PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
FTC DOCKET NO. 9435

ADMINISTRATIVE LAW JUDGE: **HON. JAY L. HIMES**

IN THE MATTER OF:

DR. SCOTT SHELL, DVM **APPELLANT**

THE AUTHORITY'S SUPPORTING LEGAL BRIEF

Comes now the Horseracing Integrity and Safety Authority, Inc. pursuant to the briefing schedule of the Administrative Law Judge, dated August 13, 2024, and submits the following Supporting Legal Brief.

PUBLIC

CERTIFICATE OF SERVICE

Pursuant to Federal Trade Commission Rules of Practice 4.2(c) and 4.4(b), a copy of this Authority's Supporting Legal Brief is being served on September 11, 2024, via Administrative E-File System and by emailing a copy to:

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Introduction

This proceeding concerns a review initiated by Dr. Scott Shell ("**Appellant**") challenging the finding that he breached the Horseracing Integrity and Safety Authority, Inc. ("**HISA**" or the "**Authority**") Anti-Doping and Medication Control Program ("**ADMC Program**").

On June 11, 2024, Hon. Hugh L. Fraser (the "**Arbitrator**"), an arbitrator appointed by the Horseracing Integrity & Welfare Unit ("**HIWU**" or the "**Agency**") for the Authority, issued a decision (the "**Decision**") concluding that Appellant violated ADMC Program Rule 3214(c) by administering the Banned Substance Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023 (the "**Administrations**").[1] The Administrations were undisputed, but the Appellant argued that Hemo 15 is not a Banned Substance.

In his Decision, the Arbitrator concluded that Hemo 15 is properly categorized as an S0 Non-Approved Substance under ADMC Program Rule 4111, and that the Appellant committed 228 Anti-Doping Rule Violations ("**ADRVs**").[2] Having determined that Hemo 15 is a Banned Substance, the Arbitrator only imposed a civil sanction inclusive of a two-year period of Ineligibility, a $25,000 fine, and payment of $10,000 towards HIWU's adjudication costs (the "**Consequences**").[3] In doing so, the Arbitrator only imposed Consequences for the first Administration and found that in the exceptional circumstances of this case, Appellant bore No Fault for the other 227 Administrations of Hemo-15.[4]

[1] Proposed Finding of Fact ("**PF**") 2, 4; Appeal Book 1 ("**AB1**") 146 (Decision) ¶8.23. References to "Rules" in this brief refer to the ADMC Program starting at 88 Fed. Reg. Vol. No. 17, 5084.
[2] PF 4, 5; AB1 143, 149 (Decision) ¶¶8.11, 9.1(a).
[3] PF 8; AB1 149-150 (Decision) ¶9.1.
[4] PF 9; AB1 149-150 (Decision) ¶8.34, 9.1(d).

On July 15, 2024, Appellant issued an Application for Review requesting an evidentiary hearing. Appellant also issued an Application to Stay the Consequences imposed under the Decision.

On August 5, 2024, Appellant's Application for a Stay and request for a hearing were denied. Accordingly, this appeal only concerns whether Appellant can establish that he was improperly found to have breached Rule 3214(c) or that the Consequences imposed on him are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

Based on the existing factual record, it is evident that Hemo 15 is a Banned Substance, and Appellant breached ADMC Program Rule 3214(c). Further, the Consequences were imposed in accordance with ADMC Program Rules 3221-3224 and are rationally connected to the relevant evidence. Therefore, the sanctions should be affirmed.

I. Procedural and Factual History

a. The HIWU Investigation

On October 4, 2023, HIWU Investigators attended Thistledown Racetrack to conduct a search of Appellant's office and make contact with his associate, Dr. Margaret Smyth. A search of a Scott Shell DVM Inc. registered veterinary truck bearing Ohio Tag No. PGL-6583, under the care and control of Dr. Smyth, resulted in the discovery and seizure of one bottle labelled Hemo 15, prescribed to Covered Horse, Mo Don't No by Dr. Scott Shell, DVM.[5]

The bottle labelled Hemo 15 was seized and placed in an evidence bag labelled as Exhibit RT-31, and subsequently sent to the Pennsylvania Equine Toxicology & Research

[5] AB1 271 (Notice); AB1 276 (Exhibit A to Notice).

