#### UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES FTC DOCKET NO. \_\_\_\_

#### **ADMINISTRATIVE LAW JUDGE:**

IN THE MATTER OF: DR. SCOTT SHELL, DVM

RESPONDENT

#### APPLICATION FOR REVIEW OF FINAL CIVIL SANCTION

#### **CERTIFICATE OF SERVICE**

Pursuant to 16 CFR §1.146(a) and 16 CFR §4.4(b), a copy of this Application for Review

of Civil Sanction is being served this 18th day of October, 2024, via first-class mail and/or

electronic mail upon the following:

Office of the Secretary Federal Trade Commission 600 Pennsylvania Avenue NW, Suite CC-5610 Washington, DC 20580

Hon. D. Michael Chappell Chief Administrative Law Judge Office of Administrative Law Judges Federal Trade Commission 600 Pennsylvania Ave. NW Washington DC 20580 (Copies to <u>Oalj@ftc.gov</u> and <u>electronicfilings@ftc.gov</u>)

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> <u>/s/ Michelle C. Pujals</u> Horseracing Integrity & Welfare Unit General Counsel

Pursuant to 15 U.S.C. §3051 et seq., 5 U.S.C. §556 et seq., and 16 C.F.R. §1.145 et seq., the Horseracing Integrity & Welfare Unit ("**HIWU**") as the "aggrieved person" appeals the decision of Arbitrator Barbara Reeves ("**Arbitrator**") in JAMS Case No. 1501000653 ("**Decision**", **Exhibit A**), which ordered a final civil sanction inclusive of a 21-month period of Ineligibility and payment of a \$20,000 fine on Dr. Scott Shell ("**Shell**"). By a Notice of Sanctions dated September 20, 2024, HIWU notified Shell that it was imposing the sanction.

HIWU requests *de novo* review of the Decision on the basis that the Arbitrator erroneously: (i) ordered that the period of Ineligibility imposed on Shell should run concurrently with a sanction that he is serving for Administration of the Banned Substance Hemo 15 ("Administration Case", **Exhibit B**); and (ii) treated four Anti-Doping Rule Violations ("ADRVs") as one act of Possession, subject to a single Fault analysis and sanction. As a result of these legal errors, the Arbitrator issued a Final Decision that is arbitrary, capricious, an abuse of discretion, prejudicial, and not in accordance with law (15 U.S.C. §3058(b)(2)(A)(iii) and 16 C.F.R. §§1.146(b)(3)).

<u>First</u>, the Arbitrator contravened the ADMC Program Rules ("**Rules**") by ordering that Shell's period of Ineligibility for Possession run concurrently with a sanction he is serving for Administration. Rule 3223(c)(2) provides that where, as here, "a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility <u>shall</u> start to run the day after the original period of Ineligibility ends." (emphasis added)

HIWU raised this breach of the Rules in its request to modify the Decision (Exhibit C). However, the Arbitrator refused to revise the sanction on the basis that: (i) HIWU's request was not a computational error within the scope of Rule 7380; and (ii) HIWU had not previously raised or briefed the application of Rule 3223(c)(2) (Exhibit D). The Arbitrator's analysis is incorrect as Rule 3223(c)(2) is mandatory, not discretionary. On appeal, the Decision is subject to *de novo* review and

the correct Rule must be applied to determine the start date of Shell's period of Ineligibility for Possession.<sup>1</sup> Allowing this misapplication of law to stand would be patently prejudicial to other Covered Persons consecutively serving multiple periods of Ineligibility in compliance with Rule 3223(c)(2).

Second, by treating Possession of four *different* Banned Substances as one ADRV, the Arbitrator erroneously engaged in one Fault analysis for four Banned Substances and imposed one sanction. HIWU notified Shell that he was found in Possession of four Banned Substances via two Notice Letters (**Exhibits F and G**), wherein HIWU sought *separate* Consequences for Possession of *each* Banned Substance. Rule 1020 defines "Possession" as "actual, physical possession or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited Substance [...].") The use of the word "Substance" is singular and illustrates that each unjustified Possession of a different Banned "Substance" is a violation.

Below Appellant asserted an alleged "compelling justification" for Possession of each Banned Substance under Rule 3214. Invoking the Arbitrator's decision in *HIWU v. Luis Jorge Perez* ("*Perez*", **Exhibit H**), HIWU argued that "compelling justification" is a fact-specific, caseby-case inquiry that must be determined on the evidence for *each* Banned Substance (Decision, ¶6.39-6.70). The Fault analysis that follows from Rules 3224 and 3225 also requires a substancespecific analysis for *each* ADRV. This approach was summarized by HIWU in its closing submissions ("**Analysis Table**", **Exhibit I**).

<sup>&</sup>lt;sup>1</sup> The Arbitrator was aware of the Administration Case, having asked for comments on its application to this proceeding (**Exhibit E**). HIWU requests that the ALJ take judicial notice of the Administration Case sanction, which was posted on <u>HIWU's website</u> on June 18, 2024.

After the hearing, the Arbitrator requested that the Parties provide any authorities on the application of Rule 3228(d) as a basis for charging separate ADRVs for each Banned Substance in issue. The Arbitrator also asked the Parties how the Administration Case affected the present proceeding (**Exhibit E** above).

In response, HIWU:

- (a) Pointed to the definition of Possession, *Perez*, Rules 3224 and 3225, and its Analysis Table to reiterate that each Banned Substance should be analyzed as a separate ADRV, irrespective of whether Rule 3228(d) applied; and
- (b) Distinguished the reasoning in the Administration Case, which has no application to this proceeding. In the Administration Case, Shell administered the *same* Banned Substance 228 times for one reason: his "sincerely wrong" belief that Hemo 15 was not a Banned Substance. On these unique facts, Arbitrator Fraser concluded that Shell bore No Fault for 227 of his 228 Administrations. In the present case, not only was Shell charged with Possessing four *different* Banned Substances, but his reasons for being in Possession of each substance also varied, and a single explanation cannot apply with equal weight to each substance ("HIWU Response", Exhibit J).

In the Decision, the Arbitrator disregarded HIWU's Response, holding that Rule 3228(d) did not apply and HIWU could not "shift theories" after the record closed (Decision, ¶7.6-7.13, 7.67-7.70). She further held that Rule 3223(c)(2) could not be relied on to support consecutive sanctions for the Possession violations (Decision, ¶7.71-7.74). The Arbitrator then proceeded to: (i) consider Shell's substantive defense, concluding that he failed to establish a compelling justification for any of the Banned Substances (Decision, ¶7.14-7.36); and (ii) apply a global Fault analysis to all four instances of Possession, concluding that Shell's objective level of Fault fell in

the Significant Fault range, but he should receive a three-month reduction due to subjective Fault factors (Decision, ¶7.42-7.60).

The Arbitrator's Decision is therefore arbitrary, capricious, prejudicial, and not in accordance with the law by:

- (a) Disregarding Rule 3223(c)(2) and ordering the period of Ineligibility for Possession to run concurrently with the Administration sanction; and
- (b) Erroneously assessing Shell's "compelling justification" for four ADRVs as one act of Possession.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 18th day of October, 2024.

#### /s/ Michelle C. Pujals

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#### HORSERACING INTEGRITY & WELFARE UNIT, A DIVISION OF DRUG FREE SPORT LLC

# EXHIBIT A

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S**

# ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000653

In the Matter of the Arbitration Between:

#### HORSE RACING INTEGRITY & WELFARE UNIT ("HIWU" or "Claimant"),

Claimant

v.

#### SHELL Dr., Scott ("Dr. Shell" or "Respondent"),

Respondent

#### 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 in Cleveland, Ohio, on April 23 – 25, 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 possession of four banned substances at a racetrack by a veterinarian who treats thoroughbred racehorses and non-racehorses.

1.2 The Respondent, Veterinarian Scott Shell ("Dr. Shell" or "Respondent"), has been charged with four separate Anti-Doping Rule Violations ("ADRVs") for Possession of Banned Substances in breach of Rule 3214(a) (the Possession Rule") of the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Program (Protocol) ("ADMC Program").

1.3 On September 28, 2023, Dr. Shell was found in possession of two jars of Carolina Gold/GABA, one tub of Isoxsuprine powder, two boxes of Bisphosphonate ("Osphos"), and one bottle of Sarapin ("Pitcher Plant"), at Thistledown Racetrack in Ohio.

1.4 Claimant Horseracing Integrity Welfare Unit ("HIWU" or "Claimant" or "the Agency"), 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 Ferrell, Senior Litigation Counsel of HIWU, and James Bunting, Esq., Alexandria Matic, Esq., and Carlos Lopez, Esq., of Tyr, LLP, of Toronto, Ontario, Canada.

1.5 Dr. Scott is a veterinarian who provided veterinary services for Thoroughbred racehorses and non-racehorses at Thistledown Racetrack, as well as veterinary services for farm horses in Ohio and West Virginia. Dr. Scott was represented in these proceedings by Andrew Mollica, Esq., based in Garden City, New York.

1.6 Pursuant to ADMC Rule 7060(a), on December 19, 2023, Samuel Reinhardt, Assistant General Counsel, HISA, gave notice that the Horseracing Integrity and Safety Authority, Inc. ("HISA") was exercising its right to participate as an observer in this proceeding.

1.7 Throughout this Final Decision, HIWU and Dr. Scott 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 Decision only to the submissions and evidence the Arbitrator considers necessary to explain her reasoning. Except as noted, the facts are generally not in dispute, though the legal effect of those facts might be.

2.2 Dr. Shell is a veterinarian licensed to practice veterinary medicine in the States of Ohio and West Virginia. Dr. Shell's veterinary and Racing Board licenses are in good standing. Dr. Shell is a Covered Person under Rule 3020(a)(3).

2.3 Dr. Shell practices veterinary medicine under the corporate name, Scott Shell DVM Inc., which includes associates, Dr. Barbara Hippie, Dr. Maggie Smyth, and Janet Duhon, who was responsible for placing orders for medicine (the "Practice")

2.4 Dr. Shell has no prior HISA violations. Prior to HISA coming into effect, he had no violations at Thistledown, and he had not been sanctioned by the Ohio Racing Commission or the Veterinary Board.

2.5 On September 28, 2023, HIWU Investigators Edward Arriola and Richard Thomas conducted searches of Dr. Shell's office at Thistledown, and his Veterinarian Truck, Ohio Tag Number PIZ-4892, as well as the Practice's veterinary truck operated by Dr. Hippie, Ohio Tag Number PDY-9013, and registered to Scott Shell DVM Inc.

- 2.6 The following Banned Substances were some of the evidence that was recovered:
  - <u>One tub of Isoxsuprine powder</u>. One tub of Isoxsuprine powder was recovered from Dr. Shell's Veterinarian Truck. A prescription label from Dr. Shell's Practice is affixed to the tub, prescribing a dose of <sup>1</sup>/<sub>4</sub> <sup>1</sup>/<sub>2</sub> scoop twice daily. The tub is not prescribed to any specific horse and no Owner is identified on the label. Isoxsuprine is a vasodilator that lacks FDA approval. It is identified as a Category S0 Banned Substance on the Prohibited List.
  - <u>Two bottles of "Carolina Gold" (GABA).</u>

Two 100 mL bottles of a substance labeled as "Carolina Gold" were recovered from Dr. Shell's Veterinarian Truck, Ohio Tag Number PIZ-4892. The prescription labels on both bottles indicate that they were prescribed by Dr. Shell to "Snazzy Horse." Snazzy is a Covered Horse (H- 000-050-099), currently stabled at Thistledown whose Attending Veterinarian on file with HISA is Dr. Shell. Carolina Gold contains GABA, as indicated on the labels affixed to both bottles, which is a neurotransmitter. GABA, or Gamma Aminobutyric Acid, is identified as a Category S0 Banned Substance on the Prohibited List.

- <u>Two boxes of Osphos (Bisphosphonate).</u> Two boxes of Osphos, a bisphosphonate, were recovered from Dr. Shell's office on the backside at Thistledown. The two boxes of Osphos were located on a shelf inside Dr. Shell's office space and were not prescribed to any specific horse. Bisphosphonates are identified as a Category S6 Banned Substance pursuant to ADMC Program Rule 4117(a).
- <u>One bottle of Sarapin.</u> One bottle of Sarapin ("Pitcher Plant"), in the truck of Dr. Hippie, a colleague who works in Dr. Shell's practice, and which truck was owned by and registered to Scott Shell DVM Inc. Sarapin (Pitcher Plant) is identified as a Category S6 Banned Substance pursuant to ADMC Program Rule 4117(e).

2.7 Dr. Shell admitted to the possession of Carolina Gold, Osphos, and Isoxsuprine, but initially denied the possession of the Pitcher Plant inasmuch as it had been found in Dr. Hippie's truck. Dr. Shell then modified his position to not dispute possession of Pitcher Plant because Dr. Hippie used it for her farm practice, and if Dr. Hippie is part of his practice for charging possession, she is also part of his practice for the defense that the Pitcher Plant was only used for her farm practice.

2.8 Dr. Hippie immediately informed HIWU Investigator, Richard Thomas, that she used the Pitcher Plant for farm calls. According to Investigator Thomas, Dr. Hippie told him that Dr. Shell does not handle farm calls. Dr. Hippie testified at the Provisional Hearing that Dr. Shell also performs farm calls. Dr. Shell asserts that he engages in a farm practice. Dr. Hippie is part of the Practice. 2.9 On October 5, 2023, the Agency served Dr. Shell with an EAD Notice Letter pursuant to ADMC Program Rule 3245, informing him that he had been found in Possession of numerous Banned Substances and that this may result in an ADRV. A Provisional Suspension was imposed on October 5, 2023, effective immediately pursuant to Rule 3247(a)(3).

2.10 Dr. Shell admitted that he was in Possession of Carolina Gold, which was labeled and prescribed to "Snazzy" (a Thoroughbred racehorse stabled in Ohio), to distribute to Thoroughbred racehorse trainers in West Virginia. Carolina Gold is a Banned Substance. Carolina Gold is also banned at racetracks in West Virginia under the West Virginia Racing Commission Rules, and it is not a substance that veterinarians need for a farm practice.

2.11 Dr. Shell produced a limited selection of records from his veterinary practice. The records that he produced show that since the enactment of the ADMC Program, Dr. Shell has provided the Banned Substances Carolina Gold, Isoxsuprine, and Pitcher Plant to ten trainers who were located at the time in West Virginia. The records showed that the Banned Substances were dispensed on a volume basis, multiple vials and dosages at a time to a trainer, usually labelled "Farm use," or "herd prescriptions." Many of these records are from after the date of the investigation, after September 28, 2023. "Herd" prescriptions are FDA compliant.

2.12 Many of Dr. Shell's billing records show that he dispensed Carolina Gold to trainers in West Virginia, under the generic Patient Name "Farm Use", without identifying which horses the Carolina Gold was intended for or administered to. Carolina Gold was dispensed to each of the following trainers in West Virginia: Tim Collins, Chris Logston, Greg Eidshun, Dennis Van Meter, Shannon Simpson, and Annette McCoy, all labeled for "Farm Use".

2.13 Dr. Shell dispensed Carolina Gold to Resvalon, a Thoroughbred, which raced in Covered jurisdictions, both before and after the dispensation. Dr. Shell testified to a document referencing the dispensing of Carolina Gold/GABA for Trainer Ginger Demczyk's horse "Banks Turbo" on November 14, 2023, a date after the search and investigation.

2.14 At present, West Virginia is not a covered jurisdiction under HIWU's regulation, due to a federal court injunction that suspended HIWU's operations there, pending an appeal.

2.15 Under the HISA Rules, Covered Horse "means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse undersection 3054(1), during the period: (A) beginning on the date of the horse's first Timed and Reported Workout at a Racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b)." 15 USC 3051(4).

2.16 The Parties dispute whether a Thoroughbred racehorse that races in jurisdictions subject to HIWU regulation, a "Covered Horse," is still a Covered Horse when it steps onto West Virginia soil. The definition of "Covered Horse" makes no reference to a horse's geographic location, which is understandable because it was promulgated in the context of a nationwide fifty-state regulation. Further, a Covered Horse remains a Covered Horse until "the date on which the horse is deemed retired pursuant to Rule 3050(b)."

2.17 The Isoxsuprine seized from Dr. Shell's truck was found without a prescription label or any other information indicating how it was to be used in Dr. Shell's practice. At the Hearing, Dr. Shell testified that he intended to use the seized Isoxsuprine to treat Cool Stance, a Thoroughbred racehorse in West Virginia. However, the only records documenting the dispensation of Isoxsuprine to identified horses are to Cool Stance, (October 13, 2023), and an old pony, AP Pony, January 2, 2024, also in West Virginia. These records are post-search and investigation.

2.18 Dr. Shell states that the Osphos seized was in his Possession to treat navicular disease in non-Covered Horses. Dr. Shell produced only one documented record evidencing that he directly dispensed Osphos to a non-Covered Horse, "Hornet," which occurred in November 2023, post-search and investigation.

2.19 Pitcher Plant/Sarapin is a non-FDA approved medication, with no approved analytical method, and is also banned at West Virginia racetracks. The records show that Dr. Shell dispensed Pitcher Plant to the following Thoroughbred racehorse trainers in West Virginia via herd prescriptions: Eddie Clouston, Greg Eidshun, Gary Welsh, Juan Gotera, Dennis Van Meter, Crystal Richison, Nestor Casacalleres, Alexis Corderro-Lopez, Mark Tomczak, and Juan Silva, all labeled for "Farm Use."

2.20 The only specific records identifying horses showed that Dr. Shell dispensed Pitcher Plant to Trainer Juan Gotera's horse "Venezuelan Dreamer" on September 15, 2023, in West Virginia. "Venezuelan Dreamer," a Thoroughbred racehorse in West Virginia, raced in a Covered jurisdiction 10 days later.

2.21 There is only one record documenting dispensing of Sarapin/Pitcher Plant, to a farm horse prior to September 28, 2023. This was by Dr. Hippie to a farm horse named "Jack Attack" on June 21, 2023. The only other record of dispensing Pitcher Plant, to "Adrian Es Bonita," is from November 2023.

2.22 Dr. Shell produced testimony that he had long treated the farm horse Cat, a non-Covered horse in Ohio, for various ailments, and he offered this as justification for the possession of Osphos in his truck at Thistledown. However, all documented dispensations of Osphos to Cat are by Dr. Hippie. Osphos was prescribed to Cat in April 2023, and was injected at that time. Dr. Shell did not produce any records showing that he possessed the confiscated Osphos for Cat specifically. Records also showed that on June 13 and August 16, 2023, Isoxsuprine Powder was prescribed to Cat. Cat's owner testified that Cat has been taking Isoxsuprine on a daily basis. However, there was no showing that the confiscated Isoxsuprine in the truck at Thistledown was also intended for Cat, and Dr. Shell did not so testify.

2.23 On March 24, 2023, HIWU's Chief of Science, Dr. Mary Scollay, conducted a seminar on the ADMC Program, its rules and regulations, and the expectations for Covered Persons. During her presentation, Dr. Scollay made the following comments:

"... [I]f the veterinarians are practicing also on a population of [N]on-Covered Horses, they're taking care of quarter horses or they've got a country practice part- time they are able to possess a Banned Substance because we don't have control over those horses, and so to the extent that they want to use bisphosphonates on a Non-Covered Horse, we can't ban them from possessing them...[W]e can't penalize people for something that we don't have control over so, you know, let's just say because we have the ability to investigate, if the story starts to get a little weird or a little extreme, you're going to get more than a raised eyebrow. But at the end of the day if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses . . . [T]he regulation addresses if there is a justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses."

2.24 Dr. Scollay provided similar advice in an email dated June 16, 2023, to the Randall Equine Vet Group:

"HISA Rule 3124. Other Anti-Doping Rule Violations involving Banned Substances or Banned Methods. The following acts and omissions constitute an Anti-Doping Rule Violations by the Covered person(s) in question: (a) possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession.

The regulation above provides for the ability to justify the possession of Banned Substances. To the extent that your practice provides veterinary care to non-covered horses—and can demonstrate (through records, day sheets, etc.) the need to carry those substances you can establish compelling justification."

#### **III. PROCEDURAL HISTORY**

3.1 On October 5, 2023, the Agency served Dr. Shell with an EAD Notice Letter pursuant to ADMC Program Rule 3245, informing him that he had been found in Possession of numerous Banned Substances and that this may result in an ADRV. A Provisional Suspension was imposed on October 5, 2023, against Dr. Shell, effective immediately pursuant to Rule 3247(a)(3).

3.2 Dr. Shell requested a Provisional Hearing pursuant to Rule 3247(b)(1), seeking to have the Provisional Suspension lifted pending final adjudication of the ADRV after a hearing on the merits. The Provisional Hearing was scheduled for October 26, 2023.

3.3 On October 25, 2023, Dr. Shell was served by the Agency with an EAD Charge of Anti-Doping Rule Violations ("Charge Letter"). The Charge Letter constituted formal notice of charges issued for three separate ADRVs resulting from the Banned Substances found in Dr. Shell's Possession. The Charge Letter also advised Dr. Shell that the Agency would be seeking: (i) a period of Ineligibility of six (6) years (two years per violation) beginning on October 5, 2023, (ii) a fine of USD \$75,000 (\$25,000 per violation), (iii) payment of some or all of the adjudication costs and HIWU's legal costs, (iv) public disclosure in accordance with Rule 3231,

and (v) all other Consequences which may be required by the Protocol or its supporting rules and documents.

3.4 On October 26, 2023, the Provisional Hearing was conducted. Both Dr. Shell and Dr. Hippie sought to have their suspensions lifted, pending a decision on the merits. In advance of the Provisional Hearing, Dr. Shell submitted veterinary records, to demonstrate his practice currently and/or recently treats or treated Non-Covered horses, and maintained a Non-Covered horse practice.

3.5 On October 30, 2026, Hearing Officer Armand Leone issued his decision, refusing to lift Dr. Shell's Provisional Suspension. In his decision on the Provisional Hearing, Arbitrator Leone Arbitrator denied Dr. Shell's defense of compelling justification for the purposes of the Provisional Hearing.

3.6 Dr. Hippie was also charged for possession, but Arbitrator Leone lifted Dr. Hippie's suspension because, inter-alia, "Dr. Hippie has shown a reasonable likelihood of success in meeting the burden of proof to demonstrate No Significant Fault or Negligence under Rule 3225 because, inter-alia, she had no role in the ordering of medications, in office operations, or in storage of medications at any office. Dr. Hippie mostly had a farm horse practice for non-Covered Horses, and she appeared to have relied on Dr. Shell on compliance with the rules."

3.7 On November 8, 2023, HIWU initiated this arbitration against Dr. Shell.

3.8 On November 10, 2023, JAMS Issued a Notice of Commencement of Arbitration. The Notice of Commencement confirmed the appointment of the arbitrator, Barbara A. Reeves, Esq., to assume carriage of this matter, and that the arbitration would be conducted in accordance with the ADMC Program Rule Series 7000 (Arbitration Procedures).

3.9 On December 4, 2023, the Agency served Dr. Shell with a further EAD Notice Letter pursuant to ADMC Program Rule 3245 (the "Pitcher Plant Notice"). The Pitcher Plant Notice informs Dr. Shell that he has been found in Possession of Pitcher Plant, a Banned Substance, and that this may result in an additional ADRV. The Pitcher Plant Notice also informs Dr. Shell that he has until December 11, 2023 to provide an explanation for the additional alleged ADRV.

3.10 Pursuant to the HIWU Anti-Doping Medication Control Program Rules 7290 (Arbitration Procedures) a preliminary hearing was held by Zoom on December 5, 2023 before sole arbitrator Barbara Reeves.

