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**

AUTHORITY'S RESPONSE TO APPLICATION FOR REVIEW OF FINAL CIVIL SANCTION

CERTIFICATE OF SERVICE

Pursuant to 16 CFR §1.146(a) and 16 CFR §4.4(b), a copy of this Authority's Response to Appellant's Application for Review of Final Civil Sanction is being served on July 25, 2024, via Administrative E-File System and by emailing a copy to:

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The Horseracing Integrity and Safety Authority, Inc.'s (the "**Authority**") files this Response to Appellant's Application for Review of Final Civil Sanction in the June 11, 2024 decision of Arbitrator Hon. Hugh Fraser (the "**Arbitrator**"), as amended, under the Anti-Doping Medication Control ("**ADMC**") Program (the "**Decision**"). The Commission should uphold the Decision and deny Appellant's request for an evidentiary hearing, as it is unnecessary to contest or supplement the record, and no basis has been demonstrated for doing so.

Each issue raised in the Application as grounds to reverse the Decision contains inaccuracies of fact and law which make it apparent that Appellant's arguments are meritless and misapprehend the content of the ADMC Program and the import of the Arbitrator's findings.

First, Appellant mischaracterizes the violation at issue. The Authority met its burden to establish a Rule 3214(c) violation. The Authority's expert witnesses clearly established that Hemo 15 is a S0 Non-Approved Substance, in accordance with the criteria in Rule 4111.[1]

It is well established under the Rules and in *lex sportiva* that a Banned Substance need not be explicitly named on the Prohibited Substances List.[2] Rather, Rule 4111 establishes that a pharmacological substance is a Banned Substance, when: (i) it is not addressed by Rules 4112 through 4117; (ii) it has no current approval by any governmental regulatory health authority for veterinary or human use; and (iii) it is not universally recognized by veterinary regulatory authorities as a valid veterinary use. Rule 4111 further clarifies that compounded products compliant with the Animal Medicinal Drug Use Clarification Act and FDA Guidance for Industry #256 are not prohibited.[3]

[1] Decision, paras. 6.2 (h)-(m).
[2] Decision, paras. 6.2 (n)-(o), 8.19.
[3] Decision, para. 8.6.

The Arbitrator accepted the evidence of Dr. Lara Maxwell, who confirmed that Hemo 15 meets each criteria in Rule 4111.[4] Dr. Maxwell rebutted the evidence of Appellant's expert, Dr. Jospeh Bertone, that Hemo 15 is a vitamin and does not require FDA approval.[5] Reviewing all the evidence, the Arbitrator concluded that there was "overwhelming evidence" that Hemo 15 is not a vitamin but is, in fact, an unapproved animal drug."[6]

Second, contrary to Appellant's assertion, Hemo 15's status as a Banned Substance does not turn on whether it contains a substance specifically listed on the Prohibited Substances List. The Authority did not argue, and the Arbitrator was not required to find, that Hemo 15's constituent elements are Banned Substances. Hemo 15 itself is a S0 Category Banned Substance.

Third, 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 administrative law judge 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 an ADMC Program Rule itself. The Arbitrator correctly rejected Appellant's argument that Rule 4111 could not be understood by Covered Persons of ordinary intelligence, acknowledging the evidence that Appellant was the only veterinarian to administer Hemo 15 after the implementation of the ADMC Program.[7]

Fourth, 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

[4] Decision, paras. 8.7-8.8.
[5] Decision, para. 8.9.
[6] Decision, para. 8.10.
[7] Decision, paras. 8.19, 8.22.

Program.[8] Appellant's reliance on *National Horsemen's Benevolent and Protective Association v. State of Texas et al.*, No. 23-10520 (5th Cir. July 5, 2024), is also misplaced. Such constitutional arguments are not properly raised in this forum.

Fifth, the Decision should not be overturned on the basis that it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[9] 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,[10] including Appellant's: (a) access to the same educational materials as other Covered Persons; (b) failure to ask questions about whether Hemo 15 was a vitamin or Banned Substance; (c) failure to verify whether he would be in compliance with the new regulations if he continued to administer Hemo 15; (d) ignorance of the drug label and cautions set out on the Hemo 15 bottle's label; and (e) failure to conduct internet research which might have alerted him to red flags about Hemo 15.[11]

As a final matter, Appellant has not shown sufficient grounds for an evidentiary hearing to contest facts found by the Arbitrator. Appellant's administrations of Hemo 15 are not in dispute. The interpretation of Rule 4111 and its application to Hemo 15 are matters of expert opinion that were considered by the Arbitrator and can be fully canvassed in briefs or oral argument. Appellant has also provided no basis to suggest that the experts need to re-testify or that new facts have altered the experts' written opinions or testimony.

[8] *HIWU v. Dominguez*, JAMS Case No. 1501000577; *HIWU v. VanMeter*, JAMS Case 1501000576.
[9] See 15 U.S.C. § 3058(b)(1).
[10] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).
[11] Decision, para. 8.30.

Appellant seeks to supplement the record with two additional cases.[12] In this regard, Appellant is not seeking to introduce "facts" but legal decisions, both of which pertain to constitutional issues that are not properly addressed here.

Pursuant to 16 CFR 1.146(c)(3), the appeal should be limited to briefing or oral argument. If the Commission determines that an evidentiary hearing should be held, the Authority requests that the witnesses presented on behalf of the Authority at the hearing be permitted to testify.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 25th day of July, 2024.

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[12] Appellant appears to have attached the incorrect case as Exhibit B.