Laboratory ("**PETRL**") for testing.[6] On December 12, 2023, PETRL returned results reporting the product's chemical composition.[7]

A subsequent review of veterinary records in the HISA Portal revealed that Dr. Shell administered Hemo 15 to 37 different Covered Horses between May 29, 2023 and October 19, 2023, for a total of 228 independent Administrations.[8]

b. Procedural History

On January 8, 2024, Appellant was issued an EAD Notice of Alleged Anti-Doping Rule Violations ("**Notice Letter**"), and a Provisional Suspension was imposed on Appellant effective immediately.[9]

On January 22, 2024, Appellant provided his response to the Notice Letter, (the "**Explanation Letter**"). The Explanation Letter outlined three reasons for the Administrations alleged: (i) Hemo 15 is a vitamin supplement for which FDA approval is not required; (ii) Hemo 15 does not explicitly appear on the Banned Substances list; and (iii) in any event, the multiple Administrations should be considered a single transaction.[10]

On February 9, 2024, Appellant was charged with 228 Administrations of a Banned Substance ("**Charge Letter**"). The Charge Letter advised Appellant that the Agency had reviewed his Explanation Letter and was satisfied that ADRVs had been committed.[11]

[6] AB1 272 (Notice).
[7] AB1 279-280 (Exhibit B to Notice).
[8] PF 2; AB1 267 (Stormer Statement) ¶¶ 10-11; AB1 282 (Exhibit C to Notice).
[9] PF 3; AB1 272 (Notice).
[10] AB1 256-258 (Explanation).
[11] PF 3; AB1 284-285 (Charge Letter).

After a hearing requested by Appellant on May 28, 2024, the Decision was issued on June 11, 2024. On June 18, 2024, HISA notified Appellant it was imposing the final civil sanctions.[12]

c. The Application for Review and Stay of Civil Sanctions

On July 15, 2024, Appellant appealed the Decision by filing an Application for Review to the FTC. On July 15, 2024, Appellant also filed an Application to Stay the Consequences imposed under the Decision, to which HISA filed a response on July 22, 2024.

On July 25, 2024, HISA filed its response to Appellant's Application for Review, asserting, *inter alia*, that (1) Appellant's arguments are "meritless and misapprehend the content of the ADMC Program and the import of the Arbitrator's findings", and (2) Appellant failed to provide "sufficient grounds for an evidentiary hearing to contest facts found by the Arbitrator."[13]

On August 5, 2024, Judge Jay L. Himes issued an Order on Appellant's Application for Review and Stay of Consequences. The Order concluded that the parties were not, in fact, seeking to alter the factual record; rather, Appellant was contesting the weight given to the evidence in the record and the Arbitrator's determination that Hemo 15 is a Banned Substance, as charged. Accordingly, the appeal was limited to briefing by the parties.[14] The Order also rejected Appellant's request for a Stay of Consequences.[15]

II. Applicable ADMC Program Rules and Jurisprudence

The Authority was created pursuant to the federal *Horseracing Integrity and Safety Act of 2020*, as amended (the "**Act**"),[16] to implement a national, uniform set of integrity and safety

[12] AB1 49 (Notice of Sanctions).
[13] AB1 101 (Response to Review Application).
[14] August 5, 2024 Order at 3-4.
[15] August 5, 2024 Order at 5-6.
[16] 15 U.S.C. 3051–3060.

rules that are applied consistently to every Thoroughbred racing participant and racetrack facility in the United States.[17]

