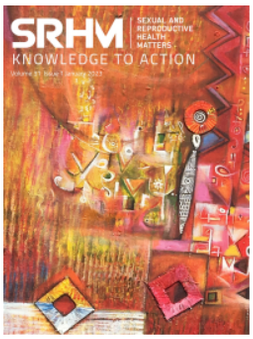

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Sexual and Reproductive Health Matters

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/zrhm21

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To cite this article: Katrina Karkazis PhD,MPH & Michele Krech JSD (03 May 2024): What do oral contraceptive pills have to do with human rights abuses in sport?, Sexual and Reproductive Health Matters, DOI: 10.1080/26410397.2024.2342105

To link to this article: https://doi.org/10.1080/26410397.2024.2342105

Accepted author version posted online: 03 May 2024.

Publisher: Taylor & Francis & The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group
Journal: *Sexual and Reproductive Health Matters*
DOI: 10.1080/26410397.2024.2342105

What do oral contraceptive pills have to do with human rights abuses in sport?

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Introduction

Sport may seem an unexpected place to find oral contraceptive pills (OCPs) at the centre of alleged violations of human rights and medical ethics. However, this is precisely the case in ongoing legal challenges to "sex testing" regulations that restrict eligibility for the women's category of athletics competition, two of which will be heard in spring 2024. In order to remain in competition, *[1] women targeted by the regulations must submit to unwanted and medically unnecessary interventions to lower their natural testosterone levels below a specified threshold. [2] World Athletics,† which governs the

* Pursuant to the regulations, any athlete who refuses to undergo an investigation or to suppress her testosterone is not eligible to compete in the female classification in international competitions or to have her performances recognised as world records.
† World Athletics was formerly known as the International Association of Athletics Federations (IAAF).

sport of track and field worldwide, promotes OCPs as the primary method for meeting this condition of eligibility.

Whereas OCPs are typically used to enhance autonomy, the opposite is true in the context of sex testing in sport: instead of enabling choice and control over one's body, the use of OCPs as a condition of regulatory compliance severely limits both. The athletes subjected to this coercive control are women diagnosed with certain "differences of sex development"[‡] and are overwhelmingly women of colour from the Global South. [3] The imposition of sex testing regulations thus echoes the colonial legacy of controlling the bodies and reproduction of women of colour, including through coercive contraception. [4,9]

Many of the women affected by World Athletics' sex testing regulations, along with various UN entities, leading NGOs, professional medical associations, and others, maintain that sex testing regulations contravene international human rights norms and principles of medical ethics. [10-19] However, despite multiple legal challenges over the last decade, [20-23] courts have largely avoided the application of these standards, [24,25] while deceptively suggesting that they have taken a rights-based approach. [26] In doing so, the legal process has functioned not as a "simple transcription device for science, automatically writing into legal decisions whatever facts science has" but as a knowledge-making enterprise. [27] (S51) The Court of Arbitration for Sport (CAS), in particular, has generated significant misunderstandings about OCPs, to the detriment of human rights and medical ethics.

With two important upcoming cases, we urgently revisit how faulty assumptions about OCPs - introduced by World Athletics and their recruited experts, and then readily accepted by the courts - have led to the sidestepping of human rights and medical ethics and, in so doing, allowed sex testing regulations to persist. As a result, a class of drugs so key to women's bodily autonomy has come to be instrumental in curtailing that very right in the context of sport. Illuminating the problematic assumptions in the factual record produced in the central case challenging sex testing regulations, brought by South African runner Caster Semenya, [21] reveals the human rights violation and unethical medical practice at the core of these regulations: a coerced "medical" intervention.

Background

Since the 1930s, certain sport governing bodies have mandated "sex tests" to determine eligibility for the women's category of competition. [28-30] Initially, these tests focused on particular aspects of body morphology, such as genital appearance and secondary sex characteristics. As molecular testing advanced, chromosomes and hormone levels became key criteria for determining female eligibility.