3.11 Appearing at the hearing on behalf of HIWU was James Bunting, Esq. and Allison Farrell, Esq., and appearing on behalf of Dr. Scott was Andrew Mollica, Esq. (individually, HIWU and Dr. Scott shall be referred to herein as "Party" and collectively as "Parties").

3.12 By agreement of the Parties, a schedule for the submission of briefs and exhibits, witness disclosures, additional pre-hearing submissions, and document production was established.

3.13 On December 7, 2023, HIWU submitted its Pre-Hearing Brief., Book of Evidence, and Book of Authorities.

3.14 On December 19, 2023, Dr. Shell submitted his Pre-Hearing Brief, and Exhibits. Dr. Shell submitted an Amended Pre-Hearing Brief and Exhibits on January 5, 2024.

3.15 The Hearing was scheduled for January 30 - 31, February 1, 2024, in person, in Cleveland, Ohio. At the joint request of the Parties, the Hearing was continued from January 30 – February 1, 2024, to April 23 – 25, 2024, to permit the Parties further time to produce documents and witness statements, including expert reports. The Parties' schedule for additional pre-hearing submissions was adjusted in light of the continued Hearing dates.

3.16 On January 8, 2024, HIWU filed a Request for Production of Documents, seeking documents supporting Dr. Shell's defense of compelling justification, along with a Redfern Schedule and Oral Compendium. Dr. Shell submitted his Response on January 11, 2024. The Arbitrator issued Document Production Order No. 1 on January 16, 2024.

3.17 Dr. Shell submitted Supplemental Disclosures, Exhibits, and Witness Statements on March 14, 2024.

3.18 HIWU submitted its Reply Brief, Reply Book of Authorities, and Reply Book of Evidence on March 29, 2024.

3.19 Dr. Shell submitted a Sur-Reply Brief, Index of Exhibits on April 5, 2024.

3.20 HIWU submitted additional Exhibits on April 23, 2024.

3.21 The evidentiary hearing proceeded on April 23-25, 2024, in person in Cleveland Ohio. At the conclusion of the evidentiary hearing, both parties confirmed that they had been given a full, fair, and equal opportunity to present their case, and the Arbitrator confirmed the closing of the evidence.

3.22 The following witnesses and experts testified at the Hearing: Dr. Mary Scollay, HIWU's Chief of Science; Dr. Dionne Benson, Chief Veterinary Officer of 1/ST Racing, who was tendered and accepted as an expert in veterinary practice; Dr. Dorrie Wallace, an Association Regulatory Veterinarian for Mahoning Valley Racecourse; Ms. Jenny Chen, Law Clerk for Tyr LLP; Dr. Scott Shell, Claimant; Ms. Janet Duhon, Dr. Shell's veterinary technician or assistant; Ms. Christine Shulman, owner of a cutting horse named Cat; Dr. Andrew Roberts, an equine clinical veterinarian, who was tendered and accepted as a veterinary expert, including in the field of country and racetrack practice. Exhibits were tendered and accepted.

3.23 The Parties submitted Closing Briefs on June 28, 2024. Closing Arguments were held on August 7, 2024. Following the Closings, counsel for all parties confirmed that they had submitted all evidence and briefing, and had nothing further to add.

3.24 The Arbitrator requested an extension of time to submit the Final Decision to September 3, 2024, and the Parties granted the request. On September 3, 2024, the Arbitrator submitted a Request for Further Authority regarding HIWU's reliance on Rule 3228(d), and notified that she was holding the Final Decision to allow time to receive and consider any such authority.

3.25 HIWU responded to the Request for Further Authority on September 4, and Dr. Shell responded on September 3 and September 5, 2024. The Arbitrator continued the suspension of the Final Decision to permit a Response from HIWU following Dr. Shell's September 5 submission. On September 9, 2024, the Arbitrator notified the Parties that not having received any further submissions, she was preparing to issue the Final Decision.

#### **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:

"(a) The Protocol applies to and is binding on:

...

(3) the following persons (each, a Covered Person): all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses."

4.2 Pursuant to section 3054 of the Act, "Covered Persons" must register with the Authority. However, they are bound by the Protocol by undertaking the activity (or activities) that make(s) them a Covered Person, whether or not they register with the Authority.

4.3 Dr. Shell is a veterinarian who is required to be and is registered with HISA. As such, the Respondent is a Covered Person who is bound by and subject to the ADMC Program.

4.4 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 7010. Applicability.

The Arbitration Procedures set forth in this Rule 7000 Series shall apply to all adjudications arising out of the Rule 3000 Series.

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."

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

"Rule 7060. Initiation by the Agency

(a) 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."

4.6 In this case, arbitration proceedings were commenced before JAMS, the designated arbitration provider. The Parties agreed that the Arbitrator would serve as the sole arbitrator in this proceeding.

4.7 No Party disputed jurisdiction here and all Parties fully participated in the proceedings without objection.

4.8 Accordingly, the Arbitrator finds that jurisdiction is proper here.

# V. RELEVANT LEGAL STANDARDS

5.1 Rule 3214(a) of the ADMC Program provides as follows:

"The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question: . . . Possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession."

5.2 Dr. Shell is a Covered Person under the ADMC Program. It is alleged and admitted that Dr. Shell was in possession of two jars of Carolina Gold/GABA, one tub of Isoxsuprine powder, two boxes of Bisphosphonate ("Osphos"), and one bottle of Sarapin ("Pitcher Plant"), each of which is a Banned Substance.

5.3 Under the ADMC Program, Possession is established by the act of purchasing a Banned Substance, where a Covered Person has exclusive control or intends to exercise exclusive control of the substance or the premises where the substance is located, or knew of the presence of the substance and intended to exercise control over it. Rule 1010 Definitions. The Parties do not dispute that Dr. Shell was in possession of the Banned Substances. Unless Dr. Shell had a compelling justification, Possession of the Banned Substances is a Violation

5.4 Pursuant to Rule 3121, the burden of proof is on the Claimant HIWU 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." Rule 3121. The burden of proof is on the Respondent to establish "compelling justification."

5.5 The World Anti-Doping Code ("WADC") provides the framework for a harmonious international anti-doping system and is widely used in international sports, and expressly acknowledged as the basis for the ADMC Program. Rule 3070 provides in pertinent part that:

"(b) 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. . . .

(d) The World Anti-Doping Code and related International Standards, procedures, documents, and practices (WADA Code Program), 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."

5.6 Pursuant to ADMC Program Rule 3223, the ineligibility, and financial penalties for a first anti- doping rule Violation of Rule 3214(a) (Possession) is:

a. Two years of Ineligibility, and

b. A Fine up to \$25,000 and Payment of some or all of the adjudication costs and the Agency's legal costs.

5.7 Where a Violation of the ADMC Program is established, the Respondent 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:

"[A]ny 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."

Rule 1010, Definitions

5.8 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)..."

5.9 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."

5.10 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."

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

"[t]he 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. The below is an effort to summarize their fundamental positions. To the extent necessary, the Arbitrator will address the various arguments that were made in the Analysis section below.

6.2 The Parties submitted hundreds of pages of briefing and exhibits in support of their contentions. As set forth below, those contentions focus on the following issue: did Dr. Shell have a compelling justification to be in possession of the four Banned Substances at Thistledown on September 28, 2023? If not, what are the appropriate Consequences? HIWU contends that Dr. Shell has not demonstrated a compelling justification; Dr. Shell contends that he did have a compelling justification because of his Non-Covered horse practice.

#### A. Dr. Shell's Contentions

6.3 The parties do not dispute Possession of the four Banned Substances. The focus of the contentions is on the compelling justification defense. Respondent Dr. Shell has the burden of proof on this issue, and thus his contentions are set forth first. Claimant HIWU retains the burden of proof on all other issues.

6.4 In addition to his racecourse practice, Dr. Shell had a Non-Covered practice, including both a farm practice in Ohio and a Non-Covered Thoroughbred practice in West Virginia.

6.5 Dr. Shell's office's Practice was a rural practice. Dr. Shell and his expert Dr. Roberts testified to the reality of a mobile veterinarian in a remote country practice, which treats hundreds of horses per day. Dr. Shell's records are not as complete as HIWU might like, because they are often made in the rain, in the dark, and while driving from farm to farm.

6.6 In accordance with the plain language of Rule 3214(a), HIWU's Chief of Science, Dr. Mary Scollay's official guidance, and the decision in *HIWU v. Perez*, Dr. Shell must prevail as he demonstrated through any type of vet records and testimony that he has a Non-Covered farm and West Virginia horse practice, and the need to "carry" the Banned Substances because he used and/or intended to use those Banned Substances on Non-Covered Horses, which constitutes compelling justification.

6.7 Veterinarian work performed in West Virginia is factually and legally a Non-Covered practice. This is because (a) there is currently an injunction prohibiting HIWU enforcement of HISA Rules in West Virginia, (b) HIWU/HISA does not operate in West Virginia, and (c) there are no HISA rules permitting HIWU to punish Dr. Shell, as opposed to a trainer, or declare Dr. Shell's work in West Virginia to be Covered.

6.8 As described below, the evidence in this case established that HIWU and HISA, through Dr. Scollay, gave explicit guidance that if veterinarians have a Non-Covered practice, they can establish compelling justification to possess ("carry") Banned Substances, through any type of record showing non-Covered practice, as HISA/HIWU does not have jurisdiction over medications that veterinarians use, prescribe, or "carry" for Non-Covered practice.

6.9 Dr. Scollay never advised anyone that compelling justification must be "predicated upon emergency situation" or "imminent treatment", she never set "time, limits, or parameters on what compelling justification means" and did not "say you had to be treating a non-covered horse on the track that day." There was no requirement that a Non-Covered horse's name be identified on a record to show use on Non-Covered horses.

6.10 Dr. Shell spoke directly to Dr. Scollay about "carrying Banned Substances on the track... [and she said] as long as you have a farm practice, and I do believe, she said, non-covered horses[,] you are allowed to carry the Banned Substances... [and] we don't have to unload our trucks and reload."

6.11 Although Dr. Scollay and Dr. Shell did not discuss West Virginia, that was not necessary, as there is no HISA enforcement in West Virginia.

6.12 HISA's Rules do not define "compelling justification." The Court of Arbitration for Sport's Definition is not controlling as it was developed in cases where athletes refused to submit to a doping test.

6.13 Neither Dr. Scollay nor HIWU ever stated that there was a conjunctive condition for compelling justification, i.e., that one had to have *both* a justification for possession the substances, *and* a Non-Covered practice, nor that an emergency was required. Rather, Dr. Scollay's statement was in response to a specific question about a farm practice. When Dr. Scollay said "and certainly a practice that incorporates Non-Covered horses" she was responding to a conference attendee's question specifically about farm horses and Non-Covered horses and then stated that a practice that incorporates Non-Covered horses "certainly" has compelling justification.

6.14 There are no Covered Horses in West Virginia, including Resvalon and Venezuelan Dreamer. As a veterinarian, not a trainer, there is no HISA Rule permitting HIWU to punish Dr. Shell in Ohio for West Virginia work. West Virginia practice is a non-Covered practice.

6.15 Herd prescriptions and use pursuant to herd prescriptions are allowed by the FDA.

6.16 Dr. Shell's produced records, while perhaps not as specific as HIWU would like, uncontestably demonstrate use and intended use of the charged Banned Substances on non-Covered horses (farm/West Virginia). Dr. Shell's testimony expanded on these records.

6.17 HIWU has argued Dr. Shell's "onus" to prove compelling justification is a "substantial height." This is incorrect. HIWU is relying on a CAS case, *Klain v. ASADA*, in which an athlete refused to take a drug test. That analysis is inapplicable here, where the "athlete"/Covered Person, Dr Shell, was attempting to comply with the official guidance given by HIWU.

6.18 There is no requirement of "substantial height" in the Rules: "Where the Protocol places the burden of proof on a Covered Person...the standard of proof shall be [a] preponderance of the evidence." Rule 3121(b)

6.19 Dr. Shell did his due diligence, studied the rules, attended presentations and he was entitled to rely on Dr. Scollay's educational statements. Dr. Shell had a violation-free practice for thirty-seven years and would not have carried the Banned Substances if Dr. Scollay did not say he could.

6.20 At minimum, Dr. Shell is faultless, and the draconian penalties/fines proposed by HIWU must be expunded or reduced to admonishment and/or a small fine.

6.21 Dr. Scollay and *Perez* state Dr. Shell had to provide "records" showing use of or intended use on Non-Covered horses. Compelling justification can be shown by any records showing Non-Covered use. There is no requirement to rule out use on every Covered horse Dr. Shell treated from the inception of HISA. Dr. Shell's burden is to show by a preponderance of the evidence, through any "records," that he used or intended to use the charged Banned Substances on Non-Covered horses, which he has done.

6.22 If a Covered Horse is driven from Ohio to West Virginia, treated in West Virginia, and driven back to Ohio, the trainer or owner is responsible, not the veterinarian. Dr. Shell did not move any horse to or from a HISA jurisdiction before/after providing legal treatment in West Virginia.

6.23 There are no veterinarian responsibility rules, only trainer responsibility rules, and there are no HISA rules allowing HIWU to punish vets like Dr. Shell for work done in West Virginia, or declare it Covered. To hold otherwise would be a due process violation of Dr. Shell's right to notice of the prohibited behavior and arbitrary and capricious rule/decision making.

6.24 Dr. Scollay admitted during testimony that "HISA is not currently operating in...[West Virginia]" and there "are non-covered races...no testing...no enforcement activities." Further, even without an injunction, absent a veterinarian Responsibility Rule, there are no HISA rules allowing HIWU to punish Dr. Shell or declare his West Virginia work Covered, even if HIWU were correct in its definition of a Covered Horse, i.e., that a Covered Horse remains a Covered Horse even when it is in West Virginia.

6.25 Dr. Roberts, Dr. Shell's expert in country and racetrack practice, testified that his understanding of Dr. Scollay's guidance is that if you treat Non-Covered horses and can demonstrate that, that you have met a burden of substantial justification that allows you to have these products for your practice. He confirmed that determination is on the totality of the records provided.

6.26 Dr. Scollay did not require any specific records, and she did not provide any clarification about the nature of the records, in her public statements. Dr. Scollay placed no conditions on the exception, only the need to "justify a non-covered practice."

6.27 During the Hearing, Dr. Scollay changed her statements and testified that compelling justification could be shown with "properly labeled [medication], prescribed for that specific horse with corresponding medical records documenting the prescription."

6.28 Dr. Shell is entitled to rely on Dr. Scollay's statements and HIWU is estopped from bringing charges. Dr. Shell proved estoppel: (1) Dr. Scollay made a clear representation of material fact that veterinarians with a Non-Covered practice have compelling justification as "[t]hey are able to possess a banned substances because we don't have control over those horses"; (2) Dr. Scollay gave official "education" so she knew veterinarians relied and would act on her representations; (3) Dr. Shell was unaware of any claimed true facts and reasonably and justifiably relied on Dr. Scollay's representation to his detriment, and would not have carried the Banned Substances if Dr. Scollay did not say he could.

6.29 In sum, as confirmed by Dr. Roberts, the records demonstrate use and/or intended use of the charged Banned Substance on non-Covered horses as required by Dr. Scollay's policy guidance and *Perez*. The records do not need to meet ex-post facto rules created by HIWU like emergencies, need for the next veterinarian to be able to treat, imminent use, rule out use on every covered horse, names of horses in herd use in Non-Covered practice. Dr. Roberts testified the records are "sufficient," even if "not great," to show compelling justification and additional records sought by Dr. Benson were unnecessary if they went to Covered horses.

6.30 Dr. Shell has compelling justification to possess the four charged Banned Substances because he proved that he used and intended to use these legal medications in a non-Covered horse practice, on a regular basis. Dr. Roberts testified the charged Banned Substance are something that you would want to have at your fingertips to prescribe on any given day, and that it is good veterinary practice to carry a few doses of these medications for use in rural areas.

6.31 Drs. Roberts and Shell testified concerning the rural geography of Dr. Shell's practice, that farms could be 100 miles away from each other, and the need to have the charged Banned Substances imminently is a substantial justification to "carry" as Dr. Shell has no way of knowing when he might be called upon to go to a farm to treat a horse. Dr. Roberts thus concluded that it is reasonable that those medications would be on Dr. Shells truck at any given time.

6.32 Dr. Shell used all the charged Banned Substances on a regular basis and should have access to these medications. Dr. Scollay told Dr. Shell he did not have to unload and reload his truck when he came to the racetrack.

6.33 Dr. Shell has established by a preponderance of evidence that he is faultless. Under Rule 3224, if Dr. Shell is faultless, "for the Anti- Doping Violation(s) charged," the penalties must be eliminated. "No Fault or Negligence" means " [Dr. Shell] did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he...otherwise committed an [ADR]." Rule 1010.

6.34 The definition of "Fault," requires the Arbitrator to consider "the degree of risk that should have been perceived by [Dr. Shell] and the level of care and investigation exercised by [Dr. Shell] in relation to what should have been the perceived level of risk." Dr. Shell exercised utmost caution, engaged in due diligence, attended a meeting, and could not have perceived any risk of an ADR. Upon the initiation of HISA, Dr. Shell read everything that they had put out, and attended a meeting at the Mahoning Valley racetrack. At the presentation, Dr. Scollay gave Dr. Shell all the guidelines and all the rules to follow. Even "exercising the utmost caution," Dr. Shell could not perceive any risk of committing a violation, because Dr. Scollay told him he was not.

6.35 The labels on Pitcher Plant and GABA bottles recovered by HIWU had the names of Covered horses Totally Obsessed and Snazzy Horse, respectively. This was an administrative

and ministerial error. Ms. Duhan, Dr. Shell's veterinarian technician or assistant, used those horses' names when ordering because they were names with which she was familiar.

6.36 There is no evidence in this case that Dr. Shell or anyone in his practice ever administered Carolina Gold or Sarapin to either Totally Obsessed or Snazzy Horse.

#### **B.** HIWU's Contentions

6.37 Dr. Shell is a Covered Person, and he was in Possession of Banned Substances in Ohio where he is clearly and unequivocally subject to the ADMC Program. Arguing that he is not subject to the Program when he is in West Virginia is entirely beside the point. He needs a compelling justification for possessing Banned Substances in Ohio. His explanation that he is flouting the ADMC Program by selling Banned Substances in West Virginia – where some of the same substances are also banned – does not justify his Possession in a Covered state.

6.38 As a Covered Person, Dr. Shell has an obligation to be knowledgeable of and comply with the ADMC Program. In this respect, ADMC Program Rule 3040 sets out the responsibility of a Covered Person to be knowledgeable of and to comply with the Protocol and Rules at all times, and to ensure that he is in strict compliance with the ADMC Program, irrespective of whether he may delegate tasks in carrying out his practice.

6.39 Compelling justification is a fact-specific, case-by-case inquiry that must be determined on the evidence.

6.40 In this case, Dr. Shell has the burden to establish a compelling justification for his Possession of Banned Substances, and to explain that the Banned Substances in issue were not prescribed to or used by Covered Horses, and then provide a compelling justification for his Possession. Any such compelling justification must be a legitimate and legal veterinary purpose, that is not connected to Thoroughbred horseracing.

6.41 Dr. Shell's interpretation of Sr. Scollay's statements is unreasonable and not supported. Taken as a whole, Dr. Scollay's statements explain that where there are veterinarians whose practice also includes Non-Covered horses, they are able to explain or justify the Possession based on the Non-Covered horse practice. However, the justification has to be justified "through records, day sheets, etc" and where the "story starts to get a little weird or a little extreme" there may not be a justification. Dr. Scollay advised that it is possible for a veterinarian to justify their Possession of Banned Substances, not that it is an unequivocal or unquestionable immunity.

6.42 There is no reasonable interpretation of Dr. Scollay's statements that would raise a legitimate expectation that all veterinarians have a blanket immunity from Possession if they also practice on Non-Covered horses.

6.43 Dr. Scollay's statements do not create an expectation that Dr. Shell was permitted to be in Possession of Banned Substances so that he could sell them to Thoroughbred racehorse

trainers while in West Virginia. It is, in this regard, notable that Dr. Shell did not contact Dr. Scollay or anyone else at HIWU to ask whether he could engage in this activity and/or whether this would be a compelling justification. In fact, Dr. Shell has provided no evidence to connect the foregoing representations to his subsequent conduct or to suggest that he was induced by any representation made by the Agency. Instead, Dr. Shell acted on his own accord, creating invoices to trainers writing "Farm Use" as the name of the patient when he knew the horse or horses in issue were Thoroughbred racehorses stabled in West Virginia, some of which raced outside of West Virginia.

6.44 In order to show a compelling justification, Dr. Shell must produce evidence of the need to carry each Banned Substance for a legitimate purpose. Dr. Shell's expert, Dr. Roberts, considered Dr. Scollay's guidance on the Possession Rule and conceded that a veterinarian needs to produce records that justify the need to carry each Banned Substance in issue to establish a compelling justification

6.45 Dr. Shell's selective production of medical records, and his failure to produce comprehensive records sufficient to show that he had a non-covered horse practice that required the carrying of the Targeted Banned Substances is a failure to support his defense of compelling justification. The purpose for which the Banned Substances are in Dr. Shell's possession is a central question in this arbitration. By raising the defense that the Banned Substances were only used in non-Covered horses, Dr. Shell assumed the burden of supporting that defense with his veterinary records for covered and non-covered horses. As such, the complete veterinary medical records for all horses in his practice from the implementation of HIWU's regulations until he was charged are relevant and material to the defense.

6.46 Dr. Shell's failure to produce fulsome records has created evidentiary gaps in his case that fail to support his asserted compelling justification. Dr. Shell's HISA records for his treatment of Covered Horses are in conflict with the records he has produced in this case: (i) there are inconsistencies between records he has produced for Snazzy Horse, Totally Obsessed, and Resvalon in the Arbitration and their HISA portal records, and (ii) HISA has prepared multiple Incident Reports that show inconsistencies between Dr. Shell's practice records and HISA portal records.

6.47 The totality of the documentary evidence is insufficient to establish a compelling justification. HIWU's expert, Dr. Benson opined that Dr. Shell had produced insufficient records to show that: (i) he maintains a non-Covered Horse practice that would justify maintaining Banned Substances in his vehicle and office; (ii) the Banned Substances in issue were only possessed for use on Non-Covered Horses; and (iii) the prescribing of Banned Substances in the name of Covered Horses was merely a ministerial error.

6.48 Dr. Shell's failure to produce full veterinary records for the horses in his practice, makes it impossible to rule out the possibility that the Banned Substances were possessed for Covered Horses. Even where Dr. Shell has produced records for specific Covered Horses (Totally Obsessed, Snazzy Horse, and Resvalon), he has failed to produce their complete medical records. Given Dr. Shell's practice of dispensing significant quantities of Banned Substances for

"Farm Use", it is unclear whether any of the trainers of these Covered Horses were dispensed such substances under a separate bill with separate records.

6.49 Dr. Shell has also failed to produce sufficient records to establish that he has an active Non-Covered horse practice. As described in Dr. Benson's initial report, it is impossible to determine whether Dr. Shell carried on an active Non-Covered horse practice as the majority of his records show that he actively dispensed medications, but do not show that those activities were performed in conjunction with farm visits, and many of the records are from after Dr. Shell was suspended in respect of the charges at issue in this Arbitration.

6.50 Dr. Shell has failed to establish a compelling justification for possession of Carolina Gold. The Carolina Gold found on Dr. Shell's truck was prescribed to Covered Horse, Snazzy, with a fill date of August 16, 2023. Even if one accepts that Ms. Duhon's erroneous ordering practices help rebut the presumption that Carolina Gold was ordered for a Covered Horse, the evidence is clear that Dr. Shell intended to, and did in fact, distribute Carolina Gold solely to Thoroughbred racehorses. This cannot constitute a compelling justification.

