

The IAAF's response to allegations made at the 2019 Play the Game conference regarding its DSD Regulations¹

As the international federation for world athletics, we have a responsibility to ensure fair competition conditions for all athletes. We want athletes to be incentivised to make the huge commitment and sacrifice required to excel in the sport, and to inspire new generations to join the sport and aspire to the same excellence. This means being clear about the competition criteria for the two classifications we have in our sport – men's events and women's events – so that everyone in the classification has a fair chance of success.

The speakers at the Play the Game conference (PTG) mischaracterised the IAAF's DSD Regulations, misstated the IAAF's arguments and evidence in support of those regulations, and repeated various arguments against the regulations that were considered and rejected by the CAS Panel that heard Caster Semenya's challenge to the legality of those regulations. It is not good enough for them now to claim that the CAS Panel was somehow incompetent to rule on that challenge. Ms Semenya was represented at those CAS proceedings by an excellent legal team. They acknowledged at the beginning of that hearing that they had no objection to the three members of the CAS Panel, chaired by a distinguished former federal judge from Australia who is not only a human rights expert (having served as part-time Commissioner of the Human Rights and Equal Opportunities Commission in Australia) but also a science PhD. At the end of the hearing, they acknowledged that they had been given a full and fair opportunity to present all of their arguments and evidence, and to challenge the counter-arguments and evidence submitted by the IAAF. The PTG speakers may not like the fact that their arguments and evidence were rejected, but rejected they were (by a majority of 2 to 1), and the speakers have not identified any flaw in the CAS panel's reasoning.

In the time and space available, we cannot correct every mistake. Instead, first we counter the repeated mischaracterisations by summarising the rationale for the DSD Regulations; and then we respond to Professor Pielke's allegations of 'four fatal flaws' in the DSD Regulations.

The rationale for the DSD Regulations

It was common ground at CAS that (a) women should be given the same opportunity as men to excel at sport; (b) male physiological advantages (including bigger and stronger bones and muscles and higher concentrations of haemoglobin) lead to a massive sex difference in sport performance (10-12% on average, across all disciplines), which means that the only way to achieve such equality is to have separate male and female competition categories; and (c) the primary driver of these male physiological advantages is the much higher level of testosterone that men have circulating in their bodies because they have XY chromosomes and therefore testes rather than XX chromosomes and therefore ovaries.²

There are two categories of athletes with female legal sex and/or gender identity who have XY chromosomes and testes and therefore have levels of circulating testosterone in the normal male range (7.7 to 29.4 nmol/L) rather than

The IAAF encourages all interested persons to read the DSD Regulations and accompanying explanatory notes in full (both available at <u>iaaf.org/about-iaaf/documents/health-science</u>), as well as the CAS panel's award dated 30 April 2019 (Award), which upheld the lawfulness and validity of the DSD Regulations (available at <u>tas-cas.org/fileadmin/user upload/CAS Award - redacted - Semenya ASA IAAF.pdf</u>).

Handelsman, Hirschberg and Bermon, *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews 39: 803-829, 2018 (academic.oup.com/edrv/article/39/5/803/5052770).

in the normal female range (0.06 to 1.68 nmol/L): (1) athletes in the 0.02% of the population with Differences in Sex Development (**DSDs**), of which the most common is 5-alpha reductase deficiency (**5-ARD**);³ and (2) transgender (male to female) athletes. The IAAF also submitted significant evidence, which the CAS accepted, that such DSD athletes derive materially the same physiological benefits from those testosterone levels as XY athletes without DSDs (as would XY athletes who change gender but maintain their testes and male testosterone levels).

The IAAF does not question in any way the female legal sex and/or gender identity of athletes in these two categories. It does <u>not</u> say that they are 'not female enough'. Instead, what it says is that, if we mean it when we say that 46 XX athletes with ovaries and therefore 0.06 to 1.68 nmol/L of testosterone should not have to compete with 46 XY athletes with testes and therefore 7.7 to 29.4 nmol/L of testosterone (and all the physiological benefits that brings), then we cannot ignore, instead we have to deal rationally and logically with the fact that 46 XY DSD athletes and MTF transgender athletes have the same biological features and therefore the same physiological advantages as those other 46 XY athletes. Not to do so, to simply ignore the biological reality, would be 'category-defeating'.

