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 TO APPELLANT'S PROPOSED FINDINGS OF FACT

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 to Appellant's Proposed Findings of Fact.

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 to Appellant's Proposed Findings of Fact is being served on September 23, 2024, via Administrative E-File System and by emailing a copy to:

Hon. Jay L. Himes
Administrative Law Judge
Office of Administrative Law Judges
Federal Trade Commission
600 Pennsylvania Ave. NW
Washington DC 20580
Via e-mail: Oalj@ftc.gov

April Tabor
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Ave. NW
Washington, DC 20580
Via email: electronicfilings@ftc.gov

Andrew J. Mollica
1205 Franklin Ave Suite 16LL
Garden City, New York 11530
Cell: (516) 528-1311
Office: (516) 280-3182
Via email to jdmol@aol.com
Attorney for Appellant

/s/ *Bryan Beauman*

Enforcement Counsel

PROPOSED FINDINGS OF FACT

1. **Dr. Shell is a veterinarian, licensed in Ohio and West Virginia. AB1 1043, ¶ 1.**

   - Agreed.

2. **On October 4, 2023, Horseracing Integrity and Welfare Unit ("HIWU") investigators confiscated a "bottle labeled 'Hemo 15" ("Bottle") from Appellant's veterinarian vehicle at JACK Thistledown Racino. AB1 271(III).**

   - Agreed.

3. **The Bottle identified pharmacy, Horse Necessities, Inc., the veterinarian, Dr. Shell, and patient, Covered Horse, "*Mo Don't No Horse*." AB1 271(III), 276.**

   - Agreed.

4. **HIWU sent the Bottle to the Pennsylvania Equine Toxicology & Research Laboratory ("PETRL") for testing. On December 12, 2023, PETRL reported the composition of the Bottle's contents. ("PETRL Report"). AB1 272, 279-80.**

   - Agreed.

5. **The PETRL Report did not identify any Banned Substances but HIWU's Chief of Science, Dr. Mary Scollay testified that reported Cobalt was "problematic." AB2 116:8-13 (Scollay); AB1 279-80.**

   - Disagree. PETRL identified a compounded combination of substances that together constitute a S0 Banned Substance. Dr. Scollay testified that the compounded substance was an S0 Banned Substance intended to mimic foreign Hemo-15 (AB2 110:13-112:13; 187:9-18), and in addition, the cobalt was problematic (AB2 116:8-13).

6. **Dr. Scollay testified Cobalt is a trace mineral, found in vitamin B-12 and could have been derived from other Bottle contents. AB2 139:9-13, 140:14-19, 141:20-142:2 (Scollay).**

   - Agreed.

7. **The Horseracing Integrity and Safety Authority ("HISA") has a threshold for Cobalt in horse's blood [or urine] and there is no evidence any horse treated by Appellant met that threshold. AB1 1074; AB2 140:21-141:2, 167:2-168:4 (Scollay).**

   - Agreed.

8. **The PETRL Report did not show evidence of "Cobalt Salt," which is a Banned Substance. AB1 279-80, 1074; AB2 143:1-144:3 (Scollay).**

   - Disagree. PETRL identified "Total Cobalt". Dr. Scollay testified that it cannot be determined if the Total Cobalt was in the form of "Cobalt Salts" (AB2 143:1-144:3).

9. **The PETRL Report identified nicotinamide, which Dr. Scollay stated is a potential metabolite of a B Vitamin and it is "under investigation" as to whether it is an actual metabolite or contaminant of formulating vitamin or drug products. Dr. Scollay stated it is a banned substance, but "as of yet because of the potential for it being a metabolite of B vitamins, it remains on a monitoring list." AB2 121:1-12 (Scollay).**

   - Agreed.

10. **Nicotinamide is not on HISA's Banned Substance list. AB1 1055-1132.**

    - Agreed.

11. **The PETRL Report did not show nicotinamide to be a Banned Substance violation, only of "significant interest." AB2 121:1-12 (Scollay).**

    - Agreed.

