PUBLIC

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 BRIEF

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Appellant submits this reply brief to the Horseracing Integrity and Safety Authority's ("**HISA**"), September 11, 2024, brief ("**HISA Br**.").

I. Introduction

HISA's argues "[b]ased on the existing factual record, it is evident that Hemo 15 is a Banned Substance," and Appellant breached Rule 3214(c). (**HISA Br., p. 4**).[1] Appellant admits administering "Hemo 15," (**RFF 2**), but HISA's did not refute that there is no evidence showing Appellant's Hemo 15 contained Banned Substances or banned constituents, that it met a test threshold, and/or how combining non-banned constituents renders it banned under Rule 4111.[2]

HISA and the Arbitrator relied on the name "Hemo 15," shorthand for vitamins, minerals, and amino acids,[3] and "[im]properly categorized" Appellant's Hemo 15 as banned under Rule 4111, (**HISA Br. p. 3**), by making faulty comparisons to foreign Hemo 15®, which makes drug claims,[4] and erroneously concluding Appellant administered Banned Substances. Rule 3214(c).[5] The Arbitrator's failure to properly appreciate that Appellant's Hemo 15 made no drug claims, did not meet the FDA definition of a drug, and did not require government approval,[6] renders the decision to credit HISA's experts' Rule 4111 analysis, erroneous.[7]

HISA's argues the "Consequences" are "rationally connected to the relevant evidence." (**HISA Br., p. 4**). Appellant conducted due diligence, had no notice that Hemo 15 was banned via the Banned Substances list,[8] or Rule 4111,[9] and because Rule 4111 requires expert opinion,

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[1] Appellant's 9/11/24 Proposed Findings of Fact ("**PFF**"). Reply Findings of Fact ("**RFF**").
[2] **PFF 4-11**, **PFF 30-36.**
[3] **PFF 14-18.**
[4] **PFF 30-31**.
[5] **PFF 37.**
[6] **PFF 15, 31.**
[7] *De novo* means "no…deference is acceptable" *Salve Regina Coll. v. Russell,* 499 U.S. 225, 238 (1991).
[8] **PFF 13**
[9] **PFF 23, 26, 35.**

Covered Persons of reasonable intelligence cannot understand what is prohibited.[10] Rule 4111 is indecipherable on its face and as applied to Appellant's Hemo 15, and the Arbitrator improperly speculated why no one else reported "Hemo 15." **PFF 37**. The Arbitrator concluded Appellant was faultless for having no warning/notice for 227 subsequent administrations after the first, **PFF 39**, thus admitting no notice Hemo 15 was banned, and illogically ignoring the same notice was not provided for the first administration. **PFF 26, 37-39.** The Consequences are not "rational," are arbitrary and capricious,[11] and should have been eliminated as Appellant was faultless. Rule 3224.

II. ADMC Program Rules and Jurisprudence

HISA argues Administration "does not require knowledge of each fact constituting an ADRV" and can be established regardless of Fault or Negligence, (**HISA Br. p. 7**), but this presumes HISA established a Banned Substance was administered, which it did not.[12] HISA relied on records, but cannot rely on the name "Hemo 15," shorthand for vitamins, minerals and amino acids, without showing what was administered was banned.[13] HISA's citation to Dr. Elena Dorofieieva shows Appellant is correct. (**HISA Br., p. 7, n. 20**). Dr. Dorofeyva administered a prohibited 1,3-dimethylbutylamine ("**DMBA**"), **as ingredient in the product** "Red Rum." ¶¶ 1, 6, 52.

Unlike Dr. Dorofeyva, Appellant's Hemo 15 was not shown to contain banned constituents, **PFF 5-11**.There was no positive test.[14] In *WADA & FIFA v CFA & Ors*, cited by HISA, athletes tested positive for oxymetserone, identified on Appendix A of FIFA's DCR. CAS

[10] **PFF 26, 30-36.** Due process violation. *Connally v. Gen. Constr. Co*., 269 U.S. 385, 391 (1926)
[11] Arbitrary and Capricious means "unreasoned." *Killian v. Healthsource Provident Adm'rs,* 152 F.3d 514, 520 (6th Cir. 1998).
[12] **PFF 4-11, 31.**
[13] **PFF 4-11, 14, 30-35.**
[14] **PFF 7, 17-18** . HISA did not show Appellant "engaged in [the] act" of administering Banned Substances. 15 U.S.C. § 3058(b)(2)(A)(i).

