

**BEFORE THE AMERICAN ARBITRATION ASSOCIATION
Commercial Tribunal**

CASE NO. 01-19-0002-7536

[REDACTED]
Claimant
v.
UNITED STATES ANTI-DOPING AGENCY,
Respondent

FINAL AWARD

We, the undersigned arbitrators, Carolyn B. Witherspoon, Mark Muedeking, and Christopher L. Campbell, having been designated in accordance with the USADA Protocol for Olympic and Paralympic Movement Testing (USADA Protocol), and operating under the American Arbitration Association ("AAA") Supplementary Procedures for the Arbitration of Olympic Sport Doping Disputes ("Supplementary Procedures"), and having been duly sworn, and after considering the proofs, arguments, submissions, evidence, and allegations submitted by the parties, and after numerous Panel deliberation telephone calls, do hereby rule as follows:

I. INTRODUCTION

- 1.1 This case involves the denial of Claimant's Therapeutic Use Exemption (TUE) on July 10, 2019, by the United States Anti-Doping Agency (USADA) in consultation with USADA's Therapeutic Use Exemption Committee (TUEC).
- 1.2 The application was for the prohibited substance dehydroepiandrosterone (DHEA).
- 1.3 The independent TUEC panel and USADA concluded that the Claimant's medical evidence did not support granting a TUE approval in accordance with the criteria set forth in the World Anti-Doping Agency (WADA) International Standard for Therapeutic Use Exemptions (ISTUE).
- 1.4 There was a subsequent submission and denial in 2020. The TUEC's denial was confirmed by medical review on April 23, 2020.

II. THE PARTIES

2.1



2.2 USADA is the independent anti-doping agency for Olympic and Paralympic sports in the United States and conducts drug testing, investigates anti-doping rule violations, manages results, and adjudicates anti-doping rule violation disputes, and is recognized as such by the United States Olympic and Paralympic Committee. USADA was represented by William Bock, III, Jeff T. Cook, and Ted Koehler.

III. PROCEDURAL HISTORY

3.3 On June 4, 2019, the Claimant submitted a TUE application for DHEA, which she supplemented several days later. On July 10, 2019, USADA sent the Claimant a TUE denial letter detailing the reasons for denying her TUE application. In its denial of the Claimant's TUE application, USADA explained in part that (1) "there was no confirmed diagnosis of a medical condition requiring the use of DHEA"; and (2) a low DHEA level alone is not a medical condition with "definite clinical manifestations."

3.4 On July 17, 2019, Claimant requested a medical review of her TUE denial.

3.5 And on August 29, 2019, Claimant requested a hearing before three AAA arbitrators to challenge the denial of her application.

3.6 On September 25, 2019, USADA informed the Claimant that it had conducted a medical review of her TUE application and confirmed that the TUE denial was appropriate. That same day USADA informed her that her application for a Recreational Competitor TUE was also denied.

3.7 The Panel ordered in Procedural Order No. 1, Nov. 5, 2019, that the parties submit stipulations. These stipulations would address the



appropriate standard of review and whether the hearing will be de novo or simply a review of the record. The stipulations were submitted but the parties could not agree to the standard or scope of review or on the procedural history. The parties were ordered to brief those issues. Procedural Order No. 2, Nov. 22, 2019.

- 3.8 The Panel advised the parties during a conference call that its scope of review was going to be limited to what had been submitted to the TUEC. The Claimant was invited to submit a new application if she desired.
- 3.9. With respect to standard of review, the parties were advised during the status conference to specifically address *Dominguez v. FIA*, CAS 2016/A/4772. Id.
- 3.10 Based on the Panel's rulings, the Claimant supplemented her record and filed a new TUE application for DHEA on March 13, 2020. The TUEC denied this application on April 2, 2020. Claimant requested a medical review on April 10, 2020, and after this review, the TUEC's denial was once again confirmed.

IV. EXPERTS

- 4.1 The parties each had their own experts.
- 4.2 The Claimant submitted medical information supporting her need for the TUE based on the opinion of Dr. [REDACTED] a naturopath physician. She is not an endocrinologist and cannot prescribe medication. She practices "an alternative to traditional medicine."
- 4.3 USADA presented the names and backgrounds of the numerous board-certified endocrinologists that had reviewed the Claimant's TUE applications and rejected her request. They were Dr. Richard Auchus, an MIT- and Washington University-educated endocrinologist who currently teaches internal medicine at the University of Michigan Medical School, and Dr. Alan Rogol, an MIT- and Duke University-educated endocrinologist. Dr. Bradley Anawalt has reviewed Claimant's application as well as the TUEC's decision and rendered the same verdict: Dr. [REDACTED] conclusions are not grounded in accepted medical practices. Dr. Anawalt is also a renowned endocrinologist and currently the vice chair of the department of medicine at the University of Washington and the Chief of Medicine at the University of Washington Medical Center.