6.51 There is no reason to use Carolina Gold in any veterinary practice, whether on or off a racetrack. Dr. Benson testified that Carolina Gold is not an FDA- approved drug and cannot be legally compounded for veterinary use. Dr. Shell's expert, Dr. Roberts, confirmed on cross-examination that he does not use Carolina Gold and has never kept it on his truck.

6.52 Both Dr. Shell and Dr. Roberts admitted that Carolina Gold is banned at racetracks in West Virginia, pursuant to West Virginia Racing Commission Rules.

6.53 The foregoing evidence clearly shows that Dr. Shell possessed Carolina Gold in Ohio (a Covered jurisdiction), to give to Thoroughbred racehorses in West Virginia (a jurisdiction that is temporarily under an injunction and has its own rules prohibiting Carolina Gold at racetracks).

6.54 At best, Dr. Shell has shown that he had an uncompelling justification to possess Carolina Gold.

6.55 Ultimately, even if there is a "legal" basis on which Dr. Shell could dispense Banned Substances in West Virginia, there was no basis for him to be in Possession of Carolina Gold at a Covered racetrack in Ohio. Further, it was incumbent on Dr. Shell to demonstrate, with evidence, that the Carolina Gold he dispensed in West Virginia was not given to Covered Horses.

6.56 Dr. Shell has failed to establish a compelling justification for possession of Isoxsuprine. The Isoxsuprine seized from Dr. Shell's truck was found without a prescription label or any other information indicating how it was to be used in Dr. Shell's practice. At the Hearing, Dr. Shell testified that he intended to use the seized Isoxsuprine to treat Cool Stance, a Thoroughbred racehorse in West Virginia.

6.57 First, Dr. Shell stated that Cool Stance suffered from founder (also known as

laminitis), and Isoxsuprine was intended to relieve pain in his feet. However, Dr. Scollay contradicted this, and testified that Isoxsuprine is not a pain relief medication. Isoxsuprine's only reported effect, vasodilation, was called into question in or about 2019, such that the FDA subsequently withdrew its approval for the product. If a veterinarian wanted to treat a horse suffering from acute founder, Dr. Scollay confirmed that there are several FDA-approved products that would provide effective pain relief, all of which are Controlled Medications under the ADMC Program.

6.58 Dr. Shell has failed to justify any need to keep Isoxsuprine on his truck at a Covered location. Despite his assertion that the Isoxsuprine seized on September 28, 2023 was intended for Cool Stance, the only records produced for this horse show that Dr. Shell dispensed Isoxsuprine more than two weeks later on October 13, 2023. Dr. Shell offered a general explanation suggesting that he keeps the Banned Substance on hand in case there is a need to use it. Accordingly, he has failed to establish a compelling justification.

6.59 Dr. Shell has failed to establish a compelling justification for possession of Osphos. The Osphos seized from Dr. Shell's office was also found without a prescription label or any other information indicating how it was to be used in Dr. Shell's practice.

6.60 Although Dr. Shell's billing records show multiple dispensations of Osphos by Dr. Hippie for a Non-Covered Horse named Cat between 2016 and 2023, Dr. Shell did not produce medical records justifying *his* need to carry Osphos for Cat specifically. Had he done so, he may have been able to establish a compelling justification. However, he has failed to produce such records or explain why Osphos was brought to a Covered location.

6.61 There is only one documented instance of Dr. Shell directly dispensing Osphos in the records produced: on November 20, 2023, Dr. Shell dispensed Osphos to a quarter horse named "Hornet." This single administration, nearly two months after HIWU investigators searched Dr. Shell's office, fails to provide any contemporaneous evidence explaining, let alone justifying, the need for Dr. Shell to keep Osphos at a Covered location.

6.62 Dr. Shell has failed to establish a compelling justification for possession of Pitcher Plant. The Pitcher Plant at issue in this proceeding was found on Dr. Hippie's veterinary truck, which was registered to Scott Shell DVM, Inc. The label on the confiscated bottle indicates that it was prescribed by Dr. Shell to Covered Horse, Totally Obsessed, with a fill date of April 27, 2023.

6.63 At the Hearing, Ms. Duhon confirmed that the Pitcher Plant was ordered at Dr. Shell's direction, for general use in the practice.

6.64 Dr. Shell's records show that he dispensed Pitcher Plant to Thoroughbred racehorse trainers in West Virginia, billed to the Patient Name "Farm Use", without any further records. This evidence does not establish a compelling justification for purchasing a Banned Substance in the name of a Covered Horse, which was then brought to a Covered racetrack.

6.65 Dr. Benson testified at the Hearing that possession and use of Pitcher Plant at a racetrack in West Virginia is prohibited under the West Virginia Racing Commission Rules because it is: (i) a non-FDA approved drug, and (ii) does not have an approved analytical method for detection.

6.66 Dr. Shell has failed to establish that the Pitcher Plant ordered for his practice did not make its way to Covered Horses within West Virginia. Accordingly, he has failed to establish a compelling justification.

6.67 Dr. Shell's records show that since the enactment of the ADMC Program, Dr. Shell has, at a minimum, provided Carolina Gold, Isoxsuprine, and/or Pitcher Plant to ten trainers of Thoroughbred racehorses located in West Virginia. These Banned Substances (which are banned by HISA and the West Virginia Racing Commission) have been sold to trainers in West Virginia without specifying the horse to which the Banned Substance is being prescribed. These West Virginia trainers are responsible for Covered Horses that have participated in over 100 races outside of West Virginia in HISA covered jurisdictions over this same period.

6.68 Dr. Shell has no justification for being in Possession of Banned Substances that are banned in both Ohio and West Virginia, much less a "compelling" justification. There was no legitimate or lawful reason for him to be in Possession of these products. He had only an illegitimate reason, which was to provide illicit substances to trainers in West Virginia, beyond the scrutiny of HISA regulations. Dr. Shell even tried to cover his tracks by listing the patient receiving the Banned Substances on his invoices as "Farm Use," when he was selling the Banned Substances to a trainer of Thoroughbred racehorses in West Virginia.

6.69 Even if the Banned Substances were not also banned in West Virginia, it is not a compelling justification for Dr. Shell to possess these substances to sell to trainers of Thoroughbred racehorses in West Virginia. Dr. Shell is using, or facilitating the use of, West Virginia as loophole to supply Banned Substances to Thoroughbred racehorses. This activity undermines the integrity of the ADMC Program and is not justified, much less compelling.

6.70 Dr. Shell's excuse for possessing Carolina Gold and Pitcher Plant prescribed to Covered Horses is that these prescriptions were a "ministerial error" made by his veterinary technician Ms. Duhon, who testified that she mistakenly used the name of a horse on the Practice's roster with which she was familiar. Neither Ms. Duhon, nor Dr. Shell have provided any documentary record that substantiate this "ministerial error." Ms. Duhon is not a licensed veterinary technician, and was not properly supervised by Dr. Shell while ordering in bulk.

6.71 Dr. Shell argues that the Agency should be estopped from bringing the charges against him based on statements made by HIWU's Chief of Science, Dr. Scollay. This argument is incorrect in both fact and law.

6.72 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. 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 dispensing Banned

Substances in West Virginia was a justification for possessing them on a racetrack in a Covered jurisdiction. Dr. Shell never sought clarification or asked any questions about whether possession for use with thoroughbreds in West Virginia was permitted.

6.73 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.

6.74 HIWU does not dispute that a veterinarian may have a compelling justification if their practice includes non-Covered Horses. However, a veterinarian must produce evidence to support his asserted compelling justification.

6.75 Dr. Shell was found in Possession of: Bisphosphonates, Carolina Gold (prescribed to Snazzy), Isoxsuprine, and Pitcher Plant (prescribed to Totally Obsessed). These are separate and distinct substances, found in separate and distinct containers. Each of the four Banned Substances constitute a distinct ADRV for which Dr. Shell is liable. The fact that they were discovered at the same time does not negate that they were separate Banned Substances all of which constitute a violation on their own.

6.76 Under Rule 3228(d), Possession of each of the Banned Substances at issue in this proceeding constitutes a separate ADRV but they are to be adjudicated together in consolidated proceedings.

6.77 The ADMC Program allows for the reduction of Consequences where the Covered Person can establish that they acted with either No Fault or No Significant Fault. On the facts of this case, Dr. Shell has not met his burden of demonstrating either and therefore should not have any of his Consequences reduced.

6.78 Rule 3227(a) provides that the period of Ineligibility otherwise applicable shall be increased by up to 2 years if the Agency establishes Aggravated Circumstances. Aggravated Circumstances include actions of a Covered Person that may justify the imposition of a Period of Ineligibility and/or fine that is greater than the otherwise applicable standard sanction. Rule 3227 sets out a non-exhaustive list of Aggravating Circumstances, which includes the Covered Person engaging "in deceptive or obstructive conduct to avoid the detection or adjudication" of an ADRV.

6.79 Dr. Shell has demonstrated a consistent and clear disregard for the ADMC Program, and towards his obligations under the Program, through his willful possession and distribution of Banned Substances to both Covered Persons actively racing in HISA jurisdictions, and specific Covered Horses (such as Resvalon and Venezulen Dreamer) actively racing in HISA jurisdictions. To deny that Covered Horses are bound by the ADMC Program illustrates to an extreme degree that Dr. Shell continues to disregard the rules. As such the Period of Ineligibility should be increased on grounds of Aggravating Circumstances.

6.80 As a consequence of these Aggravating Circumstances, HIWU requests that the Period of Ineligibility imposed on Dr. Shell be increased by two years, and an additional \$10,000 be imposed. This constitutes the maximum Consequences available under Rule 3227(a).

6.81 For the reasons set out above, HIWU now seeks the imposition of the following Consequences:

a. A period of Ineligibility of ten (10) years for Dr. Shell as a Covered Person (two (2) years for each violation and two (2) years for Aggravating Circumstances), beginning on the date a decision is rendered in this case;

b. A Fine of USD \$110,000.00 (\$25,000.00 for each violation and \$10,000 for Aggravating Circumstances) and payment of some or all of the adjudication costs; c. Any other remedies which the learned Arbitrator considers just and appropriate in the circumstances.

## VII. ANALYSIS

7.1 The charge at issue in this case is Possession. The defense is that Dr. Shell legally possessed the four Banned Substances because of his justification as a veterinarian who treated Non-Covered horses.

#### Was Dr. Shell in possession of four Banned Substances?

7.2 The parties do not dispute that Dr. Shell was in Possession of the four Banned Substances, as set forth in ADMC Rule 3214(a).

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

7.4 The Parties do not dispute that Dr. Shell is a Covered Person who was in possession of Carolina Gold, Pitcher Plant, Isoxsuprine and Osphos, which are Banned Substances under the ADMC Program. HIWU has met its burden of proving Possession of the four Banned Substances.

7.5 As sanctions for a first 3214(a) possession offense, ADMC Rule 3223(b) provides for a two-year period of ineligibility, a fine of up to \$25,000, and payment of "some or all of the adjudication costs and [HIWU's] legal costs."

7.6 Claimant HIWU asserts that under Rule 3228(d), possession of each of the Banned Substances at issue in this proceeding constitutes a separate ADRV and, therefore, seeks

the imposition of the Consequences as set out in Rule 3223, for each separate ADRV, i.e., four times the period of ineligibility and financial penalty, plus an additional penalty for Aggravated Circumstances.

7.7 Rule 3228(d) however, applies to a situation involving "one or more Banned Substance(s) or Banned Method(s), *and* (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s)..." (Emphasis added.)

7.8 This proceeding charged "one or more Banned Substances," but does not also allege violations of Controlled Medication Substances. Respondent argues that the Rules "intentionally divided the regulation of Anti-Doping Rule Violations [like 3214(a)] and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other." Rule 3010(c). As such, Respondent argues that Rule 3228(d) does not permit HIWU to charge separate counts, for the four Banned Substances recovered at the same time, as part of one incident.

7.9 The Arbitrator searched through the extensive Briefs, Exhibits, and Authorities that had been submitted, and found no authority supporting the application of Rule 3228(d) to a matter involving multiple Banned Substances, but not also involving a Controlled Medication.

7.10 On September 3, 2024, the Arbitrator requested that the Parties submit any further citations to relevant authorities regarding the applicability of Rule 3228(d) to this matter.

7. 11 On September 4, 2024, HIWU responded. HIWU did not provide any authority supporting the applicability of Rule 3228(d) to this case. Rather, HIWU submitted new theories and new arguments to address "what it considers the appropriate analysis if it is determined that Rule 3228(d) is not applicable to this proceeding."

7.12 Dr. Shell responded on September 3 and September 5, 2024, objecting to the consideration of any new positions and arguments as prejudicial to Dr. Shell, after a prosecution that lasted many months predicated upon Rule 3228(d), and after the record has been closed.

7.13 The Arbitrator agrees that Rule 3228(d) does not apply to this case, and does not support treating the charged Banned Substances as separate violations in this case. The Hearing is not reopened to allow HIWU's new theories and arguments not presented in the Pre-Hearing Brief or during the pendency of the Hearing.

## Did Dr. Shell have a compelling justification to possess the four Banned Substances?

7.14 Rule 3214 is clear that possession of a banned Substance is an Anti-Doping Rule Violation (ADRV) "unless there is compelling justification for such Possession."

7.15 Compelling justification is a fact-specific, case-by-case inquiry that must be determined on the evidence. Compelling justification is a defense, and, as such, Respondent Dr.

Shell has the burden to establish this defense. He must show that the Banned Substances in issue were not prescribed to or used by Covered Horses, and that he was justified in having them in his possession at the time and place where they were found, for a legitimate and legal veterinary purpose, that is not connected to Thoroughbred horseracing.

7.16 Dr. Shell asserts that he had a compelling justification to possess the Banned Substances in issue because he treats Non-Covered horses. He argues that Dr. Scollay told him he could possess Banned Substances on a racetrack if he had a Non-Covered practice. Period. He states that his veterinary records support that he treats Non-Covered horses, and that those records show that the Banned Substances in question were used only for Non-Covered farm horses and Non-Covered horses in West Virginia (Covered Horses in other jurisdictions). He further asserts that he has an ethical duty to carry those medications at all times to have them available for his Non-Covered horse practice.

7.17 Dr. Shell's statement that his veterinary practice includes Non-Covered horses, is thus not by itself a compelling justification for the possession, without evidence of the need to keep the Banned substances at the covered racetrack for use with Non-Covered horses.

7.17 HIWU requested Dr. Shell to produce his veterinarian records evidencing his use of the Banned Substances on Non-Covered horses, to support his defense, and brought a production motion before this Arbitrator. In ruling on that motion, the Arbitrator instructed Dr. Shell that having asserted that he had a Non-Covered horse practice that required the carrying of the four Banned Substances, "he has the burden of supporting that defense with his veterinary records for covered and non-covered horses. As such, the complete veterinary medical records for all horses in his practice from the implementation of HIWU's regulations until he was charged are relevant and material to the defense." (Discovery Order, Jan. 16, 2024.)

7.18 Dr. Shell opted instead to produce limited veterinary records. Those records showed some dispensation of the Banned Substances to farm horses and Thoroughbreds in West Virginia, but not complete records sufficient to justify the possession of the Banned Substances at the Ohio racetrack.

7.19 The statement of Dr. Scollay relied upon by Dr. Shell, "if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered Horses" references two conditions: "justification," and "a practice that incorporates Non-Covered Horses." The Arbitrator agrees that Rule 3214's defense, "unless there is compelling justification for such Possession" incorporates both elements. First, one must have a "compelling justification." Second, one must articulate and prove that compelling justification. Proof of a Non-Covered horse practice that requires the possession of the Banned Substances would be one way of proving, with facts and evidence, the need, i.e., the justification. A farm practice was the Non-Covered horse practice discussed by Dr. Scollay in response to questions posed during her presentations. At present, a veterinarian's practice in West Virginia is also a Non-Covered practice, because the HISA Rules are not in effect there.

7.20 The fact that a veterinarian's practice includes driving to West Virginia to dispense medication, including Banned Substances, to horses in West Virginia (putting aside for

the moment whether those horses are deemed Covered or Non-Covered) may be evidence of a Non-Covered practice, but is not by itself a compelling justification for possessing Banned Substances at an Ohio racetrack, any more that the fact that a veterinarian's practice in Ohio that includes driving to farms or barns to dispense medication, including Banned Substances, to farm horses, is, without more evidence, a compelling justification. A justification requires evidence of reasons and facts as to why it is justified to have the Banned Substances stored at the racetrack in an office or truck. Treating farm horses or West Virginia horses once a week for non-emergency conditions likely would not justify possessing the Banned Substances every day at an Ohio racetrack. Evidence of a Non-Covered practice that required the veterinarian to drive on a daily or several-times-a-week basis from the racetrack to treat Non-Covered horses with Banned Substances is the type of justification that, considering all the facts, a veterinarian could offer as a compelling justification.

7.21 The justification provided for possessing Banned Substances in Dr. Shell's office and truck at Thistledown was the inconvenience caused by additional travel time that would be required if Banned Substances intended for Non-Covered horses were not allowed to be stored at the Thistledown office and on his truck. The Arbitrator finds that the inconvenience of additional travel time (from racetrack to office or off-site storage) does not qualify as a compelling justification for keeping these banned substances on a truck or on a covered racetrack, unless they were medications needed on a regular basis for time-sensitive emergency treatment.

7.22 The Banned Substances found in Dr. Shell's truck and office at the covered racetrack were not emergency medications required for life-threatening injuries and did not create a compelling justification for possession on a covered racetrack.

7.23 At present, there has not been any guidance from HISA confirming how it applies its Rules to a Covered Horse that steps foot in West Virginia, and is treated by or whose trainer receives Banned Substances from, a veterinarian, while the Covered Horse is in West Virginia. Does the Covered Horse become a Non-Covered horse or remain a Covered Horse?

7.24 Under HISA Rules, a horse becomes a Covered Horse "(A) beginning on the date of the horse's first Timed and Reported Workout at a Racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b)." Under this definition, a Covered Horse stabled in or passing through West Virginia remains a Covered Horse unless and until it is "deemed retired . . . ." (By analogy, the Arbitrator notes that no one has argued that a Covered Horse stabled at Farmer Jones' farm in a barn side-by-side with farm horses becomes a "farm horse.")

7.25 The Arbitrator concludes that the dispensation of Banned Substances in West Virginia is beyond the authority of HISA or HIWU to regulate, given the current state of the record. However, that does not mean that having a clientele of Thoroughbred horse trainers in West Virginia is a compelling justification for possessing Banned Substances at Ohio racetracks. These were not emergency medications that Dr. Shell needed to have at the ready to dash to West Virginia. They could have properly been stored at his office off the racetrack or in a storage locker. Dr. Shell was using, or facilitating the use of, West Virginia as loophole to supply

Banned Substances to Thoroughbred racehorses. This activity undermines the integrity of the ADMC Program and is not justified, much less compelling.

7.26 Taking the definition of Covered Horse together with the injunction barring enforcement of the HISA rules in West Virginia, the Arbitrator is of the opinion that a Covered Horse remains a Covered Horse even while on the ground in West Virginia, but that a veterinarian may not be charged with a HISA Rule violation for treating that Covered Horse in West Virginia.

7.27 It is telling that Dr. Shell did raise the question whether he could possess Banned Substances at an Ohio racetrack for use in West Virginia for Thoroughbreds who were Covered Horses (at least when not in West Virginia), with Dr. Scollay when he spoke with her about farm horses following her presentation that he attended at the Mahoning Valley racetrack.

7.28 The banned substance Carolina Gold (gamma aminobutyric acid in injectable form) found in Dr. Shell's truck is not an FDA approved drug for any use in humans or animals. It was prescribed to Covered Horse, Snazzy, with a fill date of August 16, 2023. Even if one accepts that Ms. Duhon's erroneous ordering practices help rebut the presumption that Carolina Gold was ordered for a Covered Horse, Dr. Shell's explanation was that he could use it for Thoroughbred horses in West Virginia, where it was also banned on racetracks. The Arbitrator finds that this is not a compelling justification for the possession of Carolina Gold on a Covered racetrack in Ohio.

7.29 The Isoxsuprine seized from Dr. Shell's truck was found without a prescription label or any other information indicating how it was to be used in Dr. Shell's practice. Reviewing the evidence, the Arbitrator finds that Dr. Shell has failed to justify any need to keep Isoxsuprine on his truck at a Covered location. At the Hearing, Dr. Shell testified that he intended to use the seized Isoxsuprine to treat Cool Stance, a Thoroughbred racehorse in West Virginia. Despite his assertion that the Isoxsuprine seized on September 28, 2023 was intended for Cool Stance, the only records produced for this horse show that Dr. Shell dispensed Isoxsuprine on October 13, 2023, after the investigation. Accordingly, Dr. Shell has failed to establish a compelling justification for possession of Isoxsuprine.

7.30 The Osphos seized from Dr. Shell's office was also found without a prescription label or any other information indicating how it was to be used in Dr. Shell's practice. Dr. Shell did not produce medical records justifying his need to carry Osphos for Cat, a horse being treated by Dr. Hippie, in his office on the racetrack, rather than in Dr. Hippie's truck. The only documented instance of Dr. Shell directly dispensing Osphos was for "Hornet," on November 20, 2023, months after the search.

7.31 Dr. Shell has failed to establish a compelling justification for possession of Osphos.

7.32 The Sarapin/Pitcher Plant at issue in this proceeding indicates that it was prescribed by Dr. Shell to Covered Horse, Totally Obsessed, with a fill date of April 27, 2023. Dr. Shell in fact dispensed Pitcher Plant to Thoroughbred racehorse trainers in West Virginia,

billed as "Farm Use." This evidence does not establish a compelling justification for purchasing a Banned Substance in the name of a Covered Horse, which was then brought to a Covered racetrack. In addition, the possession of Pitcher Plant at a racetrack in West Virginia is prohibited under the West Virginia Racing Commission Rules.

7.33 Dr. Shell has failed to establish a compelling justification for possession of Pitcher Plant.

7.34 Dr. Shell's testimony confirms that there is no need to possess Banned Substances at a Covered racetrack. As Dr. Shell admitted during cross-examination, he no longer carries Carolina Gold, Isoxsuprine, Osphos, or Pitcher Plant on his truck and is still able to meet his ethical obligations.

7.35 After review and consideration of all the materials, evidence, exhibits and testimony presented, it appears to the comfortable satisfaction of the arbitrator that Respondent Dr. Shell has failed to establish a compelling justification for possession of the four Banned Substances at issue here.

7.36 Dr. Shell's testimony that he believed, albeit mistakenly, that he could carry any Banned Substance he wanted at a covered racetrack in Ohio, because he was going to dispense such a substance at some time to clients in West Virginia, although not a sufficient compelling justification, is a subjective factor that will be considered under Rule 3225 (No Significant Fault) below.

## Is the doctrine of estoppel applicable?

7.37 Dr. Shell asserts the doctrine of estoppel, relying on Dr. Scollay's statements at her presentations at Will Rogers Down, Mahoning Valley Racecourse, and in her email dated June 16, 2023, to the Randall Equine Vet Group, as set forth above.

7.38 Dr. Scollay's statements explain that where there are veterinarians whose practice also includes non-Covered Horses, they are able to explain or justify the Possession based on the non-Covered Horse practice. However, they have to justify that with facts, including "through records, day sheets, etc" and where the "story starts to get a little weird or a little extreme" there may not be a justification. Dr. Scollay advised that it is possible for a veterinarian to justify their Possession of Banned Substances, not that it is an unequivocal or unquestionable immunity.