2009/A/1817&1844 ¶¶ 30(ii), 71-79. Even if only "intent to act" is required, *Jeffrey Brown & Alberto Salazar v. USADA,* CAS 2019/A/6530&6531 ¶¶ 277-281, the act must be a violation, and HISA did not show "the act" of administering vitamins, amino acids and minerals "[was] a violation" **PFF 4-11, 31-36**; 15 U.S.C. § 3058(b)(2)(A)(ii).

III. Appellant Did Not Argue Dr. Scollay Said Hemo 15 is a Vitamin

Appellant agrees Dr. Scollay never said "Hemo 15 is a vitamin." (**HISA Br., p. 10**). Dr. Scollay stated HISA cannot require approval for "dietary supplement[s], vitamins, or mineral[s]" unless it "says it cures**,** treats…a specific disease" therefore makes a label claim. **PFF 21.** HISA should be estopped[15] from asserting that Appellant's Hemo 15, with vitamins, minerals and amino acids and no claims, **PFF 14-15,** requires government approval under Rule 4111.

IV. Due Process

HISA argues Due Process arguments were properly not considered in Arbitration but does not argue they cannot be considered here. (**HISA Br., p. 11**). Rule 4111 is a due process violation on its face and as applied to Appellant. *United States v. National Dairy Products Corp*., 372 U.S. 29, 36 (1963) (void for vagueness). The fact that only Appellant reported "Hemo 15," does not mean Rule 4111 is understandable by all Covered Persons of ordinary intelligence. (**HISA Br., p. 11**). **PFF 37.** Like Dr. Scollay, who testified she did not know anyone using Hemo 15, and would not know how it would be reported, **PFF 37,** the Arbitrator speculated as he did not know if Hemo 15 was reported differently. In this case, Rule 4111 requires expert opinion to be deciphered, hence it is impossible to tell what is banned, if the rule applies when a substance does not require government approval, or, if it is compliant with the rule, or how Rule 4111, lacking definitions and

[15] Estoppel occurs by statement that induces another to detrimentally rely. Arbitration CAS *ad hoc Division (OG Beijing) 08/002 Christel Simms v. Fédération Internationale de Natation (FINA*), order of 1 August 2008, ¶ 12.

requiring technical analysis, turns a substance like Appellant's Hemo 15, containing vitamins, minerals and amino acids, into a drug, requiring government approval and/or making it subject to Rule 4111, AMDUCA, or GFI # 256. **PFF 5 and 26-35.**

V. HISA Did Not Show Hemo 15 is a Banned Under Rule 4111

HISA argues the Arbitrator correctly found Hemo 15 is a Banned Substance under Rule 4111. (**HISA Br., pp. 8-10, 15-17**). However, *de novo* review shows the Arbitrator's reliance on Dr. Maxwell and Dr. Sharlin is flawed. Even now HISA makes clear that Dr. Maxwell and the Arbitrator relied on foreign Hemo-15®, which makes drug claims. (**HISA Br., p. 9(b); PFF 30**). Appellant's Hemo 15 makes no claims, does not meet the FDA definition of a drug, and needs no government approval. **PFF 31.** Rule 4111 is not a proper rule upon which to classify Appellant's Hemo 15 as banned. **PFF 34-35**. HISA argues its improper to mimic unapproved foreign substances (**HISA Br., p. 15**), but cites no Rule only an *ex post facto* notice.[16] Other than name, Appellant's Hemo 15 was not shown to be the same as foreign Hemo 15, **PFF 30.** The substance must be banned via the Banned Substance list or Rule 4111 and HISA failed to explain how having the same name as a foreign product renders vitamins, minerals and amino acids banned or a drug. **PFF 36.**

HISA argues the Arbitrator properly "accepted" Dr. Maxwell and Dr. Sharlin's opinions 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, as there is no form that would comply with GFI # 25 for office stock, and "it is highly unlikely" appellant compounded for individual use. (**HISA Br., pp. 9, 16**). However, in this context "compliant" means non-offensive to the rule and/or that Rule 4111, AMDUCA and/or GFI #256 do not apply. Appellant's Hemo 15 was never shown to

[16] **HISA Br., p. 15, n. 55.**

make drug claims,[17] it is not a drug under FDA rules,[18] does not require FDA approval, and therefore Appellant's Hemo 15 is either compliant with Rule 4111, and/or the rule is inapplicable. **PFF 31, 35**. AMDUCA is an "extra-label" use rule dealing with approved drugs, **PFF 28, 35** which is inapplicable and/or Appellants Hemo 15 is non-offensive because it does not have a label drug claim, therefore not an approved drug. **PFF 31, 34.**

