UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
MATTER NO._____

ADMINSTRATIVE LAW JUDGE:_____

IN THE MATTER OF:
DR. SCOTT SHELL, DVM APPELLANT

APPLICATION FOR REVIEW OF FINAL CIVIL SANCTION

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.,* Appellant Dr. Scott Shell, DVM ("**Appellant**") hereby appeals Arbitrator Hon. Hugh Fraser's June 11, 2024, decision in JAMS Case No. 1501000708, as amended, finding Appellant committed an Anti-Doping Medication Control ("**ADMC**") Program violation and imposing a final civil sanction ("**Decision," Exhibit A**). By letter dated June 18, 2024, the Horseracing Integrity and Safety Authority ("**HISA**") notified Appellant it was imposing the final civil sanctions.

Appellant requests *de novo* review and reversal of the Decision because (1) Appellant did not engage in acts found by HISA, (2) HISA did not establish Appellant committed a violation, and (3) the Decision and final civil sanction are arbitrary, capricious, an abuse of discretion, prejudicial, and otherwise not in accordance with law. 16 C.F.R. §§ 1.146(b)(1)-(3),

First, the Arbitrator erroneously concluded HISA and the Horse Racing Integrity Welfare Unit ("**HIWU**") met their burden to establish Appellant violated ADMC Program Rule ("**Rule**") 3214(c), administering Banned Substances to Covered Horses, and, factually, that Appellant's self-reported Hemo 15 administrations contained any Banned Substance. It is HISA and HIWU's burden to establish a violation by more than a preponderance of the evidence. Rule 3121. But there is no evidence Hemo 15[1] administered by Appellant contained Banned Substances. A lab Report,

[1] Appellant stated "Hemo 15" is shorthand for a group of nutrients, used as a vitamin supplement. (Decision, ¶ 8.4).

lacking foundation, admitted into evidence over Appellant's objection, (Decision, ¶ 2.5), did not show the only substance of concern in Hemo 15 seized from Appellant, cobalt, was banned cobalt salt, (*Id*. at p. 27), and there was no test evidence showing cobalt met HISA's blood threshold. (*Id*. at ¶ 6.2(g)). HISA failed to meet its burden to show a violation.[2]

Second, the Arbitrator erroneously found Hemo 15, generally, is a Banned Substance. (*Id.* at ¶ 8.11). Hemo 15 is not on HISA's Banned Substance list. (*Id*. at ¶ 8.4). Appellant was charged under catchall, Rule 4111, S0 Non-Approved Substances.[3] (*Id.* at ¶ 6.2(n)). The Arbitrator erred as Appellant's Hemo 15 is compliant with Rule 4111 because it is not addressed by Rules 4112 through 4117 (*Id*. at ¶ 8.7), it is a combination of legal nutrients, making no drug claims, requiring no government approval (*Id.* at ¶ 8.9), it is widely used as a vitamin supplement (*Id.* at ¶ 8.4), and absent drug claims, 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 inapplicable. (*Id*. at pp. 27-28).

Third, if Hemo 15 could be deemed banned, the Arbitrator erred in concluding Rule 4111 and the charges are not arbitrary and capricious, because "no other veterinarian has been charged with the administration of Hemo 15." (*Id*. at ¶ 8.22). The Decision speculates about other charges, and arbitrarily, capriciously, and unreasonably fails to credit overwhelming evidence that veterinarians of reasonable intelligence disagree when, how and if Rule 4111 applies to substances making no drug claims, that the rule is vague, incomprehensible, mandates hyper-technical analysis of other rules, and results in arbitrary enforcement. (*Id.* ¶ 8.6, pp. 24-25, 27-29). Rule 4111 does not explain how Appellant's Hemo 15, compounded from non-drugs, is subject to the rule. The Arbitrator's reliance on a boilerplate pharmacy "drug" label as opposed to evidence of

[2] This holding is arbitrary and capricious because it is not based on substantial evidence.
[3] The full text of Rule 4111 is cited in the Decision at ¶ 6.2(h).

actual drugs is irrational, (*Id*. ¶ 8.30(d)), as is reliance on AMDUCA and GFI #256 because it is unclear they apply (*Id*. ¶ 8.8). Rule 4111 lacks fixed standards, definitions, and requires judges to decide *ad hoc* what is prohibited. The Decision is also arbitrary and capricious because it fails to credit overwhelming evidence of need for expert opinion to understand and find liability under Rule 4111, evidence that Appellant's Hemo 15 made no drug claims (*Id*. p. 27), unreasonably favored HIWU's experts (*Id*. ¶ 8.8) and is not based on an understandable rule or substantial evidence.

Fourth, the Arbitrator failed to address Appellant's argument that the charges, Rule 4111 and now the Decision violate Appellant's Fifth (and Fourteenth) Amendment constitutional due process rights. (*Id*. ¶ 8.20). Due process requires notice of forbidden conduct. *FCC v. Fox TV Stas., Inc.,* 567 U.S. 239, 253 (2012). Where, as here, Covered persons of reasonable intelligence cannot discern what is prohibited, Rule 4111 is unconstitutional, and charges must be dismissed. (*Id*.; Decision ¶ 8.6, pp. 24-25, 27-29)

Fifth, based on *National Horsemen's Benevolent and Protective Association v. State of Texas et al.* No. 23-10520 (5th Cir. July 5, 2024) ("**NHPB**"), the Decision should be vacated because HISA and HIWU enforcement of HISA unconstitutionally violates the private nondelegation doctrine as private entities oversees HISA enforcement and do not function subordinately to the FTC when enforcing HISA.

Finally, if Decision is not reversed, the sanction[4] is arbitrary, capricious, an abuse of discretion, and not in accordance with law, *inter-alia*, because Appellant should have been found faultless under Rule 3224 or 3225 absent notice of the prohibited conduct. (Decision ¶ 8.30)

[4] For violation one, the Arbitrator imposed two years ineligibility, with credit for any Provisional Suspension, a $25,000 fine, $10,000 in costs, and for the remaining 227 violations, the penalties were expunged, finding no fault. (Decision, pp. 37-38).

The Decision should be reversed. Under 16 C.F.R. § 1.146(a)(1), Appellant requests an evidentiary hearing to contest the facts found by the Authority, legal interpretation, and to supplement the factual record with **Exhibit B**, the Fifth Circuit Decision in NHPB, and **Exhibit C,** a Fourteenth Amendment case, and to argue due process and absence of evidence. Further, pursuant to 16 C.F.R. § 1.148, Appellant requests a stay of the final civil sanction during these proceedings.

Dated: July 15, 2024

Respectfully Submitted,

/s/ Andrew Mollica

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CERTIFICATE OF SERVICE

Pursuant to 16 CFR 1.146(a) and 16 CFR 4.4(b), a copy of the forgoing is being served this 15th day of July, 2024, via first-class mail and/or electronic mail upon the following:

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EXHIBIT A

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

ADMINISTERED BY JAMS, CASE NO. 1501000708

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

v.