Appellant is a Veterinarian and Person engaged in the care and treatment of Covered Horses. Appellant is therefore a Covered Person under Rule 3020(a)(3).[18]

Under Rule 3070(b), the ADMC Program "shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes." However, under Rule 3070(d), the World Anti-Doping Code (the "**WADA Code**"), the comments annotating provisions of the WADA Code, and any case law interpreting the WADA Code may be considered. The WADA Code contains very similar provisions to the ADMC Program with respect to Administration, No Fault, and No Significant Fault. The WADA Code's Prohibited List also classifies Banned Substances and includes an S0 Non-Approved Substances category. Jurisprudence interpreting those provisions is therefore useful. As noted in the Preamble to the ADMC Program, international doping standards "provide a robust anti-doping framework that has been tested before arbitration tribunals for many years" and which "has generated a well-developed body of precedent and guidance for interpreting the provisions."[19]

The Decision under review concerned ADRVs for 228 independent Administrations of a Banned Substance to Covered Horses, in breach of Rule 3214(c). Administration does not require knowledge of each fact constituting an ADRV – a violation is established regardless of Fault or Negligence on the part of the Covered Person.[20] Further, pursuant to Rule 3228(c)(1), each Administration must be treated as a separate violation.

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[17] Rule 3010(a).
[18] PF 1; Appeal Book 2 ("**AB2**") 246 (Shell).
[19] 88 Fed. Reg. Vol. No. 17, 5073.
[20] See the Decision in the Case of Dr. Elena Dorofeyeva ¶ 54, 57(a), describing "administration" as a strict liability offence, and *WADA & FIFA v CFA & Ors*, CAS 2009/A/1817&1844 ¶¶ 71-79, as referenced therein. *See also Jeffrey Brown & Alberto Salazar v. USADA*, CAS 2019/A/6530&6531 ¶¶ 277-281, explaining that to

Under Rule 3223(b), the required sanction for any violation of Rule 3214(c) is a period of Ineligibility of 2 years, a fine of up to $25,000 (or 25% of the purse, whichever is greater), and payment of some or all the adjudication costs and the Agency's legal costs.[21] Where an ADRV is established, a Covered Person may be entitled to mitigation of the above noted sanctions, where he establishes on a balance of probabilities that he acted with either No Fault or Negligence (Rule 3224), or No Significant Fault or Negligence (Rule 3225). The ADMC Program provides that assessment of Fault is a specific and focused exercise which is concerned only with the Covered Person's actions leading up to the ADRV.[22] A determination of No Fault is rare and exceptional.[23]

III. The Decision

a. Hemo 15 is a Banned Substance

The Arbitrator found that Hemo 15 is a Banned Substance, such that Appellant committed the alleged Administration ADRVs. The ADMC Program sets out seven (7) categories of Banned Substances (S0-S6) in Rules 4111-4117. Pursuant to Rule 4111, pharmacological substances that meet the following definition are S0 Non-Approved Substances:

> Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI)#256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

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the extent "intent" is a part of an administration offense, it is only in respect of the intent to act – not the intent to commit an ADRV or knowledge of each fact constituting an ADRV.

[21] Rule 3223(b) provides that the sanctions delineated under that rule "shall apply." [Emphasis added].

[22] This is established in the definition of Fault provided in Rule 1020.

[23] *FIS v Therese Johaug v NIF*, CAS 2017/A/5015 ¶18: "CAS jurisprudence is very clear that a finding of No Fault applies only in truly exceptional cases."