7.39 At the Hearing, Dr. Scollay also testified about her education seminars. Consistent with her statements at Will Rogers Down, she would confirm that HISA regulations have no authority over non-Covered Horses, but explain that Possession needed to be justified and would be further investigated where suspicions or inconsistencies arose.

7.40 The Arbitrator finds that while one could pick and choose language from Dr. Scollay's statements, taken in their entirety they cannot be read to raise a legitimate expectation that all veterinarians have a blanket immunity from Possession if they also practice on Non-

Covered Horses.

7.41 In the *lex sportiva*, the doctrine of estoppel applies to prevent sports organizations from taking explicitly contradictory positions. There is no evidence here that HIWU has taken a contradictory position regarding the application of the ADMC Program. While Dr. Scollay's statements may have led to some confusion on the part of Dr. Shell, those statements do not rise to the level of estoppel. Dr. Scollay's presentations explained and were consistent with the Rules, albeit with additional commentary.

# Is Dr. Shell entitled to a reduction of Consequences or subject to an increase for Aggravated Circumstances?

7.42 Having determined that Dr. Shell committed the act of Possession under the ADMC Program, the Arbitrator may consider whether the standard two years period of ineligibility may be reduced by considering whether there was No Fault or Negligence, or No Significant Fault or Negligence or increased due to Aggravated Circumstances.

7.43 The definition of Fault in the ADMC Program 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.

7.44 To establish No Fault, a Covered Person must demonstrate that it was nearly impossible for them to reasonably suspect or know that they may be committing, or at risk of committing, an ADRV. This is a high burden to prove.

7.45 In this case, there is no dispute that Dr. Shell knew each of the substances in issue were Banned Substances under the ADMC Program. He took no measures to ensure that his vehicle did not contain Banned Substances when entering Thistledown, even though he knew that all the Banned Substances were prohibited from Possession for Covered Horses or by Covered Persons at Thistledown. Despite this knowledge, Dr. Shell possessed Carolina Gold, Pitcher Plant, Isoxsuprine and Osphos, all Banned Substances, not prescribed to any non-Covered Horse. These facts do not meet the "utmost caution" standard.

7.46 In addition, Dr. Shell is responsible for his employee, and knew or should have known that Banned Substances were incorrectly being ordered for Covered Horses. Dr. Shell did not ensure that medications ordered for Non-Covered horses be labeled with the Non-Covered horses' names.

7.47 Dr. Shell did not raise the issue with Dr. Scollay whether dispensing Banned Substances to Thoroughbred Covered Horses in West Virginia, outside of HISA jurisdiction, was

a non-covered practice and could provide a compelling justification for Possession of the Banned substances at a covered racetrack.

7.48 Dr. Shell has not met the burden of proof to demonstrate No Fault or Negligence under Rule 3224 for the possession of the charged Banned Substances.

7.49 ADMC Program Rule 3225 also allows for the reduction of sanctions where there is a finding of No Significant Fault or Negligence: "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."

7.50 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.

7.51 As described above, Dr. Shell was negligent in his ordering, storing and possession of banned substances at the Thistledown office and on his truck. Dr. Shell was aware of the ADMC Rules. Dr. Shell was responsible for ADMC compliance in his practice.

7.52 The Arbitrator finds that Dr. Shell held an erroneous belief that: (i) he was permitted to possess Banned Substances for Thoroughbred racehorses while in West Virginia; because (ii) Thoroughbred racehorses cannot be "Covered" so long as they are treated in West Virginia, outside of HISA jurisdiction.

7.53 These beliefs are not supported by the definition of a Covered Horse, and as a Covered Person, Dr. Shell had an obligation to read and understand the Rules. However, Dr. Shell's beliefs were influenced by his interpretation of Dr. Scollay's educational seminars and statements that a veterinarian with a non-covered practice could carry Banned Substances. In addition, these charges against Dr. Shell arose in the early days of the ADMC Program.

7.54 In *HIWU v Poole*, Arbitrator Benz, citing the well-known anti-doping case *Cilic v International Tennis Federation*, CAS 2013/A/3327, confirmed that the No Significant Fault or Negligence analysis requires a consideration of both "objective" and "subjective" elements of Fault, with objective elements being at the forefront. In doing so, Arbitrator Benz established three Ineligibility ranges for violations of the Program: insignificant or slight fault; moderate fault; significant fault:

a. Slight or Insignificant Fault – three (3) to ten (10) months;

- b. Moderate Fault ten (10) to seventeen (17) months; and
- c. Significant Fault seventeen (17) to twenty-four (24) months.

7.55 The objective elements of Fault determine which category of Fault the Covered Person falls within for their ADMC Program violation. The objective element describes what standard of care could have been expected from a reasonable person in the situation and determine into which category a case falls. The subjective elements of Fault then allow the Arbitrator to move the Covered Person within the range of Fault determined by the objective elements. The subjective element describes what could have been expected from that person, in light of his personal capacities, and moves up or down within that category. The Arbitrator finds this analytical approach useful.

The Arbitrator determines that Dr. Shell demonstrated significant fault for the 7.56 following reasons: (a) he was in possession of the four Banned Substances, and he was aware they were Banned Substances; (b) he had the same access to HIWU educational seminars and resources as other Covered Persons; (c) he attended the HIWU seminar conducted by Dr. Scollay at Mahoning Valley racetrack, and viewed the You Tube video made from the Will Rogers Downs seminar; (d) he did not ask Dr. Scollay any questions about whether he could possess Banned Substances at an Ohio racetrack for dispensation to trainers in West Virginia within her definition of non-covered practice; (e) he did not contact anyone else at HIWU or HISA to verify whether he would be in compliance with the new regulations if he dispensed Banned Substances to Covered Thoroughbreds in West Virginia; (f) he did not supervise the ordering and inventory of the Banned Substances that his Practice possessed; (g) Banned Substances were ordered in the name of Covered Horses (the responsibility for which is imputed to Dr. Shell); and (h) he carried those Banned Substances to the covered Thistledown racetrack, stored them there in his office and truck, rather than storing them offsite at his nearby office. A reasonable veterinarian would have stopped, asked whether the injunction in West Virginia allowed him to dispense Banned Substances to Thoroughbred racehorses who happened to cross the estate line to West Virginia. Dr. Shell did not.

7.57 Subjective factors weighing in favor of a reduction are (a) Dr. Shell is not a lawyer and did not parse Dr. Scollay's words carefully, rather relying upon Dr. Scollay's assurance of "*if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses* ... *the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses*" to conclude that he was allowed to carry the Banned Substances at Thistledown for his use in West Virginia as a non-Covered practice; and (b) the search that gave rise to this case occurred in September 2023, relatively early after the effective date of the of HISA's ADMC Program and before Dr. Scollay had refined her remarks to emphasize the importance of having a compelling justification in addition to having a non-covered practice.

7.58 Lawyers can argue that Dr. Scollay's words are subject to two interpretations, either that (1) a veterinarian must (a) prove that there is a justification to be in possession, by showing the need for the Banned Substances *and* have "a practice that incorporated Non-Covered horses", or (2) that "certainly a practice that incorporates Non-Covered horses" is sufficient to justify the possession of the Banned Substances. Dr. Shell is not a lawyer, but as a Covered Person he was bound by the Rules and has an obligation to be knowledgeable of and

comply with the ADMC Program and Rules. The Rule requires a compelling justification, which one has to prove.

7.59 HIWU emphasizes that there is a difference between Dr. Shell's possession of Isoxsuprine and Osphos, on the one hand, and of Carolina Gold and Pitcher Plant on the other, in that the former are used routinely in farm practices, whereas the latter were not possessed for any purpose other than for trainers and Thoroughbreds in West Virginia, where they are prohibited under the West Virginia Racing Commission Rules. Dr. Shell did not make that distinction, and understood that he was allowed to possess any Banned Substance as long as he had a Non-Covered practice.

7.60 After consideration of the above factors, the Arbitrator determines that Dr. Shell's objective level of fault falls in the significant fault range, and that he should receive a reduction, due to the subjective factors, of three months in his level of fault, from twenty-four (24) months to twenty-one (21) months.

7.61 Rule 3227(a) provides that the period of Ineligibility otherwise applicable shall be increased by up to 2 years if the Agency establishes Aggravated Circumstances. Aggravated Circumstances include actions of a Covered Person that may justify the imposition of a Period of Ineligibility and/or fine that is greater than the otherwise applicable standard sanction. Rule 3227 sets out a non-exhaustive list of Aggravating Circumstances, which includes the Covered Person engaging "in deceptive or obstructive conduct to avoid the detection or adjudication" of an ADRV.

7.62 Dr. Shell demonstrated a consistent and clear disregard for the ADMC Program, and towards his obligations under the Program, through his willful possession and distribution of Banned Substances to both Covered Persons actively racing in HISA jurisdictions, and specific Covered Horses (such as Resvalon and Venezulen Dreamer) actively racing in HISA jurisdiction. The Arbitrator does not view these as Aggravating Factors under Rule 3227, but rather as factors that supported her discission in finding significant fault. Labeling the prescriptions as "Farm Use" is a common practice, and the Arbitrator does not necessarily view it as rising to the level of "deceptive of obstructive conduct." Dr. Shell did not deny that he dispensed the Banned Substances to Thoroughbreds and trainers of Thoroughbreds in West Virginia.

#### Punishment-Fine, Payment Toward Legal Fees and Arbitration Costs

7.63 Under the ADMC Program, the punishment includes, in addition to a period of Ineligibility, a "Fine up to \$25,000 . . . and Payment of some or all of the adjudication costs and [HIWU]'s legal costs." Rule 3223(b).

7.64 The Arbitrator finds that Dr. Shell should suffer a period of Ineligibility of twenty-one (21) months, beginning on October 5, 2023, the date of the Provisional Suspension.

7.65 On the facts of this case the Arbitrator has determined that Dr. Shell should pay a fine of \$20,000.00 to HIWU by the end of his period of Ineligibility. This is an imprecise

calculation but one that the Arbitrator determines to be appropriate under the circumstances, particularly given the ease with which Dr. Shell could have checked with Dr. Scollay or other HISA persons to clarify any questions about his responsibilities in West Virginia.

7.66 HIWU also requests that some or all of the adjudication costs be paid by Dr. Shell. The amount of the contribution toward the arbitration costs appears, like the fine, to be purely discretionary with the Arbitrator. Based upon the circumstances of this matter, including that Dr. Shell believed, albeit erroneously, that Dr. Scollay had authorized his possession of the Banned Substances, Dr. Shell is not required to contribute toward the adjudication costs in this case.

#### Term of Ineligibility and Other Sanctions

7.67 As set forth above, HIWU relied upon Rule 3228(d) in prosecuting this case, treating the charged Banned Substances as separate violations, and seeking separate the imposition of the Consequences, as set out in ADMC Program Rule 3223, for each separate ADRV, i.e., four times the period of ineligibility and financial penalty, to run sequentially.

7.68 While preparing this Final Decision, the Arbitrator concluded that Rule 3228 on its face did not apply to the facts of this case, in that while there were multiple Banned Substances charged, Rule 3228 applies where there are both one or more Banned Substances and one or more Controlled Medications. There are no Controlled Medications charged in this matter.

7.69 The Arbitrator suspended the issuance of the Final Decision and requested the parties to provide any authority supporting the applicability of Rule 3228 here, having spent considerable time searching the record and not finding citations to such authority. HIWU responded without any supporting authority, as discussed above, and instead submitted new, alternative theories and arguments not previously briefed, argued or found in the record. Respondent objected to the submission of new theories and arguments after the close of the record.

7.70 The Arbitrator found that Rule 3228 does not apply, and that new theories and arguments may not be considered after the close of the record. Claimant may not shift theories after the case has been heard and the record closed.

7.71 While one could argue that the four Banned Substances support four violations, which in turn support four sets of Consequences, Respondent argued that these four violations arose out of a single investigation/transaction, a search of Dr. Shell's and Dr. Hippie's trucks and Dr. Shell's racetrack office at the same time.

7.72 HIWU also relies upon Rule 3223(c)(2) to support consecutive punishments for the four violations. Rule 3223(c)(2) provides: "Ineligibility and Financial Penalties for Covered Persons . . . (c) Commencement of the period of Ineligibility for a Covered Person. . . . (2) Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol,

any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends."

7.73 The Arbitrator is not convinced by HIWU's argument that Rule 3223(c)(2) supports consecutive punishments based on its language. HIWU did not introduce evidence that Dr. Shell was "already" serving a period of Ineligibility that pre-dated the imposition of the subsequent period of Ineligibility to which it refers. The date of the Provisional Suspension in this case was October 5, 2023, and HIWU identified these charges as first-time antidoping violations.

7.74 Accordingly, these are charged and ruled upon as first-time anti-doping violations for Dr. Shell that will issue simultaneously when this Final Decision issues.

#### VIII. AWARD

8.1 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 his first anti-doping rule violation of Possession. As a result, Dr. Shell shall:

1. Be suspended for a period of Ineligibility of twenty-one months, commencing October 5, 2023, the effective date of his provisional suspension, and ending on July 5, 2025;

2. Be fined \$20,000.00 to be paid to HIWU by the end of the period of Ineligibility; and

3. Not be required to pay a contribution toward HIWU's share of the arbitration costs of this proceeding.

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

IT IS SO ORDERED AND AWARDED.

Dated: September 9, 2024

Barbara Reeves

Barbara A. Reeves, Esq. Arbitrator

# EXHIBIT B

# 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. <u>THE FACTS</u>

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 multivitamin. 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. <u>RELEVANT LEGAL STANDARDS</u>

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<sup>®</sup>. 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:

- 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. <u>ANALYSIS</u>

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<sup>®</sup> 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 twohundred 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. <u>AWARD</u>

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

<u>Hugh L. Fraser</u>

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

# EXHIBIT C

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S**

## ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000653

#### In the Matter of the Arbitration Between:

HORSE RACING INTEGRITY & WELFARE UNIT ("HIWU" or "Claimant"), Claimant

v.

SHELL Dr., Scott (**"Dr. Shell" or "Respondent"**), Respondent.

Dear Madam Arbitrator,

We write in accordance with Rule 7380<sup>1</sup> to address a computational error in the Final Decision with respect to the period of Ineligibility to be imposed on Dr. Shell.

As you are aware, on June 11, 2024, Justice Fraser issued an award in *HIWU v. Dr. Scott Shell*, Case No. 1501000708 ("**Administration Case**") that declared Dr. Shell Ineligible from January 8, 2024 through January 7, 2026. The award in the Administration Case was issued after the evidentiary hearing in this matter closed, but before closing submissions.

Rule 3223(c)(2) provides that where (as here) "a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends." This is a mandatory provision and is applicable

<sup>&</sup>lt;sup>1</sup> Rule 7380 Modification of Final Decision: Within 7 days of the issuance of a final decision, any party, upon notice to the other parties, may request the Arbitral Body or Internal Adjudication Panel to correct any clerical, typographical, or computational errors in the final decision. The other parties shall ordinarily be given 5 days to respond to the request.

to Dr. Shell, who is currently serving a two-year period of Ineligibility pursuant to Justice Fraser's award.

The start date for Dr. Shell's period of Ineligibility in the present matter should be **January 8**, 2026, and he should receive credit for the two-day and three-month Provisional Suspension ("Credit Period") he has served against the 21-month period of Ineligibility, such that his period of Ineligibility expires on **July 5**, 2027. In this regard, the Credit Period of two-days and three-months is based on Dr. Shell serving a Provisional Suspension from October 5, 2023 (the date his Provisional Suspension was imposed) until January 7, 2024 (the day before his two-year Ineligibility period started to run in the Administration Case). If Dr. Shell's Ineligibility in the present matter starts on January 8, 2026, 21-months of Ineligibility less the Credit Period, results in an end date of July 5, 2027.

Heisen Hanell

Allison J. Farrell, Esq. Horseracing Integrity & Welfare Unit

Tyr LLP James Bunting, Esq. Alexandria Matic, Esq. **Representatives of HIWU** 

# EXHIBIT D

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S**

## ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000653

In the Matter of the Arbitration Between:

#### HORSE RACING INTEGRITY & WELFARE UNIT ("HIWU" or "Claimant"),

Claimant

v.

SHELL Dr., Scott ("Dr. Shell" or "Respondent"),

Respondent

#### ORDER IN RESPONSE TO POST-DECISION REQUEST FOR MODIFICATION

The Final Decision was issued in this arbitration on September 9, 2024. On September 11, 2024, Claimant submitted a Request for Modification, pursuant to Rule 73801, to address a computational error in the Final Decision with respect to the period of Ineligibility to be imposed on Dr. Shell.

The Arbitrator is of the opinion that HIWU's request does not properly fall within Rule 7380<sup>1</sup>, because it is not a request to correct clerical, typographical, or computational

<sup>&</sup>lt;sup>1</sup> Rule 7380: Modification of Final Decision: Within 7 days of the issuance of a final decision, any party, upon notice to the other parties, may request the Arbitral Body or Internal Adjudication Panel to correct any clerical, typographical, or computational errors in the final decision. The other parties shall ordinarily be given 5 days to respond to the request.

errors, but rather a request to apply a Rule, Rule 3223(c)(2), that HIWU had not previously raised or briefed. However, the Arbitrator will address the Request.

Rule 3223(c)(2) provides that where "a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends." HIWU raises this Rule for the first time in this arbitration, in this Request, submitted after the Final Decision, notwithstanding that HIWU was aware of the potential applicability of the Rule prior to submitting its post-Hearing briefing (June 28, 2024) and closing argument (August 7, 2024).

In the Request, for the first time, HIWU submits the argument that inasmuch Dr. Shell is already serving a period of Ineligibility, the start date for Dr. Shell's period of Ineligibility in the present matter should be January 8, 2026, after the original period of Ineligibility ends. HIWU points to the June 11, 2024, award in *HIWU v. Dr. Scott Shell*, Case No. 1501000708 ("*Shell Administration Case*") that declared Dr. Shell Ineligible from January 8, 2024 through January 7, 2026. That award was issued before closing submissions in this arbitration. Nonetheless, in its final Closing Submission, HIWU did not mention that there was an existing period of Ineligibility. HIWU's Reply identified the applicable consequences for a "first ADRV" ("82. Pursuant to ADMC Program Rules 3221-3223 and 3231, the Consequences for a first ADRV of ADMC Program Rule 3214(a) (Possession) for the Banned Substances. . . .") and requested that the period of Ineligibility for Dr. Shell in this arbitration "begin[] on the date a decision is rendered in this case".

HIWU is correct that the Arbitrator was aware of the *Shell Administration Case*. HIWU had cited that decision in its Closing Submission to distinguish the application of "No Fault" in that decision, from its Fault discussion in this arbitration. ("93. These circumstances are also notably different from the *Shell Administration Case*...." HIWU did not cite the *Shell Administration Case* for the position that Dr. Shell was already serving a period of Ineligibility. Had that issue been timely raised, the Parties could have briefed it. Issues could have been argued as to the applicability of Rule 3223(c)(2) to a situation in which the violations alleged in both arbitrations arose out of the same search on the same day, for example, but which were charged in separate arbitrations. While the Arbitrator saw the decision in the *Shell Administration Case* when HIWU included it in their Authorities, HIWU had not raised the fact that it had imposed a period of Ineligibility, and the Arbitrator has no way of knowing whether the period of Ineligibility had actually begun, or had been appealed, or otherwise was or was not in effect.

Absent any grounds for modifying a Final Decision based upon a Rule not previously cited or briefed or argued, and in reliance upon HIWU's positions taken throughout this arbitration, including in its Closing Submissions, the Request for Modification is Denied.

Dated: September 17, 2024

Barbara Reeves

Barbara A. Reeves Arbitrator

# EXHIBIT E

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S**

# ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000653

In the Matter of the Arbitration Between:

#### HORSE RACING INTEGRITY & WELFARE UNIT ("HIWU" or "Claimant"),

Claimant

v.

SHELL Dr., Scott ("Dr. Shell" or "Respondent"),

Respondent

#### **REQUEST FOR ADDITIONAL AUTHORITY**

Claimant HIWU asserts that under ADMC Program Rule 3228(d), possession of each of the Banned Substances at issue in this proceeding constitutes a separate ADRV and, therefore, seeks the imposition of the Consequences as set out in ADMC Program Rule 3223, for each separate ADRV, i.e., four times the period of ineligibility and financial penalty.

Rule 3228(d) however, applies to a situation involving "one or more Banned Substance(s) or Banned Method(s), *and* (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s). . . ." (Emphasis added.)

This proceeding involves one or more Banned Substances, but does not also involve Controlled Medication Substances. Respondent notes that the Rules "intentionally divided the regulation of Anti-Doping Rule Violations [like 3214(a)] and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other." Rule 3010(c). As such, Respondent argues that Rule 3228(d) does not permit HIWU to charge several counts, for several substances recovered at the same time, as part of one incident. The Parties did not provide any case authority regarding this point. HIWU did cite Amended Decision of Arbitrator Fraser in *HIWU v. Dr. Scott Shell*, Case No. 1501000708, for a different proposition, namely a situation in which the multiple administrations were all with regard to the same substance. However, would the logic used in that decision apply to this case, in that the justification offered for each of the Banned Substances, farm use and West Virginia use, is the same, and would that impact a finding regarding Consequences?

I had planned to submit the Final Decision today but, after spending the past two days searching through the briefs and submitted materials for further authority on this point, I have decided to submit this request to counsel. I will hold the Final Decision pending receipt of your response. I am not looking for another set of briefs, just citation to any relevant authority, if there is any.

Dated: September 3, 2024

Barbara Reeves

Barbara A. Reeves, Esq. Arbitrator

# EXHIBIT F



#### CONFIDENTIAL

Allison J. Farrell Senior Litigation Counsel Horseracing Integrity & Welfare Unit 4801 Main Street Suite 350 Kansas City, MO 64112-2749

October 5, 2023

<u>SENT VIA EMAIL</u> Dr. Scott Shell, DVM

#### Re: EAD Notice of Alleged Anti-Doping Rule Violations Possession of Banned Substances

Dear Dr. Shell:

This Equine Anti-Doping ("EAD") Notice letter is issued pursuant to Anti-Doping Medication Control ("ADMC") Program Rule 3245 of the Protocol (defined below) and serves to inform you that you have been found to be in possession of numerous Banned Substances and this may result in Anti-Doping Rule Violations and related Consequences. The alleged violations are described in more detail below.

#### I. Anti-Doping Rules - General

You are subject to the Equine Anti-Doping and Controlled Medication Protocol codified as Rule Series 3000 of the ADMC Program (the "Protocol"), including its supporting rules and documents. Results Management of this matter is the responsibility of HIWU. HIWU conducts Results Management in accordance with ADMC Program Rule 3240 of the Protocol and the Equine Testing and Investigations Standards. Capitalized terms used, but not defined within this letter, are as defined in Rule 1020 of the General Provisions and the Protocol.



#### II. Alleged Anti-Doping Rule Violations and Potential Consequences - Specific

Specifically, as a Covered Person as defined in ADMC Program Rule 3040 of the Protocol, ADMC Program Rule 3214(a) holds you liable for the possession of any Banned Substance absent a compelling justification. A Banned Substance is defined by ADMC Program Rule 3111(a)(1) as substances that are "prohibited at all times (Banned Substances and Banned Methods) on the basis of the Agency's determination that medical, veterinary, and/or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance of Covered Horses, or (ii) masking properties, and/or (iii) detrimental impact on horse welfare. Banned Substances are set forth in ADMC Program Rule Series 4000 and the Prohibited List.