12. **The Bottle's label states: "[t]his is a compounded drug. Not an FDA approved or indexed drug," AB1 1309, which Dr. Bertone testified is the pharmacy's standard statement and incorrect as to Appellant's Hemo 15. AB2 451:11-14 (Bertone).**

    - Agreed regarding the label. When Dr. Bertone was asked if the label was wrong, he testified: "It's my view that that's wrong. That's just a standard statement that they put beneath their pharmacy. That's what they make, is drugs." (AB2 451:11-14; emphasis added).

13. **"Hemo 15" is not on HISA's Banned Substance List. AB 1055-1132.**

    - Hemo 15 falls under the criteria of S0 Banned Substances. There are several cases in the *lex sportiva* where athletes have violated the WADC for substances not explicitly named on the Prohibited List. See, for example, *IAAF v. RFEA & Josephine Onyia* ¶90-91.

14. "Hemo 15" is shorthand for a combination of vitamins, minerals, and amino acids. AB2 222:13-15 (Shell), AB2 303:14-19 (Maxwell); AB2 379:12-14 (Bertone).

- Disagree. Dr. Maxwell's testimony explained that the compounded substance labeled Hemo 15 includes vitamins, minerals, and amino acids, but meets the criteria of an S0 Banned Substance and should be categorized as an unapproved animal drug (AB2 303:14-19; 304:4-327:7).

15. Appellant's Hemo 15 and Bottle made no label claims to treat or diagnose any condition. AB2 389:22-390:5 (Bertone); AB2 148:2-21, 155:23-156:16 (Scollay).

- The label does not make claims to treat or diagnose a condition, but in Dr. Scollay's cited testimony, she noted that the label identified the Bottle's contents as a drug (AB2 148:2-21.) Dr. Bertone also discussed several formulations of foreign Hemo-15 in his testimony, which make such claims (AB2 430:8-440:19).

16. Appellant obtained all his Hemo 15 from Horse Necessities, Inc. and ingredients were the same for 37 years. AB2 265:2-15, 270:6-14 (Shell).

- Appellant testified he obtained Hemo 15 from Horse Necessities, Inc. and believed Hemo 15 has not changed over the last 37 years and the pharmacy would have notified him if it had (AB2 265:2-15, 270:6-14). There is no evidence in the record confirming what the ingredients of Hemo 15 were when first ordered by Appellant, or whether they have changed.

17. HIWU searched the HISA Portal and found Appellant self-reported 228 "Hemo 15" administrations from May 29 to October 19, 2023, for 37 Covered Horses. AB1 267 ¶ 10.

- Agreed.

18. On January 8, 2024, HIWU alleged Appellant committed 228 violations of ADMC Program Rule ("Rule") 3214(c),[1] Administration of a Banned Substance to a Covered Horse, based on the self-reported Hemo 15 entries, alleging it is banned under Rule 4111. AB1 270-74.

[1] Hereinafter, "**Rule(s)**."

- Agreed.

19. On January 22, 2024, Appellant provided an explanation to HIWU, stating Hemo 15 is a vitamin supplement, there was no notice Hemo 15 is banned, it is not on the Banned Substance list, and vitamin supplements do not require government approval. AB1 256-58.

- This was Appellant's position. Disagree that:
    - "Hemo 15 is a vitamin supplement." Hemo 15 is a mixture of vitamins, trace minerals, and amino acids that have been compounded into an unapproved animal drug (AB2 303:10-305:12 (Maxwell)).
    - "…[T]here was no notice Hemo 15 is banned." Rule 4111 provides notice that the compounded substance labeled Hemo 15 is a S0 Banned Substance.
    - "…[V]itmain supplements do not require government approval." The FDA considers injectable vitamins to be unapproved animal drugs (AB2 328:7-329:6 (Maxwell)).

20. On February 9, 2024, HIWU charged Appellant under Rules 3214(c) and 4111 for 228 "Hemo 15" administrations. AB1 284-90.

- Agreed.