In reaching this determination, the Arbitrator accepted the evidence of HIWU's expert, Dr. Lara Maxwell, who explained why Hemo 15 meets the foregoing criteria:

(a) First, none of Rules 4112 to 4117 specifically address Hemo 15, which is a foreign pharmaceutical product that is not otherwise approved for use in the United States;

(b) Second, Hemo 15 is not approved by governmental regulatory health authorities: Hemo-15®, the product available outside the U.S., has never been approved by the FDA, and there is no FDA approved product that contains all the ingredients found in Hemo-15® by any other name; and

(c) Third, Hemo 15 is not universally recognized by veterinary regulatory authorities as having a valid veterinary use. In this regard, Dr. Maxwell opined that given the risk to benefit ratio for compounding a complex, sterile mixture, that features trace minerals that are already sufficient in adequate equine diets, the veterinary use of Hemo 15 in horses is wholly inappropriate.[24]

The Arbitrator further agreed that Hemo 15 is not saved by the "avoidance of doubt" provision in Rule 4111 because it is not otherwise compliant with AMDUCA or GFI #256. In this regard, the Arbitrator accepted the opinions of Dr. Maxwell and Dr. Joshua Sharlin, HIWU's FDA regulatory expert, that: (i) there is no form of Hemo 15 compounded for office stock that would comply with GFI #256; and (ii) given the volume of Hemo 15 that was administered by Appellant, it is highly unlikely that the Hemo 15 was compounded for each horse or administration in issue.[25] The Arbitrator also accepted Dr. Maxwell's opinion that Hemo 15 is not a medically appropriate treatment for healthy racehorses, or a necessary

[24] PF 5; AB1 142 (Decision) ¶¶8.7-8.8; AB1 408-411 (Maxwell Report) ¶14-24; AB2 313-314 (Maxwell).
[25] PF 5; AB1 143 (Decision) ¶8.10; AB1 414-415 (Maxwell Report) ¶36; AB2 324-327 (Maxwell); AB1 1297-1298 (Sharlin Report) ¶¶27-34.

alternative to treat trace mineral deficiencies. Accordingly, Hemo 15 is not the type of discretionary compounding that GFI #256 was intended to permit.[26]

In contrast to HIWU's experts, Appellant's expert witness, Dr. Jospeh Bertone, testified that Hemo 15 does not fall under Rule 4111 or under Rules 4112 to 4117,[27] as it is a vitamin and therefore does not require FDA approval.[28] The Arbitrator accepted Dr. Maxwell's opinion that Hemo 15 should be properly understood as an unapproved animal drug, discussed further at pages 16-17 below, and concluded that there is "overwhelming evidence" that Hemo 15 is *not* a vitamin.[29]

b. Dr. Scollay Did Not Misrepresent the Status of Hemo 15

The Arbitrator went on to assess Appellant's assertion that HIWU's Chief of Science, Dr. Mary Scollay, misrepresented the status of Hemo 15. Not only did Dr. Scollay testify that she has never advised any Covered Person that Hemo 15 is a vitamin,[30] but during cross-examination, Appellant admitted that Dr. Scollay never made this representation.[31] The Arbitrator walked through multiple examples of Dr. Scollay's "clear and direct guidance to Covered Persons" in the Decision,[32] and concluded that there was "no evidence whatsoever" that Dr. Scollay misled Appellant.[33]

c. The Doctrine of Estoppel Does Not Apply

The Arbitrator also rejected both of Appellant's arguments that HIWU should be estopped from bringing the Administration charges against him:

[26] PF 5; AB1 143 (Decision) ¶8.10; AB1 414 (Maxwell Report) ¶35.
[27] AB1 141 (Decision) ¶8.5; AB2 397-402 (Bertone).
[28] AB1 142 (Decision) ¶8.9; AB1 1047-1048 (Bertone Report) ¶9; AB2 379-380, 384-385, 388-391 (Bertone).
[29] PF 6; AB1 142-143 (Decision) ¶¶8.9, 8.11.
[30] PF 7; AB1 143 (Decision) ¶8.12; AB2 109 (Scollay).
[31] PF 7; AB1 145 (Decision) ¶8.17; AB2 289-290 (Shell).
[32] PF 7; AB1 143-144 (Decision) ¶¶8.13-8.16; AB1 1310-1313 (Scollay Statement) ¶¶8, 13, 16.
[33] PF 7; AB1 145 (Decision) ¶8.17.

