BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S ANTIDOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000708

In the Matter of the Arbitration Between: HORSE RACING INTEGRITY WELFARE UNIT ("**HIWU**" or "**Agency**")
Claimant

v.

DR. SCOTT SHELL ("**Dr. Shell**" or **"Respondent"**)
Respondent

AMENDED FINAL DECISION

I, THE UNDERSIGNED ARBITRATOR, having been designated, and having been duly sworn, and having duly heard the allegations, arguments, submissions, proofs, and evidence submitted by the Parties, after a full evidentiary hearing occurring in person at the JAMS Resolution Center in New York, New York, on May 28, 2024, pursuant to the Horseracing Integrity and Safety Act of 2020 and its implementing regulations, do hereby FIND and DECIDE as follows:

I. INTRODUCTION

1.1 This case involves allegations of violation of ADMC Program Rule 3214(c) for the Administration of Banned Substance Hemo 15 two hundred and twenty-eight times (228) to thirty-seven (37) Covered Horses between May 29, 2023 and October 19, 2023.

1.2 HIWU is the United States government-recognized entity responsible for sample collection and results management in the anti-doping testing of thoroughbred racehorses in the United States, pursuant to the Horseracing Integrity Act of 2020, 15 U.S.C. secs. 3051-3060. HIWU was represented by Allison J. Farrell, Esq., Senior Litigation Counsel of HIWU, and James Bunting, Esq. of Tyr LLP, Toronto, Canada.

1.3 Dr. Scott Shell is the founding veterinarian practicing within Scott Shell DVM Inc. He practices alongside two other veterinarians, Dr. Barbara Hippie and Dr. Margaret Smyth. Dr. Shell was represented in these proceedings by Andrew J. Mollica, Esq. of Garden City, New York.

1.4 Throughout this Final Award, HIWU and Dr. Shell shall be referred to individually as "Party" and collectively as "Parties".

II. THE FACTS

2.1 Below is a summary of the relevant facts and allegations based on the Parties' written submissions, pleadings, and evidence adduced at the hearing. Additional facts and allegations found in the Parties' written submissions, pleadings and evidence may be set out, where relevant, in connection with the legal discussion that follows. While the Arbitrator has considered all the facts, allegations, legal arguments and evidence submitted by the Parties in the present proceedings, the Arbitrator refers in this Final Award only to the submissions and evidence the Arbitrator considers necessary to explain his reasoning.

2.2 A number of facts are in dispute. The version of those facts, according to each party, are set forth below. The facts as found are based on the Arbitrator's assessment of the evidence, including the credibility of the witnesses, together with reasonable inferences drawn therefrom.

The Facts According to HIWU

2.3 Between May 29, 2023 and October 19, 2023, Dr. Shell administered Hemo 15 to thirty-seven (37) Covered Horses. Across these thirty-seven (37) Covered Horses, Dr. Shell administered two hundred and twenty-eight (228) separate injections of Hemo 15. This much is not in dispute.

2.4 During a search of the business facilities, vehicles and accoutrements at JACK Thistledown Racino by HIWU Investigators on October 4, 2023, a search of a Scott Shell DVM Inc. registered veterinary truck bearing Ohio Tag No. PGL-6583, under the care and control of Dr. Smyth, resulted in the discovery and seizure of one bottle labelled Hemo 15. The prescription label on the Hemo 15 indicated that it was prescribed to Covered Horse, *Mo Don't No* by Dr. Scott Shell, DVM. *Mo Don't No* is a Covered Horse trained by Jeffrey Radosevich (a Covered Person) and actively raced at Thistledown in 2023.

2.5 The bottle labelled Hemo 15 was seized and placed in an evidence bag labelled as Evidence Exhibit RT-31 and subsequently sent to the Pennsylvania Equine Toxicology & Research Laboratory ("**PETRL**") for testing. On December 12, 2023, PETRL returned results reporting the product's chemical composition.

2.6 A subsequent review of veterinary records in the HISA Portal revealed that Dr. Shell was the Attending Veterinarian, administering Hemo 15 to a total of thirty-seven (37) different Covered Horses between May 29, 2023 and October 19, 2023 for a total of two hundred and twenty-eight (228) independent Administrations of what HIWU states is a Banned Substance, to a Covered Horse.

2.7 HIWU states that there are thousands of Covered Horses and hundreds of Covered Persons for whom records have been uploaded since the inception of the ADMC Program. These records are uploaded by Veterinarians from numerous states, who log thousands of entries per month, for a variety of daily medical logs and treatments for their equine

patients. HIWU states that given this volume, it is impractical for HISA to review every entry made into the HISA Portal.

2.8 Covered Persons is defined by the Horseracing Integrity and Safety Act as "all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons (legal and natural) licensed by a State Racing Commission and the agents, assigns, and employees of such Persons and other horse support personnel who are engaged in the care, training, or racing of Covered Horses."

2.9 On January 8, 2024, HIWU formally notified Dr. Shell that he was being charged with a violation of ADMC Program Rule 3214(c), Administration of a Banned Substance to a Covered Horse.

2.10 Pursuant to ADMC Program Rule 3247(a)(1) of the Protocol, HIWU imposed a Provisional Suspension on Dr. Shell effective January 8, 2024.

The Facts According to Dr. Shell

2.11 Dr. Shell does not dispute that the search at JACK Thistledown Racino on October 4, 2023 resulted in the discovery of a bottle of HEMO 15, which he described as a multi-vitamin. He also admits that he self-reported these administrations of HEMO 15.

2.12 He cares deeply about the horses that he treats and no horse treated by him has ever tested positive for a Banned Substance.

2.13 He had not seen any prior notice about HEMO 15 being a Banned Substance.

2.14 He may have been the only veterinarian who reported the administration of HEMO 15 to his equine patients, but he was not the only veterinarian using this product.

2.15 It is his belief that HEMO 15 is short hand for a group of nutrients that are not banned by the FDA and do not fall under Rule 4111 since it is a vitamin and not a drug.

III. PROCEDURAL HISTORY

3.1 On January 8, 2024, Dr. Shell was served with an EAD Notice of Alleged Anti-Doping Rule Violations ("Notice Letter") for multiple Administrations of Hemo 15. A Provisional Suspension was imposed effective immediately. The Notice Letter also advised Dr. Shell of his opportunity to provide an explanation to the Agency, on or before January 16, 2024.

3.2 On January 22, 2024, Dr. Shell provided his response to the Notice Letter, (the Explanation Letter"). The Explanation Letter outlined three reasons for the Administrations alleged to have been administered: (i) Hemo 15 is a vitamin supplement for which FDA approval is not required, (ii) Hemo 15 does not explicitly appear on the Banned Substances list, and (iii) in any event, the multiple Administrations should be considered a single transaction.

3.3 On February 9, 2024 Dr. Shell was served with an EAD Charge of Anti-Doping Rule Violations ("Charge Letter"). The Charge Letter advised Dr. Shell that the Agency had reviewed his Explanation Letter and was satisfied that ADRVs had been committed.

3.4 On March 18, 2024, Hon. Hugh L. Fraser was appointed as Arbitrator in this proceeding.

3.5 A preliminary case management hearing was held on April 5, 2024 and was attended by both parties.

3.6 On April 8, 2024, the Arbitrator issued Procedural Order No. 1, providing in pertinent part as follows.

3.7 By agreement of the Parties as established during the preliminary hearing and by Order of the Arbitrator, the following is now in effect:

1. Regarding Briefs and Exhibits

a. Each party shall serve and file electronically a prehearing Brief on all significant disputed issues, setting forth briefly the party's positions and the supporting arguments and authorities on the dates specified below:

i. Agency's Pre-Hearing Brief: **April 5, 2024**

ii. Respondent's Pre-Hearing Brief: **May 3, 2024**

iii. Agency's Reply Brief: **May 17, 2024**

b. The parties shall submit their exhibits to be used at the hearing, electronically to the Arbitrator and to the other party on the dates their respective initial pre- hearing briefs are due. The parties shall also include with their respective submissions an index to the exhibits. All briefs, and any witness statements, shall be transmitted electronically in MS Word versions to the Arbitrator. The parties pre-hearing submission briefs shall not exceed 30 double-spaced single-sided pages and shall include all exhibits, schedules, witness statements, experts reports, and all other evidence that they intend to rely on at the hearing.

c. The Claimant shall use letters and the Respondent shall use numbers to mark their exhibits. To the extent that one party has submitted an exhibit that another party

also intends to use (such as the World Anti-Doping Code or the USADA Protocol), the other should not include a second copy of that document in its own exhibits but should otherwise refer to the exhibit submitted by the other side. The Parties shall endeavor to agree on a joint set of exhibits to minimize duplication. If possible, to make the hearing proceed more efficiently electronically, the Parties shall file their exhibits as an indexed .pdf file such that the Arbitrator and any Party can click on the index and be taken directly to the exhibit within the .pdf file of all exhibits.

2. Regarding Stipulations of Uncontested Facts and Procedure

a. In each case, if they are able to agree, the Parties shall submit a Stipulation of Uncontested Facts **on or before the date on which the first pre-hearing brief is due from the Respondent.**

b. The Parties shall, in advance of the hearing, and **no later than 48 hours before the hearing**, agree upon and submit to the Arbitrator the order of witnesses expected to testify at the hearing that they have been able to agree upon; if the Parties are unable to so agree, they shall submit their respective positions by said deadline.

3. Regarding Witnesses

a. The Respondent shall serve and file a disclosure of all witnesses reasonably expected to be called by him **on or before the due date of his pre-hearing brief.**

b. The Claimant shall serve and file a disclosure of all witnesses they reasonably expect to call on **or before the due date of its pre-hearing reply brief.**

c. The disclosure of witnesses shall include the full name of each witness, a short summary of anticipated testimony sufficient to give notice to the other side of the general areas in which testimony shall be given, copies of experts' reports and a written C.V. of any experts. If certain required information is not available, the disclosures shall so state. Each party shall be responsible for updating its disclosures as such information becomes available. The duty to update the information continues up to and including the date that hearing(s) in this matter terminate. The Arbitrator encourages the Parties to submit sworn witness statements which would constitute their direct testimony, requiring only cross-examination after a witness confirms their witness statement.

d. The parties shall coordinate and make arrangements to schedule the attendance of witnesses at the Hearing so that the case can proceed with all due expedition and without any necessary delay.