V. APPLICABLE RULES

- 5.1 The parties have stipulated that the USADA Protocol and World Anti-Doping Code (the "Code") apply in this case. In addition, the parties agree that the USADA TUE Policy and the WADA ISTUE apply to USADA's denial of Claimant's TUE application for use of DHEA in sport. Stipulations, Nov. 15, 2019.
- 5.2 The USADA TUE Policy (Policy) states that TUEs for Non-National Athletes "will be obtained in the same manner as for National-Level Athletes." Policy, Art. 4. The Policy further states that "USADA will process TUE applications for National-Level Athletes in accordance with the ISTUE." Policy, Art. 4. The ISTUE in turn sets forth detailed and stringent criteria for approving the use of prohibited substances in sport. See WADA ISTUE, Part Two, p.11.
- 5.3 There are four ISTUE requirements in Article 4.1 that an Athlete must show by a balance of probability that he/she has met to obtain a TUE. They are:
 - 5.3.1 The Prohibited Substance or Prohibited Method in question is needed to treat an acute chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.
 - 5.3.2 The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following treatment of the acute or chronic medical condition.
 - 5.3.3 There is no reasonable therapeutic alternative to the use of the Prohibited Substance or Prohibited Method.
 - 5.3.4 The necessity of the use of the prohibited substance or prohibited method is not a consequence, wholly or in part, of the prior use (without a TUE) of a substance or method which was prohibited at the time of such use.
- 5.3 Under the Protocol, USADA incorporated many of the provisions of the Code.
- 5.4 The burden throughout a TUE application and Appeal remains with the Athlete.

VI. DENIAL OF TUE

- 6.1 On April 2, 2020, USADA's TUEC detailed the multiple reasons for its denial of Claimant's TUE application based on the four ISTUE requirements in Article 4.1, all of which must be met to obtain a TUE.
- 6.2 With respect to the first ISTUE, Art. 4.1(a) requirement, USADA explained in its April denial letter:

Article 4.1(a) was not met because adrenal fatigue is not considered a credible medical diagnosis; on the other hand, adrenal insufficiency is a credible medical diagnosis and has specific criteria for it. However, there was no evidence presented that you meet any accepted criteria for either adrenal insufficiency or any of these presumed disorders (per ICD10 codes E03.8, 23.0, 23.7, 27.49, 34.0, and R89.1 as were listed throughout the documents provided) that would require treatment with DHEA. Notably, the purported and unfounded diagnoses were provided by a naturopath, not a board-certified endocrinologist.

The various associated diagnoses of disorders have not been substantiated with conventional laboratory testing. The hypothalamic-pituitary-adrenal axis has not been appropriately tested and the only level that has been done is cortisol which has been normal on several occasions. As for other axes (to support the diagnosis of hypopituitarism), you have had normal thyroid function tests (although a low TBG level making the total T4 low) with normal TSH levels. The reproductive axis is functionally cycling and the hormonal levels from the pituitary and the ovaries are appropriate. The IGF-1 level indicates normal physiologic growth hormone function and the prolactin level was also normal.

As was stated previously by the USADA TUEC in the 10 July 2019 decision letter, simply observing low endogenous DHEA levels is not adequate medical justification for DHEA supplementation. DHEA supplementation has not been demonstrated to be effective for the treatment of adrenal insufficiency and is not recognized by the Endocrine Society as standard clinical practice.

Further, the medical evidence submitted is not coherent nor does it support a diagnosis that would justify the use of DHEA. It has not been substantiated in the documentation submitted that a medical condition exists for the use of this prohibited substance based on the requirements set forth for a diagnosis of adrenal insufficiency

as was presumed. It is not possible to unequivocally conclude whether an impairment to health currently exists and would still exist if this treatment is withheld. Therefore, for the reasons mentioned above, the USADA TUEC has determined that you have failed to discharge your burden of proof in relation to ISTUE Article 4.1(a).

6.3 The TUEC Response as to the second ISTUE requirement was:

Article 4.1(b) was not met because in the absence of a properly diagnosed condition supporting the use of DHEA (a prohibited androgen) the potential for performance-enhancing effects of DHEA, as well as through conversion to testosterone, exists. You were also found to have a serum testosterone above the normal female range while taking DHEA. In the USADA TUEC's opinion, and on the basis of the analysis discussed above, you have not established that it is highly unlikely that you would benefit from any additional enhancement of their performance beyond what might be anticipated by a return to a normal state of health following the treatment with the prohibited anabolic agent DHEA.