(a) First, there was no misrepresentation by Dr. Scollay regarding the categorization of Hemo 15. Accordingly, at no time did the Agency take a contradictory position regarding the application of the ADMC Program.[34]

(b) Second, there is no requirement that a Banned Substance be explicitly named on the Banned Substances List.[35]

d. Appellant's Due Process Arguments

The Arbitrator further rejected Appellant's argument that his charges should be dismissed because the rules, as applied, violated his Fifth Amendment due process rights:

(a) First, the Arbitrator concluded that Appellant's alleged constitutional challenge was not properly before him and should be taken to a forum with the jurisdiction to consider such an argument.[36]

(b) Second, Appellant's argument that the rule under which he has been charged could not be understood by Covered Persons of ordinary intelligence and is arbitrary and capricious, was contradicted by the fact that in the period of almost one year between May 22, 2023 and May 16, 2024, no other veterinarian has been charged for administering Hemo 15.[37]

e. Sanction Analysis

Having concluded that the alleged ADRVs were established, the Arbitrator assessed the Consequences to be imposed on Appellant by bifurcating the applicable Fault analysis between (i) Appellant's first Administration of Hemo 15 and (ii) subsequent 227 Administrations.

[34] PF 7; AB1 145 (Decision) ¶8.18.
[35] AB1 145 (Decision) ¶8.19.
[36] AB1 145-146 (Decision) ¶8.21.
[37] AB1 146 (Decision) ¶8.22; AB1 1360 (Stormer Statement) ¶¶6-7.

Regarding the first violation, the Arbitrator concluded that Appellant demonstrated Significant Fault for the following reasons:

(a) Appellant had the same access to HIWU educational seminars and resources as other Covered Persons;[38]

(b) Appellant did not ask Dr. Scollay any questions about whether Hemo 15 was a vitamin outside of FDA regulation, or whether it could be considered a Banned Substance;[39]

(c) Appellant did not contact anyone else at HIWU or HISA to verify whether he would be in compliance with the ADMC Program if he continued to administer Hemo 15;[40]

(d) Appellant paid little or no notice to the label on the Hemo 15 bottle which led to the investigation of his administrations: i.e., RT-31's label clearly stated "this is a compounded drug. Not an FDA approved or indexed drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";[41] and

(e) Appellant failed to conduct internet research which might have alerted him to concerns or red flags about Hemo 15.[42]

Based on these facts, the Arbitrator imposed a period of Ineligibility equating to two years for Appellant's first ADRV, along with the maximum fine of $25,000.00 to HIWU and a contribution of $10,000 towards the adjudication costs.[43]

[38] PF 8; AB1 148 (Decision) ¶8.30(a); AB2 208-209, 247-248 (Shell).
[39] PF 8; AB1 148 (Decision) ¶8.30(b); AB1 1311 (Scollay Statement) ¶11; AB2 127 (Scollay).
[40] PF 8; AB1 148 (Decision) ¶8.30(c).
[41] PF 8; AB1 148 (Decision) ¶8.30(d); AB1 1308-1309 (Scollay Statement) ¶6; AB2 276-277 (Shell).
[42] PF 8; AB1 148 (Decision) ¶8.30(e); AB2 270-273 (Shell).
[43] PF 8; AB1 148 (Decision) ¶8.31.