Many argue that the physiological advantages derived from going through male puberty cannot be effectively addressed, and therefore there should be an absolute bar on 46 XY DSD and MTF transgender athletes competing in the female category. The IAAF prefers to be more inclusive. It therefore allows such athletes to compete in the female category — consistent with their legal sex and/or gender identity — provided that, if they want to compete in international competition in distances between 400m and one mile (which is where the vast majority of the more than thirty 46 XY DSD athletes of which the IAAF is aware have shown the most advantage), they first reduce their testosterone levels below 5 nmol/L. Outside these events at this level, there are no restrictions for DSD athletes.

The CAS panel agreed with the IAAF that 'the criteria that regulate who may compete in the "protected" female category must align with the reason for establishing that "protected" category in the first place' (Award para 564). Based on the scientific evidence presented by the IAAF (Award, paras 524-525, 528-530, 532 and 571), the CAS panel accepted that 46 XY DSD athletes have a 'significant performance advantage' over 46 XX athletes without a DSD, and that the advantage is attributable to the fact they have testes rather than ovaries and their consequent 'exposure to levels of circulating testosterone in the adult male range' (Award, paras 571-575). It therefore also accepted that it would be 'category-defeating' to permit individuals with testosterone-derived advantages to compete in the female category, given that those advantages were the reason that the female classification was established in the first place (Award, paras 562-564).

The CAS panel determined that the evidence from the field of 46 XY DSD athlete performances (most of which is, for confidentiality reasons, not publicly available) provides 'compelling evidence that the physical characteristics associated with 5-ARD give female athletes with that condition a significant and frequently determinative performance advantage over other female athletes who do not have a 46 XY DSD'; and that the 'contrast between the rare incidence of 5-ARD in the general population and the overwhelming success that women with 5-ARD have achieved [...] provides powerful evidential support for the conclusion that female athletes with 5-ARD have a significant performance advantage'. It therefore found that, to the extent the DSD Regulations discriminate between 46 XX female athletes and 46 XY DSD athletes, 'such discrimination is a necessary, reasonable and proportionate means of achieving the aim of [...] the integrity of female athletics and the upholding of the "protected class" of female athletes in certain events' (Award, para 626), and the DSD Regulations 'reflect a rational resolution of conflicting human rights' (Award, para 589).

Following the CAS decision to uphold the IAAF's DSD Regulations, and the 100 or so media calls received, answers to the 12 most asked questions were published on the IAAF website and can be found here: https://www.iaaf.org/news/press-release/questions-answers-iaaf-female-eligibility-reg.

⁵⁻ARD is a genetic mutation that causes a deficiency of the enzyme (5-alpha reductase) needed to create the hormone (DHT) responsible for forming the external male genitalia, meaning that in cases of severe deficiency 46 XY 5-ARD babies may be born with their testes inside their bodies and with ambiguous external genitalia. Historically many such babies were give a female legal sex and reared female, but 50+% changed to male sex at puberty, when their testes started producing the testosterone levels that virilised their body, and prevailing medical opinion is now that such babies should be assigned a male sex: see Ozbey and Etker, *Disorders of sexual development in a cultural context*, Arab J Urol. 2013 Mar; 11(1): 33–39; Imperato-McGinley, Peterson, Gautier and Sturla, *Androgens and the evolution of male gender identity among male pseudohemaphrodites with 5-a reductase deficiency*, 1979 N. Engl. J. Med. 300:1233-1237); Lee *et al*, *Global Disorders of Sex Development*, *Update since 2006*, Horm Res Paed 2016;85:158-180 (karger.com/Article/FullText/442975).

Fact vs fiction? The four supposed 'fatal flaws' in the DSD Regulations

Alleged 'Flaw 1': The IAAF 'completely rewrote' the DSD regulations 'on the eve of the CAS hearing' so that the regulations were not focused on 'women with high testosterone' but rather on individuals it considered to be 'biological males', such as Caster Semenya.