On September 28, 2023, HIWU Investigators recovered from your possession the following Banned Substances:

- 1. One tub of Isoxsuprine powder;
- 2. Two jars of Carolina Gold (GABA); and
- 3. Two boxes of Osphos (Bisphosphonate).

If it is agreed or determined that an Anti-Doping Rule Violation has occurred, the following Consequences may be imposed <u>per violation</u> pursuant to ADMC Program Rules 3221, 3222, and 3223: two years of Ineligibility for you; a fine of up to \$25,000 USD; payment of adjudication costs and some or all of HIWU's legal fees; and Public Disclosure pursuant to ADMC Program Rule 3620 of the Protocol.

Collectively, if all the alleged violations are agreed or determined to have occurred, your total period of combined Ineligibility would be six (6) years; the total combined fine would be \$75,000; payment of adjudication costs and some or all of HIWU's legal fees; and Public Disclosure pursuant to ADMC Program Rule 3620 of the Protocol.

#### III. Relevant Facts

On September 28, 2023, HIWU Investigators Edward Arriola and Richard Thomas conducted searches of Dr. Shell's office at JACK Thistledown Racino ("Thistledown") and his Veterinarian Truck, Ohio Tag Number PIZ-4892. The following Banned Substances were some of the evidence that was recovered:

1. <u>One tub of Isoxsuprine powder</u>.



One tub of Isoxsuprine powder was recovered from Dr. Shell's Veterinarian Truck, Ohio Tag Number PIZ-4892. A prescription label from Dr. Shell's practice is affixed to the tub, prescribing a dose of  $\frac{1}{4}$  -  $\frac{1}{2}$  scoop twice daily. The tub is not prescribed to any specific horse and no Owner is identified on the label.

Isoxsuprine is a vasodilator that lacks FDA approval. It is identified as a Category S0 Banned Substance on the Prohibited List. The tub was seized and placed in an evidence bag and labeled as Evidence Exhibit RT-8; see enclosed photographs of same.

#### 2. <u>Two bottles of "Carolina Gold" (GABA).</u>

Two 100 mL bottles of a substance labeled as "Carolina Gold" were recovered from Dr. Shell's Veterinarian Truck, Ohio Tag Number PIZ-4892. The prescription labels on both bottles indicate that they were prescribed by Dr. Shell to "Snazzy Horse." Snazzy is a Covered Horse (H-000-050-099), currently stabled at Thistledown whose Attending Veterinarian on file with HISA is Dr. Shell.

Carolina Gold contains GABA, as indicated on the labels affixed to both bottles, which is a neurotransmitter. GABA, or Gamma Aminobutyric Acid, is identified as a Category S0 Banned Substance on the Prohibited List. Both bottles of Carolina Gold were seized and placed in separate evidence bags labeled as Evidence Exhibit RT-11 and RT-14; see enclosed photographs of same.

#### 3. <u>Two boxes of Osphos (Bisphosphonate)</u>.

Two boxes of Osphos, a bisphosphonate, were recovered from Dr. Shell's office on the backside at Thistledown. The two boxes of Osphos were located on a shelf inside Dr. Shell's office space and were not prescribed to any specific horse.

Bisphosphonates are identified as a Category S6 Banned Substance pursuant to ADMC Program Rule 4117(a). The two boxes of Osphos were seized and placed together in one evidence bag labeled as Evidence Exhibit RT-17; see enclosed photographs of same.

#### **IV.** Provisional Suspension

As required by ADMC Program Rule 3247(a)(1) of the Protocol, HIWU has imposed a Provisional Suspension on you as a Covered Person effective as of <u>October 5, 2023</u>.

Pursuant to ADMC Program Rule 3229, while serving a Provisional Suspension or period of Ineligibility for an Anti-Doping Rule Violation, a Covered Person may not participate in any



capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

You have the opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension or an opportunity for an expedited hearing in accordance with ADMC Program Rule 3262 (Protocol) on a timely basis after imposition of the Provisional Suspension. Any request for a Provisional Hearing should be requested, in writing, by <u>October 10, 2023 on or before 5pm CST</u>.

Please inform HIWU, in writing at <u>afarrell@hiwu.org</u>, by <u>October 10, 2023 on or before</u> <u>5pm CST</u> if you intend to exercise your right to a Provisional Hearing. Provisional Hearings will be conducted by the Arbitral Body and heard via telephone or video conference. The Arbitral Body will only make a determination regarding whether the Provisional Suspension should be lifted pending the final adjudication of this matter; the Arbitral Body will not take up any other issues in the Provisional Hearing. ADMC Program Rule 3247(c) (Protocol) requires that a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes one of the four criteria set forth in ADMC Program Rule 3247(c)(1-4) (Protocol). Note that if you respect the Provisional Suspension, the time served under the Provisional Suspension will be credited against any period of Ineligibility that may ultimately be imposed.

#### V. Resolution and Your Rights Under the Protocol: Substantial Assistance, Early Admission, and Explanation

In accordance with ADMC Program Rule 3226 of the Protocol, you have the opportunity to provide Substantial Assistance or admit the alleged Anti-Doping Rule Violation(s) with the potential benefit of receiving a reduction to any period of Ineligibility that may be imposed. Further, you may seek to enter into a case resolution without a hearing pursuant to ADMC Program Rule 3249 (Protocol). In this case, early admittance and acceptance of the violations under ADMC Program Rule 3226(d)(2) would reduce your period of Ineligibility imposed by six (6) months per violation. Please note, at any time during or after the Results Management of your matter, you can provide Substantial Assistance and HIWU will evaluate if a suspension of all or part of any resulting Consequences is appropriate.

At this time prior to the issuance of formal charges, you have the opportunity to provide an explanation to HIWU. Please submit all applicable information along with your explanation to



HIWU's Senior Litigation Counsel, Allison Farrell, by email to <u>afarrell@hiwu.org</u> by <u>October</u> <u>11, 2023</u>. Furthermore, if you seek to enter into a case resolution without a hearing, please notify HIWU, in writing, immediately.

#### VI. Other Information

Additional Notice letters may be sent in the future based upon further review of additional evidence.

Pursuant to ADMC Program Rule 3610(b) of the Protocol, HIWU will use its reasonable endeavors to ensure that Persons under its control do not publicly identify Covered Horses or Covered Persons who are alleged to have committed a violation under the Protocol, unless and until: (i) in presence cases, the B Sample confirms the results of the A Sample analysis, or the B Sample analysis is waived; (ii) a Provisional Suspension has been imposed or voluntarily accepted; (iii) a charge has been brought; or (iv) a violation has been admitted, whichever is earlier. In such circumstances (except where the Covered Person is a Minor), HIWU shall publicly report: (i) the identity of any Covered Person who is the subject of the alleged violation; (ii) the identity of any relevant Covered Horses(s); and (iii) the rule violated and, where appropriate, the basis of the asserted violation. HIWU shall not be required to publicly report a matter if it would risk compromising an ongoing investigation or proceeding. If HIWU determines that an ongoing investigation or proceeding will no longer be compromised by public reporting, HIWU shall at such time make any public reporting. HIWU shall Publicly Disclose the resolution of an alleged violation of the Protocol in accordance with ADMC Program Rule 3620.

By copy of this EAD Notice letter, HIWU is notifying HISA. Pursuant to ADMC Program Rule 7060(a) (Arbitration Procedures), HISA is invited to participate as an observer in this case. If they accept by sending an acceptance email to HIWU at <u>afarrell@hiwu.org</u> they will receive copies of the filings in the case. Except as provided in the Protocol, HIWU will not publicly disclose the specifics of this matter until resolution of the case.

Please read this EAD Notice letter carefully and take note of the deadlines set forth herein. You have the right to contact an attorney of your choosing in an effort to seek legal advice, should you desire to do so. If you have any questions regarding this letter, please contact me at (816) 602-0945 or <u>afarrell@hiwu.org</u>.



Sincerely,

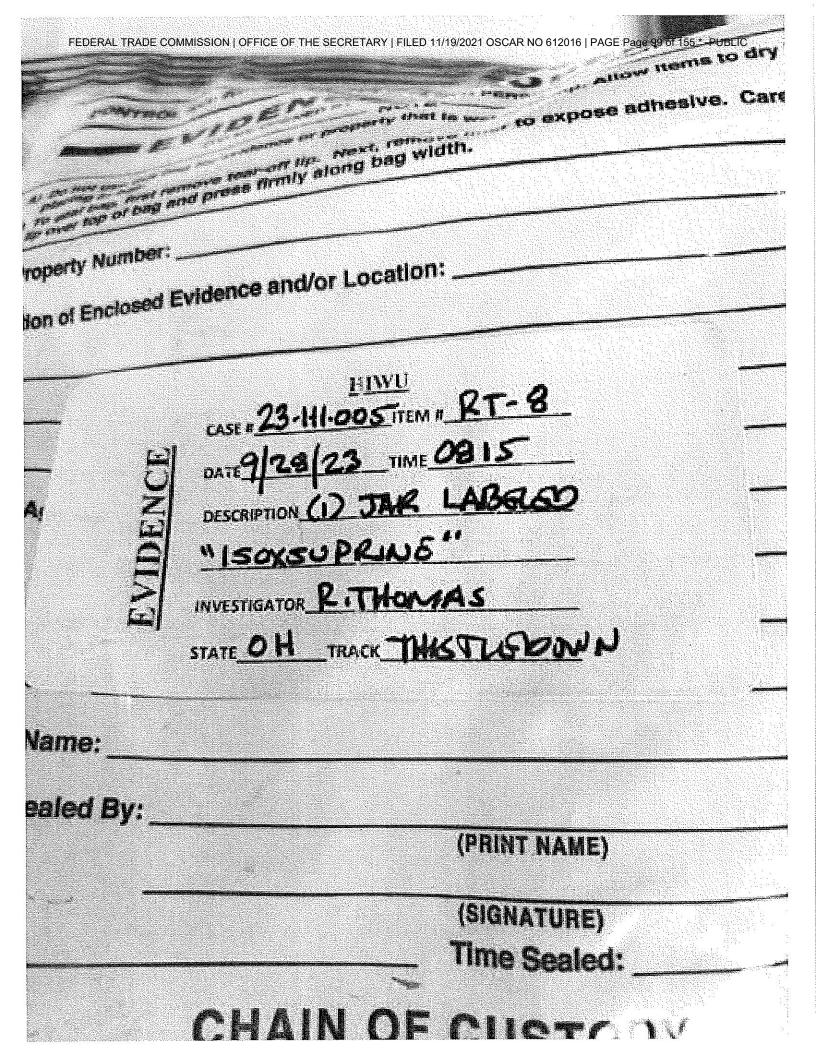
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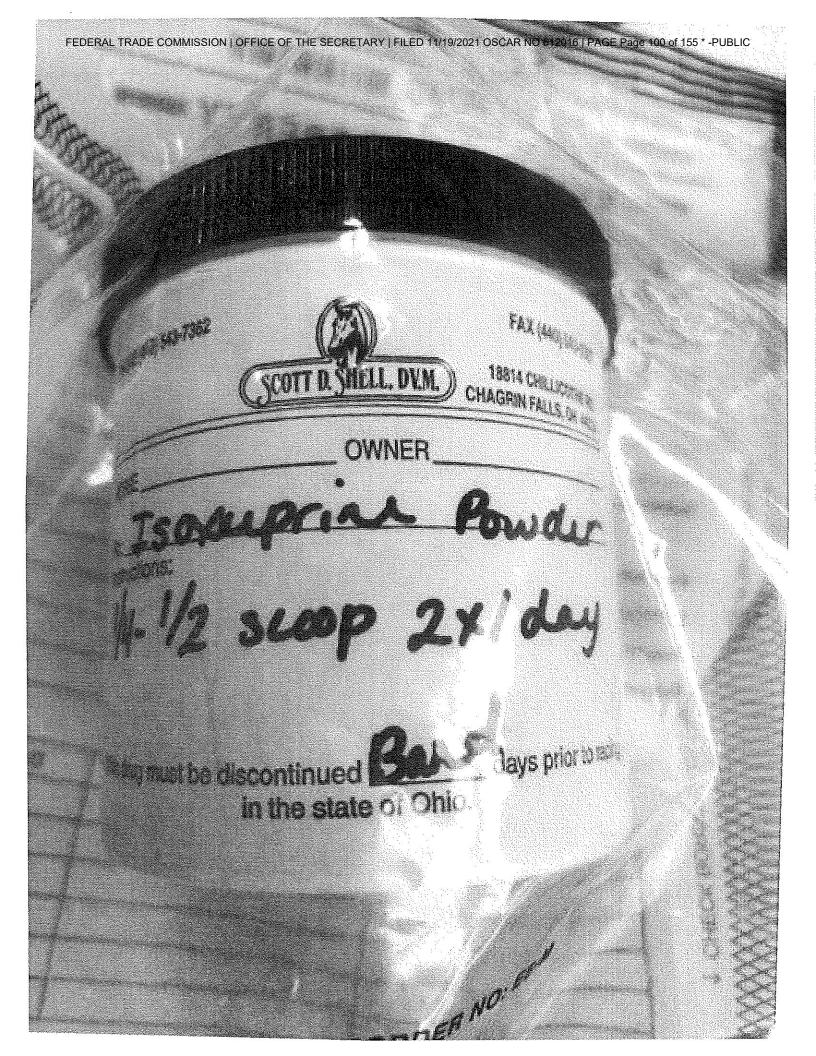
Allison J. Farrell Senior Litigation Counsel

Encl.: Evidence Photos

cc (w/ encl.): John Roach, HISA Samuel Reinhardt, HISA Lisa Lazarus, HISA

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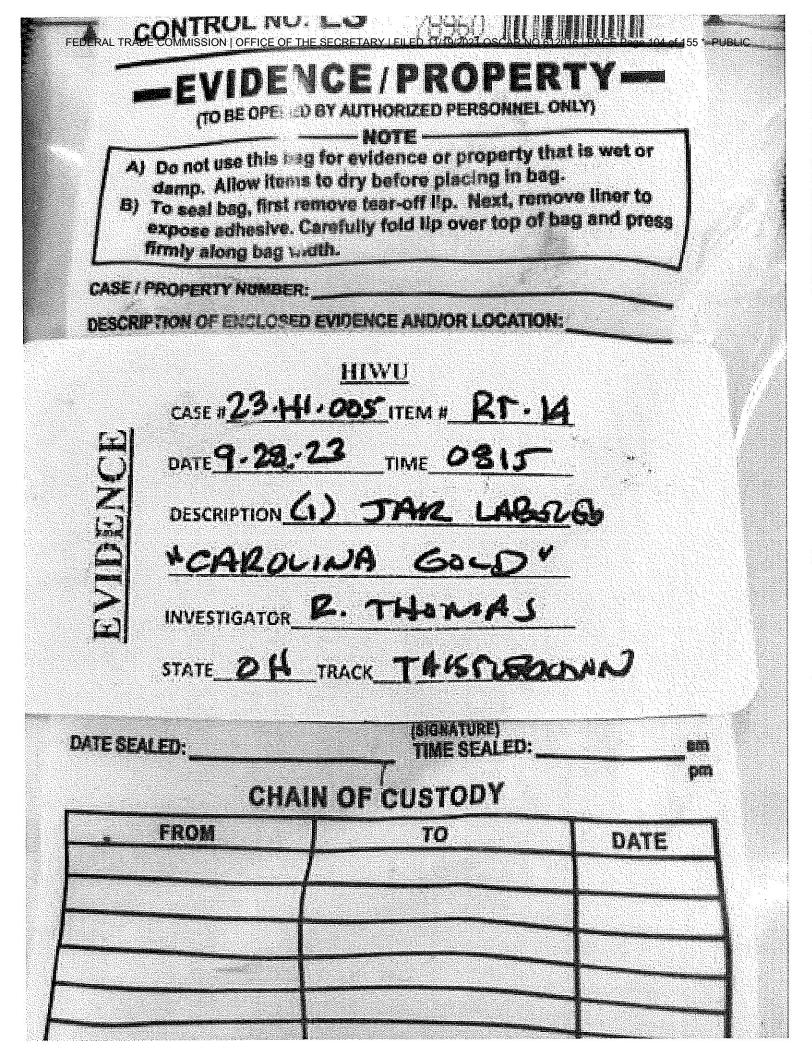
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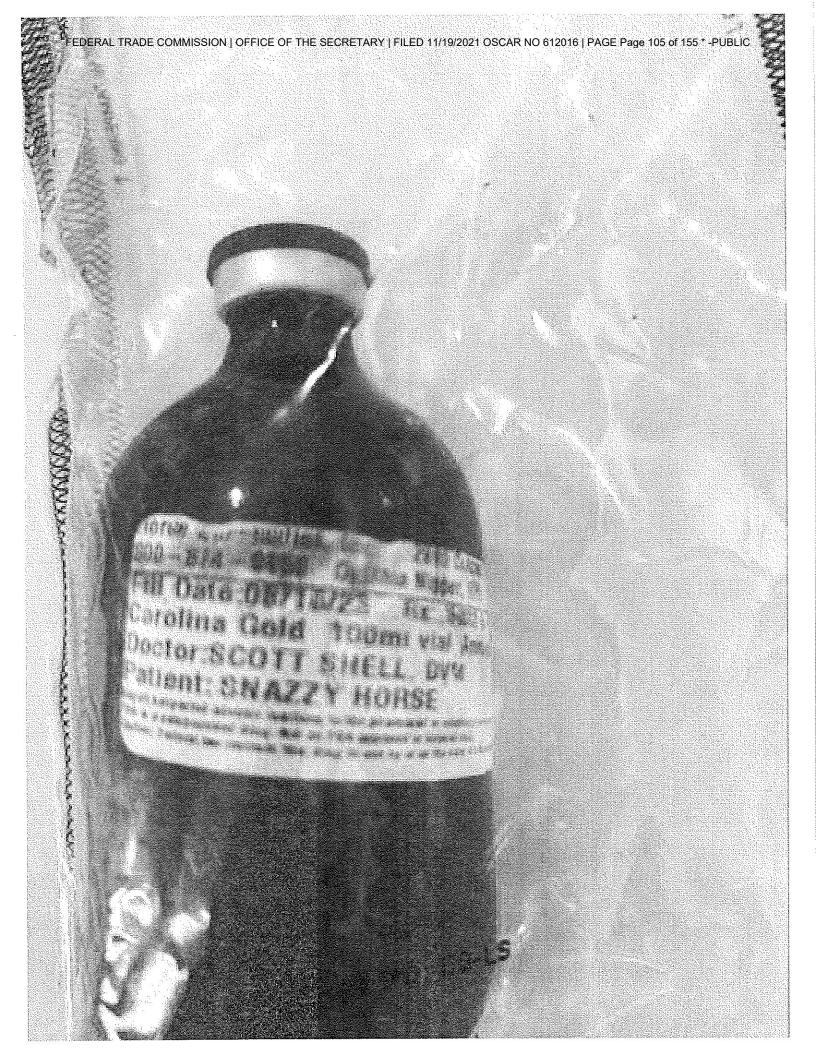
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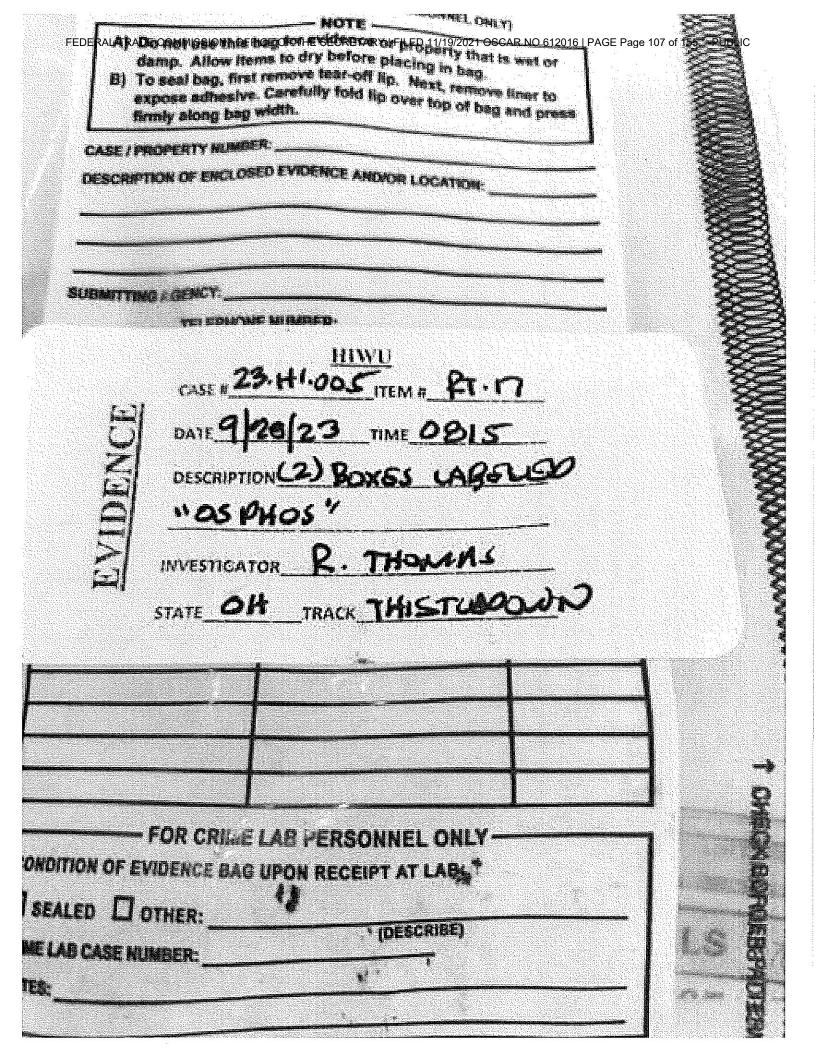
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## **OSPHOS** (clodronate injection) 60 mg/mL Responsionale

For intramuscular use in horses only.

Single use vial; discard unused boñioa.

Cauton: Federal Law restricts this drug to use by or on the order of a icessed veterinarian.

Agencies by FDA under NADA # 141-427

### 15 mL



## **OSPHOS** (clodronate injection)

60 mg/mL Bisphosphonate

For Intramuscular use in horses only.

Single use vial; discard unused portion.

Caution: Federal Law restricts this drug to use by or on the order of a Icensed veterinarian,

Dechra

Approved by FDA under NADA # 141-427

15 mL

(b) Where a Provisional Suspension is imposed pursuant to Rule 3247(a), the Responsible Person (on his or her own behalf and on behalf of the Covered Horse) and any other Covered Person made subject to the Provisional Suspension shall be given:

(1) an opportunity for a Provisional Hearing before imposition of the Provisional Suspension;

(2) an opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension; or

(3) an opportunity for an expedited final adjudication in accordance with Rule 3262 on a timely basis after imposition of the Provisional Suspension.

(c) Provisional Hearings shall be conducted by the Arbitral Body and heard via telephone or video conference call within the time frame specified in accordance with the Arbitration Procedures. The sole issue to be determined by the Arbitral Body will be whether the Agency's decision to impose a Provisional Suspension shall be maintained. The Agency's decision to impose a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes that: (1) the allegation that an Anti-Doping Rule Violation has been committed has no reasonable prospect of being upheld, e.g., because of a material defect in the evidence on which the allegation is based; (2) the Responsible Person/Covered Person charged bears No Fault or Negligence for the Anti-Doping Rule Violation that is alleged to have been committed, so that any period of Ineligibility that might otherwise be imposed for such offense would be completely eliminated by application of Rule 3224. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); (3) Rule 3225 applies and the Responsible Person/Covered Person bears No Significant Fault or Negligence and he or she will likely be given a period of Ineligibility that is not longer than the period for which he or

she has already been provisionally suspended (this ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); or

(4) exceptional circumstances exist that make it clearly unfair, taking into account all of the circumstances of the case, to impose a Provisional Suspension prior to the final hearing on the merits. This ground is to be construed narrowly and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Responsible Person, Covered Person, or Covered Horse from participating in a particular Timed and Reported Workout, Covered Horserace, or other activity shall not qualify as exceptional circumstances for these purposes.