Regarding the subsequent violations, the Arbitrator concluded that Appellant bore No Fault based on the following "exceptional" circumstances:

(a) Appellant continued to report his administration of Hemo 15 after his initial filing to the HISA Portal on May 29, 2023;[44]

(b) It should not have taken HISA almost six months to recognize that a Banned Substance was being administered by a veterinarian who was complying with his obligations to file the requisite reports into the HISA Portal;[45]

(c) HISA did not have a system in place for early detection of Banned Substances that were being reported;[46]

(d) There was no indication Appellant intended to cheat;[47]

(e) Appellant was sincere in his belief that he was using a legal substance even though he was sincerely wrong in that belief;[48] and

(f) Appellant would have taken some comfort from the fact that his reporting of the administration of Hemo 15 did not draw any immediate concern from HISA or HIWU.[49]

In light of the foregoing Fault analysis, and in accordance with Rule 3224, the Arbitrator imposed no Consequences for Appellant's subsequent ADRVs.[50]

[44] PF 9; AB1 149 (Decision) ¶8.34(a); AB2 263 (Shell).
[45] PF 9; AB1 149 (Decision) ¶8.34(b); AB1 264-267 (Stormer Statement) ¶¶3-12; AB2 32-36 (Stormer).
[46] PF 9; AB1 149 (Decision) ¶8.34(c); AB2 32-36; 47-48 (Stormer).
[47] PF 9; AB1 149 (Decision) ¶8.34(d) AB2 230-232, 235 (Shell).
[48] PF 9; AB1 149 (Decision) ¶8.34(e) AB2 219-220, 222-224, 226-229, 236-238, 240-241 (Shell).
[49] PF 9; AB1 149 (Decision) ¶8.34(f); AB2 221 (Shell).
[50] PF 9; AB1 150 (Decision) ¶9.1(d).

IV. The Standard of Review

Pursuant to 15 U.S.C. § 3058(b)(1), whether Appellant committed Administration ADRVs under Rule 3214(c) is a determination made *de novo* by an Administrative Law Judge ("**ALJ**") of the Commission, based on the existing factual record.

Pursuant to 15 U.S.C. § 3058(b)(3), a HISA civil sanction is also subject to *de novo* review by an ALJ. However, the review is limited to a determination of whether "the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[51] Despite the fact that the ALJ conducts an independent review of the record,[52] a decision or sanction will not be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law where (i) the decision abides by the applicable rules,[53] and (ii) the sanction is rationally connected to the facts.[54] Similarly, to find an abuse of discretion, the record must reveal a clear error of judgment.[55] This standard of review has been confirmed in recent FTC appeals from HISA civil sanctions, *In Re Jeffrey Poole*[56] and *In Re Luis Jorge Perez*.[57]

V. Scope of Appeal

Appellant contests his liability for the Administration violations in issue and contends that the Consequences were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. As outlined in HISA's response to Appellant's Application for Review, several of the additional grounds raised by Appellant are outside the scope of appellate review permitted under 15 U.S.C. § 3058 and 16 C.F.R. § 1.145:

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[51] 15 U.S.C. § 3058(b)(2)(A)(iii).
[52] *Agyeman v. INS*, 296 F.3d 871, 876 (9th Cir. 2002).
[53] *Guier v. Teton County Hosp. Dist.,* 2011 WY 31, 248 P.3d 623 (Wyo. 2011).
[54] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).
[55] *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.,* 422 F.3d 782, 798 (9th Cir. 2005).
[56] Docket No. 9417, November 13, 2023.
[57] Docket No. 9420, February 7, 2024.

(a) First, Appellant attempts to erroneously establish a basis for *de novo* review by characterizing Rule 4111 as "arbitrary and capricious." This effort fails: under 15 U.S.C. § 3058(b)(1), the ALJ determines whether "the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" [emphasis added] – not whether an ADMC Program Rule itself is "arbitrary and capricious".