[‡] DSD is a term used to describe a broad range of congenital conditions that involve variations in individuals' sex chromosomes, genes, external and/or internal genitalia, hormones, and/or secondary sex characteristics. People with these diagnoses may prefer other terminology such as "innate variations of sex characteristics" or "intersex traits." On the nomenclature for these conditions, which is contested and evolving, see: M. Carpenter, "Intersex Variations, Human Rights, and the International Classification of Diseases," *Health and Human Rights* 20, no. 2(2018): 205-214.

[2,28,29] In 2011, World Athletics introduced regulations that capped the permissible level of natural testosterone for women athletes. [31] It has since significantly lowered this cap and restricted its application to women with certain DSD. [1,32]

These regulations have been challenged before the CAS [20,21] - an international arbitral tribunal located in Switzerland, with exclusive jurisdiction to hear a wide range of sport-related disputes. Decisions by the CAS may be appealed only to the Swiss Federal Court (SFC). [33] After losing her case before both of these courts, [21,22] Caster Semenya filed a complaint with the European Court of Human Rights (ECHR), alleging that Switzerland breached its human rights obligations by affirming the CAS decision that allowed World Athletics' sex testing regulations to stand. According to the ECHR's initial decision, [23] neither the CAS nor the SFC effectively examined Semenya's human rights complaints.

Central to this sidestepping of human rights, and the related principles of medical ethics, has been fact-finding and fact-making regarding OCPs. Importantly, legal processes are a key venue where medical expertise underwrites "practices of clinical and population-based oversight that enable institutions to control people on national and even imperial scales." [34] However, "the scientific knowledge that the law needs for its purposes is frequently unavailable until the legal process itself creates the incentives for generating it." [27 (S54)] This is evident in Semenya's case against World Athletics, with the CAS generating knowledge based on dubious assumptions about OCPs, which demand correction. We identify two mistaken factual assumptions about OCPs underlying the CAS's analysis in Semenya's case, which seriously undermine World Athletics' claim that its regulations comply with standards of human rights and medical ethics. [35-37] As these factual assumptions have not been re-examined since, it is critical to highlight them in advance of the upcoming cases concerning World Athletics' regulation: a new case before the CAS [38] and fresh consideration of Semenya's case before the ECHR, both to be heard this spring. [39]

First, as we elaborate below, the CAS assumed that OCPs are the exclusive method by which athletes will lower their testosterone, ignoring that OCPs may not be effective in this regard and, further, that other (riskier and more invasive) methods are commonly relied on instead. [40] Second, the CAS assumed that the harms associated with OCP use for lowering testosterone would be equivalent to those associated with OCP use for contraception, ignoring not only potential differences in protocols and risks, but also the lack of benefit and, most importantly, the inherent harm of coerced medical intervention aimed at regulatory compliance.

These assumptions undergird the conclusion by the CAS panel that, despite "some grave concerns as to [their] future practical application," the regulations were not "presently and on their face disproportionate." [21 (at 619, 620)] In coming to this tentative conclusion (by majority rather than unanimity),[§] the panel emphasised that if, in practice, an athlete cannot achieve regulatory compliance through OCPs (and thus other methods must be used instead), the proportionality of the regulations would have to be reassessed. [21 (at 592,620)] The regulations were thus upheld based on unproven

[§] The Semenya case was a split decision so any reference to the panel means the majority in this case.

assumptions about OCPs. As we will show, both the efficacy and the harms of OCPs were misconstrued and therefore misused in upholding the regulations. We illuminate and correct these assumptions in hopes that future evaluations of sex testing regulations will be grounded in accurate and properly contextualised factual findings regarding OCPs. Otherwise, misunderstandings and misuses of scientific evidence will continue to justify violations of human rights and medical ethics in the context of sport.

Mistaken assumption #1: OCPs are an effective and exclusive method of regulatory compliance

In its analysis, the CAS panel encountered the "greatest difficulty" when it came to assessing the *proportionality* of the World Athletics' sex testing regulations [21 (at 584)] - that is, whether the collective interest pursued (a purported "level playing field" in women's athletics) [21 (at 426, 460)] outweighs the individual rights infringement. Central to this assessment was an endorsement of World Athletics' assumptive claim that OCPs would be the only method used to suppress an athlete's testosterone levels. [21 (at 592)] The CAS panel's uncritical acceptance of this assumption is remarkable given the scant evidence presented that OCPs can reliably achieve this goal and the panel's own acknowledgement that other methods are more effective in this regard. We address each of these points in turn.