4. Regarding the Hearing

The Hearing in this matter will commence before the Arbitrator on **May 28, 2024,** starting at 9:00 a.m. The hearing will take place in New York or Ohio, the specific location to be confirmed by April 16, 2024.

5. Regarding Submission of Documents

All documents due to be submitted hereunder hall be submitted electronically by email to the Arbitrator at hfraser@jamsadr.com using the JAMS Access system. The Parties shall not communicate with the Arbitrator directly and alone; all communications with the Arbitrator are to be copied to the opposing party, and the JAMS case manager, at the same time as the communications are made to the Arbitrator and in the same form.

6. Further Disputes Process

To the extent any dispute arises between the Parties beyond what has been stated already, any Party wishing to bring that dispute to the attention of the Arbitrator shall do so promptly, after such dispute arises by sending a brief email to the Arbitrator, copied to the other side and JAMS (and filed on the JAMS Access system), outlining in basic, brief, general terms, the nature of the dispute and their position thereon. There shall be no response to that email. The Arbitrator will, based on these two emails, determine the next steps with respect to resolving the dispute.

7. Miscellaneous Provisions

a. All deadlines and requirements stated herein will be strictly enforced. Any deviation requires the permission of the Arbitrator based on a showing of good cause by the Party seeking an extension of time.

b. This order shall continue in effect unless and until amended by subsequent order of the Arbitrator.

c. Unless specified otherwise herein, for all deadlines for any Party to take any action under this Order, the time by which such action shall be due for each such designated action shall be **midnight Pacific Time** on the date given.

d. The Parties' attention is drawn to the relevant provisions of the procedural rules that limit the liability of the Arbitrator in these proceedings. The Arbitrator agrees to participate in these proceedings on the basis that, and in reliance on the fact that, those provisions apply and the Parties agree to be bound by them. If any Party disagrees that those provisions apply here, they must notify the Arbitrator **within seven (7) days of the date of this order** in writing.

3.8 The Parties complied with the deadlines and other requirements set forth in Procedural Order No 1.

3.9 On April 18, 2024, the Arbitrator issued Procedural Order No. 2 which confirmed that the hearing in this matter would take place on Tuesday, May 28, 2024, commencing at 9:00 a.m. E.T. in person at the JAMS New York Resolution Center, New York, New York.

3.10 On April 18, 2024, A Notice of Hearing was issued, confirming the date, time and location of the hearing.

3.11 On May 15, 2024, Counsel for the Respondent brought an application to adjourn the hearing scheduled for May 28, 2024, as his expert witness Dr. Joseph Bertone was going to be on vacation on that date and would not be available to participate in the hearing.

3.12 On May 16, 2024, the Agency submitted their response to the adjournment request. HIWU expressed a strong desire to maintain the original hearing date of May 28, 2024 and offered a suggestion to receive the expert witness testimony out of order if necessary on an earlier date, to accommodate the Respondent.

3.13 On May 17, 2024, the Arbitrator rendered his decision denying the motion to adjourn the May 28, 2024 hearing date.

3.14 The evidentiary hearing proceeded as scheduled on May 28, 2024 at the JAMS Resolution Center, New York, New York commencing at 9:00 a.m. in accordance with an agreed upon hearing schedule.

3.15 HIWU was represented in person at the hearing by Allison J. Farrell, Esq. and James Bunting, Esq. of Tyr LLP Alexandria Matic, Esq. and Carlos Lopez, Esq, also of Tyr LLP appeared virtually. Andrew J. Mollica, Esq. appeared for Dr. Scott Shell.

3.16 The Agency called four witnesses during the hearing, Dr. Lara Maxwell, Melissa Stormer, Dr. Mary Scollay, and Dr. Joshua Sharlin. The Respondent, Dr. Scott Shell testified on his own behalf, and called Dr. Joseph Bertone as an expert witness.

3.17 Upon the completion of the evidence, the Respondent sought permission to provide a post hearing brief on the issue of due process. The Arbitrator granted the request to provide a post hearing brief by the close of business on June 7, 2024. The Arbitrator advised that in light of the need to make a determination on the issue of Hemo 15 on an expeditious basis, the 14 day time for a reasoned award would be maintained and a decision rendered within 14 days of the closing of the evidentiary portion of the hearing.

3.18 The Respondent submitted his post hearing brief on June 7, 2024. The Agency was given the opportunity to provide a response, and that response brief was also received on June 7, 2024.

3.19 With the receipt of the post-hearing briefs, the hearing was closed.

IV. JURISDICTION

4.1 HIWU was created pursuant to the *Horseracing Integrity and Safety Act of 2020*, 15 U.S.C. secs. 3051-3060 ("Act"), and is charged with administering the rules and enforcement mechanisms of the Horseracing Integrity and Safety Authority's ("HISA") Anti-Doping and Medication Control Program ("ADMC Program"). The ADMC Program was created pursuant to the Act, approved by the Federal Trade Commission on March 27, 2023, and implemented on May 22, 2023. *See* 88 Fed. Reg. 5084-5201 (January 26, 2023). The ADMC Program sets out the applicable rules that govern this proceeding and ground the jurisdiction of the Panel over all participants. Rule 3020 provides that the anti-doping rules set out in the ADMC Program apply to and are binding on violations by Covered Persons, and Covered Persons are defined under ADMC Program Rule 1020.

4.2 There is no dispute that Dr. Shell is a Veterinarian, and by definition, a Covered Person under ADMC Program Rule 3020(a)(3).

4.3 The Rule 7000 Series of the ADMC Program sets out the arbitration procedures governing a charged violation of the ADMC Program, providing as follows:

> *Rule 7020. Delegation of Duties*
>
> *(a) Subject to Rule 3249, Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229 (together, ''EAD Violations'') shall be adjudicated by an independent arbitral body (the ''Arbitral Body'') in accordance with the Rule 3000 Series and these Arbitration Procedures. The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body."*

4.4 Where the Agency issues a Charge Letter effecting charges on a Covered Person, arbitral proceedings are initiated pursuant to Rule 7060:

> *"Rule 7060. Initiation by the Agency*
>
> *i. EAD Violations. Unless Rule 3249 applies, if the Agency charges a Covered Person with an EAD Violation, the Agency shall initiate proceedings with the Arbitral Body. If a Covered Person is charged with both an EAD Violation and an ECM or Other Violation, the procedures for EAD Violations apply. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of EAD Violation cases, the Owner may be permitted to intervene and make written or oral submissions."*

4.5 As the Arbitral Body selected by mutual agreement of the Authority and Agency, JAMS has jurisdiction to adjudicate any ADRV matter that arises from the Rule 3000 Series of the Program.

4.6 In this case, arbitration proceedings were commenced before JAMS, the designated arbitration provider. No Party disputed jurisdiction.

4.7 Accordingly, the Arbitrator finds that he has been duly assigned by JAMS and has jurisdiction to adjudicate this dispute.

V. RELEVANT LEGAL STANDARDS

5.1 These proceedings are governed fully and exclusively by the ADMC Program. The Preamble and Rule 3010(f) expressly state that the ADMC Program pre-empts state laws. Rule 3070(b) provides that "subject to Rule 3070(d) the Protocol shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes".

5.2 Rule 3070(d) further provides that:

> *The World Anti-Doping Code and related International Standards, procedures, documents, and practices,…the comments annotating provisions of the WADA Code program, and any case law interpreting or applying any provisions, comments or other aspects of the WADA Code Program, may be considered when adjudicating cases relating to the Protocol, where appropriate.*

5.3 The jurisprudence interpreting and applying the WADC (commonly referred to as the *lex sportiva*) is of great assistance is applying the relevant legal standards. There is a well-established body of international anti-doping jurisprudence from specialized sporting arbitral tribunals including the international leader, the Court of Arbitration for Sport (the "CAS") which can inform the interpretation of the ADMC Program.

5.4 Pursuant to ADMC Program Rule 3223, the ineligibility, and financial penalties for a first Anti-Doping Rule Violation of Rule 3214(a) are:

a. *Two (2) years of Ineligibility, and*

b. A "*Fine up to $25,000 . . . and Payment of some or all of the adjudication costs and [HIWU]'s legal costs*."

5.5 Where a Violation of the ADMC Program is established, the Covered Person may be entitled to a mitigation of the applicable Consequences, only where he establishes on a balance of probabilities, that he acted with either No Fault or Negligence, or No Significant Fault or Negligence. Fault is defined in the ADMC Program as:

> "*any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of*

Fault include (but are not limited to) the Covered Person's experience and special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person, and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk. With respect to supervision, factors to be taken into consideration are the degree to which the Covered Person conducted appropriate due diligence, educated, supervised, and monitored Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, and created and maintained systems to ensure compliance with the Protocol. In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person would lose the opportunity to earn large sums of money during a period of Ineligibility, or the fact that the Covered Person or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault."

5.6 ADMC Program Rule 3224 permits the reduction of sanctions where there is No Fault or Negligence, as follows:

"*Rule 3224. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence (a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Anti-Doping Rule Violation(s) charged, the otherwise applicable period of Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3221(a) and Rule 3620)... (b) Rule 3224 only applies in exceptional circumstances...*"

5.7 No Fault or Negligence is defined by the ADMC Program as:

"*the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. For any violation of Rule 3212 or Rule 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Fault or Negligence*."

5.8 ADMC Program Rule 3225 also allows for the reduction of sanctions where there is No Significant Fault or Negligence, as follows:

"*Rule 3225. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence Reductions under this Rule 3225 are mutually exclusive and not cumulative, i.e., no more than one of them may be applied in a particular case.*

(a) General rule.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then... the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault."