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

AMENDED FINAL DECISION

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

I. INTRODUCTION

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

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

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

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

II. THE FACTS

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

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

The Facts According to HIWU

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

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

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

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

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

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

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

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

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

The Facts According to Dr. Shell

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

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

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

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

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

III. PROCEDURAL HISTORY

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

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

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

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

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

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

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

1. Regarding Briefs and Exhibits

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

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

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

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

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

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

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

2. Regarding Stipulations of Uncontested Facts and Procedure

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

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

3. Regarding Witnesses

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

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

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

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

4. Regarding the Hearing

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

5. Regarding Submission of Documents

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

6. Further Disputes Process

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

7. Miscellaneous Provisions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. JURISDICTION

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

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

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

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

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

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

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

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

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

V. RELEVANT LEGAL STANDARDS

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

5.2 Rule 3070(d) further provides that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) General rule.

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

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

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

VI. THE PARTIES' CONTENTIONS AND CLAIMS FOR RELIEF

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

HIWU's Contentions

6.2 HIWU's position may be summarized as follows:

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

It is the personal responsibility of each Covered Person:

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

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

Under the ADMC Program, Administration is defined as:

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

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

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

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

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

Rule 3122 Methods of Establishing Facts and Presumptions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Respondent's position may be summarized as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. TESTIMONY OF WITNESSES AND EXPERTS

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

For Claimant:

Melissa Stormer

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

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

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

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

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

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

Dr. Mary Scollay

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Scott Shell

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Expert Witnesses

Dr. Lara Maxwell

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Joseph Bertone

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

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

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

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

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

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

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

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

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

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

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

Dr. Joshua Sharlin

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

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

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

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

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

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

VIII. ANALYSIS

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

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

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

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

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

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

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

8.6 Rule 4111 provides that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Is The Doctrine of Estoppel Applicable?

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

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

Were Dr. Shell's Due Process Rights Violated?

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

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

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

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

Is Dr. Shell Entitled to a Reduction of Consequences?

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

No Fault or Negligence

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

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

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

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

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

No Significant Fault or Negligence

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

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

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

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

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

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

Term of Ineligibility and Other Sanctions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Dr. Shell would have taken some comfort from the fact that his reporting of the administration of Hemo 15 did not draw any immediate concern from HISA or HIWU.

IX. AWARD

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

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

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

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

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

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

IT IS SO ORDERED AND AWARDED.

Dated: June 11, 2024

Hugh L. Fraser

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

HIWU
Horseracing Integrity & Welfare Unit

NOTICE OF FINAL CIVIL SANCTIONS UNDER THE ADMC PROGRAM

June 18, 2024

SENT VIA EMAIL *sdshelldvm@gmail.com*

Scott David Shell, DVM
[redacted]

Re: EAD2023-65/EAD Charge of ADMC Program Rule 3214(c)

This serves as notice to you, Scott David Shell, DVM, that the Horseracing Integrity & Welfare Unit (HIWU) is imposing the following Consequences against you under the Anti-Doping and Medication Control (ADMC) Program in accordance with the enclosed final decision of the Arbitral Body and pursuant to 15 U.S.C. 3057(d):

1. A period of Ineligibility for you of two (2) years, as described in ADMC Program Rule 3223, beginning on January 8, 2024 (the date that a Provisional Suspension was imposed against you for this matter), and continuing through January 7, 2026;

2. A fine of $25,000 in accordance with ADMC Program Rule 3223;

3. Payment of $10,000 of adjudication costs in accordance with ADMC Program Rule 3223; and

4. Public Disclosure in accordance with ADMC Program Rule 3620.

This matter involved numerous violations of Rule 3214(c), the Administration of a Banned Substance, for the administration of the Banned Substance Hemo-15 to Covered Horses.

Review of a Final Decision and its accompanying Consequences by a federal Administrative Law Judge is available under 15 U.S.C. 3058. You will also receive a copy of the notice to the Federal Trade Commission ("FTC") of these civil sanctions. **Pursuant to 15 U.S.C. 3058(b)(1), review of the decision must be requested within thirty (30) days of HISA's notice to the FTC.** A stay of the Consequences set forth above will only be imposed if such a stay is requested from, and approved by, the applicable Administrative Law Judge.

The Consequences set forth above are effective immediately, and any financial penalties imposed, or payments required under the Arbitration Procedures, must be paid in accordance with the Final Decision of the Arbitral Body.

Please also be advised that a copy of this Notice or a summary thereof will be published on HIWU's website.

Horseracing Integrity & Welfare Unit

Michelle Pujals, HIWU General Counsel

Encls.: Final Decision of Arbitral Body
Instructions for HISA Portal

cc (w/ encls.): Andrew Mollica, counsel for Dr. Shell
HISA

HORSERACING INTEGRITY AND SAFETY AUTHORITY

Fine Payment Instructions

Pay Online on HISA (portal.hisausapps.org) **OR**

- Covered Person logs into the HISA portal at portal.hisausapps.org using their username and password
- Select "My Information" and scroll down to Rulings section for outstanding fines owing
- Ensure the email address is completed and saved
- Click on "Pay Fines" to begin payment
- Credit Card, ACH Bank Debit, Google Pay, Apple Pay accepted
- No fees to make a payment

Pay by Check:

SEND CHECK PAYMENTS AT LEAST 15 DAYS BEFORE THE DUE DATE TO ALLOW TIME FOR MAIL DELIVERY AND MANUAL PAYMENT PROCESSING. INCOMPLETE INFORMATION WILL INCREASE PROCESSING TIMES.

A Covered Person must include the following 2 items in the envelope sent to HISA:

☐ A check covering the full amount payable to HISA.

☐ A copy of the Ruling Form that includes HISA#xxx-xxx-xxx - either the Stewards Ruling Form, or a ruling that has been provided by the Racing Safety Committee, HISA board, National Stewards panel, or other Arbitral body assigned by HISA.

HISA mailing Address:

Horseracing Integrity and Safety Authority
401 W Main Street, Suite 222
Lexington, Kentucky
40507

PLEASE NOTE: ALL PAYMENTS ARE DUE WITHIN THE SPECIFIED DAYS OF THE RULING (default is 30 days unless noted otherwise). FAILURE TO PAY BY THE DUE DATE MAY RESULT IN SUSPENSION. YOU ARE ADVISED TO PAY ONLINE OR SEND CHECKS AT LEAST 15 DAYS BEFORE THE DUE DATE TO ALLOW TIME FOR MAIL DELIVERY AND MANUAL PAYMENT PROCESSING. INCOMPLETE INFORMATION WILL INCREASE PROCESSING TIMES.

Published Date: February 22, 2023

EXHIBIT B

RECOMMENDED FOR PUBLICATION
Pursuant to Sixth Circuit I.O.P. 32.1(b)

File Name: 23a0035p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

STATE OF OKLAHOMA; OKLAHOMA HORSE RACING COMMISSION; TULSA COUNTY PUBLIC FACILITIES AUTHORITY, dba Fair Meadows Racing and Sports Bar; STATE OF WEST VIRGINIA; WEST VIRGINIA RACING COMMISSION; HANOVER SHOE FARMS, INC.; OKLAHOMA QUARTER HORSE RACING ASSOCIATION; GLOBAL GAMING RP, LLC, dba Remington Park; WILL ROGERS DOWNS, LLC; UNITED STATES TROTTING ASSOCIATION; STATE OF LOUISIANA,

Plaintiffs-Appellants,

v.

