender Health (“WPATH”), the leading international organization focused on transgender health care. WPATH has approximately 2,000 members throughout the world and is comprised of physicians, psychiatrists, psychologists, social workers, surgeons, and other health professionals who specialize in health care for transgender people. From 2016 to the present, I have served on the Writing Committee for Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People.

13. I have served in various roles as a member of the Endocrine Society since 2014. I served on a nine-expert Task Force to develop the Endocrine Treatment of Transgender Persons Clinical Practice Guideline from 2014 to 2017. The experts on the Task Force which included me, a methodologist, and a medical writer co-authored the “Endocrine Treatment of Gender-Dysphoria/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline,” (“Endocrine Society Guidelines”), available at <https://academic.oup.com/jcem/article/102/11/3869/4157558>.

14. I have served as a Transgender Medicine Guidelines Drafting Group Member for the International Olympic Committee (“IOC”) since 2017.

15. Since 2019, I have also served as a drafting group member of the transgender medical guidelines of World Athletics, formerly known as the International Amateur Athletic Federation (“IAAF”).

16. I have not previously testified as an expert witness in either deposition or at trial. I am being compensated at an hourly rate of \$250 per hour for preparation of expert declarations

and reports, and \$400 per hour for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

RELEVANT MEDICAL AND SCIENTIFIC BACKGROUND

17. “Gender identity” is the medical term for a person’s internal, innate sense of belonging to a particular sex. *See* Endocrine Society Guidelines, Tbl.1 *and* Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460, Tbl.1.

18. Although the detailed mechanisms are unknown, there is a medical consensus that there is a significant biologic component underlying gender identity. Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460; Safer JD, Tangpricha V. Care of the transgender patient. *Ann Intern Med* 2019; 171:ITC1-ITC16. A person’s gender identity is durable and cannot be changed by medical intervention.

19. “Gender” is an imprecise term that can cause confusion and should be avoided for the sake of clarity. The term “gender” is sometimes used interchangeably with the term “sex.” In addition, the term “gender” is sometimes used as shorthand for “gender identity” and sometimes used as shorthand for “gender roles” and “gender expression.” But “gender identity,” “gender roles,” and “gender expression” are different things.

20. Gender roles are behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women. *See* Endocrine Society Guidelines Tbl.1. The convention that girls wear pink and have longer hair, or that boys wear blue and have shorter hair, are examples of socially constructed gender roles from a particular culture and historical period.

21. By contrast, “gender identity” does not refer to a set of socially contingent behaviors, attitudes, or personality traits that a society designates as masculine or feminine. It is an internal and largely biological phenomenon.

22. Gender expression is how a person communicates gender identity both internally and to others. *See* Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460, Tbl.1. For example, a person with a female gender identity might express her identity through typically feminine outward expressions of gender roles like wearing longer hair or more typically feminine clothing.

23. The phrase “biological sex” is an imprecise term that can cause confusion. 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 gender identity. Those attributes are not always aligned in the same direction. *See* Endocrine Society Guidelines; Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460.

24. Before puberty, boys and girls have the same levels of circulating testosterone. After puberty, the typical range of circulating testosterone for non-transgender women is similar to before puberty (<1.7 nmol/L), and the typical range of circulating testosterone for non-transgender men is 9.4-35 nmol/L. *See* Endocrine Society Guidelines (p 3888) *and* Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019.

25. On average, non-transgender boys and men as a group have better performance outcomes in most athletic competitions when compared to non-transgender girls and women as a group. Based on research comparing non-transgender boys and men with non-transgender girls and women before, during, and after puberty, there is a medical consensus that the difference in

testosterone is generally the primary known driver of differences in athletic performance between elite male athletes and elite female athletes. *See* Handelsman DJ, et al. Circulating testosterone as the hormonal basis of sex differences in athletic performance. *Endocrine Reviews* 2018; 39:803-829, (p 803).