5.9 No Significant Fault or Negligence is defined in the ADMC Program as:

"*the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence*."

VI. THE PARTIES' CONTENTIONS AND CLAIMS FOR RELIEF

6.1 The Parties asserted various arguments in their pre-hearing briefs and at the hearing. Their fundamental positions are summarized below. To the extent necessary, the Arbitrator will address various arguments that were made in the Analysis section below.

HIWU's Contentions

6.2 HIWU's position may be summarized as follows:

(a) ADMC Program Rule 3040 sets out certain obligations of the Respondent, as a Covered Person to be knowledgeable and to comply with the Protocol. Section (a) states that:

It is the personal responsibility of each Covered Person:

To be knowledgeable of and to comply with the Protocol and related rules at all times. All Covered Persons shall be bound by the Protocol and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Protocol and related rules and all revisions thereto;

(b) Rule 3214 explicitly prohibits the Administration of a Banned Substance to any Covered Horse. Subsection (c) lists the act of Administration or Attempted Administration to a Covered Horse of any Banned Substance or any Banned Method.

Under the ADMC Program, Administration is defined as:

> …providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use in a Covered Horse of a Prohibited Substance or Prohibited Method. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

(c) While the definition of Administration provides for an exception in the case of veterinary personnel involving a Controlled Medication for genuine legal and therapeutic purposes, such an exception never applies in the context of Administration to a Covered Horse of a Banned Substance such as Hemo 15.

(d) Proof of an Administration ADRV does not require a specific intent to commit an ADRV or knowledge of each fact constituting the ADRV. Accordingly, Dr. Shell's purported ignorance as to whether Hemo 15 is a Banned Substance has no relevance to establishing an Administration ADRV.

(e) Pursuant to Rule 3121, the burden of proof is on the Agency to establish that a violation of the ADMC Program has occurred to the comfortable satisfaction of the Panel. This standard of proof is higher than a balance of probabilities but lower than clear and convincing evidence or proof beyond a reasonable doubt.

(f) The Agency may establish an Administration ADRV by any reliable means, including, but not limited to admissions:

Rule 3122 Methods of Establishing Facts and Presumptions

Facts related to violations may be established by any reliable means, including admissions…

(g) In this case Dr. Shell has admitted to administering Hemo 15 to thirty-seven (37) different Covered Horses between May 29, 2023 and October 19, 2023 for a total of two hundred and twenty-eight (228) independent Administrations. The HISA Portal records have been entered as an Exhibit to the proceedings.

(h) Hemo 15 is a Category S0 Non-Approved Substance and therefore a Banned Substance, prohibited at all times. Rule 4111 of the ADMC Program sets out the criteria for substances that are to be categorized as S0 Non-Approved Substances:

> Rule 4111. S0 Non-Approved Substances. Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

(i) As set out in detail in the expert report of Dr. Lara Maxwell, Hemo 15 as it has been identified in Dr. Shell's Administration records, meets each of the three criteria of S0 Non-approved Substances.

(j) None of Rules 4112-4117 specifically address "Hemo 15", which is a foreign pharmaceutical product that is not otherwise approved for use in the United States. Hemo 15 is not approved by any governmental regulatory health authority. Though approved at various times in other countries, Hemo-15® has never been approved by the FDA. There is also no FDA-approved product that contains all the ingredients found in Hemo 15® by any other name. Furthermore, Hemo 15 is not universally recognized by veterinary regulatory authorities as having a valid veterinary use. Foreign Hemo-15® products contained more that 16 ingredients but were most often used for their effects on erythropoiesis (i.e., the process of making red blood cells). The cobalt and iron mineral constituents of hematinic agents have been touted as promoting erythropoiesis; however, (i) iron deficiency is rare in horses, as their diet contains the iron that they need, and (ii) cobalt deficiency has never been diagnosed in horses.

(k) If a particular horse requires vitamin or mineral supplements, then they are much more safely administered by mouth and do not require an intravenous route of administration. The compounding of vitamin and mineral mixtures for administration to horses has had deadly consequences for equine athletes.

(l) As Dr. Maxwell summarizes, the risks inherent in compounding a complex Hemo 15 formula significantly outweigh any potential medical need for constituent trace minerals:

> The "risk to benefit ratio" is an important concept in veterinary therapeutics, where the risk of harm posed by a therapeutic agent must be balanced against the benefit that the treatment can provide. Given the risk to benefit ratio for compounding a complex, sterile mixture that features trace minerals that are already sufficient in adequate equine diets, the veterinary use of such products in horses is wholly inappropriate.

(m) Hemo 15 is also not saved by the "avoidance of doubt" provision in Rule 4111 because it is not otherwise compliant with the Animal Medicinal Drug Use

Clarification Act ("AMDUCA") or the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) ("GFI #256"):

> a. AMDUCA explicitly prohibits compounding of drugs from bulk drug substances. No FDA-approved product exists that contains the substances found in Hemo-15®. As a result, any Hemo 15 administered to a Covered Horse by Dr. Shell would have necessarily been compounded from bulk drug substances and is therefore not compliant with the Act.
>
> b. With respect to GFI #256, this guidance provides conditions for discretionary enforcement for drugs that are "compounded from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist." On its face, Hemo 15 is not a medically appropriate treatment for otherwise healthy racehorses, nor is it a necessary alternative to treat any trace mineral deficiencies that a racehorse might have in the absence of a diagnosis. Put simply, this is not the type of discretionary compounding that GFI #256 was intended to permit.

(n) The fact that Hemo 15 is not explicitly listed on HISA's Banned Substances List is of no moment. Hemo 15 is expressly caught within the catch all Banned Substances provision in Rule 4111. It would be impossible to know or predict every combination of compounded products, and it is common for sanctions to be imposed under catch all provisions of this nature. In this regard, there are several cases in the *lex sportiva* where athletes have violated the World Anti-Doping Code ("WADC") for substances not explicitly named on the Prohibited List.

(o) One such example is the case of *IAAF v. RFEA & Josephine Onyia*, CAS 2009/A/1805, where the Panel determined that Methylhexaneamine was a Banned Substance even though it was not listed on the WADA Prohibited List:

> …while the substance found in Ms. Onyia's sample (methyhexaneamine) is not expressly identified in the WADA Prohibited List, a substance does not necessarily need to be expressly listed in the WADA Prohibited List to be considered a prohibited substance in sport. It is clear from the relevant section in the Prohibited List that not only are the stimulants specifically listed under Section 6 prohibited, but so are all related substances with a similar chemical structure or similar biological effect(s).

(p) Dr. Shell's due process argument is simply misplaced and not supported by any of the cases he cites. In *Carracedo*, the Sole Arbitrator declared that a party to any proceedings has: (i) a right to defend himself, (ii) a chance to state their case and provide their position regarding the subject matter in question, and (iii) the opportunity to present evidence that they deem relevant to their case.

(q) The Claimant submits that Dr. Shell has been afforded all these rights. He was duly notified via an EAD Notice Letter on January 8, 2024, that 228 administrations of Hemo 15 had been discovered and that he was at risk of being found to have committed multiple ADRVs. The Notice Letter also provided Dr. Shell with an opportunity to give an explanation for the administrations, which he submitted on January 22, 2024. Following his explanation, the Agency advised Dr. Shell via a Charge Letter on February 9, 2024, that it was satisfied that multiple ADRVs had been committed.

(r) The Claimant also submits that Dr. Shell has been given the same opportunity, and been subjected to the same procedures as every Covered Person before him who has been charged with a violation of the ADMC Program. He was given the same opportunity to a fair hearing and to present his case.

(s) The Claimant rejects any claim that Dr. Shell is being prosecuted because of a vendetta that HISA or HIWU has against him. The Agency maintains that with the Respondent's admission that he administered Hemo 15 on 228 occasions it would be irresponsible and a dereliction of the Agency's obligations not to charge him. The Agency submits that the fact that Dr. Shell is the only Covered Person who has been charged with Hemo 15 administrations, is because he is the only Covered Person who administered Hemo 15 after the enactment of the ADMC Program.

(t) Under the ADMC Program multiple administration ADRVs are treated as separate violations. Rule 3228(c) states that:

> (1) Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to the same Covered Horse prior to delivery of an EAD Notice may (at the Agency's discretion) be treated together as a single Anti-Doping Rule Violation, unless the facts demonstrate that there was more than one administration. Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to different Covered Horses prior to delivery of an EAD Notice may (at the Agency's discretion) each be treated as a first Anti-Doping Rule Violation. Where multiple Banned Substances are detected in a single Post-Race Sample or Post-Work Sample, each Banned Substance may (at the Agency's discretion) be treated as a separate violation.

(u) Whereas in the present case, the facts demonstrate that there was more than one Administration, the Agency has no discretion to treat multiple violations for the same Banned Substance as a single violation. Dr. Shell cannot request the amalgamation of violations for Banned Substances where the violations span across different Covered Horses. The Agency therefore submits that the Administration ADRVs are to be treated as separate ADRVs.

(v) The Respondent bears the onus to establish that a reduction of Consequences is appropriate by demonstrating on a balance of probabilities that he acted with either No Fault or Negligence, or No Significant Fault or Negligence.

(w) The Agency submits that at most, Dr. Shell's assertion that he did not know Hemo 15 was banned is relevant to whether he bears No Significant Fault and whether the resulting Consequences should be reduced. While Dr. Shell may have believed Hemo 15 was not banned (which he claims is supported by his rampant administration of it) the evidence is clear that Dr. Shell was either willfully blind to the fact that Hemo 15 was a Banned Substance, or failed to undertake reasonable and prudent steps to ascertain whether it was banned.