UNITED STATES OF AMERICA; HORSERACING INTEGRITY AND SAFETY AUTHORITY, INC.; LEONARD S. COLEMAN, JR.; NANCY M. COX; FEDERAL TRADE COMMISSION; REBECCA KELLY SLAUGHTER, in her official capacity as Acting Chair of the Federal Trade Commission; NOAH JOSHUA PHILLIPS, in his official capacity as Commissioner of the Federal Trade Commission; ALVARO BEDOYA, in his official capacity as Commissioner of the Federal Trade Commission; CHRISTINE S. WILSON, in her official capacity as Commissioner of the Federal Trade Commission; STEVE BESHEAR; ADOLPHO A. BIRCH, JR.; ELLEN MCCLAIN; CHARLES P. SCHEELER; JOSEPH DEFRANCIS; SUSAN STOVER; BILL THOMASON; D.G. VAN CLIEF; LINA KHAN,

Defendants-Appellees.

No. 22-5487

Appeal from the United States District Court for the Eastern District of Kentucky at Lexington.
No. 5:21-cv-00104—Joseph M. Hood, District Judge.

Argued: December 7, 2022

Decided and Filed: March 3, 2023

Before: SUTTON, Chief Judge; COLE and GRIFFIN, Circuit Judges.

COUNSEL

ARGUED: Matthew D. McGill, GIBSON, DUNN & CRUTCHER LLP, Washington, D.C., for Appellants. Courtney L. Dixon, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Federal Appellees. Pratik A. Shah, AKIN GUMP STRAUSS HAUER & FELD LLP, Washington, D.C., for Horseracing Authority Appellees. **ON BRIEF:** Matthew D. McGill, Lochlan F. Shelfer, GIBSON, DUNN & CRUTCHER LLP, Washington, D.C., Zach West, Bryan Cleveland, OFFICE OF THE OKLAHOMA ATTORNEY GENERAL, Oklahoma City, Oklahoma, Lindsay S. See, OFFICE OF THE WEST VIRGINIA ATTORNEY GENERAL, Charleston, West Virginia, Joseph Bocock, BOCOCK LAW PLLC, Oklahoma City, Oklahoma, Todd Hembree, CHEROKEE NATION BUSINESS, Catoosa, Oklahoma, Elizabeth B. Murrill, LOUISIANA DEPARTMENT OF JUSTICE, Baton Rouge, Louisiana, Michael Burrage, WHITTEN BURRAGE, Oklahoma City, Oklahoma, Jared C. Easterling, GREEN LAW FIRM PC, Ada, Oklahoma, for Appellants. Courtney L. Dixon, Joseph F. Busa, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Federal Appellees. Pratik A. Shah, Lide E. Paterno, AKIN GUMP STRAUSS HAUER & FELD LLP, Washington, D.C., John C. Roach, RANSDELL ROACH & ROYSE, Lexington, Kentucky, for Horseracing Authority Appellees. Benjamin M. Flowers, OFFICE OF THE OHIO ATTORNEY GENERAL, Columbus, Ohio, Paul E. Salamanca, Lexington, Kentucky, April A. Wimberg, DENTONS BINGHAM GREENEBAUM LLP, Louisville, Kentucky, Gregory G. Garre, Blake E. Stafford, LATHAM & WATKINS LLP, Washington, D.C., for Amici Curiae.

SUTTON, C.J., delivered the opinion of the court in which GRIFFIN and COLE, JJ., joined. COLE, J. (pp. 20–31), delivered a separate concurring opinion.

OPINION

SUTTON, Chief Judge. Sometimes government works. In 2020, when Congress enacted the Horseracing Safety and Integrity Act to create a national framework to regulate thoroughbred horseracing, it generated several non-delegation and anti-commandeering challenges to the validity of the Act. The lead challenge—the non-delegation challenge—turned on the reality that the Act replaced several state regulatory authorities with a private corporation, the Horseracing Authority, which became the Act's primary rule-maker and which was not subordinate to the relevant public agency, the Federal Trade Commission, in critical ways. The Fifth Circuit declared the Act unconstitutional because it gave "a private entity the last word" on federal law.

Nat'l Horsemen's Benevolent & Protective Ass'n v. Black, 53 F.4th 869, 872, 888–89 (5th Cir. 2022).

In response, Congress amended the Act to give the Federal Trade Commission discretion to "abrogate, add to, and modify" any rules that bind the industry. Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, 136 Stat. 4459 (2022). The Constitution anticipates, though it does not require, constructive exchanges between Congress and the federal courts. *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 635 (1952) (Jackson, J., concurring) (explaining that "interdependence" and "reciprocity" should characterize the relationship between the branches as much as "separateness" and "autonomy"). A productive dialogue occurred in this instance, and it ameliorated the concerns underlying the non-delegation challenge. As amended, the Horseracing Act gives the FTC the final say over implementation of the Act relative to the Horseracing Authority, allowing us to uphold the Act as constitutional in the face of this non-delegation challenge as well as the anti-commandeering challenge.

I.

Unlike other sports, no one authority traditionally has regulated horseracing. Instead, 38 state regulatory schemes have supplied an array of protocols and safety requirements. Kjirsten Lee, *Transgressing Trainers and Enhanced Equines*, 11 J. Animal & Nat. Res. L. 23, 26 (2015). Most Americans know horseracing through occasional high-visibility races, say the Kentucky Derby on the first Saturday of May, or high-visibility books, say *Seabiscuit*. But as the partly and fully initiated alike can appreciate, the sport comes with risk. Racing a dozen or more jockeys atop large horses around a mile or more track, all with prize money and gambling positions at stake, creates plenty of danger. Over the last seventy years or so, fatal accidents for jockeys during horseraces have exceeded that of drivers in NASCAR races. Peta L. Hitchens *et al.*, *Jockey Falls, Injuries, and Fatalities Associated with Thoroughbred and Quarter Horse Racing in California 2007–2011*, at 3, Orthopedic J. Sports Med. (2013) (129 jockeys killed between 1940 and 2012); *How Many NASCAR Drivers Have Died Racing?*, Motor Racing Sports, https://tinyurl.com/2d3xnazy (last visited Feb. 6, 2023) (82 NASCAR drivers killed between 1950 and 2021). Faring no better, almost 500 thoroughbreds died in 2018 alone due to

racing injuries. *Why Horse Racing Is So Dangerous*, Nat'l Geographic (Jan. 21, 2020), https://tinyurl.com/ycyf5rhv.

Whether it's the risk of pushing horses past their limits or the risks associated with unsafe tracks and doping, or other health and safety issues facing horses and jockeys, no one doubts the imperative for oversight. The question, as is so often the case, is whether the regulation should be national or local.

In 2020, Congress answered national but did so in conventional and unconventional ways. Conventionally, it enacted the Horseracing Integrity and Safety Act to nationalize regulatory authority over thoroughbred racing. 15 U.S.C. §§ 3051–60. Less conventionally, it chose to use a private nonprofit corporation—the Horseracing Integrity and Safety Authority—to do some of the regulating.

The Act charges the Horseracing Authority with "developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program." *Id.* § 3052(a). The Authority's jurisdiction also includes the "safety, welfare, and integrity" of covered thoroughbreds, jockeys, and horseraces. *Id.* § 3054(a)(2)(A). The Authority may expand the Act's coverage to other breeds upon request by a state racing commission or a breed governing organization. *Id.* § 3054(*l*).

The Horseracing Authority funds its operations through fees on the horseracing industry. Each year, it calculates its budget and apportions amounts owed by each State. *Id.* § 3052(f)(1)(C). The States have two options. They may collect the fees themselves from covered entities and remit the fees to the Authority. *Id.* § 3052(f)(2)(D). Or they may allow the Authority to collect the fees directly. *Id.* § 3052(f)(3)(A)–(C).

