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

ADMINSTRATIVE LAW JUDGE: JAY L. HIMES

IN THE MATTER OF:

DR. SCOTT SHELL, DVM **APPELLANT**

APPELLANT'S REPLY TO HISA'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Appellant submits the following reply Proposed Findings of Fact and Conclusions of Law.

PROPOSED FINDINGS OF FACT

1. Dr. Scott Shell ("**Appellant**") is a Covered Person under the ADMC Program.[1]

1. Agree.

2. Appellant administered Hemo 15, 228 times to 37 Covered Horses between May 29, 2023 and October 19, 2023 (the "**Administrations**").[2]

2. Agree, but disagree Appellant's Hemo 15 is a Banned Substance. **Appellant's Proposed Findings of Fact, September 11, 2024 ("PFF") 31-35.**

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]

3. Agree.

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**").

4. Agree.

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 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]

5. Agree Arbitrator accepted and concluded this.

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[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).
[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.

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]

6. Agree Arbitrator accepted and concluded this.

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]

7. Agreed.

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]

8. Agreed.

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]

9. Agreed.

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.

10. Dispute. The Decision did not properly apply Rules 3121 or 4111. HISA did not prove by more than a preponderance of the evidence, Appellant administered a Banned Substance, **PFF**

[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 the Decision: AB2 208-209, 247-248, 270-273, 276-277 (Shell); AB1 1308-1309, 1311 (Scollay Statement) ¶¶6-11; AB2 127 (Scollay).
[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).

4-16, or that Appellant's Hemo 15 is banned under Rule 4111. **PFF 26-37.** The Consequences were improper under Rule 3224, as Appellant had no notice that Hemo 15 was banned under Rule 4111 or the Banned Substance list, **PFF 13, 26,** and he could "not reasonably have known or suspected, even with the exercise of utmost caution," that he committed a violation. 88 Fed. Reg. Vol. No. 17, p. 5088.

11. The Arbitrator clearly considered, applied, and followed all applicable rules of the ADMC Program.

11. Dispute. The Arbitrator did not follow Rule 3121 as HISA did not meet its burden of proof **PFF 4-16,** improperly applied Rule 4111, as Appellant's Hemo 15 makes no drug claims, is not a drug requiring FDA approval, AMDUCA is inapplicable, and there is no proof Appellant's Hemo 15 was compounded from "drugs" or "bulk drug substances," making it GFI # 256 compliant or inapplicable. **PFF 30, 26-36.** Appellant's Hemo 15 complies with and/or Rule 4111 is inapplicable. **PFF 30, 26-36.** The Arbitrator improperly applied Rule 3224 as Appellant is faultless. **PFF 37-38.**

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.

12. Dispute that the Arbitrator accurately assessed all relevant evidence including that Appellant's Hemo 15 makes no drug claims, that it did not need FDA approval, and he did not consider the definition of "drug" and "bulk drug substances." **PFF 30, 26-39.** The arbitrator did not consider due process arguments and the impact of expert opinion**. PFF 26, 37.**

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).

13. Dispute. There is no evidence Appellant administered a Banned Substance, **PFF 4-16, 36,** and his Hemo 15 was compliant with (non-offensive) and/or Rule 4111 does not apply. **PFF 27-36.**

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 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.

14. Dispute. Appellant cannot logically have notice for a first administration and then not have notice for the second. **PFF 38-39**. The absence of notice applied to all administrations, and Appellant was faultless under Rule 3224. **PFF 13, 26, 35.**

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.

15. Agreed as Appellant is faultless. **PFF 23, 26.**

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.

16. Dispute. Appellant had no notice Hemo 15 was banned. **PFF 13, 26, 35.** The need for expert opinion means Rule 4111 is constitutionally vague. *United States v. National Dairy Products Corp*., 372 U.S. 29, 36 (1963). The Arbitrator speculated why no one else reported "Hemo 15." **PFF 37-38**. If Appellant is faultless for having no warning/notice for 227 subsequent administrations, **PFF 39**, he also had no notice for the first, and ignoring this fact is "unreasonable," arbitrary and capricious. *Killian v. Healthsource Provident Adm'rs,* 152 F.3d 514, 520 (6th Cir. 1998).

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.

17. Dispute. **PFF 1-39.**

Dated: September 23, 2024

Respectfully Submitted,
/s/ Andrew Mollica

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WORD COUNT AND SPECIFICATIONS CERTIFICATION

I Andrew Mollica, Esq. certify that the above Reply Proposed Findings of Fact and Conclusions of law were prepared using a computer, Microsoft Word Program, that I used Times New Roman Font, that HISA's proposed finding of fact and conclusions of law are single spaced and then Appellant's reply is set forth in double space, with numbers corresponding to HISA's numbering, HISA's headings, and that I conducted a word count with the Microsoft program, and not including caption, cover page, table of contents, signatures, service documents, and/or HISA's Proposed Findings of Fact and Conclusion of Law, and HISA's Headings this document is **488 words**, including any of Appellant's footnotes (not HISA's).

September 23, 2024 /s/ ***Andrew Mollica***

Andrew J. Mollica

CERTIFICATE OF SERVICE

Pursuant to 16 CFR §1.146(a) and 16 CFR §4.4(b), a copy of this Appellant's Reply to HISA's Proposed Findings of Fact and Conclusions of Law, is being served on this September 23, 2024, via Administrative E-File System and by emailing a copy to:

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