(x) The Agency submits that in order to meet the standard of care of a reasonable, prudent veterinarian in his approach to discerning whether Hemo 15 is a Banned Substance, Dr. Shell should have:

- Proceeded cautiously after noticing that "Hemo-15" is not registered or approved as a U.S. product.
- Noted that Hemo-15® is a foreign drug product that therefore cannot be legally imported into the U.S. without specific permissions.
- Observed that "Hemo-15" products have been repeatedly in the news for European racing violations, which should have suggested extreme caution in using such products on the race track.
- Perceived that the websites that sell "Hemo-15" appear to be disreputable for the purpose of U.S. sales of pharmaceuticals.
- Sought written clarification (or any clarification for that matter) as to whether Hemo 15 is a Banned Substance.

By failing to carry out these measures, the Agency submits that Dr. Shell cannot receive a reduction in Consequences under either No Fault or No Significant Fault.

(y) The Agency does not agree that the doctrine of estoppel is applicable to proceedings of this nature but argues that even if the doctrine did apply, the Respondent cannot rely on the statements of Dr. Mary Scollay, HIWU's Chief of Science, to assert that the Agency should be estopped from pursuing these charges. At no point did Dr. Scollay say that Hemo 15 is a vitamin, or an otherwise approved substance, and Dr. Shell never sought clarification or asked any questions about whether Hemo 15 was a Banned Substance. The Claimant submits that at most, Dr. Shell chose to hear what he wanted to hear rather than what Dr. Scollay said, and did not take any steps to verify his belief. In this regard, it is noteworthy that since the inception of the ADMC Program, Dr. Shell is the only Covered Person who has administered Hemo 15.

(z) Furthermore, the Agency submits that Dr. Shell's position misunderstands the law of estoppel. In the *lex sportiva*, the doctrine of estoppel "primarily prevents sports organizations from taking explicitly contradictory positions". The CAS has clearly stated that estoppel should have a more limited scope of application in disciplinary proceedings and matters involving regulatory interpretation, than in matters of contractual interpretation. The Agency argues that at no time have they taken a contradictory position regarding the application of the ADMC Program.

(aa) In response to the Respondent's post-hearing brief which expanded on his due process argument, the Agency submits that the arbitration hearing is not the proper forum in which to raise a due process challenge and that the substantive arguments made by Dr. Shell regarding due process, procedural entitlements and the constitution are misplaced in this limited jurisdiction forum.

(bb) Based on the above submissions, the Agency seeks the imposition of the following Consequences:

(i) A period of ineligibility equating to two (2) years for Dr. Shell as a Covered Person for each ADRV, beginning on the date of the published decision, with any credit afforded for any Provisional Suspension served in the interim;
(ii) A fine of USD $25,000 for each ADRV committed;
(iii) Payment of some or all of the adjudication costs;
(iv) Any other remedies which the learned Arbitrator considers just and appropriate in the circumstances.

6.3 ***Dr. Shell's Contentions***

The Respondent's position may be summarized as follows:

1. Dr. Shell maintains that he is wholly innocent as Hemo-15 is not a Banned Substance and is fully compliant with HISA Rule 4111. Moreover, as Hemo-15 is not listed on HIWU's Banned Substance list, Dr. Shell had no due process notice that the Hemo-15 would be deemed a Banned Substance, and to the extent that HIWU has classified it as such, and charged him for 228 prior administrations, it is a violation of Dr. Shell's due process rights and constitutes arbitrary and capricious rule making.

2. The sheer number of charged administrations alone demonstrates that Dr. Shell had no notice that Hemo-15 was a Banned Substance. After HIWU investigators located a bottle labelled "Hemo 15" in a veterinary truck operated by Dr. Shell's practice associate, Dr. Margaret Smyth, Melissa Stormer, the Investigative Analyst for HIWU ran a search query for Hemo 15 on the HISA Portal. That search showed that Dr. Shell had posted Hemo 15 entries from May 29, 2023 through to October 19, 2023 and documented 228 administrations of Hemo 15 to Covered Horses, clearly indicating that he made no effort to hide those administrations.

3. The Hemo 15 at issue in this case is not a Banned Substance and Dr. Shell's expert witness, Dr. Joseph Bertone has confirmed that assertion.

4. Dr. Mary Scollay, HIWU's Chief of Science, gave a presentation at Mahoning Valley Race Track, that was attended by Dr. Shell, wherein Dr. Scollay advised veterinarians that vitamins, like Hemo 15, are not subject to FDA approval and therefore do not need FDA approval under the HISA rules.

5. Dr. Shell detrimentally relied on Dr. Scollay's statement in his practice and continued to provide Hemo 15 to his equine patients, therefore he is faultless and HIWU should be estopped from bringing charges.

6. The charge of 228 administrations reflects a vendetta against Dr. Shell, which seeks to destroy the career of a well-respected veterinarian. The penalties being sought by HIWU are draconian and amount to a life time ban for Dr. Shell.

7. Dr. Shell carried out his due diligence, studied the rules, and did not see Hemo 15 listed as a Banned Substance on the HISA Banned Substances list. Dr. Shell had no notice that he could be charged for Hemo 15.

8. Dr. Bertone, a well-respected expert, gave testimony that Hemo 15 is not a Banned Substance, but rather a vitamin supplement. Furthermore, Dr. Shell was entitled to rely on the guidance given by Dr. Scollay regarding vitamins in light of the fact that Hemo 15 is a vitamin supplement.

9. Dr. Shell is faultless or possesses such a minimal degree of fault, that the penalties should be expunged or reduced to a warning and/or a very small fine.

10. HIWU has not satisfied its burden to demonstrate that Hemo 15 is a Banned Substance or that Dr. Shell has committed a violation of the ADMC Program rules.

11. Hemo 15 has been around for years. A cursory review of the internet shows that Hemo 15 is available for purchase across veterinary medication websites and advertised for use in horses. It has been administered to horses for decades and is literally everywhere according to Dr. Bertone.

12. Hemo 15 is not specifically listed on the HIWU Banned Substances list. Hemo 15 meets the standards of the FDA and is lawful to sell and use. Hemo 15 is a vitamin that is most typically provided to older horses that struggle to eat, or horses that are anemic. As a vitamin or nutritional supplement, Hemo 15 does not require FDA approval because according to Dr. Bertone, the FDA generally does not approve vitamins at all. Vitamins are not used to diagnose or treat any medical condition, they are used instead because they are beneficial to overall well-being.

13. In the expert opinion of Dr. Bertone, as a vitamin, Hemo 15 is fully compliant with FDA GFI #256, which permits compounding and makes no distinction between orally administered or parenterally administered substances.

14. Due process dictates that an individual be provided with advance notice of conduct that a regulatory body deems improper. Here, there is nothing in HIWU's published list of Banned Substances that would give a reasonably prudent veterinarian notice that he/she should be concerned about administering Hemo 15. In addition, HIWU charging Dr. Shell for administration of Banned Substances based on the nutrient

combination, Hemo 15, violates his Fifth Amendment due process right to notice of the prohibited behavior to be penalized.

15. Due process has been recognized by the Court of Arbitration for Sport as the right to be heard, to be given a fair hearing and the opportunity to present one's case. In order for the hearing to be fair, Dr. Shell was required to have notice that Hemo 15 was a Banned Substance and then he could be charged for administration of this vitamin supplement, but no such notice was given in the Rules. Since Hemo 15 is arguably not even a Banned Substance, any effort to charge Dr. Shell with administration of Hemo 15 as a Banned Substance is a violation of due process.

16. HIWU had every opportunity to list Hemo 15 as a Banned Substance if it wanted to, but it intentionally chose not to do so and gave no notice that it was a punishable offence to administer Hemo 15.

17. The notion of a reminder notice sent to all Ohio Covered Horsemen that Hemo 15 was a Banned Substance is untrue, disingenuous and misleading as no previous notice was ever given to any Ohio horseman or to Dr. Shell that Hemo-15 was a Banned Substance. This further demonstrates that there was no notice prior to the administrations that are being charged in this case.

18. HIWU should be estopped from bringing charges since Dr. Scollay in her presentation at Mahoning Valley Racetrack explicitly told Dr. Shell and other veterinarians that vitamins are not subject to FDA approval and therefore, they do not need to have FDA approval in order to avoid being classified as a Banned Substance.

19. If Dr. Shell is unable to persuade the tribunal that Hemo 15 is not a Banned Substance, he has established by a preponderance of the evidence that he bears No Fault for the alleged violations and thus the draconian penalties being sought by HIWU should be eliminated or reduced.

20. Even if he had used the utmost caution, Dr. Shell could not have reasonably known or suspected that he committed an Anti-Doping Rule Violation, as Hemo 15 is not on the Banned Substance List. Dr. Shell takes his veterinary practice seriously, he reads all the HISA Rules, regularly read bulletins or material put out by HISA or HIWU, and attended Dr. Scollay's conference to ensure that he was in compliance with the rules. There was no rule or guidance that would have alerted Dr. Shell to the fact that he was doing anything wrong by administering Hemo 15 and that is why he did not seek to hide his 228 administrations.

21. It is submitted that Dr. Shell easily meets the standard for No Significant Fault or Negligence, when viewed in the totality of the circumstances. Hemo 15 has long been used on horses as a vitamin supplement, and Dr. Shell cannot be faulted for believing that he was administering legal vitamin supplements for the well-being of the horses. This coupled with Dr. Scollay's statement about vitamins, would have led any reasonable veterinarian to believe that he was legally and properly administering a vitamin supplement

and there were no set of circumstances that would have led him to discover or even believe that he was committing an ADMC violation.

22. A violation should not be found, but if so found, there should also be a finding of No Fault or No Significant Fault, and Dr. Shell should only receive, at most, a warning and/or a small fine.