# EXHIBIT G

FEDERAL TRADE COMMISSION | OFFICE OF THE SECRETARY | FILED 11/19/2021 OSCAR NO 612016 | PAGE Page 112 of 155 \* -PUBLIC



### CONFIDENTIAL

Allison J. Farrell Senior Litigation Counsel Horseracing Integrity & Welfare Unit 4801 Main Street Suite 350 Kansas City, MO 64112-2749

December 4, 2023

DELIVERED VIA EMAIL Dr. Scott Shell, DVM

#### Re: EAD Notice of Alleged Anti-Doping Rule Violation Possession of Banned Substance

Dear Dr. Shell:

This Equine Anti-Doping ("EAD") Notice letter is issued pursuant to Anti-Doping Medication Control ("ADMC") Program Rule 3245 of the Protocol (defined below) and serves to inform you that in addition to the Banned Substances for which you were already charged on October 25, 2023, you have been found to be in possession of an additional Banned Substance and this may result in an additional Anti-Doping Rule Violation and related Consequences. The alleged additional violation is described in more detail below.

#### I. Anti-Doping Rules - General

You are subject to the Equine Anti-Doping and Controlled Medication Protocol codified as Rule Series 3000 of the ADMC Program (the "Protocol"), including its supporting rules and documents. Results Management of this matter is the responsibility of HIWU. HIWU conducts Results Management in accordance with ADMC Program Rule 3240 of the Protocol and the



Equine Testing and Investigations Standards. Capitalized terms used, but not defined within this letter, are as defined in Rule 1020 of the General Provisions and the Protocol.

#### II. Alleged Anti-Doping Rule Violations and Potential Consequences - Specific

Specifically, as a Covered Person as defined in ADMC Program Rule 3040 of the Protocol, ADMC Program Rule 3214(a) holds you liable for the possession of any Banned Substance absent a compelling justification. A Banned Substance is defined by ADMC Program Rule 3111(a)(1) as substances that are "prohibited at all times (Banned Substances and Banned Methods) on the basis of the Agency's determination that medical, veterinary, and/or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance of Covered Horses, or (ii) masking properties, and/or (iii) detrimental impact on horse welfare. Banned Substances are set forth in ADMC Program Rule Series 4000 and the Prohibited List.

#### A. One bottle of Sarapin (Pitcher Plant).

If it is agreed or determined that an Anti-Doping Rule Violation has occurred, the following Consequences may be imposed pursuant to ADMC Program Rules 3221, 3222, and 3223: two years of Ineligibility for you; a fine of up to \$25,000 USD; payment of adjudication costs and some or all of HIWU's legal fees; and Public Disclosure pursuant to ADMC Program Rule 3620 of the Protocol.

If this new violation is agreed or determined to have occurred, your total period of combined Ineligibility for all four alleged violations would be eight (8) years; the total combined fine would be \$100,000; payment of adjudication costs and some or all of HIWU's legal fees; and Public Disclosure pursuant to ADMC Program Rule 3620 of the Protocol.

#### III. Relevant Facts

On September 28, 2023, HIWU Investigators Edward Arriola and Richard Thomas conducted searches of Dr. Shell's office at JACK Thistledown Racino ("Thistledown") and his Veterinarian Truck, Ohio Tag Number PIZ-4892. The following Banned Substances were some of the evidence that was recovered: (1) one tub of Isoxsuprine Powder, (2) two jars of Carolina Gold (GABA), and (3) two boxes of Osphos (Bisphosphonate).

In addition to these Banned Substance, one bottle of Sarapin (Pitcher Plant) was recovered from Scott Shell DVM Inc.'s Veterinarian Truck, Ohio Tag Number PDY-9013, parked on the backside at Thistledown. The bottle of Sarapin (Pitcher Plant) was located inside the truck storage unit and was prescribed to Totally Obsessed (H-000-021-292). The prescription label indicated



that the Sarapin was prescribed by Dr. Scott Shell. Totally Obsessed is a Covered Horse whose Attending Veterinarian on file with HISA is Dr. Scott Shell.

The truck was being driven by Dr. Barbara Hippie, an associate of Dr. Scott Shell DVM Inc. The most current owner registration shows that the current title holder of the truck is Scott Shell DVM Inc.

Sarapin (Pitcher Plant) is identified as a Category S6 Banned Substance pursuant to ADMC Program Rule 4117(e). The bottle of Sarapin (Pitcher Plant) was seized and placed in an evidence bag labeled as Evidence Exhibit RT-3; see enclosed photographs of same.

#### IV. Provisional Suspension

As required by ADMC Program Rule 3247(a)(1) of the Protocol, HIWU has already imposed a Provisional Suspension on you as a Covered Person effective as of and pursuant to an EAD Notice served to you on October 5, 2023, and affirmed following a Provisional Hearing Decision on October 30, 2023. A Provisional Suspension in respect of <u>the additional alleged Anti-Doping Rule Violation for possession of Sarapin (Pitcher Plant)</u> is imposed on you as a Covered Person effective as of <u>December 4, 2023</u>.

Pursuant to ADMC Program Rule 3229, while serving a Provisional Suspension or period of Ineligibility for an Anti-Doping Rule Violation, a Covered Person may not participate in any capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

You have the opportunity for a Provisional Hearing on the additional alleged Anti-Doping Rule Violation for possession of Sarapin (Pitcher Plant) on a timely basis or an opportunity for an expedited hearing in accordance with ADMC Program Rule 3262 (Protocol) on a timely basis. Any request for a Provisional Hearing should be requested, in writing, by <u>December 11, 2023, on or before 5pm CST</u>.

Please inform HIWU, in writing at <u>afarrell@hiwu.org</u>, by <u>December 11, 2023, on or</u> <u>before 5pm CST</u> if you intend to exercise your right to a Provisional Hearing. Provisional Hearings will be conducted by the Arbitral Body and heard via telephone or video conference. The Arbitral Body will only make a determination regarding whether the Provisional Suspension in respect of the additional alleged Anti-Doping Rule Violation for possession of Sarapin (Pitcher



Plant) should be lifted pending the final adjudication of this matter; the Arbitral Body will not take up any other issues in the Provisional Hearing. ADMC Program Rule 3247(c) (Protocol) requires that a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes one of the four criteria set forth in ADMC Program Rule 3247(c)(1-4) (Protocol). Note that if you respect the Provisional Suspension, the time served under the Provisional Suspension will be credited against any period of Ineligibility that may ultimately be imposed.

### V. Resolution and Your Rights Under the Protocol: Substantial Assistance, Early Admission, and Explanation

In accordance with ADMC Program Rule 3226 of the Protocol, you currently have the opportunity to provide Substantial Assistance or admit only the additional alleged Anti-Doping Rule Violation for possession of Sarapin (Pitcher Plant) with the potential benefit of receiving a reduction to any period of Ineligibility that may be imposed. Further, you may seek to enter into a case resolution without a hearing pursuant to ADMC Program Rule 3249 (Protocol). In this case, early admittance and acceptance of the additional alleged violation under ADMC Program Rule 3226(d)(2) would reduce your period of Ineligibility imposed by six (6) months only for the additional alleged violation. Please note, at any time during or after the Results Management of your matter, you can provide Substantial Assistance and HIWU will evaluate if a suspension of all or part of any resulting Consequences is appropriate.

At this time prior to the issuance of formal charges for the additional alleged violation, you have the opportunity to provide an explanation to HIWU. Please submit all applicable information along with your explanation to HIWU's Senior Litigation Counsel, Allison Farrell, by email to <u>afarrell@hiwu.org</u> by <u>December 11, 2023</u>. Furthermore, if you seek to enter into a case resolution without a hearing, please notify HIWU, in writing, immediately.

#### VI. Other Information

Additional Notice letters may be sent in the future based upon further review of additional evidence.

Pursuant to ADMC Program Rule 3610(b) of the Protocol, HIWU will use its reasonable endeavors to ensure that Persons under its control do not publicly identify Covered Horses or Covered Persons who are alleged to have committed a violation under the Protocol, unless and until: (i) in presence cases, the B Sample confirms the results of the A Sample analysis, or the B Sample analysis is waived; (ii) a Provisional Suspension has been imposed or voluntarily accepted; (iii) a charge has been brought; or (iv) a violation has been admitted, whichever is earlier. In such



circumstances (except where the Covered Person is a Minor), HIWU shall publicly report: (i) the identity of any Covered Person who is the subject of the alleged violation; (ii) the identity of any relevant Covered Horses(s); and (iii) the rule violated and, where appropriate, the basis of the asserted violation. HIWU shall not be required to publicly report a matter if it would risk compromising an ongoing investigation or proceeding. If HIWU determines that an ongoing investigation or proceeding by public reporting, HIWU shall at such time make any public reporting. HIWU shall Publicly Disclose the resolution of an alleged violation of the Protocol in accordance with ADMC Program Rule 3620.

By copy of this EAD Notice letter, HIWU is notifying HISA. Pursuant to ADMC Program Rule 7060(a) (Arbitration Procedures), HISA is invited to participate as an observer in this case. If they accept by sending an acceptance email to HIWU at <u>afarrell@hiwu.org</u> they will receive copies of the filings in the case. Except as provided in the Protocol, HIWU will not publicly disclose the specifics of this matter until resolution of the case.

Please read this EAD Notice letter carefully and take note of the deadlines set forth herein. You have the right to contact an attorney of your choosing in an effort to seek legal advice, should you desire to do so. If you have any questions regarding this letter, please contact me at (816) 602-0945 or <u>afarrell@hiwu.org</u>.

Sincerely,

Alim Havel

Allison J. Farrell Senior Litigation Counsel

Encls.: Evidence Photos

cc (w/ encls.): Andrew Mollica, Esq., counsel for Dr. Shell John Roach, HISA Samuel Reinhardt, HISA Lisa Lazarus, HISA FEDERAL TRADE COMMISSION | OFFICE OF THE SECRETARY | FILED 11/19/2021 OSCAR NO 612016 | PAGE Page 117 of 155 \* -PUBLIC

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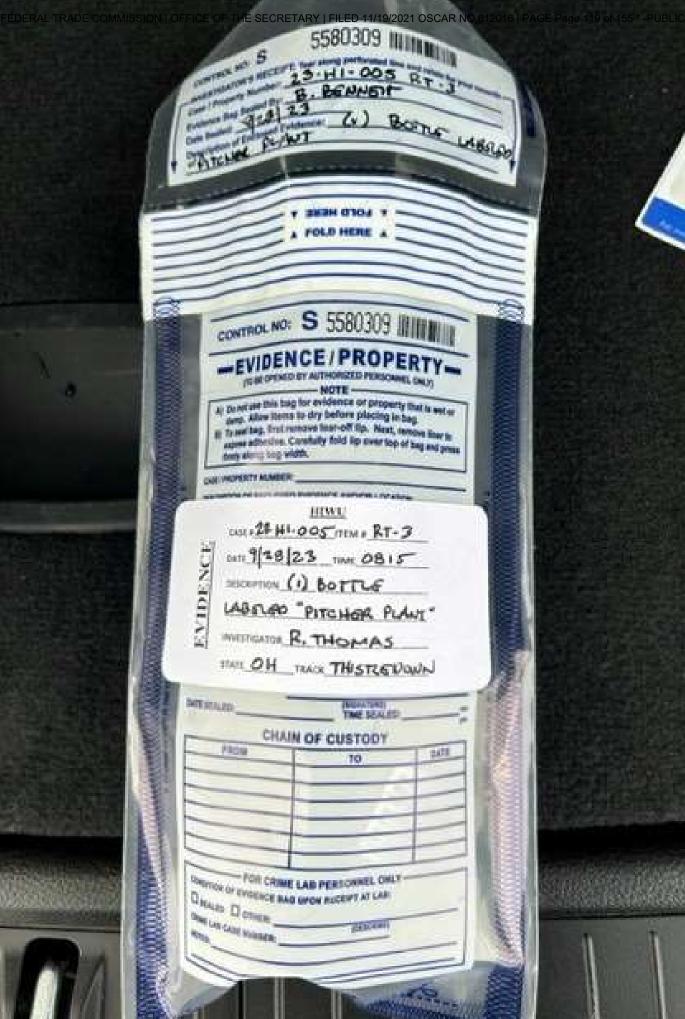
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## EXHIBIT H

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL**

ADMINISTERED BY JAMS, CASE NO. 1501000589

#### In the Matter of the Arbitration Between:

### HORSE RACING INTEGRITY WELFARE UNIT, Claimant

v.

LUIS JORGE PEREZ, Respondent.

#### 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 in New York, New York, via Zoom, on September 18, 2023, 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 possession of a prohibited substance at a racetrack by a veterinarian who treats thoroughbred racehorses and non-racehorses.

1.2 The Respondent, Veterinarian Luis Jorge Perez ("Dr. Perez" or "Respondent"), has been charged with an anti-doping rule violation for Possession of a Banned Substance in breach of Rule 3214(a) of the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Program (Protocol) ("ADMC Program").

1.3 Two tubs of the Banned Substance Levothyroxine Sodium Powder ("Thyro-L") were found in Dr. Perez's trailer at the Belmont Park. This is the first asserted anti-doping rule violation (ADRV) brought against a veterinarian for possession of Thyro-L since the ADMC Program took effect on May 22, 2023.

1.4 Claimant Horseracing Integrity Welfare Unit ("HIWU" or "Claimant" or "the Agency"), 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 initially by Allison Ferrell, Senior Litigation Counsel of HIWU, and Zachary P.

Ceriani, Esq., Investigations Counsel of HIWU, who was later joined by James Bunting, Esq., of Tyr, LLP, of Toronto, Ontario, Canada.

1.5 Dr. Perez is veterinarian who provided veterinary services for thoroughbred racehorses and non-racehorses at Belmont Park. Dr. Perez was represented in these proceedings by Robert Del Grosso, Esq., based in Mineola, New York.

1.6 Pursuant to ADMC Rule 7060(a), on July 20, 2023, Sam Reinhardt, Assistant General Counsel, HISA, gave notice that the Horseracing Integrity and Safety Authority, Inc. ("HISA") was exercising its right to participate as an observer in this proceeding.

1.7 Throughout this Final Decision, HIWU and Dr. Perez 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 Decision only to the submissions and evidence the Arbitrator considers necessary to explain his reasoning. Except as noted, the facts are generally not in dispute, though the legal effect of those facts might be.

#### The Facts According to HIWU

2.2 On March 21, 2023, Dr. Perez attended the seminar session that <u>HIWU held at</u> the Belmont Park. During this seminar, Dr. Mary Scollay, Chief of Science for HIWU presented on the ADMC Program. Dr. Scollay's presentation clearly discloses, among other things, that Thyro-L (thyroxine) would be banned.

2.3 Dr. Scollay presented a similar seminar on March 24, 2023, at Will Rogers Downs, in Oklahoma. During that seminar, Dr. Scollay was asked by one of the attendees about veterinarians whose practice includes farm work or Non-Covered Horses and whether the Possession rules applied to them. Dr. Scollay responded explaining that veterinarians whose practice includes Non-Covered Horses "*are able to possess of a Banned Substance*"....*the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses.* 

2.4 On Friday, June 9, 2023, New York Racing Association ("NYRA") investigator Tony Patricola attended Trailer #2 in the Veterinarian's Village following a phone call from Fire Marshal Joseph McSweeney. On attending the trailer, Mr. Patricola observed used injection needles that were lying on the floor of the trailer. Mr. Patricola also found that the medical waste in Trailer #2 was being packaged in cardboard boxes and stored in the trailer instead of being disposed regularly as is required by agreement with the NYRA. Investigator Patricola engaged in a discussion with Dr. Perez about the medical waste and generally found Dr. Perez to be agitated, argumentative and uncooperative.

2.5 Mr. Patricola then attended Dr. Perez' trailer next to Barn 15 (Trailer #6). Dr. Perez advised investigator Patricola that Trailer #6 functioned as his office. On the inside of the perimeter fence of the trailer, and throughout the trailer, Mr. Patricola again found a disarray of garbage and medical waste. The trailer was generally disorganized with garbage and boxes throughout so that it was impossible to walk through without climbing over garbage.

2.6 Investigator Patricola located two (2) one-pound tubs of Thyro-L. Investigator Patricola then asked Dr. Perez to show him the safe where he was storing his controlled substances in compliance with DEA regulations. Dr. Perez refused to do so. At this point, Investigator Patricola called Naushaun Richards, the Director of Intelligence and Strategy, for HIWU and briefed him on the situation and notified him that he had found a Banned Substance, Thyro-L, in Dr. Perez's trailer.

2.7 At approximately 12:30 pm, HIWU investigators Greg Pennock, Richard Thomas, and Brian Bennett (collectively referred to as "HIWU Investigators") arrived at Trailer #6 and conducted a search. During the search, investigator Brian Bennet seized two (2) one-pound tubs of Thyro-L. Along with the Thyro-L, HIWU Investigators also seized an unmarked bottle containing liquid of unknown origin, which was later confirmed to contain Cyproheptadine, Metronidazole and Prednisolone. When asked about the clear liquid, Dr. Perez was unable to recall what substances were inside and advised that he had forgotten that the container was in his refrigerator.

2.8 Dr. Perez eventually agreed to show HIWU Investigators where he stored his controlled substances. They were in the back room of the trailer in an unsecured box that was not capable of being locked. Dr. Perez was told that the substances were not adequately secured but did not appear to be concerned with the matter.

2.9 During the search, Dr. Perez stated that he knew Thyro-L was a Banned Substance and, although he couldn't remember when, he estimated that the Thyro-L would have been purchased approximately 6 months prior (around January 2023). Dr. Perez also advised stated that "[t]he Thyro-L is just sitting in a box."

2.10 After the search was conducted, Dr. Perez was interviewed by HIWU Investigators. After being advised by the investigators of their identity and the nature of the interview, Dr. Perez made the following statements:

(a) The Thyro-L located in Trailer #6 belonged to him;

(b) He had purchased the Thyro-L prior to the implementation of the ADMC Program;

(c) He was aware that Thyro-L had become a Banned Substance but failed to properly dispose of it;

(d) The "Thyro-L was just sitting in a box" and he had not used it since it had become a Banned Substance, but that it had been used by Dr. Perez before becoming a Banned Substance on a case-by-case basis and with approval to do so; and

(e) That Thyro-L was not a bad product but had to be properly used and not overly utilized.

2.11 At no point did Dr. Perez advise that the Thryo-L was being administered to a Non-Covered Horse.

2.12 On June 13, 2023, Dr. Perez was issued a Notice of Alleged Anti-Doping Rule Violation for the Possession of Banned Substance (Thyro-L) ("Notice Letter") and imposed a Provisional Suspension effective as of June 14, 2023.

2.13 On June 17, 2023, Dr. Perez responded to HIWU's Notice Letter, in writing. In his letter, Dr. Perez admitted his Possession of Thyro-L, stating "For this failure I accept full responsibility. My offense though was not intentional." Dr. Perez also provided the following explanations in his June 17, 2023, letter:

(a) In January 2023, Dr. Perez ordered a number of different medications intended to be kept in his stock in case the need arose where they would be required, that order included among others, two (2) one-pound containers of Thyro-L;

(b) At the time of purchasing the Thyro-L, it was not a Banned Substance pursuant to the ADMC Program;

(c) He had not used the medication in 6 months;

(d) He admitted that he should have done a thorough search of the trailer before the implementation of the ADMC Program on May 22, 2023, but "completely forgot" about the Thyro-L was in his trailer.

2.14 On June 26, 2023, the Agency charged Dr. Perez with Possession of a Banned Substance ("Charge Letter"). The Charge Letter advised that Dr. Perez' explanation of the circumstances leading to the alleged violation did not satisfy his burden to establish a "compelling justification" that would excuse the Possession of the Banned Substance as required by ADMC Program Rule 3214(a).

2.15 On July 10, 2023, counsel to Dr. Perez, sent a letter to HIWU advising of his involvement in the matter and acknowledging that (1) Dr. Perez had admitted to the anti-doping violation charged, and (2) Dr. Perez sought to agree to mitigated Consequences with HIWU, failing which the sanction would be disputed at a contested hearing.

2.16 An agreement on the reduction of Consequences was not reached.

#### The Facts According to Dr. Perez

2.17 Dr. Perez is a Doctor of Veterinary Medicine having graduated from the University of Tuskegee School of Veterinary Medicine in 2011. He practiced at the Louisiana Quarter Horse Circuit in 2011 through 2012; Parx Park in 2013, Fingerlakes Park in 2013 to 2018, and Belmont Park, Aqueduct, and Saratoga in 2018 to present.

2.18 On June 9, 2023, HIWU investigators were notified by NYRA investigator Anthony Patricola that he had observed a banned substance in Dr. Perez's office located in Trailer Six in the Veterinarian's Village at Belmont Park.

2.19 On June 9, 2023, at approximately 12:30 PM, HIWU investigators responded to Mr. Patricola's location and conducted a search of Dr. Perez's office in Trailer Six. During the search, HIWU Investigator Brian Bennett recovered two (2), one-pound canisters of Thyro-L (Levothyroxine Sodium Powder for horses). Levothyroxine is classified as an S4 Banned Substance pursuant to Prohibited List Rule 4115 and Appendix 1 to Rule Series 4000. Investigator Bennett seized the canisters as evidence. Dr. Perez stated he purchased and possessed the Thyro-L, to HIWU Investigator Richard Thomas, and stated further that he was aware the substance was then a Banned Substance.

2.20 Dr. Perez told the Investigators he had purchased said medication in or January 2023, for use in his veterinary practice for racehorses and non-racehorses at the horseracing tracks stated above. The Investigators scared him to the point that it was difficult to think and answer their questions fully and accurately. English is Dr. Perez's second language and there is a natural delay in his understanding and response. He advised that the substance was his, that he purchased it, that he was aware it was banned, that he did not use it after it was banned (May 22, 2023, 18 days prior to the search and seizure), and that it could be possessed and used legally for non-covered horses if indicated.

2.21 During the search, the Investigators also located an unlabeled bottle containing an unknown substance. The substance was seized, packaged, and sent out for testing and analysis. The subsequent analysis of same determined that said substance was not banned.

2.22 Pursuant to ADMC Program Rule 3247 (a)(3) of the Protocol, HIWU imposed a provisional suspension on Dr. Perez effective June 14, 2023, said suspension continuing to date. Said suspension prohibited Dr. Perez's participation in any capacity in any activity involving covered horses, or in any other activity taking place at a Racetrack or Training Facility.

2.23 Dr. Perez by letter, sent on or about June 17, 2023, without assistance of legal counsel, admitted the possession charge and sought to mitigate consequences with HIWU pursuant to Rule 3249 but requested a Hearing regarding same.

2.24 In or about March 24, 2023, in a meeting of the Thoroughbred Racing Association of Oklahoma, Dr. Mary Scollay, DVM, Chief of Science, HIWU, stated a veterinarian can possess a banned substance if said substance were for use on a non-covered horse at a racetrack.

2.25 In or about March 26, 2023, Dr. Scollay advised that a stable pony is not a Covered Horse and so HISA (Horseracing Integrity & Safety Authority) does not have jurisdiction over said horses. She further advised that Thyro-L may be prescribed and dispensed for Non-Covered Horses.