26. Even though there are ranges of testosterone that are considered typical for non-transgender men and women, many non-transgender women have testosterone levels outside the typical range.

a. Approximately 6% to 10% of women have a condition called polycystic ovary syndrome (PCOS), which can raise women's testosterone levels up to 4.8 nmol/L.

b. Some 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 that are typically female. They do not develop the physical characteristics associated with typical male puberty.

c. Other individuals with 46,XY DSD may have responsive testosterone receptors. These individuals may have female gender identity but at puberty they may start to develop higher levels of testosterone along with secondary sex characteristics that are typically masculine.

**WORLD ATHLETICS AND IOC POLICIES
FOR WOMEN WITH HYPERANDROGENISM**

27. World Athletics is the international governing body for the sport of track-and-field athletics. Beginning in 2011, World Athletics (then known as IAAF) began requiring that women with elevated levels of circulating testosterone lower their levels of testosterone below a threshold amount in order to compete in elite international women's sports competitions. Under the 2011 regulations, women with hyperandrogenemia (defined as serum testosterone levels above the normal range) were allowed to compete only if they demonstrated that they had testosterone levels below 10 nmol/L or that they had CAIS, preventing their bodies from responding to testosterone.

28. In 2014, the Court of Arbitration for Sport (CAS) suspended the IAAF regulations. CAS accepted the IAAF position that testosterone is a key factor for competitive athletic advantage but asked the IAAF to provide additional evidence to demonstrate that differences were relevant at the levels of testosterone being considered for determination of eligibility in the women's category of competition.

29. The IAAF then issued revised regulations in 2018 after a study that showed a significant improvement in athletic performance among women with higher testosterone levels for some sports. *See* Bermon S, Garnier P-Y. Serum androgen levels and their relation to performance in track and field: mass-spectrometry results from 2127 observations in male and female elite athlete. *Br J Sports Med* 2017; 51:1309-1314.

30. The revised regulations lowered the maximum testosterone threshold to 5 nmol/L.

31. The revised regulations were upheld by the Court of Arbitration for Sport in 2019.

WORLD ATHLETICS AND IOC POLICIES FOR WOMEN WHO ARE TRANSGENDER

32. Formal eligibility rules for the participation of transgender women in the Olympics were published in 2003. The rules required that transgender women athletes could compete in women's events only if they had genital surgery, a gonadectomy (*i.e.*, removal of the testes), and legal documentation of female sex.

33. However, many women who are transgender are treated with medicines alone and don't have gonadectomy. As well, many jurisdictions do not have systems to document the sex of transgender people. In some jurisdictions, being transgender is illegal, and disclosure that someone is transgender can be unsafe.

34. Therefore, in 2015, the IOC adopted new guidance modeled after the IAAF's 2011 regulations for non-transgender women with hyperandrogenism. Under the new IOC guidance, women who are transgender must demonstrate that their total testosterone level in serum has been below 10 nmol/L for at least one year prior to competition. The 10 nmol/L threshold was the same threshold set by the IAAF's 2011 regulations.

35. In 2019, the IAAF adopted regulations based on the IOC guidance allowing women who are transgender to participate if they have lowered their total testosterone level in serum beneath a particular threshold for at least a year before competition. Unlike the IOC, the IAAF set the threshold at 5 nmol/L, which was the same threshold set by the IAAF's 2018 regulations for non-transgender women with hyperandrogenism that had been upheld by the CAS when contested.

36. The IOC and IAAF rules are consistent with the Endocrine Society Guidelines for the treatment of women who are transgender, which recommend that hormone therapy target circulating testosterone levels to a typical female range at or below 1.7 nmol/L (Endocrine

Society Guidelines, p. 3887) and with the study of testosterone levels achieved in practice by medically treated women who are transgender (Liang JJ, et al. Testosterone levels achieved by medically treated transgender women in a United States endocrinology clinic cohort. *Endocrine Practice* 2018; 24:135-142).

**PARTICIPATION OF GIRLS AND WOMEN WHO ARE TRANSGENDER
IN THE SCHOLASTIC CONTEXT**

37. 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 other contexts.