The factual assumption that OCPs can effectively suppress testosterone below the designated threshold was based on very limited evidence, and ignored not only significant gaps in the evidence, but also evidence to the contrary. The CAS panel understood from two clinicians that, anecdotally, "ordinary doses" of OCPs are "efficient in reducing testosterone to normal female levels." [21 (at 593)] However, the only evidence on this point cited in the CAS decision came from a single expert called by World Athletics, Angelica Lindén Hirschberg, a professor of obstetrics and gynecology and a key architect of the regulations. [21 (at 368)] The entirety of Hirschberg's cited testimony on this issue consisted of two points. First, "[o]ral contraceptives . . . are the simplest and most direct way to lower testosterone levels." [21 (at 374)] Second, Hirschberg had apparently suppressed the testosterone of *one* of her patients from well-above to well-below the mandated threshold using OCPs. [21 (at 593)]

No studies were presented - as they do not exist - to establish whether, how, or for what period of time testosterone can be suppressed below a specified level using OCPs. Moreover, the expert witnesses disagreed about the likelihood that OCPs can reduce and keep stable an athlete's testosterone level,[**] [21 (at 487)] and confirmed that because testosterone suppression *per se* is not an approved use of OCPs, there are no guidelines for how to use them for this purpose.[††] [21 (at 593)] The panel acknowledged that the only person at the hearing with any experience using OCPs in this way was Semenya.[‡‡] [21 (at 593)] She testified that World Athletics had used her as a "lab rat" by "experimenting" with how OCPs would affect her testosterone levels, [21 (at 83)] and that it had been difficult to maintain her testosterone levels

[**] "The experts were unable, however, to reach agreement in respect of the following Matters: … the extent to which oral contraceptives can cause athletes with 46 XY DSD to have a reduced level of testosterone that is stable."
[††] "There are no current guidelines to instruct how a clinician would use oral contraceptives to reduce testosterone levels in a woman with a 46 XY DSD to less than 5 nmol/L and keep it at that level, but there are expert clinicians who have done so (such as Prof. Hirschberg, who says that she treats each person on an individual basis)."
[‡‡] "The evidence of such treatment on elite athletes is extremely limited; it consists principally of evidence concerning Ms. Semenya's use of oral contraceptives to reduce her testosterone levels."

below the mandated threshold. Further, the doctor responsible for negotiating Semenya's testosterone suppression with World Athletics confirmed that her testosterone levels showed significant fluctuation, including "spikes" significantly over the maximum threshold. [21 (at 103,612)] While the CAS panel expressed concern that OCPs may not consistently maintain testosterone below the mandated threshold, §§ [21 (at 622)] it left it to World Athletics "to ensure that this requirement is workable in practice." [21 (at 617)]

Given the CAS panel's findings that "[t]here is not a single established protocol for how to lower the testosterone levels of DSD athletes to below [a mandated threshold]" [21 (at 486)] and that OCPs are "not as efficient in inhibiting testosterone" as other methods, [21 (at 592)] it is not far-fetched that other methods might be required. [41] Still, the panel did not engage with the evidence that other methods had, in fact, been recommended and used already. For instance, Semenya's physician testified that World Athletics officials had "made it clear [to her] that their preferred treatment [sic] for an elite female athlete…is gonadectomy," an irreversible surgery to remove the reproductive glands, to which Semenya objected. [21 (at 101)] Moreover, a 2013 study revealed that gonadectomies had been performed on four young women, between the ages of 18 and 21 from "from rural or mountainous regions of developing countries," who were sent to one of World Athletics' designated referral centres to be evaluated under the regulations.*** [42 (p. E1056)] Although the examining doctors acknowledged that leaving the women's gonads intact carried "no health risk," they informed the women that removing them would "allow them to continue elite sport in the female category." [42 (p. E1057)] Women pressured to undergo this intervention, including two seen in Nice, have publicly spoken out about the harmfulness of the experience. [14,43]

The CAS panel acknowledged that other methods of lowering testosterone, including gonadectomy and gonadotrophin-releasing hormone (GnHR) agonist pills, are "likely to have greater side effects." [21 (at 592, 486)] However, it did not consider these harms in its analysis. Soon after the CAS upheld the regulations, though, World Athletics confirmed that these other methods might be used: "To lower their testosterone levels…affected athletes can either (a) take a daily oral contraceptive pill; or (b) take a monthly injection of a GnRH agonist; or (c) have their testes surgically removed (a 'gonadectomy')". [44] The assumption that OCPs are an effective and exclusive method used to comply with the regulations was therefore incorrect, undermining a key factual basis of the CAS panel's decision.

