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 REPLY 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 Reply Legal Brief.

CERTIFICATE OF SERVICE

Pursuant to Federal Trade Commission Rules of Practice 4.2(c) and 4.4(b), a copy of this Authority's Reply Legal Brief is being served on September 23, 2024, via Administrative E-File System and by emailing a copy to:

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Appellant's opening legal brief does not accurately set out the charges brought against him, the evidence led at the Arbitration, or the Arbitrator's analysis in the Decision.[1] Appellant also raises matters outside the scope of this appeal by making constitutional arguments and otherwise alleging that Rule 4111 is arbitrary and capricious. In this Reply, HISA responds to Appellant's erroneous assertions and arguments.

I. Hemo 15 is a Banned Substance

Appellant was charged under Rule 3214(c) because he administered a compounded substance labeled Hemo 15 which meets the criteria of a S0 Non-Approved Substance,[2] – not, contrary to Appellant's assertion, because he administered the foreign, brand name drug "Hemo 15". Appellant similarly confuses the basis for the case against him by focusing on the contents of RT-31 and asserting that no Banned Substances were detected therein. This position is incorrect. At no time has HIWU argued that Appellant's Hemo 15: (i) is trademarked Hemo 15® from Europe; (ii) contains constituent Banned Substances; or (iii) is banned based on the cobalt and/or nicotinamide contained therein.[3] The Hemo 15 at issue is a <u>combination</u> of ingredients compounded into a substance that is "intended to mimic foreign products that are not approved for use in the United States",[4] and which is properly classified as a Banned Substance under Rule 4111.

Notably, Appellant's misconceived focus on the constituent elements of Hemo 15 is circular. If Appellant's position were correct, there would be no need for Rule 4111 because a S0 Banned Substance would have to include an expressly listed Banned Substance. This is contrary to both the express wording and the intent of Rule 4111, which requires applying the Rule's criteria to the pharmacological substance under review – not its ingredients.

[1] Capitalized terms have the same meaning as defined terms in the Authority's opening brief.
[2] AB1 272; AB1 142, ¶¶8.6-8.8; AB2 313-327 (Maxwell).
[3] Appellant' Legal Brief ("**ALB**") 2-3.
[4] AB1 272.

II. The Test on *De Novo* Review

The scope of *de novo* review is prescribed by 15 U.S.C. §3058(b)(2)(A), which requires the ALJ to consider whether: (i) Appellant engaged in the acts alleged; (ii) such acts are in violation of the ADMC Program; and (iii) the final civil sanction was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Appellant has failed to establish any of these grounds on appeal.

a. The Decision Was Reasonable

The Decision offered a reasoned explanation as to why Hemo 15 is a Banned Substance. Whereas Appellant's HISA Portal records constitute an admission that he administered compounded Hemo 15 to Covered Horses, the legal conclusion that Appellant's Hemo 15 is a Banned Substance follows from the Decision's analysis of Rule 4111, based on the opinions in Dr. Maxwell's two expert reports[5] and Dr. Sharlin's reply report,[6] all of which were reiterated in their testimony and rightly accepted by the Arbitrator.[7] HISA relies on its opening brief with respect to the correct analysis of Rule 4111 and its application to Hemo 15, including the analysis to be applied in respect of AMDUCA and GFI #256. Appellant's disagreement with this analysis, or the weight afforded to HIWU's experts, does not mean that the Arbitrator failed to offer a "reasoned explanation" based on "substantial evidence", as Appellant alleges.[8]

i. Hemo 15 is an Unapproved Animal Drug

Appellant's criticism of the Decision is largely based on misplaced assertions that the Arbitrator failed to appreciate that Appellant's Hemo 15 makes "no label claims of treatment for any condition".[9] When a vitamin makes treatment claims it becomes a drug;[10] however, the absence of treatment claims on RT-31's label is of no moment because Appellant's Hemo 15 is

[5] AB1 407-414 (Maxwell Report); AB1 1285-1287 (Maxwell Reply).
[6] AB1 1292-1295, 1296-1298 (Sharlin Report).
[7] AB1 142-143, ¶¶8.6-8.11.
[8] ALB 3-4, citing *Killian v. Healthsource Provident Adm'rs*.
[9] ALB at 4-7. Appellant asserts that this is the "most significant fact".
[10] AB1 1311-1312, ¶¶13-14 (Scollay Statement).

not a vitamin. The Arbitrator rightly concluded that there is "overwhelming evidence" that Hemo 15 is an unapproved animal drug .[11]