GFI # 256 concerns compounding from approved "drugs" or "bulk drug substances" and Appellant's Hemo 15 **constituents** were not shown to meet the FDA definition of a "drug" or "bulk drug substances" **PFF 31, 27-28, 31-36.** Dr. Maxwell presumed Appellant's Hemo 15 was being given to treat a malady, when Appellant testified it was not,[19] and Dr. Bertone testified you cannot "impugn" intent without a label claim. **PFF 31.** Dr. Maxwell's opinion that Hemo 15 is not "a medically appropriate treatment" is irrelevant as it is vitamin supplement, not a medical treatment. (**HISA Br., p. 9-10**; **PFF 31).**

HISA argues Appellant only criticizes the Decision and weight of the evidence. (**HISA Br. p. 16**). This ignores the meaning of *de novo* review, and that the Arbitrator acted arbitrarily and capriciously in seriously failing to appreciate the significance of the fact that Appellant's Hemo 15 made no claims. *Erickson v. Metropolitan Life Ins*. Co., 39 F.Supp.2d 864, 870 (E.D. Mich. 1999).

HISA's analysis under Rule 4111 is wrong as a matter of law. Dr. Maxwell incorrectly presupposed that Appellant's Hemo required FDA approval, (**HISA Br. p. 16(a)),** and incorrectly implied injection changes vitamins or dietary supplements into an unapproved animal drug. **PFF 27, 29**. Dr. Sharlin admitted in the FDA approval process, it is the claim that makes it a drug, but did not show how Appellant's Hemo 15 met the FDA definition of a "drug" or was compounded

[17] **PFF 15.**
[18] **PFF 31, 36.**
[19] **PFF 26**.

from "bulk drug substances, rending AMDUCA and GFI # 256 inapplicable. **PFF 36**. While the FDA expressed concerns about injectable vitamins, **PFF 29**, route of administration does not make it a drug. **PFF 35.** Dr. Maxwell relied on foreign Hemo 15 claims to conclude Appellant Hemo 15 was "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" (**HISA Br., p. 16(a)-17**), when Appellant's Hemo 15 and its constituents were not shown to meet the definition of a "drug" or "bulk drug substances." **PFF 27-36.** Thus, Appellant's Hemo 15 is compliant with (non-offensive), or not banned under Rule 4111 as it is inapplicable.

VI. The Consequences Are Arbitrary and Capricious

The Arbitrator did not "reasonably conclude[] that Appellant's first administration of Hemo 15 involved a significant degree of Fault" (**HISA Br., p.17**). HISA is correct, fault considers if Appellant "did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution" commission of a violation (***Id***.).

Appellant had no notice Hemo 15 is banned via the Banned Substance list **or** Rule 4111 and Appellant did due diligence. **PFF 13, 26**. Dr. Scollay said you cannot use unapproved foreign products (**HISA Br., p. 18(a))**, but Appellant's Hemo 15 was identical to foreign Hemo 15. **PFF 25, 30.** HISA and Congress must enact clear rules, it is not Appellant's obligation to ask. *FCC v. Fox TV Stas., Inc.,* 567 U.S. 239, 253 (2012). HISA makes much of the label on Appellant's Hemo 15 bottle, but it was clear from its contents that Dr. Bertone correctly testified the label was a standard pharmacy label incorrectly identifying Appellant's Hemo 15 as a drug. **PFF 12.**

The Arbitrator's analysis of fault was arbitrary, capricious (unreasonable) because the same "exceptional" reasons, (**HISA Br., p. 18**), making Appellant faultless for the subsequent 227 administrations, applies to the first. HISA was found at fault for not warning Appellant Hemo 15 was banned after the first administration. **PFF 38-39**. Appellant cannot logically have notice for

administration number one that disappears for administration two. What is clear is that there was no notice to Appellant - ***at all*** - for all 228 administrations**. PFF 13, 26**. Thus, the Consequences are arbitrary and capricious because Appellant was faultless under Rule 3224 or alternatively 3225.

VII. Private Delegation Violation

HISA's opening brief did not address private delegation doctrine. Appellant stands on his brief.

VIII. Conclusion

Based on the foregoing, the Decision should be reversed, Consequences annulled, and the charges dismissed.

Dated: September 23, 2024

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WORD COUNT AND SPECIFICATIONS CERTIFICATION

I Andrew Mollica, Esq. certify that the above Reply Brief was prepared using a computer, Microsoft Word Program, that I used Times New Roman Font, double spaced text, that I followed the order of HISA arguments, and that I conducted a word count with the Microsoft program, and not including caption, cover page, signatures, service documents, this document is **1997 words**, including footnotes.

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 Brief** is being served on this September 23, 2024, via Administrative E-File System and by emailing a copy to:

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