The Act empowers the Horseracing Authority to promulgate rules on a variety of subjects: prohibited medications, laboratory protocols and accreditation, racetrack standards and protocols, injury analysis, enforcement, and fee assessments. *Id.* § 3053(a). The Authority also develops procedures for its investigatory and subpoena powers. *Id.* § 3054(c). Once issued, the rules preempt state law. *Id.* § 3054(b).

The Horseracing Authority implements the rules, monitors compliance, and investigates potential rule infractions. *Id.* § 3054(c), (h), (i). The Act directs "the Authority and Federal or State law enforcement authorities" to "cooperate and share information" whenever a covered person may have violated federal or state law in addition to one of the Authority's rules. *Id.* § 3060(b). After investigating, the Authority may enforce the rules through internal adjudications or civil lawsuits. *Id.* §§ 3054(j), 3057(c).

Under the Horseracing Act as originally passed, the Federal Trade Commission played a limited role. The FTC published the Authority's proposed rules for public comment. *Id.* § 3053(b)(1). After the comment period, the FTC had to approve the rules if they were "consistent" with the Act and with other "applicable rules approved by the Commission." *Id.* § 3053(b)–(c). The FTC also could issue an "interim" rule if it had "good cause" to do so and if the rule was "necessary to protect" the welfare of horses or the integrity of the sport. *Id.* § 3053(e) (2020); *see* 5 U.S.C. § 553(b)(B).

This framework prompted legal challenges. In a case filed in federal court in Texas, several claimants argued that the Act violated the Constitution by delegating unmonitored lawmaking power to a private entity. The Fifth Circuit agreed, reasoning that the FTC's oversight was insufficient because the FTC could not modify the rules or otherwise question the Horseracing Authority's policy choices. *Black*, 53 F.4th at 872–73, 886–87. Our court faced a similar challenge. Oklahoma, West Virginia, Louisiana, their racing commissions, and other entities (collectively, Oklahoma) claimed that the Act unlawfully delegated federal power to a private entity and unlawfully commandeered the States. The district court dismissed Oklahoma's claims.

After the Fifth Circuit issued its decision and after we heard oral argument in our case, Congress enacted, and the President signed into law, an amendment to the Act that increased the FTC's oversight role. The amendment eliminated the FTC's interim-rule authority and instead gave sweeping power to the FTC to create rules that "abrogate, add to, and modify the rules of the Authority." 15 U.S.C. § 3503(e) (as amended). Oklahoma maintains that the Act remains unconstitutional.

II.

Mootness. First things first: Does the amendment to the Act transform this live controversy into a moot one? When Congress amends a statute, it is true, pending claims challenging the law sometimes become moot. *See City of Pontiac Retired Emps. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (en banc) (per curiam). Not invariably, however. If the revised statute continues to place a non-trivial burden on the plaintiff that arises from the same theory of unconstitutionality set forth in the complaint, the case remains live. *Kenjoh Outdoor, LLC v. Marchbanks*, 23 F.4th 686, 692–93 (6th Cir. 2022). A similar conclusion applies if the amendment does not affect other features of the challenge. Both exceptions apply here.

The amendment to § 3053(e) of the Horseracing Act does not moot Oklahoma's non-delegation claim. While significant to the outcome of the case, this singular amendment changes little about the Act's basic structure. The revised Act "operates in the same fundamental ways," with the Authority proposing and enforcing rules and with the FTC overseeing all of them, the key difference being that the FTC has far more oversight authority than it had before. *Id.* at 693. The revised Act likewise presents fundamentally the "same controversy," with Oklahoma continuing to argue that the Act gives too much unsubordinated power to a private entity. *Id.*; *see Cam I, Inc. v. Louisville/Jefferson Cnty. Metro Gov't*, 460 F.3d 717, 720 (6th Cir. 2006). Nor does the Act moot Oklahoma's anti-commandeering claim. In reality, the amendment does not change that dispute in any material way.

Remand. One other preliminary point remains. If the legislature changes a law while a live challenge to it remains on appeal, appellate courts may remand the case for the district court to take the first look at the revised law. *Hadix v. Johnson*, 144 F.3d 925, 934 (6th Cir. 1998), *abrogated on other grounds*, 530 U.S. 327 (2000). The option is discretionary, not mandatory. In this instance, we see "little to be gained" from a remand because Oklahoma brings facial challenges that raise only legal issues and because the parties and panel have already devoted considerable time and resources to the dispute. *Id.* at 935; *see Phelps-Roper v. Troutman*, 712 F.3d 412, 417 (8th Cir. 2013) (per curiam). Fortifying this conclusion is the reality that the challengers have asked us to proceed to the merits.

III.

A.

Non-delegation. Through the United States Constitution, the People separated the powers of the National Government into three branches. They vested the legislative power in Congress, the executive in the President, and the judicial in the federal courts. U.S. Const. art. I, § 1; *id.* art. II, § 1; *id.* art. III, § 1. The People also constrained each branch's use of its power through counterweights in the other branches. To preserve this balance, the Constitution bars further delegations of power between the branches. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001).

What about delegations to private entities? Surely, if the Vesting Clauses bar the three branches from exchanging powers among themselves, those Clauses bar unchecked reassignments of power to a non-federal entity. Just as it is a central tenet of liberty that the government may not permit a private person to take property from another private person, *Calder v. Bull*, 3 U.S. (Dall.) 386, 388–89 (1798) (Chase, J.), or allow private individuals to regulate other private individuals, *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116, 122 (1928), it follows that the government may not empower a private entity to exercise unchecked legislative or executive power. Those who govern the People must be accountable to the People. Completely transferring unchecked federal power to a private entity that is not elected, nominated, removable, or impeachable undercuts representative government at every turn.

Precedent confirms that unchecked delegations to private entities at a minimum violate core separation-of-power guarantees. Consider *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). A federal statute gave the President discretion to create codes of fair competition based on proposals from private entities. *Id.* at 542. Rejecting the government's view that private participation cured any surplus delegation to the President, the Court explained that transforming private groups into legislatures was "utterly inconsistent" with the constitutional design. *Id.* at 537.

The Court applied the same standard to the Bituminous Coal Act. In *Carter v. Carter Coal Co.*, the Court concluded that, by empowering coal producers to set wages and to control the businesses of others, the Act amounted to a "delegation in its most obnoxious form" because such regulation "is necessarily a governmental function." 298 U.S. 238, 310–11 (1936). Appreciating the problem, Congress amended the Act the next year to give the Coal Commission, a government entity, the power to set prices. *See Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 388 (1940). After Congress subordinated the private coal producers to a public body (the Coal Commission) that could modify or reject their proposals, the Court determined that the statute did not impermissibly delegate "legislative authority to the industry." *Id.* at 399.

Taken together, these cases draw a line between impermissible delegation of unchecked lawmaking power to private entities and permissible participation by private entities in developing government standards and rules. *Adkins* shows that a private entity may aid a public federal entity that retains authority over the implementation of federal law. *Id.* at 388. But if a private entity creates the law or retains full discretion over any regulations, *Carter Coal* and *Schechter* tell us the answer: that it is an unconstitutional exercise of federal power. *See Carter Coal*, 298 U.S. at 311; *Schechter*, 295 U.S. at 537.