(b) Second, the Arbitrator correctly stayed within his jurisdiction by refusing to address Appellant's constitutional arguments. Multiple arbitrators have similarly held that an arbitration hearing is not the proper forum to address the adequacy of due process afforded under the ADMC Program.[58]

VI. Hemo 15 is a Banned Substance

Appellant erroneously suggests that HIWU failed to meet its burden to establish the charged ADRVs because there is no evidence that the Hemo 15 administered by Appellant contained Banned Substances. However, this position misconstrues the nature of the case brought against Appellant. As HIWU argued, and the Arbitrator rightly concluded, Hemo 15 is itself a Banned Substance:

(a) The Notice Letter advising Appellant of the ADRVs he would eventually be charged with explained from the outset that Hemo 15 is "an illegally compounded product intended to mimic foreign products that are not approved for use in the United States" and is "prohibited at all times as a category S0 Non-Approved Substance pursuant to ADMC Program Rule 4111".[59] HIWU's case against Appellant was never contingent on Hemo 15 containing constituent Banned Substances.

[58] *HIWU v. Dominguez*, JAMS Case No. 1501000577 ¶4.7; *HIWU v. VanMeter*, JAMS Case No. 1501000594 ¶3.15.
[59] PF 3; AB1 272 (Notice).

(b) As set out in detail at pages 9-10 above, the Arbitrator accepted the evidence of HIWU's expert, Dr. Maxwell, who explained why Hemo 15 meets the criteria of an S0 Non-Approved Substance under Rule 4111.

(c) The fact that Hemo 15 is not explicitly listed on HISA's Banned Substances List is also of no moment. It is impossible to know or predict every combination of compounded products that may arise in the veterinary world, and it is common for sanctions to be imposed in the anti-doping context under "catch all" provisions like Rule 4111. In this regard, there are several cases in the *lex sportiva* where athletes have violated the WADC for substances not explicitly named on the Prohibited List.[60]

Appellant's criticism of the Decision amounts to a critique of how the Arbitrator weighed the evidence before him, having preferred Dr. Maxwell's analysis over Appellant's expert, Dr. Jospeh Bertone, who argued that Hemo 15 is a vitamin and is not subject to FDA approval. The Arbitrator correctly rejected Dr. Bertone's assertions, which were readily refuted by Dr. Maxwell, who explained why Hemo 15 is not a vitamin and should be properly understood as an unapproved animal drug:

(a) First, there is no dietary supplement regulatory classification for animal food substances and products – they are either considered "foods" or "new animal drugs", depending on their intended use. Hemo 15 is not a dietary product or food and should therefore be understood as a drug. Since Hemo 15 is not FDA approved, it would be classified as an unapproved drug;

(b) Second, foreign Hemo-15® products are registered as pharmaceutical agents with standard drug labels, with similar elements to an FDA-approved drug label. These

[60] See, for example, *IAAF v. RFEA & Josephine Onyia*, CAS 2009/A/1805 ¶90; CONI Advisory Opinion, CAS 2005/C/841 ¶56; and *Jakub Wawrzyniak v. HFF*, CAS 2009/A/2019 ¶24.

foreign products also meet the FDA definition of a drug, which is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals…"; and

(c) Third, the FDA has directly expressed concerns about the use of injectable vitamins, including their classification of such products as unapproved animal drugs.[61]

The Arbitrator rightly concluded that: (i) there is "overwhelming evidence" that Hemo 15 is not a vitamin; and (ii) Hemo 15 is properly categorized as an S0 Non-Approved Substance.[62]

VII. The Consequences Were Imposed in Accordance with the ADMC Program and Are Rationally Connected to the Evidence

Appellant has also failed to establish that the Consequences imposed in respect of the first ADRV are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Rather, the Arbitrator reasonably concluded that Appellant's first administration of Hemo 15 involved a significant degree of Fault, based on a consideration of relevant factors.[63]

As the Arbitrator rightly noted, No Fault or Negligence is a defined term under the ADMC Program and sets a high standard for a Covered Person to meet (emphasis added):

> No Fault or Negligence means the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation.[64]

[61] PF 6; AB1 142-143 (Decision) ¶¶8.9, 8.11; AB1 1280-1282, 1284-1285 (Maxwell Reply) ¶4, 6, 9; AB2 327-329 (Maxwell).
[62] PF 5, 6; AB1 143 (Decision) ¶8.11.
[63] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).
[64] AB1 146 (Decision) ¶8.24; Rule 1020 Definitions, 88 Fed. Reg. Vol. No. 17, 5088.