VII. TESTIMONY OF WITNESSES AND EXPERTS

7.1 The following is a summary of the testimony of the witnesses called in the present arbitration:

For Claimant:

Melissa Stormer

Ms. Stormer is an Investigative Analyst with HIWU. She testified that pursuant to Rule 2251 (b) of the ADMC Program, there is a requirement that every Veterinarian who treats a Covered Horse submit the following records in electronic format to the HISA Portal within 24 hours of examination or treatment:

(1) The identity of the Horse treated;
(2) The name of the Trainer of the Horse;
(3) The name of the Veterinarian;
(4) Contact information for the Veterinarian (phone, email address);
(5) Any information concerning the presence of unsoundnesss and responses to diagnostic tests;
(6) Diagnosis;
(7) Condition treated;
(8) Any medication, drug, substance, or procedure administered or prescribed, including date and time of administration, dose, route of administration (including structure treated if local administration), frequency, and duration (where applicable) of treatment;
(9) Any non-surgical procedure performed (including but not limited to diagnostic tests, imaging, and shockwave treatment) including the structures examined/treated and the date and time of the procedure;
(10) Any surgical procedure performed including the date and time of the procedure; and
(11) Any other information necessary to maintain and improve the health and welfare of the Horse.

Ms. Stormer added that Covered Persons are issued a user login, a unique number. The information is entered into the HISA Portal. Ms. Stormer observed that there are thousands of Covered Horses and hundreds of Covered Persons for whom records have been uploaded

since the inception of the ADMC Program. She added that as a matter of expediency, it is impractical for HIWU or HISA to review every entry made into the HISA Portal.

Ms. Stormer testified that after the investigation conducted at Mahoning Valley Race Track on October 5, 2023 and the discovery of the bottle of Hemo 15, she was asked by her supervisor, Shaun Richards, Director of Intelligence and Strategy for HIWU, to execute a query of the HISA Portal for "Hemo 15" entries. She ran a search query beginning with a start date of May 22, 2023 which was the first day of the enactment of the ADMC Program.

The search revealed that from May 28, 2023 through to October 19, 2023, Dr. Shell had documented 228 administrations of Hemo 15 to Covered Horses. On January 1, 2024 Ms. Stormer summarized a list of administrations of Hemo 15 by Dr. Shell to Covered Horses by creating a tracking sheet, (the "Hemo 15 Tracking Sheet"). The Hemo 15 Tracking Sheet identified thirty-seven (37) Covered Horses where Dr. Shell was listed as the treating veterinarian for the administration of Hemo 15 on at least one occasion.

Dr. Mary Scollay

Dr. Scollay is the Chief of Science for HIWU. As Chief of Science, she oversees HIWU's Science Department, including education efforts surrounding the Anti-Doping and Medication Control ("ADMC") Program. In that capacity Dr. Scollay made on site visits to 30 race tracks across the country. Her colleague, Dr. Patty Marquis also made a similar one hour presentation at a number of race tracks.

One of the presentations made by Dr. Scollay took place at Mahoning Racetrack, where Dr. Shell was in attendance. Dr. Scollay testified that for each of the seminars that she conducted prior to the implementation of the ADMC Program, she always used the same slide decks and would only change the title page to reflect the correct date and location of the presentation. The seminar that she provided at Will Rogers Downs was video recorded and posted on the Thoroughbred Racing Association of Oklahoma Facebook page.

Dr. Scollay testified that her presentations were not meant to constitute comprehensive training for veterinarians on the new program and were not intended to be the sole source of information relating to FDA products and compounding. Slide 51 of her presentation showed substances that fall under the S0 category. Where there was historical use, the veterinarians needed to get it out of their trucks. She mentioned in her presentation that some substances are approved in other countries, but not in the United States. Dr. Scollay testified that compounded substances cannot have FDA approval adding that there is an exception when compliant with the Animal Medicinal Drug Use Clarification Act and the FDA Guidance for Industry #256.

Dr. Scollay acknowledged that vitamins do not require FDA approval. She maintained however that Hemo 15 is not a vitamin and denied ever saying that it was or intimating that it was. She stated that Hemo 15 is a compounded product that contains some vitamins as well as other minerals and ingredients and is not approved for use in the United States. Dr. Scollay added that Hemo 15 is not specifically named in the prohibited list of

substances. She also noted that Hemo 15 is not approved for veterinary or human use and is not recognized by any Federal authority for veterinary or human use. She stated that compounded products require a medically justifiable use and suffering or death will not result if an animal was not given Hemo 15.

Dr. Scollay confirmed that she has not had any conversations with anyone who has used Hemo 15. She stated that she has always made herself as accessible as possible to Covered Persons to deal with any of their questions or concerns and does this at the end of each presentation. Dr. Scollay testified that Dr. Shell never called her to ask about the categorization of Hemo 15.

Dr. Scollay reviewed the documentation from the Pennsylvania laboratory and commented that the cobalt detected in the sample was a concern and the nicotinamide was also significant in that it is potentially a metabolite of a B vitamin. Dr. Scollay observed that there has never been a case of documented disease or death as a result of Cobalt deficiency. She opined that race horses shouldn't be anemic. If a horse were to become anemic, her approach would be to diagnose the cause of the anemia and address the cause.

On cross-examination she confirmed that there are more than 1400 substances on the Banned Substances list, but the words HEMO 15 do not appear on the list. To her knowledge there has been no discussion about placing HEMO 15 on the banned substances list. Dr. Scollay also testified on cross-examination that cobalt is a trace mineral and the amount of cobalt found in the sample was not quantified.

Dr. Scollay also testified that she did not think it was appropriate to give a prescription drug designed for one horse to another horse, adding that an oral medication dispensed to a specific patient should not be then put on a label for a different horse. Dr. Scollay also stated that in order to pass the bar for AMDUCA, "suffering or death will result." HISA regulations specifically mention AMDUCA.

Dr. Scollay reiterated the statement in her affidavit in which she discussed in the educational seminars other issues relevant to this case, including: (i) that the labelling of vitamin products can render some vitamins non-approved animal drugs requiring FDA approval, (ii) that Covered Persons need to review the labels of the products they are using, and (iii) that drugs approved in other countries are not necessarily approved in HISA jurisdictions.

Dr. Scollay emphasized in her testimony that it's the claim on the label that she was most concerned about. In her educational seminars, she mentioned the issue of vitamins and FDA approval and pointed out that if the labeling on the product has a drug claim, if the labeling says it cures, it treats, it prevents, it mitigates a specific disease condition, or it very specifically affects the structure or function of a system in the body, that's a drug claim.

Dr. Scollay observed that the label of the Hemo 15 that was seized from Dr. Shell clearly reads in fine print: "This is a compounded drug. Not an FDA approved or indexed drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian".

Dr. Scollay stated that the fact that Hemo 15 has been around for decades or that it is still used does not make it any less of a Banned Substance. As Chief of Science for HIWU she attested to her belief that HIWU's charges for violations of the ADMC Program are not the result of a vendetta against Dr. Shell but are the result of the administration of the ADMC Program.

With regard to the reminder notice issued to Covered Persons on December 20, 2023, Dr. Scollay confirmed that the reason and timing of the reminder issued to Covered Persons was a direct result of the administration of Hemo 15 by Dr. Shell. She added that the reason for the publication of the reminder arose from concerns that Dr. Shell, as a Veterinarian, may have misled Covered Persons, including Trainers and Owners, to think that the use of Hemo 15 was permitted when it clearly is not.

Dr. Scott Shell

Dr. Shell has been a practicing veterinarian for 37 years. He had never been sanctioned or suspended prior to 2023. He testified that he works six days a week, 12 to 14 hours a day. His business is an LLC and he has two other veterinarians in his practice, Dr. Hippie and Dr. Smyth. They share the workload. He and Dr. Smyth tend to focus on the horse track while Dr. Hippie focuses on the farm calls. They have an ambulatory service in which they go to see the horses. The practice is concentrated in north east Ohio, in a primarily rural area.

Dr. Shell testified that when he heard about HISA and the changes it was bringing about, he went to seminars, reviewed emails from HIWU and did everything that he could to ensure that he was following the rules. He recalled attending a presentation from Dr. Scollay at the Mahoning track. He had a big concern about the banned substances that he had heard about. The horses that he treated on the various farms were not Covered Horses.

Dr. Shell testified that after the meeting, he spoke to Dr. Scollay and asked about the banned substances that he had on his truck for Non-Covered horses. It was his recollection that Dr. Scollay advised him that he did not have to unload and reload his truck.

Dr. Shell stated that he regularly reviewed the HISA update emails which would come in day and night. He added that he researched the banned substances list. Dr. Shell recalled a day in September, 2023, when he was doing his rounds at the first barn that he was scheduled to visit. As he was walking out, he saw two SUVs blocking his truck. HIWU agents were waiting to examine the truck. When the HIWU investigators found some banned substances he told them that he had gotten the okay from Dr. Scollay. He was later charged with a violation of the ADMC rules and was suspended following a provisional hearing.

Dr. Shell testified about a return visit by HIWU investigators that took place in October, 2023 when his truck was once again examined, leading to the discovery of the Hemo 15. That discovery resulted in charges that were brought against Dr. Shell in January, 2024. Dr. Shell also recalled that in December, 2023, Dr. Scollay came to examine his truck along with the HIWU investigators.

Dr. Shell stated that he believes HIWU has a vendetta against him and are directly attacking him because of his testimony in the Vanmeter case which resulted in that individual being cleared of the charges.

Dr. Shell recounted his belief that Hemo 15 is a vitamin that he and his colleagues had used without question because of their belief that it was a vitamin and "vitamins don't count". He testified that he had been using Hemo 15 as a vitamin supplement for three decades. He stated that he would have stopped using Hemo 15 had he been contacted and told that Hemo 15 is considered a banned substance. He believes that there was no intention to levy any charges relating to Hemo 15 until after the seizure from his truck.

Dr. Shell added that he has never claimed that Hemo 15 has a medical use. He identifies horses that would benefit from the use of Hemo 15. He then calls the compounder, in this case "Horse Necessities" and they compound it and send it out for the horse in question. Dr. Shell observed that he applies Hemo 15 to all his horses, Clydesdales, race horses and even mules. He added that he has not experienced a bad reaction or death from the use of Hemo 15 in the 30 years that he has been using the product and deemed it to be a good product.