Mistaken assumption #2: OCPs are not harmful because many women use them for contraception

The gravity of the CAS panel's unexamined assumption that OCPs would be an effective and exclusive method of complying with the regulations was compounded when it came to assessing their harms. The panel not only disregarded the (likely more serious) harms of all other methods [21 (at 244)] - a major

§§ "The Panel notes the strict liability aspect of the DSD Regulations and repeats its concern as to an athlete's potential inability to remain in compliance with the DSD Regulations in periods of full compliance with treatment protocols, and, more specifically, the resulting consequences of unintentional and unavoidable non-compliance." However, the panel considered this possibility "speculative" and "hypothetical" since the newest regulations were not yet in force. [21 (at 619)]

*** This article provided the first window into the implementation of World Athletics' regulations. Since its publication, many have argued that these practices violate human rights and medical ethics. [4-11]

oversight in itself – but it also minimised the harms of OCPs based on limited evidence of their use for contraception, extended this minimisation of harm to their use for testosterone suppression and ignored the lack of benefit and inherent harm of their use when directed at regulatory compliance rather than health outcomes. We address each of these compounding assumptions in turn.

With respect the potential harms of OCP use, the panel relied on the claim, primarily from Hirschberg, that the side effects would be no different than "those experienced by the many thousands, if not millions" of women taking OCPs for contraception. [21 (at 598)] The more serious of these were identified as deep venous clots, which can lead to pulmonary embolism, stroke or even death, as well as hypertension, liver dysfunction and tumours. [21 (at 184, 244, 250, 251)] The evidence that OCPs are nonetheless "very safe" again came solely from Hirschberg, who simply stated that OCPs are "used by up to 40% of young women in the Western world" and "are usually well tolerated with few side effects." [21 (at 347)] She elaborated that while OCPs increase the risk of deep venous clots, the baseline risk is "very low" and medical complications arising from OCP use are "very rare." [21 (at 347)]

Notably, however, Hirschberg's single study published on the topic of OCPs tells a different story. In a press release for the study, Hirschberg and colleagues emphasised the dearth of scientific evidence about the health effects of OCPs:

"Despite the fact that an estimated 100 million women around the world use contraceptive pills we know surprisingly little today about the pill's effect on women's health. The scientific base is very limited as regards the contraceptive pill's effect on quality of life and depression and there is a great need for randomised studies where it is compared with placebo." [45]

Hirschberg and her co-authors found that OCP use resulted in an overall reduction in quality of life, including negative effects on mood, self-control, and energy. [46] Even where these negative changes were relatively small, the authors emphasised that they "are likely to be of clinical importance for individual women." [46 (p. 1242)] However, this evidence does not seem to have been presented to the CAS panel, which instead accepted Hirschberg's simplified account that the harms associated with OCPs are minimal, despite ample evidence to the contrary. [21 (at 184, 231, 244, 250-251)]

On top of this was the assumption that the supposedly minimal side effects of OCPs when used for contraception would be the same as when used for testosterone suppression. This is remarkable given that no expert witness was certain whether higher doses would be required for this aim or to what degree higher doses would increase the risk or intensity of side effects. ††† [21 (at 487)] Semenya and her doctors, however, provided first-hand evidence about the intolerable side effects of OCPs when used for the purposes of testosterone suppression. ‡‡‡ [21 (at 56, 78-80, 100, 105, 594)] While the panel generally accepted

††† At least one expert testified that "[i]t is likely that high levels of each of the three agents will be needed in order to reduce testosterone to below that level, further increasing the risk of serious side effects" [21 (at 250)].
‡‡‡ Semenya testified that she experienced side effects including weight gain, feverish symptoms, and consistent abdominal pain, leaving her feeling unwell and unable to focus.

this evidence, it also found that the negative mental and physical effects to which Semenya testified had "not been shown to be attributable simply and exclusively to the use of oral contraceptives." [15 (at 598)] Further, the panel noted that the side effects of OCPs described by Semenya "potentially affect all the women who take them." [21 (at 595)] The panel thus swiftly extended the minimisation and normalisation of OCP side effects from one context (contraception) to another (testosterone suppression).