Decisions from the courts of appeals hold this line. Private entities may serve as advisors that propose regulations. *See Sierra Club v. Lynn*, 502 F.2d 43, 59 (5th Cir. 1974); *Cospito v. Heckler*, 742 F.2d 72, 87–89 (3d Cir. 1984); *Todd & Co. v. SEC*, 557 F.2d 1008, 1012–13 (3d Cir. 1977). And they may undertake ministerial functions, such as fee collection. *See Pittston Co. v. United States*, 368 F.3d 385, 395–97 (4th Cir. 2004); *United States v. Frame*, 885 F.2d 1119, 1128–29 (3d Cir. 1989), *abrogated on other grounds*, 521 U.S. 457 (1997). But a private entity may not be the principal decisionmaker in the use of federal power, *Pittston Co.*, 368 F.3d at 395–97, may not create federal law, *Texas v. Rettig*, 987 F.3d 518, 533 (5th Cir. 2021), may not wield equal power with a federal agency, *Ass'n of Am. R.R. v. U.S. Dep't of Transp.* (*Amtrak I*), 721 F.3d 666, 671–73 (D.C. Cir. 2013), *vacated on other grounds*, 575 U.S. 43 (2015), or regulate unilaterally, *Black*, 54 F.4th at 872.

An illuminating example comes from securities law. The Securities and Exchange Commission regulates the securities industry with the assistance of private, self-regulatory organizations called SROs. The SROs propose rules for the industry, and they initially enforce the rules through internal adjudication. The SEC oversees both the rulemaking and the enforcement. As to the rules, the SEC approves proposed rules if they are consistent with the Maloney Act, and may "abrogate, add to, and delete from" an SRO's rules "as the Commission deems necessary or appropriate." 15 U.S.C. § 78s(b)(2)(C), (c). As to enforcement, the SEC applies fresh review to the SRO's decisions and actions. *Id.* § 78s(e); *see Sartain v. SEC*, 601 F.2d 1366, 1369–71 (9th Cir. 1979). In case after case, the courts have upheld this arrangement, reasoning that the SEC's ultimate control over the rules and their enforcement makes the SROs permissible aides and advisors. *See R.H. Johnson & Co. v. SEC*, 198 F.2d 690, 695 (2d Cir. 1952); *Todd & Co.*, 557 F.2d at 1012–13; *First Jersey Secs., Inc. v. Bergen*, 605 F.2d 690, 697 (3d Cir. 1979); *Sorrell v. SEC*, 679 F.2d 1323, 1325–26 (9th Cir. 1982); *see also Amtrak I*, 721 F.3d at 671 n.5 (describing the SROs' role as "purely advisory or ministerial").

These sources all suggest that, at a minimum, a private entity must be subordinate to a federal actor in order to withstand a non-delegation challenge. Whether subordination always suffices to withstand a challenge raises complex separation of powers questions. Simplifying matters for today, if not for a future day, the parties accept this framing of the appeal. As the case comes to us, then, the determinative question is whether the Horseracing Authority is inferior to the FTC.

B.

The Horseracing Authority is subordinate to the agency. The Authority wields materially different power from the FTC, yields to FTC supervision, and lacks the final say over the content and enforcement of the law—all tried and true hallmarks of an inferior body.

Rulemaking. As amended, the Horseracing Act gives the FTC supervision over the rules that govern the horseracing industry. At the outset, the Horseracing Authority drafts rules on racetrack safety and anti-doping matters, and the FTC must approve those proposals if they are consistent with the Act. 15 U.S.C. § 3053(c)(2). But, critically, as the FTC "deems necessary or

appropriate," it "may abrogate, add to, and modify the rules." *Id.* § 3053(e) (as amended). The FTC's power to abrogate and change the Authority's rules creates "a clear hierarchy." *Black*, 53 F.4th at 888–89.

Section 3053(e)'s amended text grants the FTC a comprehensive oversight role. The Act provides that the FTC may act as it "finds necessary or appropriate to ensure the fair administration of the Authority, to conform the rules of the Authority to requirements of this Act and applicable rules approved by the Commission, or otherwise in furtherance of the purposes of this Act." 15 U.S.C. § 3053(e) (as amended). The final catchall indicates that § 3053(e) spans the Horseracing Authority's jurisdiction. The parties are one in agreeing that this section allows the FTC to modify rules "if it wishes." Appellants' Suppl. Br. 1.

A comparison with § 3053(e)'s pre-amendment language reenforces the point. Before the amendment, § 3053(e) allowed the FTC to adopt interim rules only if "necessary," and only if good cause existed to bypass the Administrative Procedure Act's notice and comment procedures. 15 U.S.C. § 3053(e) (2020). The Fifth Circuit concluded that the ability to "make temporary rules on a break-glass-in-case-of-an-emergency basis" did not give the FTC sufficient control. *Black*, 53 F.4th at 883. The FTC could overrule the Authority only in rare, extreme cases, making it the inferior, not the superior, rule-maker. The amended section, by contrast, requires no emergency, no good cause, no necessity. The FTC now may create new rules or modify existing rules as it deems "appropriate to" advance "the purposes of [the] Act." 15 U.S.C. § 3053(e) (as amended). That amounts to true oversight authority.

With § 3053(e)'s broad power to write and rewrite the rules comes policymaking discretion. *See Cospito*, 742 F.2d at 88–89. When the FTC decides to act—whether by abrogating one of the Horseracing Authority's rules or introducing its own—the FTC makes a policy choice and necessarily scrutinizes the Authority's policies. That is no less true when the FTC decides *not* to act. In either setting, the FTC may "unilaterally change regulations," *Amtrak I*, 721 F.3d at 671, and "is free to prescribe" the rules, showing that it "retains ultimate authority," *Cospito*, 742 F.2d at 88. In a recent rule, the FTC recognized as much, explaining that its new "rulemaking power" allows it to "exercise its own policy choices."

Order Ratifying Previous Commission Orders 3, Fed. Trade Comm'n (Jan. 3, 2023), https://tinyurl.com/dkenwspt.

In full, § 3053(e)'s amended text gives the FTC ultimate discretion over the content of the rules that govern the horseracing industry and the Horseracing Authority's implementation of those rules. By the same token, ultimate "law-making is not entrusted to the [Authority]." *Adkins*, 310 U.S. at 399; *see Frame*, 885 F.2d at 1129. That makes the FTC the primary rule-maker, and leaves the Authority as the secondary, the inferior, the subordinate one. *See Adkins*, 310 U.S. at 388.

Accountability considerations lead to the same destination. Before the amendment, the Fifth Circuit determined that the FTC could not question the Horseracing Authority's policy choices or modify its rules. *Black*, 53 F.4th at 886–87. It followed that the Authority, a private entity beyond public control, alone was responsible for the exercise of government power in this area. Not so anymore. With its new ability to have "the final word on the substance of the rules," the FTC bears ultimate responsibility. *Id.* at 887; *cf. Lynn*, 502 F.2d at 59. The People may rightly blame or praise the FTC for how adroitly (or, let's hope not, ineptly) it "ensure[s] the fair administration of the Authority" and advances "the purposes of [the] Act." 15 U.S.C. § 3053(e) (as amended).