21. Dr. Scollay gave HISA educational presentations, including on March 24, 2023 at Will Rogers Downs, wherein she stated the FDA does not approve or give vitamins ability to have approval, and HISA can't require approval, but if the label on a dietary supplement, vitamins, or mineral says it cures, treats, prevents, mitigates a specific disease condition, or it very specifically affects the structure or function of a system in the body, that is a drug claim, and now it meets the FDA definition of a drug. If they don't need approval a veterinarian can carry vitamin supplements that have no drug claims. AB 1307, ¶ 3, 1311-12, ¶ 13; AB2 137:5-9, 162:22-163:19 (Scollay).

- Dr. Scollay made these comments, but also testified that Hemo 15 is not a vitamin, and she never said it was in any of her presentations (AB2 108:9-109:13).

22. Before HISA, Appellant practiced veterinary medicine for 37 years, was never

disciplined, and/or charged with malpractice. AB2 199:9-200:18 (Shell).

- Agreed this was Appellant's testimony.

23. In preparation for HISA, Appellant educated himself, reviewed the Banned Substance list, emails, watched seminars and attended Dr. Scollay's seminar at Mahoning Valley. AB2 208:5-209:4, 241:13-20, 247:6-248:12, 250:14-19, 260:10-261:11 (Shell).

- Agreed this was Appellant's testimony.

24. Appellant testified Hemo 15 is a vitamin supplement containing amino acids, vitamins, and minerals, and he used it safely for three decades. AB2 222:8-15 (Shell).

- Agreed this was Appellant's testimony. Dr. Maxwell and Dr. Sharlin testified that Hemo 15 is a drug (AB2 303:10-305:12; (Maxwell) AB2 496:2-18 (Sharlin)).

25. Appellant did not use Hemo 15 to treat any conditions, and foreign Hemo 15 with claims, has no connection to his Hemo 15. AB2 224:8-13, 226:1-9 (Shell).

- This was Appellant's testimony. Appellant also testified that he uses Hemo 15 throughout his practice (AB2 227:9-16). When asked about the efficaciousness of his administrations to racehorses, Appellant testified: "It's been very...it is very efficacious. There are amino acids like lysine that are in the Hemo 15. Lysine is the number one amino acid that is lacking in racehorses" (AB2 240:19-22).

26. Appellant testified Hemo 15 did not fall under Rule 4111 as a vitamin supplement that is not regulated (by the government), it is not covered under Rules 4112-4117, AB2 236:8-237:15 (Shell), he made no claim Hemo 15 treats ailments, it is widely accepted in the United States, AB2 237:20-237:12 (Shell), he had no notice that it was a Banned Substance, it is not on the Banned Substance list, AB2 229:13-230:15 (Shell), and as a veterinarian he was compliant with compounding rules. 252:2-254:5 (Shell).

- Agreed this was Appellant's testimony.

27. HIWU expert Dr. Laura Maxwell testified "Hemo 15" is a Banned Substance under Rule 4111, AB2 315:5-7 (Maxwell), that the FDA has two divisions of animal products, "foods" or "drugs" and Hemo 15 is a new animal drug because it meets FDA's definition of a drug which is "intended to cure, mitigate, treat, or prevent a disease," it is "not taken by mouth," AB2 304:8-23, 307:22-308:17 (Maxwell), and it does not "appear to have valid veterinary use" as there is no known Cobalt deficiency in horses. AB2 314:15-22 (Maxwell).

- Dr. Maxwell's cited evidence at AB2 314:15-22 is not fully summarized in the proposed finding of fact. See above citation for exact wording.

28. Dr. Maxwell testified the Animal Medicinal Drug Use Clarification Act ("AMDUCA") permits use of approved "drugs in an extra label fashion" and Hemo 15 is not compliant with AMDUCA because it is not an approved drug. AB2 315:20-316:12 (Maxwell). Dr. Maxwell stated GFI #256 deals with compounding drugs from bulk drug substances, and Hemo-15 does not meet the requirements of GFI #256 as it does not meet the requirements of compounding for office stock as it is not on a required list of permitted "drugs for compounding" and Appellant did not compound for individual use. AB2 318:4-324:22 (Maxwell).