Dr. Shell maintained that prior to being charged he was not put on notice that Hemo 15 was a banned substance even after checking the banned substance list periodically. He observed that he made no attempt to conceal the 228 times that he administered Hemo 15 and questioned why anyone would repeatedly report something that they thought was a banned substance.

Dr. Shell believes that he was one of the first veterinarians to register on the HISA site and noted that several friends of his who were also veterinarians were hesitant to register and waited before they signed up. He testified that he was aware that HISA can review the entries in the portal. He now understands the "catch all" rule but still maintains that Hemo 15 does not fall into the category of substances that are dealt with in rules 4111 to 4117.

Dr. Shell stated that he was caught completely by surprise when he saw Dr. Scollay's reminder notice and it made him question what she was talking about as well as the timing of the message.

Dr. Shell testified that he has used several different compounders over the years, the most recent being Horse Necessities. When he first started to order Hemo 15, he did his due diligence in understanding what substances were compounded in the Hemo 15. He can't say today what those components are without contacting Horse Necessities. His head technician is the one who now calls Horse Necessities to place the orders.

Dr. Shell was confident that the Hemo 15 that was used in his practice was compounded in the United States and was satisfied that the compounding pharmacy would have notified him if there was a change in the composition or ingredients of Hemo 15. Dr. Shell admitted that he has never googled Hemo 15, nor has he ever read any news articles about Hemo 15.

Dr. Shell testified that he understood his obligations to stay abreast of the rules. He recalled attending the presentation given by Dr. Scollay at Mahoning Valley Race Track as well as watching the You Tube presentation that was given at Will Rogers Downs. He confirmed his understanding that non-approved substances are prohibited from use and that administering a banned substance is prohibited under the ADMC program.

When questioned about the label on the Hemo 15 bottle that was seized, which stated "this is a compounded drug. Not an FDA approved or indexed drug", Dr. Shell replied that Horse Necessities was responsible for the labelling on the product. Dr. Shell confirmed that no workup was conducted to determine which horses had a vitamin deficiency and that none of the 37 horses that received the Hemo 15 injections were ever at risk of death or suffering if they did not receive Hemo 15. Dr. Shell also stated that he would order Hemo 15 for one horse such as "Mo Don't No" and use it for other horses as well.

Dr. Shell confirmed that Dr. Scollay never said that Hemo 15 was a vitamin. When questioned as to how it was determined that 37 horses would receive the Hemo 15 administration, Dr. Shell replied that it was a trainer by trainer determination as to who gets the Hemo 15.

Expert Witnesses

Dr. Lara Maxwell

Dr. Maxwell is an expert witness called by HIWU. She is a Doctor of Veterinary Medicine, a Diplomate of the American College of Veterinary Clinical Pharmacology and is a Professor of Pharmacology at the Oklahoma State University's College of Veterinary Medicine. Dr. Maxwell was called by the Claimant as an expert witness to provide an independent expert opinion on Veterinarian pharmacology, FDA rules, and the classification of Hemo 15 as a Banned Substance under the ADMC Program.

Dr. Maxwell testified that Hemo 15 is the trade name applied to the injective pharmaceutical substance. It was approved in Canada, Australia and Italy, but its approval was later withdrawn by Canada and Australia. It is an unapproved animal drug in the U.S.

Dr. Maxwell stated that Hemo 15 meets the definition of a drug. She referenced a number of websites that listed Hemo 15 for sale and remarked that some of the claims associated with the product on those websites raised obvious red flags.

Dr. Maxwell opined that Hemo 15 did not meet any of the criteria of Rule 4111. She stated that iron deficiencies in horses are rare and to her knowledge there has never been a cobalt deficiency recorded in horses. Dr. Maxwell concluded that Hemo 15 meets the requirement

to be labeled as an S0 Non-Approved Substance. She confirmed that AMDUCA is the act that allows veterinarians to use drugs, but observed that Hemo 15 is not compliant with AMDUCA. Dr. Maxwell stated that there is no approved version of Hemo 15 in the U.S. and an animal's health must be in jeopardy in order for it to be used by a veterinarian in extra labeled drug use where compounding has occurred.

Dr. Maxwell noted that GFI #256 is the guidance for industry given by the FDA. It allows for compounding. One use is patient specific, the other is compounding for office stock. Patient specific compounding is for use with a specific patient. It was Dr. Maxwell's opinion that office stock drugs are required when there is a rapid need for the veterinarian to be able to access the drug, for example, when a horse who was sick and needed the medication right away. In those circumstances, office stock could be administered immediately to the patient without a prescription.

Dr. Maxwell testified that prescriptions should be specific to one patient and one patient's prescription should not be shared with another patient. She believes that Dr. Shell's testimony about sharing a prescription for one horse with other horses would be contrary to the Veterinary Practice Act. More specifically, Dr. Shell was following a practice wherein he was using a patient specific prescription when in fact he was breaking it apart from that bottle and using it for whichever patient he wanted to apply it to as if it were office stock. In Dr. Maxwell's opinion such office stock compounding for Hemo 15 is not permitted.

Dr. Maxwell disagreed with Dr. Bertone's characterization that Hemo 15 is a vitamin, not a drug. She maintains that even if it contains vitamins, it can still be considered a drug and it doesn't matter whether the drug contains vitamins or not. It's the FDA definition that matters according to Dr. Maxwell.

In her second report, Dr. Maxwell outlines several steps that Dr. Shell could have taken to better inform himself on the status of Hemo 15. Those steps include:

a. Proceeding cautiously after noticing that "Hemo-15" is not registered or approved as a U.S. product.
b. Noting that Hemo-15® is a foreign drug product that therefore cannot be legally imported into the U.S. without specific permissions.
c. Observing that "Hemo-15" products have been repeatedly in the news for European racing violations, which should have suggested extreme caution in using such products on the racetrack.
d. Perceiving that the websites that sell "Hemo-15" appear to be disreputable for the purpose of U.S. sales of pharmaceuticals.
e. Seeking written clarification from Dr. Scollay and HISA as to whether "Hemo-15" is a Banned Substance.

Dr. Maxwell added that that even a simple google search would have provided Dr. Shell with important information.

Dr. Maxwell was questioned about the lab report and admitted that she did not know what the specific protocol for those laboratories were or what the specific percentage of the substances collected were. She added that a foreign animal drug compound in any amount would be prohibited in any event.

Dr. Joseph Bertone

Dr. Bertone received his Doctor of Veterinary Medicine from the New York State College of Veterinary Medicine, Cornell University. He was a professor of equine medicine at the College of Veterinary Medicine, Western University of Health Sciences from 2003 to 2022, and also served as Adjunct Professor at California Polytechnic Institute from 2003 to 2010 in addition to numerous other teaching positions. Dr. Bertone has served as a Veterinary Medical Officer at the Food and Drug Administration ("FDA") where he completed an FDA Fellowship in Pharmacology. He has been seated on multiple American Association of Equine Practitioner committees and has received numerous awards and distinctions in the field of Veterinary Medicine.

Dr. Bertone reviewed the Expert Report of Dr. Lara Maxwell, dated April 5, 2024 and determined that her conclusion that Compounded Hemo 15 is a Banned Substance under Rule 4111 is incorrect because Hemo 15 does not meet the criteria of a prohibited substance under Rule 4111. In his report Dr. Bertone concluded that Hemo 15 meets the standards of the FDA and is lawful to sell and use.

Dr. Bertone testified that it's much easier to say Hemo 15 than to list a number of supplements. In his view the distinction between vitamin and drug boils down to the claims being made by the substance. He understands that Hemo 15 makes no medical claim. Dr. Bertone opined that in Europe horses are a food animal and he believes that in Canada horses are considered to be food as well.

Dr. Bertone stated that Dr. Shell was completely compliant with FDA regulations in his use of compounds. He observed that a pharmacy can only distribute a substance if there is an animal's name on it, but that you could literally purchase gallons of a substance as long as it had an animal's name on the purchase order.

Dr. Bertone testified that GFI means "guidance for industry", that it's not a law, it's what they would like you to do. He maintained that it was perfectly proper for Dr. Shell to put the name of a horse on the prescription even if he intended to use it for more than one horse.

Dr. Bertone stated that Hemo 15 is not on the banned list and with regard to the discovery of cobalt in the lab results, we don't know if the cobalt was cobalt salt or what the levels were. He opined that most drinking water and even distilled water has cobalt in it.

Dr. Bertone remarked that a lot of things that are administered to horses don't have a drug approval. He also commented that it was 40 years between the Food and Drug Act, and the enactment of AMDUCA. He believes that AMDUCA contains "pie in the sky

recommendations", adding that AMDUCA does not apply in the present case, because Hemo 15 is not a drug. In Dr. Bertone's opinion, the FDA will never bother to deal with Hemo 15 because Hemo 15 does not make a claim to be a drug and in any event, the FDA gives very low priority to anything that involves horses.

For Dr. Bertone the key element to consider is that Hemo 15 was never marketed with a claim, and there is no disclaimer needed because there is no claim.

Dr. Bertone published a book on equine pharmacology in 2000. He stated that he was not aware of any other published books on equine pharmacology and was not aware of the book on equine pharmacology authored by Dr. Maxwell and others in 2014. Although Dr. Bertone mentioned in his expert report that he had conducted a simple search of the internet, he did not keep a list of sites that he had researched.

When questioned about the appearance of the word "drug" on the label of the Hemo 15 bottle seized from Dr. Shell, Dr. Bertone described the labelling as "a mistake" which is only a standard statement. Dr. Bertone concluded his testimony by stating that as far as he is concerned, the Hemo 15 used in this case is legal. The constituent ingredients are all legal according to Dr. Bertone.