2.26 To date, neither HISA nor HIWU have promulgated any written procedure or regulation regarding the prescribing and dispensing of a banned substance for a non-covered horse at a racetrack. No prohibition of said practice has been issued.

2.27 Dr. Perez does not dispute that two tubs of the Banned Substance Levothyroxine Sodium Powder ("Thyro-L") were found in Dr. Perez's trailer at the Belmont Park.

2.28 Dr. Perez contends that the medication would be required to be stored at the racetrack due to the unfeasibility of transporting the non-covered horse off the racetrack to administer the medication.

#### The Stipulated Facts

2.29 The Parties submitted the following joint stipulation of facts, following the submission of their briefs:

"1. Dr. Perez is a licensed veterinarian in the state of New York and a Covered Person under the Anti-Doping and Medication Control Program ("ADMC Program") pursuant to ADMC Program Rule 3020.1

2. In March 2023, Dr. Perez attended the seminar conducted by Dr. Mary Scollay, Chief of science for the Horseracing Integrity & Welfare Unit ("HIWU"), presented on the ADMC Program, its rules, regulations, and expectations for Covered Persons. On March 24, 2023, Dr. Scollay made a presentation in Oklahoma. During that presentation Dr. Scollay made the following comments:

... if the veterinarians are practicing also on a population of non-Covered horses, they're taking care of quarter horses or they've got a country practice part-time they are able to possess a Banned Substance because we don't have control over those horses, and so to the extent that they want to use bisphosphonates on a Non-Covered horse, we can't ban them from possessing them... we can't penalize people for something that we don't have control over so, you know, let's just say because we have the ability to investigate, if the story starts to get a little weird or a little extreme, you're going to get more than a raised eyebrow. But at the end of the day if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses... the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses.

3. On Friday June 9, 2023, New York Racing Association ("NYRA") investigators and HIWU investigators attended and searched Trailers #2 and #6 located at Belmont Park Racetrack and belonging to Dr. Perez, Fire Marshall investigators were also in attendance.

4. During the search of Trailer #6, HIWU investigators were shown the location of and seized two (2) one-pound tubs of a substance known as Levothyroxine ("Thyro-L") that were in a box sitting on top of a cabinet unit inside the office area of the trailer.

5. Levothyroxine is an S4 metabolic hormone classified under the ADMC Program list as a Banned Substance.

6. On June 13, 2023, Dr. Perez was issued a Notice of Alleged Anti-Doping Rule Violation ("ADRV") for the Possession of a Banned Substance ("Notice Letter"), in violation of ADMC Program Rule 3214(a).

7. On June 17, 2023, Dr. Perez responded to HIWU's Notice Letter, stating that he accepted full responsibility and that his offense was not intentional. Dr. Perez also advised that:

(a) In January 2023, Dr. Perez ordered a number of different medications intended to be kept in his stock in case the need arose where they would be required, that order included among others, two (2) one-pound containers of Thyro-L;

(b) At the time of purchasing the Thyro-L, it was not a Banned Substance pursuant to the ADMC Program;

(c) He had not used the medication in 6 months; and

(d) He admitted that he should have done a thorough search of the trailer before the implementation of the ADMC Program on May 22, 2023, but "completely forgot" about the Thyro-L in his trailer.

8. While Dr. Perez confirms he made the statements set out in paragraph 7 above, he disputes the evidentiary and/or legal position of HIWU that these statements constitute an admission of any nature or kind.

9. On June 26, 2023, the Agency charged Dr. Perez with Possession of a Banned Substance ("Charge Letter"). The Charge Letter advised Dr. Perez that his explanation of the circumstances leading to the alleged violation did not satisfy his burden to establish a "compelling justification" as would be required to excuse the Possession of a Banned Substance pursuant to ADMC Program Rule 3214(a). 10. Dr. Perez confirms and acknowledges that the substance found in the two (2) onepound tubs was Thyro-L. He further confirms and acknowledges that he was in possession of the two tubs. However, Dr. Perez asserts that he was in lawful possession of Thyro-L."

#### **III. PROCEDURAL HISTORY**

3.1 On June 13, 2023, Dr. Perez was issued an Equine Anti-Doping ("EAD") Notice of Alleged Anti-Doping Rule Violation for the Possession of Banned Substance (Thyro-L) ("Notice Letter") and imposed a Provisional Suspension effective as of June 14, 2023.

3.2 On June 26, 2023, HIWU charged Dr. Perez with Possession of a Banned Substance ("Charge Letter"). The Charge Letter advised that Dr. Perez' explanation of the circumstances leading to the alleged violation did not satisfy his burden to establish a "compelling justification" that would excuse the Possession of the Banned Substance as required by ADMC Program Rule 3214(a).

3.3 On July 14, 2023, HIWU initiated arbitration against Dr. Perez.

3.4 On July 25, 2023, JAMS Issued a Notice of Commencement of Arbitration and Notice of Appointment of Provisional Hearing Arbitrator ("Commencement Letter") to all parties. The Commencement Letter confirmed the appointment of the arbitrator, Barbara A. Reeves, Esq., to assume carriage of this matter, and that the arbitration would be conducted in accordance with the ADMC Program Rule Series 7000 (Arbitration Procedures).

3.5 An organizational preliminary scheduling hearing was convened on July 28, 2023. After initial discussion, the parties requested that the hearing be adjourned to permit them time to discuss resolution.

3.6 On August 3, 2023, the Parties submitted a letter to the Arbitrator whereby they advised the Arbitrator that they had agreed to move ahead with a hearing on the merits and forego the hearing to lift the provisional suspension, and they had agreed that the Arbitrator would serve as the Arbitrator for the evidentiary hearing as no schedule setting or consideration of the merits had been had on the application to lift the provisional suspension.

3.7. On August 10, 2023, based on the Parties' agreed major dates, Arbitrator Reeves issued Procedural Order No. 1 in this matter declaring the hearing to be conducted on September 18, 2023, starting at 9:00am local time at the New York JAMS Resolution Center, 620 Eighth Avenue, New York, NY, and via the JAMS remote Zoom platform, if necessary, for any participants.

3.8 That Order was updated and corrected on August 25, 2023, Procedural Order No. 2 (to reflect a different order of submission of the pre-hearing briefs), and provides in pertinent part as follows:

Pursuant to the HIWU Anti-Doping Medication Control Program Rules 7290 (Arbitration Procedures) a conference call was held by Zoom on July 28, 2023, before sole

arbitrator Barbara Reeves ("Arbitrator"). Procedural Order No. 1 was issued on August 10, 2023. On August 24, 2023, counsel for Claimant reminded the Arbitrator that Dr. Perez has admitted the ADRV and he bears the onus of establishing that the Consequences should be reduced based on a finding of No Fault or No Significant Fault. As such, it was agreed that Dr. Perez would deliver his Pre-Hearing Brief first and HIWU would respond. The Arbitrator corrects the order of the briefing in this Order.

Appearing at the hearing on behalf of HIWU was Zachary Ceriani, Esq., and James Bunting, Esq., and appearing on behalf of Mr. Perez was Robert Del Grosso, Esq. (individually, HIWU and Mr. Perez shall be referred to herein as "**Party**" and collectively as "**Parties**").

The Parties requested that the matter be adjourned to permit time to confer. On August 3, 2023, the Parties submitted a joint letter to the Arbitrator agreeing upon the following schedule, and hearing location, and by Order of the Arbitrator, the following is now in effect:

- 1. <u>Regarding Briefs and Exhibits</u>
  - 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. Respondent's Pre-Hearing Brief: <u>August 25, 2023</u>; and
    - ii. Claimant's Pre-Hearing Brief: September 1, 2023.
  - b. The Parties shall submit their exhibits to be used at the hearing, electronically to the Arbitrator and the other Party <u>on the dates their</u> <u>respective initial pre-hearing briefs are due</u>. The Parties also shall include with their respective submissions an index to the exhibits. <u>All</u> <u>briefs, and any witness statements, shall be transmitted electronically in</u> <u>MS Word versions to the Arbitrator.</u>
  - c. Respondent used letters to mark his exhibits, and therefore Claimant shall use numbers to mark its exhibits, or the Parties may submit a joint set of exhibits, numbered or lettered as they agree. 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.
- 2. <u>Regarding Stipulations of Uncontested Facts and Procedure</u>
  - a. In each case, if they are able to agree, the Parties shall submit a

Stipulation of Uncontested Facts <u>on or before the date the first pre-</u> <u>hearing brief is due from Respondent</u>. The Parties did not do so, but may still attempt to agree on a Stipulation of Uncontested Facts.

- b. Claimant shall state efforts undertaken to agree to stipulations of uncontested fact with Respondent and the points of disagreement; Claimant may respond within seven (7) days thereafter.
- c. The Parties shall, in advance of the hearing, and <u>no later than 48 hours</u> <u>before the hearing</u>, agree upon and submit to the Arbitrator the order of witnesses 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. <u>Regarding Witnesses</u>
  - a. Respondent shall serve and file a disclosure of all witnesses reasonably expected to be called by Respondent <u>on or before the due date of his pre-hearing brief</u>. [Respondent has already submitted his pre-hearing brief and witness disclosures.]
  - b. Claimant shall serve and file a disclosure of all witnesses reasonably expected to be called <u>on or before the due date of its initial pre-hearing</u> <u>brief</u>.
  - 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 (defined below) so that the case can proceed with all due expedition and without any unnecessary delay.
- 4. <u>Regarding the Hearing</u>

The Hearing in this matter will commence before the Arbitrator in person on <u>September 18, 2023</u>, starting at <u>9:00am</u> local time at the New York JAMS Resolution

Center, 620 Eighth Ave., 34th Floor, New York, NY 10018, and via the JAMS remote Zoom platform, if necessary for any participants.

#### 5. <u>Regarding Submission of Documents</u>

All documents due to be submitted hereunder shall be submitted electronically by email to the Arbitrator at breeves@jamsadr.com and shall be submitted 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 other side, and the JAMS case manager, at the same time as the communications are made to the Arbitrator and in the same form.

#### 6. <u>Further Disputes Process</u>

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 filing on the JAMS Access system), outlining in basic, brief, general terms the nature of the dispute, their position thereon, and the relief being requested with relation thereto. The other side shall file a response, distributed to the same email list (and file with JAMS Access) and in line with the original email **shortly thereafter** briefly outlining in basic, 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. <u>Miscellaneous Provisions</u>
  - 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 <u>midnight Eastern Time</u> 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 <u>within seven (7)</u> <u>days of the date of this order</u> in writing.

3.9 On September 13, 2023, the Arbitrator issued Procedural Order No. 3, providing in pertinent part as follows:

"A Final Status Conference was held on September 11, 2023, and the following orders are made regarding the conduct of the Hearing.

1. Pursuant to agreement of the Parties, the Hearing will be held on September 18, 2023, via the JAMS remote Zoom platform, commencing at 9:00am (EDT), or such different time as determined by mutual agreement of the Parties.

2. The Parties shall provide the Arbitrator with a Joint Witness list, identifying the order in which the witnesses will be called, and an estimate of the length of their testimony, by close of business Friday, September 15, 2023.

3. The Parties shall provide the Arbitrator with a Joint Statement of Uncontested Facts by close of business Friday, September 15, 2023.

4. Counsel for Dr. Perez requested leave to submit an additional exhibit. Counsel shall confer. Absent a showing of undue prejudice, the Arbitrator will allow the additional exhibit.

5. The Hearing will be recorded using the Zoom link, and a copy of the recording will be provided to each party for use, if needed, in preparing a transcript."

3.10 The evidentiary hearing proceeded via the JAMS Zoom platform, commencing at 9:00am (EDT), on September 18, 2023. At the conclusion of the evidentiary hearing, both parties confirmed that they had been given a full, fair, and equal opportunity to present their case, and the Arbitrator confirmed the closing of the evidence.

3.11 Upon the adjournment of the hearing, and the closing of the evidence, the Arbitrator commenced writing this Final Decision. On October 14, 2023, the Arbitrator requested a one-week extension to complete the Final Decision, and the Parties agreed to the extension.

#### **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:

"(a) The Protocol applies to and is binding on:

•••

(3) the following persons (each, a Covered Person): all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses."

4.2 Pursuant to section 3054 of the Act, "Covered Persons" must register with the Authority. However, they are bound by the Protocol by undertaking the activity (or activities) that make(s) them a Covered Person, whether or not they register with the Authority.

4.3 Dr. Perez is a veterinarian who is required to be and is registered with HISA. As such, the Respondent is a Covered Person who is bound by and subject to the ADMC Program.

4.4 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 7010. Applicability.

The Arbitration Procedures set forth in this Rule 7000 Series shall apply to all adjudications arising out of the Rule 3000 Series.

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."

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

"Rule 7060. Initiation by the Agency

(a) 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."

4.6 In this case, arbitration proceedings were commenced before JAMS, the designated arbitration provider. The Parties agreed that the Arbitrator would serve as the sole arbitrator in this proceeding.

4.7 No Party disputed jurisdiction here and all Parties fully participated in the proceedings without objection.

4.8 Accordingly, the Arbitrator finds that jurisdiction is proper here.

#### V. RELEVANT LEGAL STANDARDS

5.1 Rule 3214(a) of the ADMC Program provides as follows:

"The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question: . . . Possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession."

5.2 Dr. Perez is a Covered Person under the ADMC Program. It is alleged and admitted that Dr. Perez was in possession of Levothyroxine (Thyro-L), which is identified on the Prohibited List – Technical Document as a Category S4 Banned Substance. Additionally, Rule 4415(e) identifies "thyroid hormone and thyroid hormone modulators" as Category S4 Banned Substances under the umbrella of "Hormone and metabolic modulators".

5.3 The ADMC Program defines "Possession" as follows:

"Possession means actual, physical possession, or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists). If the Covered Person does not have exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists, constructive Possession shall only be found if the Covered Person knew about the presence of the Prohibited Substance or Prohibited Method and intended to exercise control over it. There shall be no Anti-Doping or Controlled Medication Rule violation based solely on Possession if, prior to receiving notification of any kind of any violation, the Covered Person has taken concrete action demonstrating that the Covered Person never intended to have possession and has renounced possession by explicitly declaring it to the Agency. Notwithstanding anything to the contrary in this definition, the act of purchasing (including by any electronic or other means) a Banned Substance or Banned Method constitutes Possession by the Covered Person who makes the purchase, whether or not the Banned Substance or Banned Method purchased is ever delivered to the Covered Person."

#### Rule 1010 Definitions

5.4 In summary, under the ADMC Program, Possession is established (in the absence of a compelling justification for the Possession) by the act of purchasing a Banned Substance, where a Covered Person has exclusive control or intends to exercise exclusive control of the substance or the premises where the substance is located, or knew of the presence of the substance and intended to exercise control over it.

5.5 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.*" Rule 3121.

5.6 The World Anti-Doping Code ("WADC") provides the framework for a harmonious international anti-doping system and is widely used in international sports, and expressly acknowledged as the basis for the ADMC Program. Rule 3070 provides in pertinent part that:

"(b) 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...

 (d) The World Anti-Doping Code and related International Standards, procedures, documents, and practices (WADA Code Program), 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."

5.7 The definition of Possession in the ADMC Program is substantively identical to the definition of possession in the WADC (*see* Article 2.6).

5.8 ADMC Program Rule 3040 sets out certain obligations of a veterinarian such as Dr. Perez, as a Covered Person in pertinent part as follows:

"Rule 3040. Core Responsibilities of Covered Persons

(a) Responsibilities of All Covered Persons

It is the personal responsibility of each Covered Person:

(1) 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 related rules, 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; . . . 5.9 Pursuant to ADMC Program Rule 3223, the ineligibility, and financial penalties for a first anti- doping rule Violation of Rule 3214(a) (Possession) is:

a. Two years of Ineligibility, and

b. A "Fine up to \$25,000... and Payment of some or all of the adjudication costs and the Agency's legal costs.

5.10 Where a Violation of the ADMC Program is established, the Respondent 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."

Rule 1010, Definitions

5.11 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)..."

5.12 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."

5.13 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."

5.14 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. The below is an effort to summarize their fundamental positions. To the extent necessary, the Arbitrator will address the various arguments that were made in the Analysis section below.

#### HIWU's Contentions

6.2 HIWU asserted that by having the Thyro-L in his Trailer #6 on the date it was found, after the effective date of the ADMC Program, Dr. Perez is guilty of Possession. Dr. Perez knew that Thyro-L was a banned substance as of that time. Dr. Perez acknowledged that he had purchased Thyro-L before the implementation of the ADMC Program, that he had used Thyro-L prior to the ADMC Program coming into effect, and that he should have, but failed to, clean out his trailer and dispose of the Thyro-L before the ADMC Program came into effect. Dr. Perez never told HIWU that he was in possession of the Thyro-L stored at Belmont Park for administration to Non-Covered Horse(s). Dr. Perez's defense, that he had the Thyro-L because it was needed for treatment of Non-Covered Horses is not credible, he asserted it only after multiple admissions of an ADRV when he came across a video of Dr. Scollay two months after he was first served with the EAD Notice.

6.3 HIWU contends that Dr. Perez is not entitled to reduced consequences because he has not shown No Fault or Negligence, or No Significant Fault or Negligence.

6.4 The Respondent's circumstances clearly and demonstrably fall short of the threshold necessary to establish No Fault or No Significant Fault.

- (a) The Respondent stored a Prohibited Substance within Trailer #6 at Belmont Park despite it being clearly being a Banned Substance. Dr. Perez ought to have known, or at the very least, reasonably suspected that he could be at risk of committing an ADMC Program violation.
- (b) Dr. Perez himself admitted to HIWU Investigators that he knew Thyro-L was a Banned Substance and that he ought to have conducted a thorough search of Trailer #6 before the implementation of the ADMC Program. The fact that he "completely forgot" that it was there, is a marked departure from the high standard expected of the duty of utmost care. Dr. Perez knew he had purchased Thyro-L in the months leading up to the ADMC Program, he also knew that when he purchased it, he left it in the shipping container and stored it in Trailer #6.
- (c) The fact that Dr. Perez acquired the Banned Substance before the implementation of the ADMC Program is inconsequential. It was and continues to be Dr. Perez' duty as a Covered Person to be knowledgeable of and to comply with the Protocol and related rules at all times. Dr. Perez did not exercise utmost caution after the implementation of the ADMC Program on May 22, 2023. He simply failed to comply with his duty as a Covered Person.

6.5 The practices and behavior of Dr. Perez further exacerbate the circumstances of this case. Indeed, Dr. Perez is a licensed veterinarian in the state of New York, he has duties both under the ADMC Program and professional obligations as veterinarian. Despite his education, Dr. Perez kept a disorganized, unsafe, and unsanitary workplace. Dr. Perez clearly did not know, nor make efforts to keep inventory of the controlled substances he was possessing, nor did he properly store his controlled substances. In this regard:

(a) There were hundreds of injection needles lying on the floor in his trailers;

(b) There was medical waste packaged in cardboard boxes without confirmation of proper disposal practices in his trailer;

(c) Trailer #6 was completely disorganized with garbage boxes thrown throughout so that it was impossible to walk through without climbing over garbage;

(d) Dr. Perez initially failed to cooperate and show where he was safely storing and locking his controlled substances;

(e) When Dr. Perez finally complied and showed where the controlled substances were, they were not properly stored in a lockable box/container;

(f) In Trailer #6 there was an unmarked container with clear liquid that Dr. Perez could not identify, and that he had forgotten was being stored in the refrigerator.

6.6 These facts not only demonstrate a failure to act with *utmost caution*, they suggest improper professional practice that represent a departure from *an ordinary standard of care* expected of a veterinarian.

6.7 Thyro-L is not used for emergency treatment of horses, but rather is a medication that is administered after diagnosis. This was testified to by Dr. Scollay, and is further evidenced by the fact that Dr. Perez does not keep Thyro-L in his triage case. Thyro-L can be readily obtained by ordering it when needed.

6.8 The determination of whether there is a compelling justification for possessing a banned substance must be made on a case-by-case basis, based upon the evidence in each case. For example, a veterinarian might establish a compelling justification if he could show that he was treating a specific horse, evidenced by veterinary records including the diagnosis and prescription for the medication. Dr. Perez did not produce any evidence that he was treating any horse with Thyro-L at the time that it was found in his trailer, or that he had recently treated any horse with Thyro-L.

6.9 Dr. Perez's position seeking a blanket exception to veterinarians being in possession of Thyro-L based on a theoretical hypothesis, that a veterinarian might have need for Thyro-L for a Non-Covered Horse at some time.

6.10 In the alternative, if the arbitrator determines that No Significant Fault or Negligence has been established, HIWU submits that Dr. Perez falls into the highest range of Fault and should only be granted a minimal reduction in Consequences (at most two months). In this respect, where No Significant Fault or Negligence is established, the Arbitrator may determine the applicable reduction in Consequences having regard to three ranges of objective fault.

- (a) Slight or Insignificant Fault -3 to 10 months
- (b) Moderate Fault -10 to 17 months
- (c) High or Significant Fault -17 to 24 months
- 6.11 Dr. Perez bears a very high degree of Fault.
- 6.12 HIWU requested the following relief in its pre-hearing Brief:

"(a) A period of Ineligibility of two (2) years for Dr. Perez as a Covered Person, beginning on June 13, 2023, the date the Provisional Suspension was imposed;

(b) A fine of USD \$25,000.00;

(c) Payment of all or some of the adjudication costs;

(d) Any other remedies which the Arbitrator considers just and appropriate in the circumstances."

#### Dr. Perez's Contentions

6.13 In or about March 26, 2023, Dr. Scollay advised that a stable pony is not a covered horse and so HISA (Horseracing Integrity & Safety Authority) does not have jurisdiction over said horses. She further advised that Thyro-L may be prescribed and dispensed for non-covered horses.

6.14 Dr. Perez contends that he has an absolute right to possess Thyro-L as a veterinarian who treats Non-Covered Horses and who may need the medication for their treatment. He has thirty stable ponies, Non-Covered Horses, at Belmont Park. It is impractical to move a horse off the racetrack premises to treat it, and therefore he has a compelling justification for keeping a stock of Thyro-L in his trailer at the racetrack.

6.15 Neither HISA nor HIWU have promulgated any written procedure or regulation regarding the prescribing and dispensing of a banned substance for a non-covered horse at a racetrack. No prohibition of a veterinarian possessing Thyro-L to have in stock to treat Non-Covered Horses has been issued.

6.16 Dr. Perez not only possessed the banned substance, but he did so legally because said substance can be prescribed and dispensed for a non-covered horse such as stable ponies for which Dr. Perez provides services. Thus, this case is not one of No Significant Fault or Negligence but instead one of legal possession for legal purposes, period, and Dr. Scollay's videotaped statements and HISA and HIWU's non-regulation of racehorse banned substances for non-covered horses at racetracks are the strongest evidence that Dr. Perez legally possessed Thyrol-L on June 9, 2023.

6.17 Dr. Perez seeks the following relief:

"Dr. Perez legally possessed Thyrol-L at Belmont Park on June 9, 2023 and his suspension issued on June 14, 2023 must be lifted and his full privileges to practice veterinary medicine at all horse racetracks be hereby resumed."

#### VII. ANALYSIS

7.1 The charge at issue in this case is one of Possession of Thyro-L, a Banned Substance, under the ADMC Program. The defense is that Dr. Perez legally possessed the Thyro-L because of his justification as a veterinarian who treated Non-Covered Horses.

7.2 There is no dispute that Dr. Perez was in possession of two one-pound tubs of a substance known as Levothyroxine ("Thyro-L") in his Trailer #6, on June 9, 2023, after the implementation of the ADMC Program on May 22, 2023. Levothyroxine is an S4 metabolic hormone classified under the ADMC Program list as a Banned Substance.