Enforcement. A similar conclusion applies to enforcement of the Act. The Horseracing Authority's enforcement duties are extensive, granted. The Authority implements the Act, investigates potential rule violations, and enforces the rules through internal adjudications and external civil lawsuits. Even so, the FTC's rulemaking and rule revision power gives it "pervasive" oversight and control of the Authority's enforcement activities, just as it does in the rulemaking context. *Adkins*, 310 U.S. at 388.

Take an example to illustrate the point. Imagine that the Horseracing Authority began enforcing its rule without giving thought to the procedural rights of jockeys, trainers, and other industry participants. Section 3053(e) gives the FTC the tools to step in. To ensure a fair enforcement process, the FTC could issue rules protecting covered persons from overbroad subpoenas or onerous searches. The FTC could require that the Authority provide a suspect with

a full adversary proceeding and with free counsel. And the FTC could require that the Authority meet a burden of production before bringing a lawsuit or preclear the decision with the FTC. In these ways as well as others, the FTC may control the Authority's enforcement activities and ensure that the FTC, not the Authority, ultimately decides how the Act is enforced.

Topping this oversight off, the FTC has full authority to review the Horseracing Authority's enforcement actions. 15 U.S.C. § 3058(c)(1)–(2). After an independent review, the FTC may reverse the Authority's decision. *Id.* § 3058(c)(3). As with rulemaking, so with adjudication: The Authority's adjudication decisions are not final until the FTC has the opportunity to review them. *See Cospito*, 742 F.2d at 88; *Todd & Co.*, 557 F.2d at 1012–14. All told, the Horseracing Authority is "subject to [the FTC's] pervasive surveillance and authority," revealing that the Authority "operate[s] as an aid to the [FTC]," nothing more. *Adkins*, 310 U.S. at 388.

Whether the FTC becomes a demanding taskmaster or a lenient one, the FTC *could* subordinate every aspect of the Authority's enforcement "to ensure the fair administration of the Authority . . . or otherwise in furtherance of the purposes of [the] Act." 15 U.S.C. § 3053(e) (as amended). That potential suffices to defeat a facial challenge, where Oklahoma must show that the Act is unconstitutional in all its applications. *United States v. Salerno*, 481 U.S. 739, 745 (1987).

C.

In seeking to head off this conclusion, Oklahoma points out that the amendment does not change one feature of the Act—that the FTC has power only to review proposed rules by the Authority for "consistency" with the Act, a standard of review that, it says, does not pick up policy disagreements. 15 U.S.C. § 3053(c). Maybe so. But even if that is the case, the FTC's later authority to modify *any* rules for any reason at all, including policy disagreements, ensures that the FTC retains ultimately authority over the implementation of the Horseracing Act. The FTC's review authority in this respect parallels similar authority exercised by the SEC under the Maloney Act. *Compare* 15 U.S.C. § 78s(c) (providing that the SEC "may abrogate, add to, and delete from . . . the rules of [the private entity] as the Commission deems necessary or

appropriate"), *with* 15 U.S.C. § 3053(e) (as amended) (providing that the FTC "may abrogate, add to, and modify the rules of the Authority . . . as the Commission finds necessary or appropriate"). The same is true in the Coal Act. *See* Bituminous Coal Act of 1937, Pub. L. No. 75-48, § 4, 50 Stat. 72, 78 (providing that the Coal Commission could "approve, disapprove, or modify" proposals).

Before the amendment, Oklahoma observed that the SEC's modification power gives the SEC "largely unbounded authority to craft [the private entity's] regulations as it sees fit." Reply Br. 7. The same is now true under the Horseracing Act. The lack of a modification power, moreover, was the "key distinction" the Fifth Circuit identified between the Maloney and Horseracing Acts. *Black*, 53 F.4th at 887. The amendment to § 3053(e) eliminates that distinction. Even if other less-material distinctions between the two laws remain, the FTC's new discretion to adopt and modify rules correctly places the private Horseracing Authority in a subordinate position to the public FTC. All of this explains why every court of appeals to address the validity of such delegations under the Maloney Act and the Coal Act, as noted, has upheld them.

Oklahoma worries that the Horseracing Authority's rules could govern a dispute until the FTC undoes rules it dislikes. It's true that the FTC's modification authority under § 3053(e), as it currently exists, customarily would run through ordinary rulemaking. But that current reality need not be a future reality. For one, the threat of modification is not likely to miss the attention of the Authority. For another, the FTC has power to initiate new rules, not just to modify rules it does not like. To the extent this timing gap creates a problem, the FTC is free to resolve it ahead of time. It might, for example, adopt a rule that all newly enacted rules do not take effect for 180 days, thereby giving the FTC time to review rules and prepare preemptive modifications.

This argument overlooks another reality. When the FTC reviews the Horseracing Authority's proposed rules, it asks not just whether they are "consistent" with the Act; it also asks whether they are "consistent" with other "applicable rules approved by the Commission." *Id.* § 3053(c)(2). Any risk of a policymaking gap between initial consistency review and initial full review will diminish over time as the FTC chooses to exercise—or not to exercise—its

complete authority to initiate new rules or modify old ones. Over time, the FTC's threshold consistency review will account for its own full-throated rulemaking power.

Oklahoma notes that the FTC's duty under the Administrative Procedure Act to explain any changes to the rules limits its hand. But that just means it may not arbitrarily alter the rules. The APA does not limit the FTC's authority to disagree with the Horseracing Authority over a policy choice delegated to the agency by Congress. The FTC "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). It is enough that "there are good reasons" for the new policy "and that the agency believes it to be better." *Id.*

No matter, Oklahoma adds: The Horseracing Authority's ability to expand its jurisdiction to breeds other than thoroughbreds escapes the FTC's review. Not so. The FTC's § 3053(e) power allows it to revoke the Authority's decision or place procedural and substantive conditions on any such decision.

Oklahoma points to the Horseracing Authority's ability to enforce the Act through civil lawsuits, asserting that the ability cannot reside outside the executive branch. "Difficult and fundamental questions," we agree, arise when private entities enforce federal law. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 197 (2000) (Kennedy, J., concurring). But this is not an as-applied challenge to an individual enforcement action; it is a facial challenge to the Act. The FTC's ultimate authority over all rules promulgated under the Act, which would include any rules related to enforcement, offers a potent answer to this concern in the context of a facial challenge. The Authority's enforcement through internal adjudication and external lawsuits is subordinate to the FTC. The other reality is that the parties simply have not engaged with this feature of the Act, including briefing with respect to founding-era or contemporary analogs showing the role private entities may, and may not, play in law enforcement. That omission is understandable. From the start, Oklahoma litigated this claim as one turning on "governmental oversight" of and "accountability" for the Horseracing Authority's activities, not as a categorical Article II inquiry or as a question of historical meaning. R.53 ¶ 150; R.98 at 23–24. We thus will decide the case as it comes to us, and save resolution of such

questions, if such questions there be, for a day when the Authority's actions and the FTC's oversight appear in concrete detail, presumably in the context of an actual enforcement action.

IV.

Oklahoma separately claims that two provisions of the Horseracing Act, § 3060(b) and § 3052(f), violate the anti-commandeering guarantee of the Tenth Amendment. Oklahoma lacks standing to challenge the first provision, and the second one does not count as a cognizable form of commandeering.

A.

Oklahoma initially sets its sights on § 3060(b), which requires state authorities to "cooperate and share information" with the Horseracing Authority or federal agencies. Right or wrong about whether this requirement amounts to commandeering, Oklahoma and the other State plaintiffs lack standing to challenge it.

