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**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 PROPOSED FINDINGS OF FACT AND
CONCLUSIONS OF LAW & ORDER**

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 Proposed Findings of Fact and Conclusions of Law.

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 Proposed Findings of Fact and Conclusions of Law is being served on September 11, 2024, via Administrative E-File System and by emailing a copy to:

Hon. Jay L. Himes
Administrative Law Judge
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PUBLIC

PROPOSED FINDINGS OF FACT

1. Dr. Scott Shell (“**Appellant**”) is a Covered Person under the ADMC Program.¹
2. Appellant administered Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023 (the “**Administrations**”).²
3. On January 8, 2024, Appellant was issued an EAD Notice of Alleged Anti-Doping Rule Violations (“**Notice**”) advising that he was in violation of ADMC Program Rule 3214(c) for the Administrations. The Notice advised 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. On February 9, 2024, Appellant was charged with 228 Administrations of a Banned Substance.³
4. The June 11, 2024 decision of Hon. Hugh L. Fraser (the “**Arbitrator**”), (the “**Decision**”) concluded that Hemo 15 is an S0 Non-Approved Substance under ADMC Program Rule 4111, and the Appellant committed 228 Anti-Doping Rule Violations (“**ADRVs**”).
5. The Arbitrator accepted the opinion of HIWU’s expert, Dr. Lara Maxwell, who explained why Hemo 15 meets the criteria set out in ADMC Program Rule 4111. The Arbitrator also accepted the opinions of HIWU’s experts Dr. Maxwell and Dr. Joshua Sharlin, in concluding that Hemo

¹ Appeal Book 2 (“**AB2**”) 246 (Shell).

² Appeal Book 1 (“**AB1**”) 267 (Stormer Statement) ¶10-12; AB1 282 (Exhibit C to Stormer Statement); AB2 263 (Shell).

³ AB1 271-272 (Notice); AB1 284-285 (Charge Letter).

PUBLIC

15 is not saved by the “avoidance of doubt” provision in Rule 4111 because it is not otherwise compliant with AMDUCA or GFI #256.⁴

6. The Arbitrator accepted Dr. Maxwell’s opinion that Hemo 15 should be properly understood as an unapproved animal drug and concluded that there is “overwhelming evidence” that Hemo 15 is *not* a vitamin.⁵
7. The Arbitrator concluded that Dr. Mary Scollay, HIWU’s Chief of Science did not misrepresent the status of Hemo 15 to Appellant and provided clear and direct guidance to Covered Persons before the roll out of the ADMC Program. Dr. Scollay testified that she has never advised any Covered Person that Hemo 15 is a vitamin, and during cross-examination, Appellant admitted that Dr. Scollay never made this representation.⁶
8. The Arbitrator concluded that Appellant demonstrated Significant Fault for his first Administration ADRV based on the factors set out in ¶8.30 of the Decision and imposed civil sanctions of a two-year period of Ineligibility, \$25,000 fine, and payment of \$10,000 towards HIWU’s adjudication (the “Consequences”).⁷

⁴ AB1 142 (Decision) ¶¶8.7-8.8, 8.10; AB1 408-411, 414-415 (Maxwell Report) ¶14-24, 35-36; AB2 313-314, 324-327 (Maxwell); AB1 1297-1298 (Sharlin Report) ¶¶27-34.

⁵ AB1 142-143 (Decision) ¶¶8.9, 8.11; AB1 1280-1282, 1284-1285 (Maxwell Reply) ¶4, 6, 9; AB2 327-329 (Maxwell).

⁶ AB1 143 (Decision) ¶¶8.12-8.17; AB1 1310-1313 (Scollay Statement) ¶¶8-16; AB2 109 (Scollay); AB2 289-290 (Shell).

⁷ AB1 148 (Decision) ¶¶8.30-8.31. See the following references for evidence supporting the factors set out in ¶8.30 of the Decision: AB2 208-209, 247-248, 270-273, 276-277 (Shell); AB1 1308-1309, 1311 (Scollay Statement) ¶¶6-11; AB2 127 (Scollay).