Notably, the panel also proceeded on the unverified assumption that these effects would not worsen with the new lower cap on testosterone mandated by World Athletics' revised regulations. [21 (at 586)] Further, the panel assumed that clinicians would "individualise treatment to minimise side effects" [21 (at 598)] - a sensible approach when the goal is a particular medical goal or benefit (e.g., contraception) but much less feasible when the goal is *per se* to lower testosterone below a specific threshold. [47] The panel disregarded this contradiction, however, by equating two very different contexts of OCP use.

Altogether, this minimisation and false equivalence of the harms associated with OCPs distracted from the greatest mis-contextualisation of all: unlike those who choose to take OCPs for some medical benefit (such as contraception), athletes who undergo interventions based on the threat of losing their career do so absent, and even despite, considerations of health and wellbeing. The failure of the CAS panel to account for this difference completely undermined its assessment of the harms caused by the regulations. To put it simply, even if using OCPs to comply with the regulations carried the exact same health risks as using OCPs for contraception, there is no health benefit in the former case against which to balance those risks. OCPs are not benign, no matter how many people use them, but their use may be considered beneficial (to a patient and their physician) in light of a desired health benefit or goal. Choice is foundational to these decisions. [47] When the goal is regulatory compliance, there is neither free choice nor medical benefit; there are only harms. And foremost among these is coerced manipulation of one's body - a significant harm in and of itself, which the CAS panel (and the SFC after it) largely ignored.

Correcting factual assumptions to uphold human rights and medical ethics

Human rights experts have asserted that World Athletics' sex testing regulations contravene internationally recognised human rights norms and standards. They infringe not only on the right to equality and non-discrimination, but also on the right not to be subjected to degrading treatment and the right to privacy, both of which entail rights to health, bodily autonomy, and psychological integrity. [12-14,17-19,48] Moreover, experts in medical ethics have emphasised that the regulations impede physicians' ability to uphold their ethical obligations, including respect for autonomy, beneficence, non-maleficence, justice, and non-discrimination. [2,10,11, 15,16,49]

This intersection of human rights concerns and medical ethics concerns stems from the central harm of World Athletics' sex testing regulations: a coerced bodily intervention. Importantly, individuals exhibiting DSD are among the populations who are disproportionately subjected to involuntary or forced medical interventions, including contraceptive practices [50,51] and "normalising" procedures. [52] Such

interventions are squarely prohibited by international human rights law,[§§§,] [51] as well as by the principles of medical ethics that guide physicians' interactions with patients. [49] However, these standards have fallen to the wayside when it comes to sex testing regulations in sport.

Assessing compliance with the complementary standards of human rights and medical ethics often requires a specific evaluation of benefits and harms: Do the collective benefits of a regulatory decision outweigh the harms caused to individuals? Do the benefits of a medical intervention outweigh its harms to the person concerned? However, courts' incorrect assumptions about OCPs have seriously misconstrued the harms of sex testing regulations in sport. As we have shown, the CAS has assumed – and thereby generated – facts about OCPs that are either seriously in doubt or demonstrably false, and which obscure the very serious harm inherent in a coerced and medically unnecessary bodily intervention (whether in the form of OCPs or otherwise).