Standing arises from the Constitution's mandate that federal courts decide only "Cases" or "Controversies." U.S. Const. art. III, § 2, cl. 1. A plaintiff must establish standing for each claim he presses and each statutory provision he challenges. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207–08 (2021). To do that, he must point to an injury that is traceable to the defendant's conduct and that a judicial decision can redress. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). In a pre-enforcement challenge like this one, a plaintiff must also allege a "credible threat" of future enforcement. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014).

Oklahoma has not carried this burden. Even if Oklahoma is correct that § 3060(b) unlawfully orders the States to cooperate, the provision does not contain a penalty or enforcement mechanism. And Oklahoma does not point to any actual or threatened enforcement actions. An unenforceable statutory duty does not give rise to Article III standing, *California v. Texas*, 141 S. Ct. 2104, 2113–14 (2021), and "mere conjecture" about possible enforcement is not any better, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 420 (2013).

Oklahoma asserts in response that wrongdoing will "frequently" implicate both federal and state law, and thus trigger the duty to cooperate. R.86 at 10. But the question is not how often the opportunity for cooperation may arise; it is whether the defendants can or will mandate cooperation when that time comes. Even so, Oklahoma notes, the Horseracing Authority may penalize States that refuse to cooperate. But the Authority's sanction power extends only to covered persons, a term that does not include States. 15 U.S.C. §§ 3051(5), 3054(d), 3057(a)(1); *see Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991). The same is true of the Authority's ability to initiate civil lawsuits. 15 U.S.C. § 3054(j).

Absent a credible allegation that the Horseracing Authority or the FTC can or will enforce § 3060(b), Oklahoma lacks standing to challenge it. *California*, 141 S. Ct. at 2115.

B.

Oklahoma separately claims that § 3052(f) puts the States to an unconstitutionally coercive choice. While § 3052(f)'s threat of preemption gives Oklahoma standing, *Kentucky v. Biden*, 23 F.4th 585, 597–601 (6th Cir. 2022), the provision does not commandeer the States.

Congress may not require the States, separate sovereigns all, to implement federal programs. *Printz v. United States*, 521 U.S. 898, 925 (1997). Nor may the federal government issue "orders directly to the States" to carry out this or that federal program. *Murphy v. NCAA*, 138 S. Ct. 1461, 1475 (2018). At the same time, Congress may "encourage a State to regulate" or "hold out incentives" in hopes of "influencing a State's policy choices." *New York v. United States*, 505 U.S. 144, 166 (1992).

One option in this last respect is that Congress may encourage the States through conditional preemption. *Hodel v. Va. Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264, 290 (1981). Instead of preempting state law altogether, Congress may offer States a regulatory role contingent on following federal standards. *New York*, 505 U.S. at 167–68. The choice brings consequences. If a State participates, it often has discretion in how it implements the program. *See Hodel*, 452 U.S. at 289. If a State decides not to participate, the State's activities are preempted. By offering States such a non-coercive choice—regulate or be preempted—

Congress has not violated any constitutional imperatives. *Murphy*, 138 S. Ct. at 1479; *New York*, 505 U.S. at 167; *Hodel*, 452 U.S. at 288–91; *FERC v. Mississippi*, 456 U.S. 742, 769 (1982).

That's how § 3052(f) operates. It presents States with a choice, not a command. States may elect to collect fees from the industry and remit the money to the Horseracing Authority or States may refuse. That's their call. If a State participates, it gains discretion over how the fees are collected. 15 U.S.C. § 3052(f)(2)(D). If a State refuses, the Authority collects the fees itself, and the State "shall not impose or collect from any person a fee or tax relating to anti-doping and medication control or racetrack safety matters." *Id.* § 3052(f)(3)(D).

This scheme fits comfortably within the conditional preemption framework. Section 3052(f) "simply establish[es] requirements for continued state activity in an otherwise pre-emptible field." *FERC*, 456 U.S. at 769; *see Printz*, 521 U.S. at 925–26. And because Congress may regulate horseracing under its commerce power, there is nothing unconstitutional about Congress "offer[ing] States the choice of regulating that activity according to federal standards or having state law pre-empted." *New York*, 505 U.S. at 173–74.

Section 3052(f) also lacks the hallmark of commandeering: a "direct" order to the States. *Murphy*, 138 S. Ct. at 1476. Section 3052(f)'s statement that a State "shall not impose or collect" certain fees may sound like a command, true enough. *Id.* § 3052(f)(3)(D). But preemption often carries that tone, as similar language in other statutes confirms. *See, e.g.*, 42 U.S.C. § 7543(a) (1988) ("No State . . . shall adopt or attempt to enforce any standard relating to control of emissions . . . ."); 49 U.S.C. § 40116(b) ("[A] State . . . may not levy or collect a tax [or] fee . . . on an individual traveling in air commerce . . . ."). Because Congress often speaks in this manner, "it is a mistake to be confused" by preemption provisions that "appear to operate directly on the States." *Murphy*, 138 S. Ct. at 1480. Congress in this instance offers the States a choice, as Oklahoma all but concedes. Reply Br. 2, 25, 26, 27 (referring to § 3052(f) as a "threat of preemption"). A choice is not a command. *See Printz*, 521 U.S. at 925–26.

All of this is not to say "that the choice put to the States—that of either abandoning regulation" or assisting the Authority—is an easy one or a good one as a matter of policy.

FERC, 456 U.S. at 766. Fraught though it may be, Congress has not commandeered the States by putting them to this choice.

Oklahoma's principal counterargument is that a choice between collecting fees and losing fee collecting authority is illegitimate, coercive, or punitive. We don't think so.

Oklahoma begins by arguing that § 3052(f)'s choice—collect fees for the Horseracing Authority or stop collecting entirely—commandeers the States because Congress may not force the States to adopt either alternative. *See New York*, 505 U.S. at 175–76. Congress may not force a State to collect fees, true. *Printz*, 521 U.S. at 933. But Congress may use its commerce power to preempt the field of horseracing, preventing States from imposing fees. *See FERC*, 456 U.S. at 764; *Gonzales v. Raich*, 545 U.S. 1, 22 (2005). Threatening to do so, it follows, is a "conditional exercise of [a] congressional power." *New York*, 505 U.S. at 176.

Oklahoma's response that a "threat of preemption," Reply Br. 25, is coercive runs aground on contrary precedent. The Court has rejected the argument "that the threat of federal usurpation of their regulatory roles coerces the States." *Hodel*, 452 U.S. at 289; *New York*, 505 U.S. at 176.

Even so, Oklahoma continues, threatening a State's taxing authority is especially coercive. We fail to see how. The validity of conditional preemption does not fluctuate with the power that is threatened. *See Hodel*, 452 U.S. at 290–91. This would not be the first time a State's taxing power was preempted. *See Aloha Airlines, Inc. v. Dir. of Tax'n*, 464 U.S. 7, 14 n.10 (1983); *Exxon Corp. v. Hunt*, 475 U.S. 355, 360–63 (1986).