False: On 9 January 2019, more than five weeks before the CAS hearing, the IAAF gave notice that it would remove Congenital Adrenal Hyperplasia (CAH) and a CAH-variant from the list of relevant DSDs, because individuals with these DSDs only have high testosterone levels if their adrenal conditions are uncontrolled, in which case they would suffer side-effects that would make elite sports performance impossible. That was the <u>only</u> change made to the DSD Regulations. All other aspects, including the high testosterone trigger, remained exactly the same. And well before that, in a pleading it filed in August 2018, the IAAF had made it clear that it 'does not seek to question in any way the assigned sex or the gender identity of DSD athletes, whether as male, female, 'gender X', or 'without gender'. It fully respects their dignity and their right not to have that status/identity questioned or to be stigmatised in any way. But still the IAAF has to address rationally and fairly the biological facts set out above. [...] If it is not fair and meaningful for a female athlete to have to compete with a male athlete whose testes produce 10-30 times more testosterone than her ovaries produce, so too it is not fair and meaningful for that female athlete to have to compete with a DSD athlete who also has testes that produce 10-30 times more testosterone than she does'.

Alleged 'Flaw 2': The IAAF used 'flawed empirical science to establish the restricted categories', namely a 2017 analysis of data 'shot through with errors' that established a correlation in certain events between the testosterone levels and performances of female athletes at the 2011 and 2013 World Championships.

<u>False</u>: Although the paper in question⁴ did show a correlation between testosterone and performance in certain events even at the very low levels seen in 46 XX athletes (i.e., without even considering the massive disparity in testosterone levels between 46 XY and 46 XX athletes), the IAAF did not apply the DSD Regulations to all of those events. Instead, it only applied them to events where the significant majority of the thirty+ 46 XY DSD athletes of which the IAAF is aware competed and excelled. The CAS accepted that this was a rational basis for singling out these events (Award, para 607).

It is also worth noting that, after considering all of the evidence, including that of Professor Pielke (which was markedly less strident at the hearing than it is now), the CAS panel also found that the study in question '(even as an observational study) provides empirical data which demonstrate that the IAAF's scientific evidence concerning the physiological effects of increased testosterone levels translates, in a real world competitive context, to a significant and often determinative performance advantage' (Award, para 536). Recent research published after the CAS Award also supports this conclusion. A double blind, randomised placebo-controlled trial investigated the effects of testosterone supplementation in young athletically active XX women (increasing serum testosterone levels from – on average – 0.9 nmol/L to 4.3 nmol/L in the supplemented group) and found a causal relationship between elevated testosterone and increased aerobic capacity, and an increase in muscle mass.⁵

Alleged 'Flaw 3': 'IAAF uses flawed theoretical science to reclassify certain females as "biological males" (because it relied on a 2019 scientific paper by Clark et al that reported a large bimodal divergence in testosterone concentrations between men and women, and reported individuals with 5-ARD to be in the male range, which paper was in error, because in fact the testosterone concentration range for individuals with 5-ARD overlaps with both the male and female range⁶).

The data underlying the 2017 paper critiqued by Professor Pielke were reconsidered by the authors (along with the criticisms themselves) in a 2018 paper published in the British Journal of Sports Medicine: Bermon, Hirschberg, Kowalski, Eklund, *Serum androgen levels are positively correlated with athletic performance and competition results in elite female athletes.* Br J Spmts Med 2018;52: 1531-1532 (https://bjsm.bmj.com/content/52/23/1531).

Hirschberg, Elings Knutsson, Helge, Godhe, Ekblom, Bermon, Ekblom, *Effects of moderately increased testosterone concentration on physical performance in young women: a double-blind, randomised, placebo-controlled study*, British Journal of Sports Medicine, online 15 October 2019, (doi:10.1136/bjsports-2018-100525).

⁶ Clark et al, Large divergence in testosterone concentrations between men and women: Frame of reference for elite athletes in sexspecific competition in sports, a narrative review, Clinical Endocrinology 90:15-22., 2019

<u>False</u>: Once again, the IAAF is not reclassifying any females as 'biological males', whether using testosterone levels or otherwise. Instead it is saying that it would be irrational and illogical, in organising athletic competition, to ignore the fact that 46 XY DSD females have exactly the same biological characteristics as 46 XY male athletes have that give them the physiological advantages that make mixed competition unfair.