PUBLIC

9. The Arbitrator concluded that Appellant bore No Fault for the subsequent 227 Administration ADRVs, based on the “exceptional” circumstances set out in ¶8.34 of the Decision, and imposed no Consequences in respect of these violations.⁸

PROPOSED CONCLUSIONS OF LAW

10. The Decision considered and applied HISA’s ADMC Program imposed the Consequences in accordance with ADMC Program Rules 3221-3224.
11. The Arbitrator clearly considered, applied, and followed all applicable rules of the ADMC Program.
12. The Arbitrator assessed all relevant evidence in concluding that Hemo 15 is an S0 Non-Approved Substance in accordance with ADMC Program Rule 4111 and is therefore a Banned Substance.
13. Appellant committed 228 independent ADRVs by administering Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023, in contravention of ADMC Program Rule 3214(c).
14. The Arbitrator appropriately considered the universe of relevant factors in assessing Appellant’s degree of Fault in respect of his first ADRV and determined that Appellant bore a significant degree of Fault. Accordingly, the Arbitrator imposed a period of Ineligibility

⁸ AB1 149-150 (Decision) ¶8.34, 9.1(d). See the following references for evidence supporting the factors set out in ¶8.34 the Decision: AB2 219-224, 226-232, 235-238, 240-241, 263 (Shell); AB1 264-267 (Stormer Statement) ¶¶3-12; AB2 32-36, 47-48 (Stormer).

PUBLIC

equating to two years, along with the maximum fine of \$25,000.00 to HIWU and a contribution of \$10,000 towards the adjudication costs.

15. The Arbitrator appropriately considered the universe of relevant factors in assessing Appellant's degree of Fault in respect of his subsequent 227 ADRVs and determined on the exceptional facts of this case that Appellant bore No Fault. Accordingly, the Arbitrator imposed no Consequences for Appellant's latter 227 ADRVs.
16. The Consequences are not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. They are supported by and rationally connected to the evidence.
17. Appellant's appeal contesting the liability and civil sanctions imposed in the Decision is rejected and the sanctions in the Decision of a 24-month period of Ineligibility, \$25,000 fine, and \$10,000 contribution towards HIWU's adjudication costs are affirmed.

PUBLIC

PROPOSED ORDER

The undersigned Administrative Law Judge (“ALJ”), having reviewed the parties’ submitted proposed findings of fact and conclusions of law, supporting legal briefs, and reply to conclusions of law and briefs, makes the following findings of fact and conclusions of law.

Introduction

On July 15, 2024, Appellant filed an Application for Review and an Application for a Stay of Consequences in respect of the Decision. The Decision determined that Appellant violated Rule 3214(c) of HISA’s ADMC Program by administering the Banned Substance Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023. At first instance, the Administrations were undisputed, but 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 thus a Banned Substance, such that Appellant committed 228 ADRVs.

The Arbitrator 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, arising from Appellant’s first Administration of Hemo 15 to a Covered Horse on May 29, 2023. With respect to the remaining 227 ADRVs, the Arbitrator concluded that Appellant bore No Fault and imposed no period of Ineligibility or other Consequences.

In his Application for Review, Appellant requested an evidentiary hearing to, *inter alia*, contest facts and legal interpretation, supplement the factual record with two cases, and to argue due process and absence of evidence. On July 25, 2024, HISA filed its response to

PUBLIC

Appellant's Application for Review, asserting, *inter alia*, that Appellant failed to provide sufficient grounds for an evidentiary hearing.

On August 5, 2024, it was ordered 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. Accordingly, the appeal was limited to briefing by the parties only.

This appeal is concerned only with whether Appellant was properly found liable for Administration violations under Rule 3214(c) of the ADMC Program, and whether the civil sanctions imposed upon Appellant are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

The Decision

The Arbitrator found that Hemo 15 is a Banned Substance, such that Appellant committed the alleged Administration ADRVs. Pursuant to Rule 4111, pharmacological substances that meet the following definition are S0 Non-Approved Substances, and thus Banned 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.

The Arbitrator accepted the evidence of HIWU's expert, Dr. Lara Maxwell, who provided an opinion confirming that Hemo 15 meets the pharmacological criteria of an S0 Non-

PUBLIC

Approved Substance.⁹ 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 #256.¹⁰

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.

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;¹¹
- (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;¹²
- (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;¹³
- (d) Appellant paid little or no notice to the label on the Hemo 15 bottle which led to the investigation of his administrations;¹⁴ and

⁹ AB1 142 (Decision) ¶¶8.7-8.8.

¹⁰ AB1 143 (Decision) ¶8.10.

¹¹ AB1 148 (Decision) ¶8.30(a); AB2 208-209, 247-248 (Shell).

¹² AB1 148 (Decision) ¶8.30(b); AB1 1311 (Scollay Statement) ¶11; AB2 127 (Scollay).

¹³ AB1 148 (Decision) ¶8.30(c).

¹⁴ AB1 148 (Decision) ¶8.30(d); AB1 1308-1309 (Scollay Statement) ¶6; AB2 276-277 (Shell).