- Dr. Maxwell testified that Hemo 15 does not meet the requirements of compounding for office stock as it is "not on the list of permitted drugs for compounding bulk substances". (See AB2 326:5-24, 327:1-7 for correct reference.)
- For Dr. Maxwell's full testimony on Appellant's compounding practices for office versus individual stock, see AB2 323:16-325:20.

29. Dr. Maxwell stated the FDA "expressed concerns" about injectable vitamins. AB1 1284-85.

- Dr. Maxwell stated that the FDA has expressed concerns about the use of injectable vitamins as unapproved animal drugs (AB1 412 ¶ 28).

30. Dr. Maxwell and the Arbitrator cited to, "[f]oreign Hemo-15® products," which makes drug claims. AB1 142, ¶ 8.7, 408, ¶ 14. Aside from name, there is no evidence Appellant's Hemo 15 is the same as the foreign product. AB2 337:18-338:2 (Maxwell).

- See AB1 408 ¶14 and 142 ¶8.7 for language used by Dr. Maxwell and the Arbitrator.
- AB2 337:18-338:2 is a reference to Dr. Maxwell's testimony during cross-examination. Dr. Maxwell was asked about "sites" she reviewed related to "European Hemo 15", which she opined on in her reply report (AB1 1282-1284, ¶7-8). Dr. Maxwell testified that she doubted the compounding pharmacy made its knock-off Hemo 15 from foreign products.
- On re-direct, Dr. Maxwell confirmed that Dr. Shell had not produced any ingredient list

from Horse Necessities and could not directly compare the compounded Hemo 15 used in his practice with the foreign versions (AB2 364:17-366:20).

31. **Appellant's expert, Dr. Joseph Bertone, testified Appellant's Hemo 15 is a vitamin supplement, makes no label drug treatment claims, therefore it is not a drug, it does not need FDA approval as a drug, AB2 379:8-380:9, 382:20-386:1, 399:1-15 (Bertone), it is acceptable in the United States veterinary community, AB2 380:11-17, 382:6-18 (Bertone), and foreign, trademarked Hemo 15, that makes drug claims, is inapplicable to Hemo 15 in the United States. AB2 381:1-20, 457:16-458:1 (Bertone). Dr. Bertone testified "you cannot impugn intent," as a claim to treat a condition must be on the label, otherwise it is not a drug. AB2 388:12-389:1 (Bertone). Dr. Bertone testified Hemo 15 is not on the Banned Substance list and nothing else would lead him to conclude it is banned. AB2 393:9-18 (Bertone).**

    - Dr. Bertone testified to the foregoing points. During cross-examination, he also testified that foreign Hemo 15 products make treatment claims, and he expected that Hemo 15 compounded in the US would be substantially similar (AB2 430-439).

32. **GFI #256 is guidance, not law. AB2 387:15-388:2 (Bertone).**

    - This was Dr. Bertone's testimony. Dr. Maxwell and Dr. Sharlin discussed the purpose of GFI #256 in their evidence (AB1 413-414 ¶34 (Maxwell Report); AB1 1296-1296 ¶¶20-25 (Sharlin Report)).

33. **Hemo 15 is not addressed under Rules 4112 to 4117. Rule 4111(i). AB2 398:8-16 (Bertone).**

    - Hemo 15 is addressed under Rule 4111 (AB2 110:13-112:13 (Scollay); AB2 312:10-327:7 (Maxwell)).

34. **Dr. Bertone testified Hemo 15 is not a drug and therefore does not require government approval, rendering Rule 4111(ii) inapplicable. AB2 398:18-399:23 (Bertone).**

    - This was Dr. Bertone's testimony, contrary to the Bottle's label which states that Hemo 15 "… is a compounded drug. Not an FDA approved or indexed drug" (AB1 1309).