What the IAAF proved at CAS, and the claimants (including Professor Pielke) did not dispute, is that the normal serum testosterone range for 46 XX females is 0.06 to 1.68 nmol/L, that 46 XX females with PCOS may have slightly higher testosterone levels than that, but that a woman with ovaries would not have testosterone levels above 5 nmol/L unless she was doping or she had a testosterone-producing tumour. The IAAF also produced evidence (which the claimants again did not dispute) that increasing testosterone levels from the normal female range even just to 7.3 nmol/L causes a marked increase in muscle size and strength and in haemoglobin.² For these reasons, the CAS accepted that it was rational and necessary to require 46 XY DSD athletes to reduce their testosterone levels below 5 nmol/L in order to compete in the female category in the affected disciplines (paras 615, 610-11).

The Clark paper was not even published when the DSD Regulations were issued. But it entirely supports that 5 nmol/L limit. Professor Pielke is correct that the authors subsequently acknowledged that <u>prepubescent</u> 46 XY females with 5-ARD had testosterone levels in the normal female range, but that is not surprising (their testes would only start producing higher levels of testosterone on puberty), and it does not undermine in any way any part of the IAAF's case. In particular, it does not undermine in any way the very clear evidence (1) that a woman with ovaries would not have testosterone levels above 5 nmol/L unless she was doping or she had a testosterone-producing tumour, and (2) that increasing testosterone levels from the normal female range even just to 7.3 nmol/L causes a marked increase in muscle size and strength and in haemoglobin.

Alleged 'Flaw 4': The DSD regulations 'require that medical professionals violate widely held guidelines for medical and research ethics' and 'take perfectly healthy people and turn them into patients', 'simply for the cosmetics of sport'.

False: The DSD Regulations comply in all respects with medical and ethical guidelines, and with the medical consensus as to the appropriate approach in cases of 46 XY DSD individuals. First, where a female presents with levels of testosterone in the normal male range, diagnosis is important, not least because the cause could be a cancerous tumour, for which urgent treatment is required (as happened in one case identified under the DSD Regulations). Moreover, athletes with primary amenorrhea by the age of 16 require proper medical review for diagnosis and appropriate care. The IAAF has located independent experts around the world to carry out such diagnosis, and pays the costs of such diagnosis for the athletes involved. The DSD Regulations are clear that it is then for the athlete to decide, in consultation with her own doctor, and based on that doctor obtaining her informed consent, whether she wants treatment to reduce her testosterone levels at all, and (if so) which of the different treatment options (including different hormonal suppression options, as well as gonadectomy) is right for her. The IAAF is not responsible for and does not pay for any such treatment. However, the IAAF submitted clear evidence from clinicians who are expert in this field that reducing serum testosterone to normal female levels is the recognised standard of care for 46 XY DSD individuals with a female gender identity (whether those individuals are athletes or not).

In response to recent claims made in the media, the IAAF has never advised any DSD athlete that it prefers that they undergo gonadectomy. Nor has the IAAF ever forced any DSD athlete to undergo gonadectomy (or any other surgery), or paid for any of their treatment. In particular, contrary to the claims made by Ugandan athlete Annet Negesa, neither the IAAF nor its Medical and Science Department Director, Dr Stéphane Bermon, was involved in her treatment or recommended any course of treatment to her (in fact, Dr Bermon has never even met Ms Negesa).⁷ And contrary to the claims made by Dr Dreyer (Caster Semenya's doctor), the contemporaneous written evidence confirms (1) that the IAAF never suggested that gonadectomy was its preference for Caster Semenya out of the different options available, and (2) that its interest was in her returning to elite sport as quickly as possible.

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(https://onlinelibrary.wiley.com/doi/full/10.1111/cen.13840) (https://onlinelibrary.wiley.com/doi/full/10.1111/cen.14068).

and

Erratum