Dr. Joshua Sharlin

Dr. Sharlin received a B.S. degree in zoology from the University of Iowa, an M.S. degree in physiology from the University of Maryland, and a Ph.D. in physiology from the University of Georgia. He worked as a United States Food and Drug Administration reviewer and as a consultant to FDA-regulated industries for nearly 30 years. While at the FDA from 1992-1994, Dr. Sharlin worked as a primary reviewer and a statistical reviewer at the Center for Veterinary Medicine ("CVM") examining New Animal Drug Applications ("**NADA**").

It was Dr. Sharlin's conclusion that Hemo 15 is not an FDA Approved Drug. He disagrees with the assertions of Dr. Bertone that Hemo 15 is merely a vitamin, and submits that Hemo 15 should be understood as an unapproved animal drug.

Dr. Sharlin points to a number of factors in arriving at his conclusion, including the label on the bottle of Hemo 15 seized from Dr. Shell's practice, which states "…this is a compounded drug. Not an FDA approved or indexed drug". Dr. Sharlin testified that based on his experience, language is very important, noting that "when the FDA uses the term drug, that's exactly what they mean, 'drug'". Dr. Sharlin was concerned about attempts to do an end run around the FDA by merely saying "there is no claim therefore it's not a drug".

Dr. Sharlin also points to the analytical testing results for the Hemo 15 bottle (RT-31) which show that RT-31 includes 12 ingredients, only some of which are vitamins, which have been compounded into a solution.

Dr. Sharlin disagrees with Dr. Bertone's assertion that Hemo 15 is compliant with GFI #256, and opines instead that Hemo 15 does not qualify for enforcement discretion under GFI #256 as is clearly supported by the FDA's guidance on the same. On the assumption that Dr. Shell administered Hemo 15 compounded for office stock, Dr. Sharlin states that the only question to consider is whether Hemo 15 is on the "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals".

After consulting the link for the "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals", Dr. Sharlin found that neither Hemo 15 nor any of its constituent elements are on that list. He concludes therefore that Hemo 15 fails to qualify for enforcement discretion as specified in GFI #256 and is a misbranded drug, the introduction of which is a prohibited act if being introduced into interstate commerce.

VIII. ANALYSIS

8.1 While all evidence and legal authorities submitted were considered by the Arbitrator, this section necessarily refers only to the evidence and law that the Arbitrator relied upon in reaching this Final Decision.

8.2 Pursuant to Rule 3121, the burden of proof is on the Agency to establish that a violation of the ADMC Program has occurred to the comfortable satisfaction of the Panel. This standard of proof is higher than a balance of probabilities but lower than clear and convincing evidence or proof beyond a reasonable doubt.

8.3 In this case it is undisputed that Dr. Shell administered Hemo 15 to thirty-seven (37) different Covered Horses between May 29, 2023 and October 19, 2023 for a total of two hundred and twenty-eight (228) independent Administrations. The first issue to be determined is whether the Hemo 15 was a Banned Substance.

Is Hemo 15 a Category S0 Non-Approved Substance or a Vitamin?

8.4 Dr. Shell asserts that Hemo 15 is a short hand for a group of nutrients, a widely used vitamin supplement that he has incorporated into his veterinary practice for over thirty years. He argues that the nutrient combination was known to HISA founders when they promulgated the ADMC program and they could have easily listed Hemo 15 on the list of banned substances had they been so inclined.

8.5 Dr. Shell's expert witness, Dr. Bertone testified that Hemo 15 does not fall under Rule 4111 or under Rules 4112 to 4117. Dr. Shell insists that Hemo 15 is a vitamin, it is not a drug and therefore not subject to FDA compliance. He has argued that AMDUCA is irrelevant if Hemo 15 is not a drug. He maintains that there should be no distinction between intravenous administration of Hemo 15 and other administrations of the substance. Dr. Shell has argued that Hemo 15 was not considered to be a drug until six months after

the Agency discovered his legal administration of the substance and it was at that point that they sought to reclassify it as a banned substance.

8.6 Rule 4111 provides that:

> Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI)#256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

8.7 Dr. Lara Maxwell explained why Hemo 15 is an S0 Non-Approved Substance. None of Rules 4112 to 4117 specifically address Hemo 15, which is a foreign pharmaceutical product that is not otherwise approved for use in the United States. Hemo 15 is not approved by governmental regulatory health authorities. Hemo-15® has never been approved by the FDA. There is no FDA approved product that contains all the ingredients found in Hemo-15® by any other name. Hemo 15 also meets the third requirement of Rule 4111, in that it is not universally recognized by veterinary regulatory authorities as having a valid veterinary use.

8.8 Dr. Maxwell commented on the risk to benefit ratio concept in veterinary therapeutics where the risk of harm posed by a therapeutic agent must be balanced against the benefit that the treatment can provide. She opined that given the risk to benefit ratio for compounding a complex, sterile mixture that features trace minerals that are already sufficient in adequate equine diets, the veterinary use of such products in horses is wholly inappropriate. The Arbitrator agrees with Dr. Maxwell's conclusion that Hemo 15 is also not saved by the "avoidance of doubt" provision in Rule 4111 because it is not otherwise compliant with AMDUCA or the GFI #256.

8.9 In support of Dr. Shell, Dr. Bertone opines that Hemo 15 is a vitamin and therefore does not require FDA approval. However, Dr. Maxwell in her reply report contradicts that opinion by stating that Hemo 15 is an unapproved animal drug for the following reasons:

> (a) There is no dietary supplement regulatory classification for animal food substances and products – they are either considered "foods" or "new animal drugs", depending on their intended use. Hemo 15 is not a dietary product or food and should therefore be understood as a drug. Since Hemo 15 is not FDA approved, it would be classified as an unapproved drug.
>
> (b) Foreign Hemo-15® products are registered as pharmaceutical agents with standard drug labels, with similar elements to an

> FDA-approved drug label. These foreign products also meet the FDA definition of a drug, which is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals…"
>
> (c) The FDA has directly expressed concerns about the use of injectable vitamins, including their classification of such products as unapproved animal drugs.

8.10 The Arbitrator accepts Dr. Maxwell's and Dr. Sharlin's testimony that there is no form of Hemo 15 compounded for office stock that would comply with GFI #256 and given the volume of Hemo 15 that was administered by Dr. Shell, it is highly unlikely that the Hemo 15 was compounded for each horse or administration in issue. The Arbitrator also accepts Dr. Maxwell's opinion that Hemo 15 is not a medically appropriate treatment for healthy racehorses and is not a necessary alternative to treat any trace mineral deficiencies a horse might have. Thus Hemo 15 is not the type of discretionary compounding that GFI #256 was intended to permit.

8.11 Dr. Shell's repeated declarations notwithstanding, there is overwhelming evidence that Hemo 15 is not a vitamin but is in fact an unapproved drug. It is properly categorized as an S0 Non-approved Substance.

Did Dr. Scollay misrepresent the status of Hemo 15 to Dr. Shell?

8.12 Dr. Shell has asserted that Dr. Scollay told him and other veterinarians that vitamins do not require FDA approval and that this occurred during a HIWU educational seminar prior to the implementation of the ADMC Program at Mahoning Racetrack. Dr. Scollay gave evidence that she has never advised any Covered Person that Hemo 15 is a vitamin, because it is not. She added that in all the seminars that she has conducted, she has been consistent with her messaging and has used substantively identical lecture slides to guide her discussion.

8.13 One example that Dr. Scollay highlighted occurred at the 31:00 minute mark of the Will Rogers Downs video where she discussed that foreign approved products without FDA approval are not permitted under the ADMC Program:

> The last category, substances that are approved for use in other countries but don't have approval in this country. You get lucky you get a really good horse and you're going to send them overseas to win the Epsom Derby. Okay, that horse needs treatment over there, make sure you bring home the money, and the horse but leave the drugs behind. Because if they are approved in another country, that does – they do not have approval here, they don't have FDA approval here, and bringing them back to the racetrack represents risk for you.

8.14 Dr. Scollay reviewed her records and confirmed that she never received any queries from Dr. Shell or his practice about Hemo 15. She adds that as a reasonable and prudent veterinarian, she would have expected Dr. Shell to make such inquiries if he was unsure of the status of Hemo 15 under the ADMC Program.

8.15 At minute 35:00 of the Will Rogers Downs video, Dr. Scollay discussed the issue of vitamins and FDA approval. She said the following:

> Okay. Important note here because there have been a few people saying vitamins don't have FDA approval, so they must be banned substances, and that's simply not the case. The FDA does not approve vitamins they don't regulate. So, if the FDA doesn't give them the ability to have FDA approval, HISA can't require them to be FDA approved. Alright, so your veterinarian can carry vitamins, administer vitamins, you can have vitamins in the barn. They don't have FDA approval, they're not going to have it, they don't need it.
>
> Now, there's one important exception to all of that, with respect to dietary supplements, vitamins, minerals, herbal preparations, that sort of thing. If the labeling on the product has a drug claim, if the labeling says it cures, it treats, it prevents, it mitigates a specific disease condition, or it very specifically affects the structure or function of a system in the body. That's a drug claim. And now, that bucket of vitamins and minerals meets the FDA's criteria for being a drug, and now it's an unapproved new animal drug. It doesn't have FDA approval, and it should and it is a banned substance.
>
> So I urge you to become label readers. Because if the vitamin mineral supplement says that it cures OCD, if it says it prevents tying up, if it says it stops bleeding, those are drug claims, and that is now a banned substance.

8.16 If that guidance wasn't sufficient, Dr. Scollay issued a further warning at minute 37:00 of the Will Rogers Downs video about the problems that could arise for Covered Persons related to the labelling placed on these substances by manufacturers.

> All right. Now what I think is going to happen is that the manufacturers of these products are going to re-label everything with legitimate FDA approved claims. They can have claims for general health benefits, supports lung function, supports a healthy immune system, supports bone health. But if they can start making claims about epiphysitis, about OCD, right, those are very specific disease conditions and those claims make that product a drug. So please look at what you've got in your barn, so that you don't get caught in the

> blind switch with the bandsaw, because of what a manufacturer has created a problem for you.