38. Most of the athletes competing in elite international competitions have already completed puberty. But in middle school and high school, athletes' ages typically range from 11-18, with different athletes in different stages of pubertal development. Increased testosterone begins to affect athletic performance at the beginning of puberty, but those effects continue to increase each year of puberty until about age 18, with the full impact of puberty resulting from the cumulative effect of each year. As a result, a 14, 15, or 16-year old has experienced less cumulative impact from testosterone than a 17 or 18-year old. The concerns that animated the World Athletics and IOC policies are, therefore, more attenuated at the high school or junior high school level.

39. There are also important differences between elite international competition and competition at the college level. The National College Athletics Association allows women who are transgender to participate on the same teams as other women after one year of testosterone suppression. Unlike the IOC and World Athletics policies, the NCAA policy does not require ongoing testosterone testing, which is required at the elite levels. Under the NCAA policy, which

has been in effect since 2011, transgender student-athletes certify that they have been on hormone therapy for a period of one year.

40. The World Athletics and IOC policies are more stringent because those organizations must develop policies that cannot be manipulated by governments that are not bound by the rule of law. For example, there have been many well-known examples of state-sponsored doping scandals. The Russian Olympic team is currently banned from international competition due to an organized doping effort. Also, there have been cases where governments have issued fraudulent birth certificates and identification documents. In 2000, Yang Yun was a medal winner in Gymnastics from the Chinese team. She later reported that she was 14-years-old at the time in violation of the rule that all athletes for her events had to be at least 16-years-old. In 2008, He Kexin was 14-years-old when participating in Gymnastics for the Chinese team in violation of the same rule that athletes be at least 16-years-old in those events. A new passport for Ms. He had hastily appeared 6 months prior to the Olympic Games that year with a new birth year so that Ms. He could qualify.

41. To confront the significant problem of state-sponsored cheating, World Athletics and the IOC have to develop eligibility criteria for transgender athletes that can be independently verified to prevent manipulation by non-transgender athletes, and that do not depend on the gender marker listed on identification documentation issued by an athlete's home country. Those concerns do not apply to scholastic athletic competitions in the United States. Scholastic athletic associations can rely on school records to show that an athlete is a girl who is transgender and has socially transitioned to live consistently with her gender identity as a girl.

42. The eligibility criteria for World Athletics and the IOC were also created as part of a system in which elite athletes in international competitions are already regulated and

monitored in some circumstances like for doping. Within that context, testing female athletes' levels of testosterone is somewhat analogous to the types of restrictions and invasion of privacy that already exist.

43. By contrast, in athletic competitions that are not as heavily regulated and monitored, it is hard to justify singling out girls who are transgender, girls with 46,XY DSDs, or girls who may just appear more typically masculine for special testosterone requirements that impose a significant additional burden.

WEST VIRGINIA'S HB 3293

44. There is no medical justification for West Virginia's categorical exclusion of girls who are transgender from participating in scholastic athletics on the same teams as other girls.

45. HB 3293 states that “[c]lassification of teams according to biological sex is necessary to promote equal athletic opportunities for the female sex.” The law defines “biological sex” as “an individual’s physical form as a male or female based solely on the individual’s reproductive biology and genetics at birth.”

46. West Virginia’s definition of “biological sex” does not reflect any medical understanding of that ambiguous term. As noted above, 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 gender identity. Those attributes are not always aligned in the same direction. *See* Endocrine Society Guidelines; Safer JD, Tangpricha V. Care of transgender persons. *N Engl J Med* 2019; 381:2451-2460. For example, if West Virginia defines “biological sex” solely based on “reproductive biology and genetics at birth” 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.

47. Even as applied to people without intersex characteristics or 46,XY DSDs, the statutory definition of “biological sex” is inconsistent with West Virginia’s stated goal of “promot[ing] equal athletic opportunities for the female sex.” A person’s genetic makeup and internal and external reproductive anatomy are not useful indicators of athletic performance and have not been used in elite competition for decades.