35. **Dr. Bertone testified AMDUCA is a drug use compliance act, and it does not apply as Appellant's Hemo 15 is not being administered as a drug to mitigate disease, and Appellant's Hemo 15 is "compliant" with GFI #256, AB2 417:5-18 (Bertone), as**

Appellant's medical records identified individual horses, AB2 419:22-420:19, 471:14-17 (Bertone) and the FDA website now permits compounding from "products from a pharmacist" and/or therefore GFI #256 does not even apply. AB2 385:3-386:1, 417:14-18 (Bertone). Dr. Bertone testified route of administration does not make Hemo 15, dietary, or injectable vitamins drugs, without drug claims. AB2 383:8-384:4 (Bertone). Dr. Bertone testified, aside from FDA experts, the public and veterinarians have relatively no understanding of the issues addressed in Rule 4111. AB2 508:10-510:7 (Bertone).

- Dr. Bertone testified to these points. With respect to the following statement and citation ("and the FDA website now permits compounding from "products from a pharmacist" and/or therefore GFI #256 does not even apply. AB2 385:3-386:1, 417:10-18"), there is no evidence in the record of the FDA website to which Dr. Bertone referred.

36. **HIWU expert Dr. Joshua Sharlin opined everything in the animal world is either food, food ingredients, or a drug. AB2 494:16-24 (Sharlin). Dr. Sharlin states in analysis of GFI # 256, the "first question to consider under [the FDA] flowchart is whether the compounded drug in issue was created to fulfill a prescription for a specific animal." AB1 1297, and "[t]here are two possible sources for the active ingredient in a compounded drug: an FDA-approved drug, or a bulk drug substance." AB1 1856. Dr. Sharlin opined Hemo 15 is a drug, not compliant with GFI # 256 but agreed with Dr. Bertone that when it comes to the FDA approval process every starts with the drug claim, and then opined about making an "end-run" around FDA regulations because a "claim" is not a requirement of a compounded drug label. AB2 497:4-503:5 (Sharlin). A "bulk drug substance" is defined as "any substance intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." AB1 1136.**

- The quote to AB1 1297 is incomplete.
- For Dr. Sharlin's full comments on Dr. Bertone's testimony regarding drug claims, see AB2 501:17-503:5.
- The definition of "bulk drug substance" is incomplete and comes from GFI #256 – not from Dr. Sharlin (AB1 1136).

37. **Arbitrator Hon. Hugh Fraser's ("Arbitrator") June 11, 2024, Amended Decision, in JAMS Case No. 1501000708, found Appellant committed 228 violations under Rule 3214(c) based on 228 self-reported administrations of "Hemo 15" to 37 Covered horses, under Rule 4111. AB1 113, 143, ¶ 8.11. ("Decision") and Rule 4111 can be "understood by Covered Persons of ordinary intelligence and is [not] arbitrary and capricious," as**

only Appellant reported Hemo 15. AB1 146, ¶ 8.22. Dr. Scollay did not know anyone using Hemo 15 so she could not speculate on how it would be reported. AB2 170:21-171:6 (Scollay).

- With respect to AB1 146, ¶8.22, the Arbitrator was responding to arguments made in Appellant's Post-Hearing Brief (AB1 1726, ¶1). See AB1145-146, ¶8.20-8.22 for the Arbitrator's full reasons.

38. **The Arbitrator imposed penalties ("Civil Sanction") consisting of (a) two years ineligibility, with credit for any Provisional Suspension; (b) a fine of $25,000; (c) payment of $10,000 costs, and (d) he found no fault for 227 of the 228 counts, expunging the penalties for those counts. AB1 149-50(IX).**

- Agreed.

39. **The Arbitrator found Appellant at fault for not further researching, asking questions about Hemo 15, and its label, but held it was understandable that he continued administration of the substance after his initial reporting (for five months) without warning or consequence". AB1 149, ¶ 8.34.**

- The Arbitrator did not state that it was "understandable" Appellant would continue administering Hemo 15; he stated, among other factors, that 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." See the full Fault analysis at AB1 148-149, ¶¶8.30-8.34.