6.5 The TUE Response as to the third ISTUE requirement was:

Article 4.1(c) was not met as there was no medical evidence for any endocrine disorder presented. Without a confirmed diagnosis of a medical condition, it is not possible to establish whether permitted alternatives exist or functional causes can be ruled out. The clinical evaluation did not specifically exclude other common causes of poor well-being such as sleep disorders, mood disorders and environmental causes. These causes were cited in previous TUE submissions, which were denied, because these functional causes can be addressed by you through alternative means and do not require the use of an anabolic agent. It was noted that you have "tried multiple treatments," yet there was no elaboration on which treatments have been trialed, other than testosterone, nor what the resulting effects were (regarding either efficacy or safety). Should you at some point be properly diagnosed with chronic primary adrenal insufficiency (this is due to a dysfunction of the adrenal glands from congenital or acquired causes), a TUE for DHEA will only be considered in women who have significantly impaired mood or sense of well-being despite optimal glucocorticoid replacement.

- 6.6 The final ISTUE requirement addresses whether Claimant's prior use of prohibited substances caused the condition for which the TUE is required. The TUEC Response was:

On the basis of your medical history and medical file, the USADA TUEC considers that there is insufficient evidence that the current need for your use of DHEA is a consequence, either wholly or in part, of the prior use, without a TUE, of another prohibited substance or method (ISTUE 4.1(d)). However, the USADA TUEC notes that prior use of DHEA does not suppress the body's ability to produce DHEA, whereas glucocorticoid administration (which has not been explicitly excluded in the application) will transiently lower DHEA production. Based on the information submitted, it does not initially appear that the request for the use of DHEA is a consequence of other substance use; however, there is insufficient evidence to determine that with a high degree of certainty.

VII. STANDARDS OF REVIEW IN APPEALS OF THE DENIAL OF TUES

- 7.1 The parties differ as to what standards of review should apply in an appeal of TUE denial. The Claimant argues that the Panel should determine if she met the four conditions based on the balance of probabilities (more likely than not). USADA argues that the appropriate standard is to determine whether the decision of the TUEC was arbitrary and capricious.
- 7.2 The Claimant admitted that she, as the party seeking to change the ruling on her TUE application, maintained the burden to show by a balance of probabilities that she met the applicable standards. See *ISFF v. WADA, CAS/2013/A/* and *Berger v. WADA, CAS 2009/A/1948*.
- 7.3 USADA argued that the standard as outlined in *Dominguez at* ¶ 102 should apply. That standard is that "appeals may still be permitted on the ground that the [TUEC] decision was arbitrary, grossly disproportionate, irrational or perverse or otherwise outside of the margin of discretion, or taken in bad faith or without the due process rights provided to the athlete." This is comparable to the "arbitrary and capricious standard" used in court reviews of agency decisions.
- 7.4 The parties agree that there are narrow circumstances under which the determination of USADA and the TUEC should be overturned.

7.5 The Panel does not need to make that decision on which standard should be applied to this case as the same decision can be reached under either standard.

VIII. FINDINGS

8.1 The Claimant has not met her burden to show that she met all of the requirements of Article 4.1.

8.2 Specifically, the Claimant cannot establish that she has an acute chronic medical condition for which DHEA is a necessary treatment.

8.3 The Claimant did not show that her use of DHEA was unlikely to enhance her performance. The records reflected that her testosterone and dihydrotestosterone levels rose while taking DHEA and that her "dihydrotestosterone was more than three times the upper limit of normal on August 26, 2019" according to Dr. Anawalt's expert report. USADA Ex. 22. Further, the Claimant did not establish a legitimate diagnosis from which to analyze whether a permitted alternative exists and even if Claimant established the diagnoses or needed treatment for the described symptoms, DHEA is not an accepted form of treatment and permitted alternatives exist.

8.4 There was insufficient information in the medical records to determine whether other substances, such as glucocorticoids, may have had an impact on her DHEA production.

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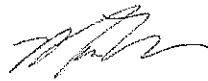
IX. DECISION AND AWARD

- 9.1 On the basis of the foregoing facts, legal analysis, and conclusions of fact, this Panel renders the following decision:
- 9.2 The TUEC decision denying the Claimant a TUE is affirmed.
- 9.3 The parties shall each bear their own attorney's fees and costs associated with this arbitration;
- 9.4 The administrative fees of the American Arbitration Association, and the compensation and expenses of the arbitrators and the Panel, shall be borne entirely by USADA and the United States Olympic and Paralympic Committee;
- 9.5 This Award shall be in full and final resolution of all claims and counterclaims submitted this Arbitration. The Panel has considered all of the arguments made by the parties, whether or not they are specifically referenced in this Award. All claims not expressly granted herein are hereby denied.

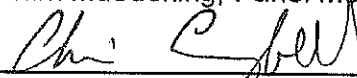
It is so ordered this 23rd day of June, 2020.



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