48. Age-grade competitive sports records show minimal or no differences in athletic performance between non-transgender boys and non-transgender girls before puberty. *See* Handelsman DJ, *et al.* Circulating hormonal basis of sex differences in athletic performance. *Endocrine Reviews* 2018; 39:803-29, p.812. There is a scientific consensus that performance advantage observed for non-transgender men compared to non-transgender women is due to circulating testosterone levels that typically diverge significantly between non-transgender males and females starting at puberty. *Id.* In other words, non-transgender men and boys as a group perform better than non-transgender women and girls as a group because of circulating testosterone—not because of their “reproductive biology and genetics at birth.”

49. By excluding girls who are transgender based on “biological sex,” and defining that term to mean “reproductive biology and genetics at birth,” West Virginia prevents a girl who is transgender from participating on girls’ teams even if she is pre-pubertal, or receiving puberty blockers, or initiated gender-affirming hormone therapy without going through endogenous puberty. These girls never experience the effects of high levels of testosterone and accompanying physiological changes. Rather, they go through puberty with the same levels of

hormones as other girls and develop typically female physiological characteristics, including muscle mass and bone structure.

50. Girls and women who are transgender and who do not go through endogenous puberty are similarly situated to women with XY chromosomes who have complete androgen insensitivity syndrome. It has long-been recognized that women with CAIS have no athletic advantage simply by virtue of having XY chromosomes. *See also* Handelsman DJ, *et al.* Circulating testosterone as the hormonal basis of sex differences in athletic performance. *Endocrine Reviews* 2018; 39:803-29, p .820 (summarizing evidence rejecting hypothesis that physiological characteristics are driven by Y chromosome).

51. Even as applied to girls and women who are transgender and who have gone through endogenous puberty, HB 3293 is dramatically out of step with even the most stringent policies of elite international athletic competitions. Unlike the policies of the IOC, World Athletics, or the NCAA, HB 3293 excludes girls and women who are transgender from participating on girls' and women's sports teams even if they have suppressed their circulating levels of testosterone through gender-affirming hormone therapy.

52. Some critics of the IOC, World Athletics, and NCAA policies have speculated that lowering the level of circulating testosterone does not fully mitigate the athletic advantage derived from endogenous puberty. But there is no basis to assert with any degree of confidence that this hypothesis is true. Based on the limited data available, it is equally or more plausible to hypothesize that women who are transgender could be at a net *disadvantage* after receiving gender affirming hormone therapy, as compared to non-transgender women.

53. For example, transgender women who go through typically male puberty will tend to have larger bones than non-transgender women, even after receiving gender-affirming

hormone therapy. But larger bones may be a *disadvantage* for transgender women who have typically female levels of circulating testosterone. Muscle mass will be decreased with the shift to female levels of circulating testosterone. Having larger bones without corresponding levels of testosterone and muscle mass would mean that a runner has a bigger body to propel with less power to propel it.

54. Similarly, in a sport where athletes compete in different weight classes (*e.g.* weight lifting), the fact that a transgender woman has bigger bones may be a disadvantage because her ratio of muscle-to-bone will be much lower than the ratio for other women in her weight class who have smaller bones.

55. There are only two studies examining the effects of gender-affirming hormone therapy on the athletic performance of transgender female athletes. 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.

56. 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.


57. 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.

58. Even 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. In the academic literature these are referred to as “performance enhancing polymorphisms” or “PEPs.” A PEP is a variation in the DNA sequence that is associated with improved athletic performance. For example, variations in mitochondrial DNA have been associated with greater endurance capacity and greater mitochondrial density in muscles. Other PEPs are associated with blood flow or muscle structure. *See* Ostrander EA, et al. Genetics of athletic performance. *Annu Rev Genomics Hum Genet* 2009; 10:407-429. These variations have proven to have a significant

impact on athletic ability, unlike bone or lung size in transgender women. 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 as a result of performance enhancing polymorphisms.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 5/10/2021



A handwritten signature in black ink, consisting of a large, stylized 'J' and 'S' followed by a horizontal line, positioned above a solid horizontal line.

Joshua D. Safer, MD, FACP, FACE

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