These unappreciated harms have only been exacerbated by World Athletics' further revisions of the regulations: expanding them to apply to all, rather than just some, track and field events; significantly reducing the maximum permissible level of testosterone; considerably extending the period of time this lower level must be consistently maintained before the athlete regains eligibility; and reinstating the possibility of ineligibility in cases where an athlete's testosterone rises above the mandated level despite her compliance with prescribed interventions.[****] It is therefore all the more important that courts, including the CAS, the SFT, and the ECHR, do not simply accept the factual assumptions made by the CAS panel in its last decision. The panel itself warned against this, noting that "Semenya has raised matters regarding the difficulty of complying with the requirements imposed under the [regulations] that, if established, could lead to a different conclusion as to the proportionality of the [regulations]." [21 (at 621)] We have also pointed to additional incorrect factual assumptions, not acknowledged by the panel, which heighten the need to reassess proportionality.

As things stand, the narrative of harm has focused on the "unfairness" of the putative athletic advantage conferred by testosterone, while overlooking the serious harms of coerced bodily interventions, and the standards of human rights and medical ethics they so blatantly infringe. All the while, athletes have been left to subject themselves to unwanted, under-studied, and medically unnecessary interventions in

§§§ International human rights law prohibits "forced or coerced medical interventions with respect to intersex characteristics, such as non-emergency medical interventions performed without full, free and informed consent" as well as "discrimination against intersex persons, including in … sports." [51 (at 1)]

**** The regulations initially only applied to running events between 400 metres and 1 mile, but now apply to all track and field events. The maximum permissible level of testosterone has been reduced from 10 nmol/L (in 2011) to 5 nmol/L (in 2018) to 2.5 nmol/L (in 2023). This time period has been increased from 6 months (in 2018) to 24 months (in 2023). Between the hearing and decision in *Semenya v. IAAF* [15] [15 (at 44)] World Athletics added a provision to its regulations (para. 3.15) stipulating that if its Medical Manager is satisfied that an athlete's failure to maintain her circulating levels of blood testosterone below the mandated threshold was temporary and inadvertent, World Athletics "will not impose any period of ineligibility…or disqualify any results." The latest (2023) version of the regulations stipulate instead that where an athlete is able to satisfy the Expert Panel on the balance of probabilities that their failure to keep their testosterone level below the mandated threshold was unintentional, the athlete "will be ineligible to compete in the female classification…for such period (if any) as the Expert Panel shall consider necessary to protect fair competition in the female classification."

order to "prove" that those interventions are harmful. [28] This makes a mockery of international standards of human rights and medical ethics, which are ultimately aimed at proactive fulfilment and prevention of violations.[††††] It has also interfered in Semenya's ability to access a remedy,[‡‡‡‡] with the CAS panel, the SFC, and others distracted by the normalisation of OCPs as minimally harmful regardless of (coercive) context - a distraction resulting from the generation of "facts" without regard to context and embodied realities.

Courts have thus relied on unverified and mis-contextualised facts about OCPs and their associated harms to find World Athletics' sex testing regulations proportionate. Going forward, courts must correct these erroneous assumptions and evaluate the regulations in light of the complementary requirements of human rights and medical ethics, which prohibit bodily interventions that are both coerced and medically unnecessary. Otherwise, by legitimating misinformation, courts will continue to sanction the denial of basic rights and the violation of medical ethics.

Disclosure statement:

No potential conflict of interest was reported by Katrina Karkazis. Michele Krech was retained as a consultant by counsel for Caster Semenya in the legal case before the CAS referenced in this article.

Provenance:

This article was not commissioned and went through external peer review.

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[††††] Obligations under international human rights law are often described according to a "respect, protect, and fulfill" framework. See: United Nations Office of the High Commissioner for Human Rights, "International Human Rights Law," https://www.ohchr.org/en/instruments-and-mechanisms/international-human-rights-law: "The obligation to respect means that States must refrain from interfering with or curtailing the enjoyment of human rights. The obligation to protect requires States to protect individuals and groups against human rights abuses. The obligation to fulfil means that States must take positive action to facilitate the enjoyment of basic human rights."

[‡‡‡‡] In the context of business and human rights, obligations of States and the responsibilities of corporate entities are often described according to a "protect, respect, and remedy" framework. The latter entails both state-based and non-state-based grievance mechanisms. See: United Nations Office of the High Commissioner for Human Rights, *Guiding principles on business and human rights : implementing the United Nations "Protect, Respect and Remedy" framework* (UN, New York, 2011), https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf .

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