Notably, Appellant argues that Dr. Maxwell cannot "impute" that Appellant's Hemo 15 was intended to cure or treat a disease;[12] however, these arguments privilege Appellant's self-serving "beliefs", over Dr. Maxwell's clear analysis on the classification of Hemo 15 as an unapproved animal drug. As Dr. Maxwell explained, Hemo 15 is properly considered a "new animal drug" instead of a "food" and noted the FDA's concerns about the use of injectable vitamins, including their classification as unapproved animal drugs. Moreover, her reference to foreign Hemo-15® products and their similarity to FDA-approved drug labels is relevant, as the Hemo 15 at issue is an illegally compounded drug that mimics foreign products.[13]

Appellant also alleges that Dr. Sharlin "pre-supposed" Appellant's Hemo 15 is a drug,[14] when, in fact, Dr. Sharlin pointed to FDA guidance that considers injectable vitamin solutions – like Appellant's Hemo 15 – to be unapproved animal drugs.[15]

ii. There is No Incongruence in the Civil Sanction

With respect to the Civil Sanction imposed, Appellant mischaracterizes the Arbitrator's findings. The Arbitrator did not conclude that it was "understandable" Appellant continued to administer Hemo 15 for five months after his initial reporting; rather, he noted that among other "exceptional" factors, 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."[16] There is no incongruity in: (i) concluding that Appellant failed to take steps to adequately inform himself that Hemo 15 was banned before his first Administration under the

[11] AB1 143 ¶8.11.
[12] ALB 6.
[13] AB1 142-143 ¶¶8.9, 8.11; AB1 1280-1282, 1284-1285 (Maxwell Reply) ¶4, 6, 9; AB2 327-329 (Maxwell); AB1 272.
[14] ALB 6.
[15] AB1 1294-1295 ¶¶16-19 (Sharlin Report).
[16] AB1 149 ¶8.34(f).

ADMC Program; but (ii) acknowledging that Appellant should have the benefit of a No Fault finding in circumstances where his subsequent Administrations were detected months later.[17]

iii. The Arbitrator Did Not "Speculate" About Other Veterinarians

Finally, the Arbitrator's Decision and Civil Sanctions are not otherwise arbitrary or capricious because the Arbitrator "speculated" as to why no other veterinarians reported administrations of Hemo 15.[18] This was not mere speculation – HIWU led evidence that Appellant was the only veterinarian who continued to record administrations of Hemo 15 after the ADMC Program came into effect.[19] While the Arbitrator rightly noted that this evidence cuts against Appellant's assertion that Rule 4111 "could not be understood by Covered Persons of ordinary intelligence",[20] Rule 4111 itself is not under review on this appeal.

b. There Was No Procedural Unfairness

Appellant makes various arguments regarding his constitutional due process rights – none of which are properly the subject of this appeal. However, Appellant's underlying argument that he was not afforded notice that Hemo 15 is a Banned Substance is also of no legal moment. This position is addressed in HISA's opening brief: it would be impossible for the Authority to know or predict every combination of compounded products, and it is common for sanctions to be imposed under catch all provisions like Rule 4111. There are several cases in the *lex sportiva* where athletes have violated the WADC for substances not explicitly named on the Prohibited List.[21]

[17] AB1 148-149 ¶8.30, 8.34.
[18] ALB 10.
[19] AB1 1359-1360 ¶¶5-7 (Second Stormer Statement).
[20] AB1 146 ¶8.22.
[21] See *IAAF v. RFEA & Josephine Onyia* ¶90-91; CONI Advisory Opinion ¶56; and *Jakub Wawrzyniak v. HFF* ¶24.

c. Appellant Raises Arguments Outside the Scope of this Appeal

Appellant otherwise seeks to have his charges vacated on the basis that Rule 4111 violates his constitutional due process rights, without consideration of the Arbitrator's jurisdiction. The Arbitrator permitted Appellant to file a post-hearing brief on this issue but concluded that Appellant's constitutional challenge was not properly before him.[22] The Arbitrator correctly reached this conclusion having regard to multiple decisions in which arbitrators have held that an arbitration hearing is not the proper forum to address the adequacy of due process afforded under the ADMC Program.[23]

Appellant's criticism of Rule 4111 also amounts to an improper collateral attack on Rule 4111. Under Rule 3113(c), the FTC's regulation classifying substances and methods into categories or classes on the Prohibited List or Technical Document – Prohibited Substances is "final and shall not be subject to any challenge by any Covered Person or other Person on any basis…". Moreover, under 15 U.S.C. §3058(b)(2)(A)(iii), an ALJ determines whether "the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" – not an ADMC Program Rule itself.

Finally, Appellant's argument that "private entities enforcing HISA unconstitutionally violates the private nondelegation doctrine" is outside the scope of this appeal. Constitutional issues are not properly before his forum and the scope of review is limited by 15 U.S.C. §3058(b)(2)(A).

[22] AB1 145-146 ¶8.21.
[23] *HIWU v. Dominguez* ¶4.7; *HIWU v. VanMeter* ¶3.15.

/s/*Bryan H. Beauman*

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