8.17 There is no evidence whatsoever that Dr. Scollay misled Dr. Shell. The examples cited above demonstrate Dr. Scollay's clear and direct guidance to Covered Persons as the new program was about to roll out. On cross-examination, Dr. Shell admitted that Dr. Scollay never said that Hemo 15 was a vitamin. Dr. Shell heard what he wanted to hear. Dr. Scollay stated after each of her presentations that she could be contacted if there were any questions or if any clarification was required. Dr. Shell did not take advantage of that invitation.

Is The Doctrine of Estoppel Applicable?

8.18 Dr. Shell has argued that the Agency should be estopped from bringing the charges against him, based on statements made by Dr. Scollay and based on the fact that Hemo 15 is not specifically listed on the Banned Substances List. Both arguments must fail. As stated above, there was no misrepresentation by Dr. Scollay regarding the categorization of Hemo 15. At no time did the Agency take a contradictory position regarding the application of the ADMC program. It was Dr. Shell's insistence that Hemo 15 is a vitamin that resulted in the eventual laying of these charges by HIWU. Dr. Shell had many opportunities to verify that he was not contravening the new regulations by continuing to use Hemo 15 on Covered Horses, yet he failed to do so.

8.19 Secondly, as stated above, there was no requirement in the ADMC Program, nor in the established *lex sportiva* that a Banned Substance be explicitly named on the Banned Substances List. The reasons why Hemo 15 is a Banned Substance have been well set out. There is no evidence of any induced errors or attempts by HIWU representatives to obfuscate the status of Hemo 15 so that Dr. Shell unwittingly continued to administer this substance without fear of sanction. In fact, on the evidence given by Melissa Stormer, between May 22, 2023, which was the first day of the enactment of the ADMC Program, and May 16, 2024, the day on which she conducted her most recent search of the HISA Portal, no administrations for Hemo 15, other than Dr. Shell's have occurred. There was only one veterinarian who continued to consistently, and at high volume, administer Hemo 15 to Covered Horses after the enactment of the ADMC Program. That veterinarian was Dr. Shell.

Were Dr. Shell's Due Process Rights Violated?

8.20 Dr. Shell seeks dismissal of HIWU's charges or elimination of all penalties, arguing that the rules as applied, "violate Dr. Shell's Fifth Amendment due process right to notice of the prohibited behavior, and absent a rule understandable by Covered Persons of ordinary intelligence, the rules and charges constitute arbitrary and capricious decision/rule making".

8.21 Dr. Shell's argument can be summarily dismissed for two reasons. Firstly, as has been stated by other Arbitrators dealing with similar constitutional arguments, this

arbitration hearing is not the proper forum in which to raise this type of challenge. Any argument that Dr. Shell's Fifth Amendment due process rights were violated should be taken to a forum that has the jurisdiction to consider such an argument. This constitutional challenge is one that is not properly before this Arbitrator and will therefore not be considered.

8.22 Furthermore, Dr. Shell's argument that the rule under which he has been charged could not be understood by Covered Persons of ordinary intelligence and is arbitrary and capricious, is contradicted by the fact that in the period of almost one year between May 22, 2023 and May 16, 2024, no other veterinarian has been charged with the administration of Hemo 15.

Is Dr. Shell Entitled to a Reduction of Consequences?

8.23 I have determined that Hemo 15 is a Banned Substance and that this Banned Substance was administered by Dr. Shell to thirty-seven (37) Covered Horses on two-hundred and twenty-eight (228) occasions between May 29, 2023 and October 19, 2023. The question to be determined now is whether the otherwise applicable Consequences should be reduced after an assessment of Dr. Shell's degree of fault.

No Fault or Negligence

8.24 No Fault or Negligence is a defined term under the ADMC Program and sets a high standard for a Covered Person to meet:

> No Fault or Negligence means the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation.

8.25 In order to establish No Fault Covered Persons must establish that despite the exercise of the utmost caution, they could not have reasonably known or suspected that they were committing an ADRV. The WADC contains a commentary that underlines the standard that has to be met in order to meet this threshold.

> [A reduction of sanctions due to no fault or negligence] will only apply in exceptional circumstances, for example, where an Athlete could prove that, despite all due care, he or she was sabotaged by a competitor.

It's well established therefore that No Fault is reserved for the most exceptional circumstances.

No Significant Fault or Negligence

8.26 ADMC Program Rule 3225 alternatively allows for the reduction of sanction where there is a finding of No Significant Fault or Negligence:

> Reductions under this Rule 3225 are mutually exclusive and not cumulative, i.e., no more than one of them may be applied in a particular case.
>
> (a) General Rule
>
> Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then…the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault.

8.27 The ADMC Program defines No Significant Fault or Negligence as:

> the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence.

8.28 The Arbitrator makes reference once again to the definition of Fault in the ADMC Program:

> Fault means any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include (but are not limited to) the Covered Person's experience and special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person, and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk….In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault.

Term of Ineligibility and Other Sanctions

8.29 Dr. Shell administered Hemo 15, a Banned Substance, to a Covered Horse two hundred and twenty-eight (228) times. The Arbitrator has determined that an Anti-Doping

Rule Violation occurred when Hemo 15 was administered to a Covered Horse. HIWU is seeking the same sanction for each of the 228 violations pursuant to ADMC Program Rules 3221, 3222, and 3223, including but not limited to: a fine of $25,000; a period of two years of Ineligibility for Dr. Shell and payment of some or all of the adjudication costs.

8.30 The Arbitrator will deal with the first ADRV, before addressing the remaining 227 violations. With regard to this initial violation which was confirmed by the initial entry into the HISA Portal on May 29, 2023, the Arbitrator finds that Dr. Shell demonstrated significant fault for the following reasons:

(a) He had the same access to HIWU educational seminars and resources as other Covered Persons. He attended at least one HIWU seminar conducted by Dr. Scollay and viewed the You Tube video made from the Will Rogers Downs seminar.

(b) He did not ask Dr. Scollay any questions about whether Hemo 15 was a vitamin outside of FDA regulation or whether it could be considered a Banned Substance.

(c) He did not contact anyone else at HIWU or HISA to verify whether he would be in compliance with the new regulations if he continued to administer Hemo 15.

(d) He paid little or no notice to the label on the Hemo 15 bottle which led to the investigation of his administrations. (RT-31) clearly stated that "this is a compounded drug. Not an FDA approved or indexed drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(e) He failed to conduct internet research which might have alerted him to the concerns or red flags about Hemo 15.

8.31 For these reasons the Arbitrator determines that Dr. Shell will be subject to a period of Ineligibility equating to two (2) years for the first ADRV, beginning on the date of the published decision, with credit afforded for any Provisional Suspension served in the interim. On the facts of this case the Arbitrator has determined that Dr. Shell should pay the maximum fine of $25,000.00 to HIWU by the end of his period of Ineligibility. Dr. Shell is also required to make a contribution of $10,000 towards the adjudication costs.

8.32 HIWU has asked the Arbitrator to impose significant consequences for each of the two hundred and twenty-eight ADRVs. It was earlier determined that since there was more than one Administration, and since multiple Covered Horses were involved, the Agency did not have the discretion to treat multiple violations for the same Banned Substance as a single violation. Were the Arbitrator to impose such a sanction it would not be an accurate reflection of the unique circumstances of this case and would be disproportionate and excessive.

8.33 The Arbitrator also has concerns that Dr. Shell's self-reporting of his use of Hemo 15 was received and not actioned upon by HIWU for almost six months. No explanation

was given for this delay except to point out that HISA was receiving thousands of entries into its portal. Dr. Shell was at fault for not recognizing that Hemo 15 was a Banned Substance, but it is understandable that his continued administration of the substance after his initial reporting without warning or consequence, would have given him some satisfaction that he was not breaking any rules. The Arbitrator has carefully considered the definition of Fault that appears in the ADMC Program Rule 1020, and has come to the conclusion that for the remaining 227 Anti-Doping Rule Violations, Dr. Shell is not at Fault.

8.34 It is understood that No Fault applies only in the most extreme and exceptional circumstances. The exceptional circumstances that the Arbitrator relies on are as follows:

(a) Dr. Shell continued to report his administration of Hemo 15 after his initial filing to the HISA Portal on May 29, 2023.

(b) This occurred during the early administration of the program but it should not have taken HISA almost six months to recognize that a Banned Substance was being administered by a veterinarian who was complying with his obligations to file the requisite reports into the HISA portal.

(c) At that point, HISA apparently did not have a system in place for early detection of Banned Substances that were being reported.

(d) There is no indication that Dr. Shell intended to cheat.

(e) Dr. Shell was sincere in his belief that he was using a legal substance even though he was sincerely wrong in that belief.

(f) Dr. Shell 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.

IX. AWARD

9.1 On the basis of the foregoing facts, legal analysis, and conclusions of fact, the Arbitrator renders the following decision:

(a) Dr. Shell is found to have committed two hundred and twenty-eight Rule 3223 Anti-Doping Rule Violations. For the first ADRV he is not eligible for any period of reduction. He will serve a period of Ineligibility of two (2) years beginning on the date of the published decision, with credit afforded for any Provisional Suspension served in the interim.

(b) Dr. Shell shall pay a fine of $25,000.

(c) Dr. Shell shall be required to pay a contribution of $10,000 toward the adjudication costs in this matter.

(d) For the remaining 227 Anti-Doping Rule Violations, Dr. Shell bears no Fault or Negligence for these violations and no period of Ineligibility or other Consequences shall be imposed on him;

This Decision shall be in full and final resolution of all claims and counterclaims submitted to this arbitration. All claims not expressly granted herein and hereby denied.

IT IS SO ORDERED AND AWARDED.

Dated: June 11, 2024

Hugh L. Fraser

Hon. Hugh L. Fraser, O.C.
Arbitrator