7.3 The Thyro-L product was lawfully purchased by Dr. Perez, at a time when it was not a Banned Substance, before the implementation of the ADMC Program. There was no evidence that the Thyro-L was used by Dr. Perez on any horse after the implementation of the ADMC Program.

7.4 Dr. Perez was aware that Thyro-L was a banned substance as of the date it was found in his trailer, Trailer #6. On March 21, 2023, Dr. Perez had attended a presentation by Dr. Mary Scollay, HIWU's Chief of Science, at Belmont Park, where Dr. Scollay discussed the pending implementation of the ADMC Program, and she specifically mentioned that Thyro-L would become a Banned Substance upon implementation of the ADMC Program on May 22, 2023.

7.5 Thyro-L is a medication that is used to treat horses with a thyroid condition, and it may also be used to treat horses with a certain metabolic disorder. For that reason, a veterinarian may consider it prudent to keep a supply of the medication in stock so that he has it available if needed to treat a horse. HIWU, through Dr. Scollay, acknowledged in a recorded presentation on. March 26, 2023, that veterinarians may use Thyro-L to treat Non-Covered Horses, specifically stating that veterinarians "are able to possess a Banned Substance, and to administer and "carry"

7.6 The parties dispute whether Dr. Perez was legally in possession of Thyro-L, as a veterinarian whose practice included Non-covered Horses, including thirty stable ponies at Belmont Park.

7.7 Dr. Perez was aware that the ADMC Program was new and that it regulated the use and possession of certain substances that may have previously been permitted.

7.8 Dr. Perez admits that he learned in a seminar presented by HIWU's Dr. Scollay before the implementation of the ADMC Program that the Thyro-L was specifically banned under the new rules and that all Covered Persons should undertake a "spring cleaning" of the medications and other substances in their trailers, offices, or barns before the implementation of the ADMC Program. Dr. Perez admits he did not do that.

7.9 Dr. Perez had purchased the Thyro-L six months earlier and forgot that it was in his Trailer #6. Trailer #6 was a complete mess, with boxes of medical waste and other trash covering the floor and surfaces of the desk and furniture, and his controlled medications were not secured.

7.10 During the March 24, 2023, HIWU seminar, the recording upon Dr. Perez relies, Dr. Scollay was asked by one of the attendees about veterinarians whose practice includes farm work or Non-Covered Horses and whether the Possession rules applied to them. Dr. Scollay responded:

"But at the end of the day if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses... the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered Horses." (Emphasis added.)

7.11 However, in her Declaration, she expanded that statement, to add the phrase, "for administration to a Non-Covered Horse(s)" ("a veterinarian could be in possession of a Banned Substance 'if there is a justification for them to be in Possession of a Banned Substance' for administration to a Non-Covered Horse(s).")

7.12 HIWU argues that this is entirely consistent with the requirement under the ADMC Program for a Covered Person such as Dr. Perez to provide a "compelling justification" for his Possession of a Banned Substance, and that a "compelling justification" would mean that the veterinarian was administering the Banned Substance to a Non-covered Horse. HIWU contends that Dr. Perez was in Possession and was not administering the Thyro-L to a Non-Covered Horse as of June 9, 2023, thus has not demonstrated a "compelling justification" and therefore there is a violation. Dr. Scollay, however, used the word "justification" in the HIWU seminars in the context of a veterinarian who administers or carries the medication and whose practice "incorporates Non-Covered Horses."

7.13 Rule 3214 is clear that possession of a banned Substance is an Anti-Doping Rule Violation (ADRV) "unless there is *compelling* justification for such Possession." (Emphasis added.)

7.14 While this is a legally correct interpretation of the regulatory use of the phrase "compelling justification," as interpreted by the jurisprudence of the Court of Arbitration for

Sport (CAS), we are faced here with the practical question of what could have been expected from a reasonable person in the situation, a veterinarian who has a practice that includes Non-Covered Horses, would understand to be his obligation regarding the possession of a Thyro-L, a Banned Substance, when Thyro-L had been regularly in his possession in the past, and was still allowed to be in his possession "to administer or carry" for Non-Covered Horses. As Dr. Scollay said, "the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered Horses." Neither Dr. Scollay nor anyone from HIWU cautioned the veterinarians that the law requires a compelling justification, or that it would be interpreted to require that they were limited to possessing the Banned Substance only if and when they were actually administering it or had proof that they were about to administer it or had just administered it.

7.15 Dr. Perez did not submit evidence that the reason he possessed the Thyro-L on June 9, 2023, after it became a Banned Substance, was because he was administering or intending to administer it to Non-Covered Horses. That explanation is a theoretical justification raised by his counsel, after the fact. Dr. Perez produced no evidence that he responsibly cleaned out his trailers to comply with implementation of the ADMC Program, and originally admitted that he had forgotten that the Thyro-L was in his trailer.

7.16 The ADMC Program was new and no veterinarians, including Dr. Perez, had experience under it. The HIWU representative travelled to racetracks across the country to educate those equestrian professionals who were about to become Covered Persons, but due to the limited time and recent implementation, as of June 9, 2023, there was only one education session at Belmont Park. Finally, there was no evidence that Dr. Perez intended to use Thyro-L on Covered Horses or did so.

7.17 On the one hand, Dr. Perez took no steps to get rid of the Thyro-L once it became a Banned Substance, or to inquire what he needed to do to comply. On the other hand, the HIWU told veterinarians that they could possess Thyro-L "*if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered Horses.*" HIWU did not explain that the regulation requires a "compelling justification," including evidence that the veterinarian was using the Thyro-L to currently treat Non-Covered Horses, positions it is taking in this matter.

7.18 An agency must defend its actions based on the reasons it gave.

#### **Punishment-Ineligibility**

7.19 Having determined that Dr. Perez committed the act of Possession under the ADMC Program, the Arbitrator may consider whether the standard two years period of ineligibility may be reduced by considering whether there was No Fault or Negligence, or No Significant Fault or Negligence. For a charge of Possession, unlike for charges of Use or Presence, there is no predicate to reaching the No Significant Fault or Negligence standard (such as having to show source). Accordingly, in Possession cases, once the elements of Possession are

found to be present, the analysis proceeds directly to the fault analysis to the extent that has been asserted by a charged party.

7.20 The definition of No Fault or Negligence is as follows:

"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..."

7.21 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..."

7.22 Dr. Perez's admission that he did not clean out his trailer following HIWU seminar, establishes sufficient negligence to preclude the Arbitrator from finding No Fault or Negligence.

7.23 Under a finding of No Significant Fault or Negligence Dr. Perez could be Ineligible for anywhere between three months and twenty-four months, all depending on the level of fault. Rule 3225(a). This is a broad range of possible Ineligibility. Other cases considering this issue across a similarly broad range have found it useful, analytically, to break the range into three basic groupings: insignificant or slight fault; moderate fault; significant fault. *See*, CAS 2013/A/3327 *Cilic v. International Tennis Federation*.

7.24 The CAS Panel analysis in *Cilic* considered both the objective and the subjective level of fault. The objective element describes what standard of care could have been expected from a reasonable person in the situation and determine into which category a case falls; the subjective element describes what could have been expected from that person, in light of his personal capacities, and moves up or down within that category.

7.25 Applying the *Cilic* ranges as a guide, the Arbitrator breaks down the twenty-one months of possible periods of Ineligibility into roughly three seven-month ranges of objective fault: slight or insignificant: three to ten months; moderate: ten to seventeen months; significant: seventeen to twenty-four months.

7.26 The Arbitrator determines that Dr. Perez's conduct demonstrates that he objectively falls into the moderate or middle range of objective fault, for the reasons discussed above. He was still in possession of Thyro-L after it became a Banned Substance, he was aware

it was a Banned Substance, he failed to clean out his trailers, he did nothing to get rid of the Thyro-L after it became a Banned Substance, nor did he inquire whether he needed to get rid of it, his workplace trailers were disorganized, unsafe, and unsanitary, and he did not know, nor make efforts to keep inventory of, the controlled substances he was possessing, nor did he properly store his controlled substances, and he had not used Thyro-L on Covered Horses since it became a Banned Substance. In addition, an an objective factor the Agency's statements in its education seminars that a veterinarian, with a practice that included Non-Covered Horses, has *"justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses"* informs the standard of care that could have been expected from a reasonable veterinarian with a practice tha includes Non-Covered Horses. Such a veterinarian would believe he had justification for continuing to possess a Banned Substance such as Thyro-L that was lawful for use on Non-Covered Horses in their care.

7.27 Subjective factors operate somewhat in Dr. Perez's favor. Dr. Perez had been operating under the former rules, his possession of Thyro-L was lawful at the time he came into possession, there was only one education session at Belmont Park, there was no evidence that he used the Thyro-L after implementation of the ADMC Program, he had purchased it at least six months ago, and he forgot he had it.

7.28 This presents an unusual situation: the Agency's statements to veterinarians at the seminars could lead veterinarians to reasonably believe that they could lawfully possess administer and carry Thyro-L if their practice included Non-Covered Horses, for use with Non-Covered Horses. However, Dr. Perez, while objectively falling into the category of a veterinarian whose practice Non-Covered Horses at Belmont Park, did not rely on the Agency's statements, and possessed the Thyro-L because he had forgotten he had it in his trailer.

7.29 After consideration of the above factors, the Arbitrator determines that Dr. Perez's objective level of fault falls in the moderate range, and that he should receive a reduction, due to the subjective factors, of three months in his level of fault, (moderate) from what normally would have been seventeen (17) months.

7.29 The Arbitrator finds that Dr. Perez should suffer a period of Ineligibility at the middle of the moderate range, fourteen (14) months, commencing on June 13, 2023 (the date of implementation of his provisional suspension).

#### Punishment-Fine, Payment Toward Legal Fees and Arbitration Costs

7.30 Under the ADMC Program, the punishment includes, in addition to a period of Ineligibility, a "Fine up to \$25,000 . . . and Payment of some or all of the adjudication costs and [HIWU]'s legal costs." Rule 3223(b). These consequences appear to be mandatory in their application; in other words, upon finding a violation, the Arbitrator must also make a finding on the applicable fine and the payment of the adjudication costs and HIWU's legal costs.

7.31 Rule 3223(b) requires the Arbitrator to issue a fine of some amount "up to \$25,000". The amount of this fine, however, appears to be entirely discretionary with the Arbitrator, though some amount of fine appears to be mandatory.

7.32 The Arbitrator determines that on the facts of this case, considering the inexperience of Dr. Perez with the ADMC Program, the limited training he received, the Agency's lack of clarity, and the absence of any impermissible use of the substance in question or any violation other than the Possession itself, the potential \$25,000.00 fine is reduced and assessed at \$5,000.00, to be paid by the end of Dr. Perez's period of ineligibility.

7.33 HIWU also requests that some or all of the adjudication costs be paid by Dr. Perez. The amount of the contribution toward the arbitration costs appears, like the fine, to be purely discretionary with the Arbitrator. Based upon the circumstances of this matter, including that the Agency sought the maximum allowable punishment, notwithstanding the factors addressed above, Dr. Perez is not required to contribute toward the adjudication costs in this case.

#### VIII. AWARD

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

a. Dr. Perez is found to have committed his first anti-doping rule violation of Possession. As a result, Dr. Perez shall:

1. Be suspended for a period of Ineligibility of fourteen (14) months, commencing June 14, 2023, the effective date of his provisional suspension, and ending on August 13, 2024;

2. Be fined \$5,000 to be paid to HIWU by the end of the period of Ineligibility; and

3. Not be required to pay a contribution toward HIWU's share of the arbitration costs of this proceeding.

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

IT IS SO ORDERED AND AWARDED.

Dated: October 9, 2023

ower

Barbara A. Reeves, Esq. Arbitrator

## EXHIBIT I

#### **Banned Substance Analysis**

- Compelling justification is a fact-specific, case-by-case inquiry that must be determined on the evidence.<sup>1</sup>
- Under the Possession Rule, the onus is on Dr. Shell to establish that the Banned Substances in issue were not prescribed to or used by Covered Horses, and then establish a compelling justification for his Possession. Any such compelling justification must be a legitimate and legal veterinary purpose, that is not connected to Thoroughbred horseracing.<sup>2</sup>
- Dr. Shell's own expert, Dr. Roberts, considered Dr. Scollay's guidance on the Possession Rule and conceded that a veterinarian needs to produce records that justify the need to carry each Banned Substance in issue to establish a compelling justification.<sup>3</sup>

Banned Substance	Prescription	Justification
Carolina Gold	<ul> <li>Prescribed to a Covered Horse <ul> <li>Must demonstrate ministerial error to have a compelling justification.</li> <li>There is no coherent explanation for prescription errors involving at least two pharmacies and four Covered Horses.</li> <li>Dr. Shell and Ms. Duhon also gave contradictory evidence on ordering practices.</li> </ul> </li> </ul>	<ul> <li>No justification for farm use <ul> <li>There is no reason, much less a compelling reason, for Dr. Shell or any veterinarian to have Carolina Gold on a veterinarian truck at a racetrack in Ohio.</li> <li>Carolina Gold is not part of a farm practice, as confirmed by three different veterinarians testifying in this case including Dr. Shell's expert.</li> <li>In any event, the confiscated Carolina Gold was intended for Thoroughbred racehorse trainers in West Virgnia.</li> </ul> </li> <li>Justification for West Virginia practice is uncompelling <ul> <li>Carolina Gold has no veterinary use in any practice, on or off track. It is also prohibited at West Virginia racetracks.</li> <li>Dispensing Carolina Gold to West Virginia trainers, who also race Thoroughbred racehorses in Covered jurisdictions, is an uncompelling reason to possess a Banned Substance in Ohio.</li> <li>The records fail to show which horses Carolina Gold was dispensed to.</li> <li>There are no veterinary medical records corroborating examinations or diagnoses for "herd prescriptions".</li> </ul></li></ul>

<sup>&</sup>lt;sup>1</sup> HIWU's Closing Written Submissions at para 35, citing Arbitrator Reeves in *HIWU v. Perez.* 

<sup>&</sup>lt;sup>2</sup> HIWU's Closing Written Submissions at para 36.

<sup>&</sup>lt;sup>3</sup> HIWU's Closing Written Submissions at para 37, citing the Cross Examination of Dr. Andrew Roberts.

Banned Substance	Prescription	Justification
Pitcher Plant	<ul> <li>Prescribed to a Covered Horse</li> <li>Must demonstrate ministerial error to have a compelling justification.</li> <li>See above for errors and concerns relating to the proffered ministerial error.</li> </ul>	<ul> <li>Justification is uncompelling</li> <li>There is no reason, much less a compelling reason, for Dr. Shell to have Pitcher Plant on a veterinarian truck at a racetrack in Ohio.</li> <li>Dr. Shell repeatedly dispensed Pitcher Plant to racehorse trainers in West Virginia showing that Dr. Shell uses Pitcher Plant in conjunction with his Thoroughbred racehorse practice.</li> <li>"Herd prescriptions" were dispensed to trainers in West Virginia with no confirmation of the intended recipient, and a number of these trainers raced horses in Covered jurisdictions – i.e., "Venesualean Dreamer" received Pitcher Plant and raced in a Covered jurisdiction 10 days later.</li> <li>Pitcher Plant is prohibited at West Virginia racetracks.</li> <li>There is one documented dispensation of Pitcher Plant by Dr. Hippie to a farm horse named "Jack Attack". This does not establish regular use of Pitcher Plant on farm horses by Dr. Hippie or a compelling justification for Dr. Shell's purchase of Pitcher Plant in the name of a Covered Horse, which was then brought to a Covered racetrack.</li> <li>"Adrian Es Bonita" record is from November 2023 and is irrelevant.</li> </ul>
Osphos	N/A	<ul> <li>Possession for "Cat" is not sufficiently supported</li> <li>All documented dispensations of Osphos to Cat are by Dr. Hippie.</li> <li>Dr. Shell did not produce records showing that he possessed the confiscated Osphos for Cat specifically.</li> <li>Ongoing treatment relationship with Cat is not a basis for Dr. Shell to possess Osphos at a Covered racetrack.</li> <li>"Hornet" record from November 2023 is irrelevant.</li> </ul>
Isoxsuprine	N/A	<ul> <li>Possession for "Cat" is not sufficiently supported</li> <li>Dr. Shell did not testify, or produce records showing, that the confiscated Isoxsuprine was intended for Cat specifically.</li> <li>Ongoing treatment relationship with Cat is not a basis to possess Isoxsuprine at a Covered racetrack (see above).</li> </ul>

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Banned Substance	Prescription	Justification
		<ul> <li>Possession for "Cool Stance" is not sufficiently supported</li> <li>Dr. Shell testified that he possessed the confiscated Isoxsuprine for Cool Stance.</li> <li>Use for pain relief is questionable and there are no records showing a need for Isoxsuprine prior to the September 2023 search.</li> <li>Nonetheless, actual or potential need to dispense Isoxsuprine to any West Virginia horse is not a reason to bring the same to a Covered racetrack.</li> <li>"AP Pony" record from February 2024 is irrelevant.</li> </ul>

## EXHIBIT J

#### **BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S**

### ANTI-DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000653

#### In the Matter of the Arbitration Between:

#### HORSE RACING INTEGRITY & WELFARE UNIT ("HIWU" or "Claimant"), Claimant

v.

SHELL Dr., Scott (**"Dr. Shell" or "Respondent"**), Respondent

The Horseracing Integrity & Welfare Unit ("HIWU") hereby submits this Response to Arbitrator Reeves' September 3, 2024 "Request For Additional Authority." HIWU specifically addresses what it considers the appropriate analysis if it is determined that Rule 3228(d) is not applicable to this proceeding and whether the analysis of Justice Fraser in *HIWU v. Dr. Scott Shell*, Case No. 1501000708 (the "Administration Case") could be applied here.

Under the ADMC Program Rules, *each* unjustified Possession of a Banned Substance is a separate stand-alone violation.

First, the definition of "Possession" under ADMC Program Rule 1020 defines "Possession" as "actual, physical possession or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited **Substance**[...].") The use of the word "Substance" – is in the singular – and illustrates each unjustified Possession of a different Banned "Substance" should lead to a stand-alone violation.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Note that each alleged violation is charged by substance, not by bottle, vial, or box. For example, Dr. Shell possessed two bottles of Banned Substance Carolina Gold and was charged once for Possession of this Banned Substance.

Second, the fact that Possession of each Banned Substance is a separate violation under the Rules is clear from how Panels assess whether a Covered Person has established a "compelling justification." Each Banned Substance that was possessed must be weighed against the facts asserted as the compelling justification for *that specific Substance*: "The determination of whether there is a compelling justification for possessing a banned substance [singular] must be made on a case-by-case basis, based upon the evidence in each case. For example, a veterinarian might establish a compelling justification if he could show that he was treating a specific horse, evidenced by veterinary records including the diagnosis and prescription for the medication [singular]." *HIWU v. Luis Jorge Perez*, JAMS Case No. 1501000589 at para. 6.8.

Third, the Fault-based analysis that follows from the establishment of a Possession ADRV under Rules 3224 (No Fault/Negligence) and 3225 (No Significant Fault/Negligence) requires a substance-specific Fault analysis for each Substance that assesses both the objective and subjective circumstances for the violation. This is clear from the circumstances of this case as set out in the Agency's Closing Submissions Table – Banned Substance Analysis, filed August 7, 2024 ("Table"). The Table demonstrates why each alleged Possession violation must be analyzed on a substance-specific basis: to wit, the validity of Dr. Shell's offered justification for possessing each Substance depends on the medical validity of each Banned Substance, its regulatory status, and the evidence Dr. Shell produced (or did not produce) establishing his compelling justification such as "veterinary records including the diagnosis and prescription for the medication."

By way of illustration, Dr. Shell's claimed compelling justification of use of Carolina Gold in non-Covered Horses cannot hold *any* weight because there is no reason, much less a compelling reason, for Dr. Shell to possess Carolina Gold, prescribed to a Covered Horse, at a Covered Racetrack in Ohio. Carolina Gold has no valid use in any veterinary practice and is also banned by the West Virginia Racing Commission at West Virginia horseracing tracks. Dispensing Carolina Gold to trainers in West Virginia, who also race Thoroughbred racehorses in Covered jurisdictions, is an uncompelling reason to possess a Banned Substance in Ohio. Further, there is little rationale to reduce the period of Ineligibility for Carolina Gold under the resulting Fault analysis because this substance is objectively and subjectively a Substance that is *not* permitted on a racetrack and has no valid veterinary use in a farm practice.

In contrast, Osphos and Isoxsuprine can have a legitimate use in a farm practice, and, unlike Carolina Gold and Pitcher Plant, they are not banned by both HIWU and the West Virginia Racing Commission.<sup>2</sup> There could therefore, in a different case with supporting veterinary records, be a compelling justification for their Possession for use in a farm practice and the degree of Fault analysis may well be different.

With regard to the reasoning used by Justice Fraser in the Administration Case, that analysis is not applicable here. In the Administration Case, Dr. Shell administered the *same* Banned Substance (Hemo 15) 228 times over a five-month period.<sup>3</sup> Dr. Shell further testified that he administered that same Banned Substance 228 times for one reason: his ("sincerely wrong")<sup>4</sup> belief that Hemo 15 was not a Banned Substance.

<sup>&</sup>lt;sup>2</sup> HIWU maintains that use of a Banned Substance in a non-HISA jurisdiction can never be a compelling justification for the Possession of a Banned Substance **at a Covered Racetrack within a HISA jurisdiction**. Such Banned Substances must be stored off the Racetrack, for example, at the veterinarian's office.

<sup>&</sup>lt;sup>3</sup> Counsel for Dr. Shell agrees that Justice Fraser's Amended Decision does not apply here: "It should also be noted that Justice Fraser did not address nor did he cite Rule 3228(d), in his decision. Rather Justice Fraser cited 3228(c), hence the case is totally inapposite." *See* message from Attorney Andrew Mollica, dated Sept. 3, 2024.

<sup>&</sup>lt;sup>4</sup> Amended Decision, *HIWU v. Dr. Scott Shell*, Case No. 1501000708 at para. 8.34(e).

On these unique facts, Justice Fraser concluded that Dr. Shell bore No Fault for 227 of the 228 administrations.<sup>5</sup> Here, Dr. Shell possessed four *different* Banned Substances at a Covered Racetrack in Ohio. The explanation of a farm practice and West Virginia practice is not the same nor is there a single proffered justification. Dr. Shell's stated reasons and circumstances for being in possession of each substance varies and a single explanation cannot be applied with equal weight to each Banned Substance. Nor would the Rules permit an overarching analysis of this nature. At most, the fact that Dr. Shell's evidence amounts to a mistaken assumption that he could carry any Substance he wanted at a Racetrack in Ohio, provided he was going to use such a substance in West Virginia, is a subjective factor that could be considered under Rule 3225 (No Significant Fault).

In sum, HIWU submits that each Possession of each Banned Substance constitutes a separate ADRV as demonstrated by: (i) Rule 1020 (definition of Possession); (ii) the compelling justification analysis set forth by this Panel in *HIWU v. Luis Jorge Perez*, JAMS Case No. 1501000589 at para. 6.8; and (iii) in the substance-specific objective/subjective Fault analysis required by ADMC Program Rules 3224 and 3225.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 4th day of September, 2024.

<u>Allison J. Farrell</u> Allison J. Farrell, Esq. Horseracing Integrity & Welfare Unit

Tyr LLP James Bunting, Esq. Alexandria Matic, Esq. **Representatives of HIWU** 

<sup>&</sup>lt;sup>5</sup> Justice Fraser specifically held: "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."