The WADC contains a commentary that underlines the exceptional standard that must be met to accord with this threshold (emphasis added):

> [A reduction of sanctions due to No Fault or Negligence] will only apply in exceptional circumstances, for example, where an Athlete could prove that, despite all due care, he or she was sabotaged by a competitor.[65]

As set out in detail at page 12 above, the Arbitrator considered multiple factors, all arising from the evidence before him, which plainly cut against Appellant's assertion that he should have been found faultless:[66]

(a) Despite Appellant's insistence that he had no "notice" that Hemo 15 was a Banned Substance, he had the same access to educational materials as other Covered Persons, but was the only veterinarian to document administrations of Hemo 15 in the HISA Portal after the ADMC Program came into effect.[67] These educational materials included Dr. Scollay's seminars in which she specifically discussed that foreign approved products without FDA approval are not permitted under the ADMC Program, and emphasized the importance of reading product labels.[68] Appellant did not otherwise make inquiries about the status of Hemo 15 under the ADMC Program;[69] rather, as the Arbitrator noted, Appellant "heard what he wanted to hear."[70]

(b) Moreover, despite Appellant's continued insistence that Hemo 15 is a vitamin, the Hemo 15 used in his practice clearly identified the substance as a non-FDA approved drug. This was clearly set out on the bottle of RT-31 which read, "this is

[65] AB1 146 (Decision) ¶8.25; AB1 910 (WADA Code, note 65).
[66] PF 8; AB1 148 (Decision) ¶8.30.
[67] AB1 1360 (Stormer Statement) ¶¶6-7.
[68] AB1 1310-1313 (Scollay Statement) ¶¶8-16.
[69] AB1 1311 (Scollay Statement) ¶11; AB2 127 (Scollay).
[70] AB1 145 (Decision) ¶8.17.

a compounded drug. Not an FDA approved or indexed drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian".[71]

(c) Finally, despite Appellant's insistence that Hemo 15 has been around for years and is available for purchase across veterinary medication websites, basic internet searches would have alerted Appellant to red flags about Hemo 15. Notably, Appellant's own Pre-Hearing Brief included examples of three websites selling Hemo 15, all of which were consistent with documented illicit drug distributors that sell equine drugs directly to consumers.[72]

These factors show that Appellant could have and should have suspected that Hemo 15 was a Banned Substance. His conduct falls well short of the "exceptional circumstances" required for a finding of No Fault for his first ADRV.

Conclusion

The Decision considered and applied the ADMC Program in imposing liability for Administrations of a Banned Substance under Rule 3214(c) and civil sanctions of a two-year suspension, $25,000 fine, and $10,000 contribution to HIWU's costs in accordance with Rule 3223(b). The Arbitrator's findings of liability and Consequences imposed are in keeping with the statutory framework, rationally connected to the evidence, and were made with adequate consideration of the circumstances.

It is significant that in respect of the other 227 Administrations, the Arbitrator made a No Fault determination. As referenced above, establishing No Fault is a strenuous standard and only occurs in exceptional circumstances. The Arbitrator fairly considered the unusual circumstances of this case and instead of imposing Consequences for the other Administrations,

[71] AB1 1308-1309 (Scollay Statement) ¶6.
[72] AB1 1282-1284 (Maxwell Reply) ¶¶7-8, commenting on AB1 1051-1053 (Shell Exhibit 3); AB2 308-312 (Maxwell).

concluded that Appellant established No Fault. While that determination is unusual, it is rationally connected to the facts in this case and struck a reasonable and fair balance in favor of Appellant.

The imposed sanctions of the Arbitration should therefore be affirmed, and the Appeal should be dismissed.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 11th DAY OF SEPTEMBER 2024

/s/*Bryan H. Beauman*

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