PUBLIC

- (e) Appellant failed to conduct internet research which might have alerted him to concerns or red flags about Hemo 15.¹⁵

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.¹⁶

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;¹⁷
- (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;¹⁸
- (c) HISA did not have a system in place for early detection of Banned Substances that were being reported;¹⁹
- (d) There was no indication Appellant intended to cheat;²⁰

¹⁵ AB1 148 (Decision) ¶8.30(e); AB2 270-273 (Shell).

¹⁶ AB1 148 (Decision) ¶8.31.

¹⁷ AB1 149 (Decision) ¶8.34(a); AB2 263 (Shell).

¹⁸ AB1 149 (Decision) ¶8.34(b); AB1 264-267 (Stormer Statement) ¶¶3-12; AB2 32-36 (Stormer).

¹⁹ AB1 149 (Decision) ¶8.34(c); AB2 32-36; 47-48 (Stormer).

²⁰ AB1 149 (Decision) ¶8.34(d) AB2 230-232, 235 (Shell).

PUBLIC

- (e) Appellant was sincere in his belief that he was using a legal substance even though he was sincerely wrong in that belief;²¹ 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.²²

In light of the foregoing Fault analysis, and in accordance with ADMC Program Rule 3224, the Arbitrator imposed no Consequences for Appellant's subsequent ADRVs.²³

The Standard of Review on Appeal

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.”²⁴ Despite the fact that the ALJ conducts an independent review of the record,²⁵ 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,²⁶ and

²¹ AB1 149 (Decision) ¶8.34(e) AB2 219-220, 222-224, 226-229, 236-238, 240-241 (Shell).

²² AB1 149 (Decision) ¶8.34(f); AB2 221 (Shell).

²³ AB1 150 (Decision) ¶9.1(d).

²⁴ 15 U.S.C. § 3058(b)(2)(A)(iii).

²⁵ *Agyeman v. INS*, [296 F.3d 871, 876](#) (9th Cir. 2002).

²⁶ *Guier v. Teton County Hosp. Dist.*, 2011 WY 31, [248 P.3d 623](#) (Wyo. 2011).

PUBLIC

(ii) the sanction is rationally connected to the facts.²⁷ Similarly, to find an abuse of discretion, the record must reveal a clear error of judgment.²⁸ This standard of review has been confirmed in recent FTC appeals from HISA civil sanctions, *In Re Jeffrey Poole*²⁹ and *In Re Luis Jorge Perez*.³⁰

Conclusions of Law

1. The Decision considered and applied HISA's ADMC Program imposed the Consequences in accordance with ADMC Program Rules 3221-3224.
2. The Arbitrator clearly considered, applied, and followed all applicable rules of the ADMC Program.
3. The Arbitrator assessed all relevant evidence in concluding that Hemo 15 is an S0 Non-Approved Substance in accordance with ADMC Program Rule 4111 and is therefore a Banned Substance.
4. Appellant committed 228 ADRVs by administering Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023, in contravention of ADMC Program Rule 3214(c).
5. The Arbitrator appropriately considered the universe of relevant factors in assessing Appellant's degree of Fault in respect of his first ADRV and determined that Appellant bore a significant degree of Fault. Accordingly, the Arbitrator imposed a period of Ineligibility

²⁷ *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).

²⁸ *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, [422 F.3d 782, 798](#) (9th Cir. 2005).

²⁹ [Docket No. 9417](#), November 13, 2023.

³⁰ [Docket No. 9420](#), February 7, 2024.

PUBLIC

equating to two years, along with the maximum fine of \$25,000.00 to HIWU and a contribution of \$10,000 towards the adjudication costs.

6. The Arbitrator appropriately considered the universe of relevant factors in assessing Appellant's degree of Fault in respect of his subsequent 227 ADRVs and determined on the exceptional facts of this case that Appellant bore No Fault. Accordingly, the Arbitrator imposed no Consequences for Appellant's latter 227 ADRVs.
7. The Consequences are not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. They are supported by and rationally connected to the evidence.
8. Appellant's appeal contesting the liability and civil sanctions imposed in the Decision is rejected and the sanctions in the Decision of a 24-month period of Ineligibility, \$25,000 fine, and \$10,000 contribution towards HIWU's adjudication costs are affirmed.

Based on the foregoing findings of fact and conclusions of law, it is hereby

ORDERED AND ADJUDGED as follows:

The Commission hereby **AFFIRMS** the Decision and **UPHOLDS** the civil sanctions imposed in the Decision, dated June 11, 2024.

Entered this _____ day of _____, 2024

Hon. Jay L. Himes
Administrative Law Judge