Oklahoma presses the point that Congress's financial incentives may become so overwhelming that a State effectively cannot refuse. *See South Dakota v. Dole*, 483 U.S. 203, 211–12 (1987). Grafting this principle on conditional preemption raises legal and factual problems. Legally, it is bereft of support; no case evaluates conditional preemption by looking to a State's monetary incentives. Factually, Oklahoma falters because it does not quantify its expected loss. *See NFIB v. Sebelius*, 567 U.S. 519, 580–82 (2012) (opinion of Roberts, C.J.) (comparing an incentive to a State's budget). Without knowing how much money is at stake, how are we to say the sum is too high?

Oklahoma adds that the threat is punitive because it serves no purpose other than to obtain compliance. Conditional preemption, however, amounts to a "permissible method of encouraging a State to conform to federal policy." *New York*, 505 U.S. at 168; *see FERC*, 456 U.S. at 766. And a State that sees itself as a sovereign sometimes must act like one. Another reason is not difficult to find anyway. The fee provisions ensure that a single entity—whether a State or the Authority—imposes fees on the horseracing industry for all anti-doping and racetrack safety matters. Eliminating "double taxation" and fostering uniformity are adequate grounds to preempt parallel collection regimes. *Aloha Airlines*, 464 U.S. at 9–10; *see Coventry Health Care of Mo., Inc. v. Nevis*, 581 U.S. 87, 97–99 (2017); *Gade v. Nat'l Solid Waste Mgmt. Ass'n*, 505 U.S. 88, 99 (1992) (plurality).

Oklahoma next argues that Congress failed to "appropriate the funds needed to administer the program" by forcing States to pay for collecting fees even if they refuse to act as the Authority's fee collector. *Murphy*, 138 S. Ct. at 1477. Not so. Private parties pay for the Authority's operations. 15 U.S.C. § 3052(f)(2)(D), (3)(B). And if a State does not collect fees under the Act, the Authority incurs the cost of doing so. Even if States suffer a pocket-book loss from preemption, that does not force them to pay for the program. *See Hodel*, 452 U.S. at 288.

Oklahoma also worries that the scheme blurs accountability. Conditional preemption, however, leaves a State and its citizens with "the ultimate decision as to whether or not the State will comply." *New York*, 505 U.S. at 168. The ability to choose ensures that state and federal entities are accountable for their roles. *See id.*

We affirm.

CONCURRENCE

COLE, Circuit Judge, concurring. While I agree with the majority's conclusions that the Act is facially constitutional, and its analysis in full in Part IV, I write separately because I depart slightly from its framing of the issue and its analysis of the private nondelegation doctrine.

I. ISSUE ON APPEAL

As a threshold matter, I note what is before us on appeal. In 2020, with wide bipartisan support, Congress passed, and then-President Trump signed into law, the Horseracing Integrity and Safety Act ("HISA" or "the Act"). Pub. L. No. 116-260, §§ 1201–12, 134 Stat. 1182, 3252–75 (2020) (codified at 15 U.S.C. §§ 3051–60). Petitioners challenged the Act's constitutionality and appealed the district court's dismissal of the case for failure to state a claim. A few weeks after this panel heard oral argument in the appeal, Congress amended the Act. *See* Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, 126 Stat. 4459, 5231–32 (2022) (codified as amended at 15 U.S.C. § 3053(e)). Congress amended section 3053(e), which now provides that:

> The Commission, by rule, in accordance with section 553 of title 5, United States Code, may abrogate, add to, and modify the rules of the Authority promulgated in accordance with this Act as the Commission finds necessary or appropriate to ensure the fair administration of the Authority, to conform the rules of the Authority to requirements of this Act and applicable rules approved by the Commission, or otherwise in furtherance of the purposes of this Act.

15 U.S.C. § 3053(e). Under the current form of the statute, the Federal Trade Commission ("FTC") can, in certain circumstances delineated in the Act, and through proper rule-making procedures as required by the Administrative Procedure Act, "abrogate, add to, and modify" existing rules promulgated by the Horseracing Integrity and Safety Authority ("Authority"). *Id.*

Today, our review is cabined to the statute as amended, withholding judgment on the previous version or other circuits' handling of the original statute. To the extent that the cogent majority opinion goes further—opining in dicta that the original statute was unconstitutional—I note that not only does such analysis not carry the force of law, but also that

I disagree, as I believe the original statute was constitutional because the private Authority has always been subordinate to the FTC.

II. PRIVATE NONDELEGATION DOCTRINE

The nondelegation doctrines broadly refer to judicially imposed limits on Congress's ability to constitutionally delegate authority to others. Specifically, Congress cannot delegate its legislative authority to an executive agency unless the statute contains an "intelligible principle" guiding the agency. *See Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality opinion); *see also Mistretta v. United States*, 488 U.S. 361, 372 (1989). This is the public nondelegation doctrine. The private nondelegation doctrine refers to constitutional concerns that arise where a private entity—rather than a government entity—wields significant power to execute a statutory scheme. *See Carter v. Carter Coal Co.*, 298 U.S. 238 (1936). Only the latter of these, private nondelegation, is at issue here.

I agree with the majority that the Act is constitutional under the private nondelegation doctrine, and also that the main test for this issue is whether the private entity is subordinate to the federal agency. But I write separately because I diverge from the majority's analysis in two ways: (1) the source of the private nondelegation doctrine, and (2) the precise framing of the private nondelegation question.

A. Source of Private Nondelegation Doctrine

The private nondelegation doctrine is rooted in both due process and separation of powers concerns. Indeed, the earliest invocations of the private nondelegation doctrine arose in the context of local regulations. *See Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116, 121–22 (1928); *Thomas Cusack Co. v. City of Chicago*, 242 U.S. 526, 530 (1917); *Eubank v. City of Richmond*, 226 U.S. 137, 143–44 (1912). In these cases, localities granted private homeowners the power to create zoning laws for their neighborhood, and the Supreme Court found these ordinances violated property owners' federal due process rights. *Eubank*, 226 U.S. at 143–44. "The Court was concerned that private property owners, with their own interests at stake, had been given total, standardless control over an important aspect of their

neighbors' property." *Rice v. Vill. of Johnstown*, 30 F.4th 584, 589 (6th Cir. 2022) (citing *Eubank*, 226 U.S. at 143).

The separation of powers concerns, meanwhile, stem from the Vesting Clauses, inasmuch as the Constitution vests each of the three branches of government with specific powers and responsibilities. Article I of the Constitution grants Congress legislative power, Article II grants the President executive power, and Article III grants the federal courts judicial power. "Accompanying that assignment of power to Congress is a bar on its further delegation." *Gundy*, 139 S. Ct. at 2123; *see Mistretta*, 488 U.S. at 371 ("The nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government."). Therefore, when a statute confers "the power to regulate the affairs of an unwilling minority" onto a private entity, that "is legislative delegation in its most obnoxious form[.]" *Carter Coal*, 298 U.S. at 311. But when the private entity "operate[s] as an aid to the [agency]" and is "subject to [the agency's] pervasive surveillance and authority, . . . law-making is not entrusted to the [private entity]" and so such a "statutory scheme is unquestionably valid." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 388, 399 (1940).

Notably, in its federal private nondelegation cases, the Supreme Court has blurred the lines between the two rationales, opting not to definitively root the private nondelegation doctrine in one or the other, and often referring to both. For instance, in *Carter v. Carter Coal*, the first case applying the private nondelegation doctrine to a federal statute, the Court ruled that a portion of the Bituminous Coal Conservation Act of 1935 was unconstitutional under the private nondelegation doctrine. 298 U.S. at 311. In invalidating the statute, the Court found the delegation at issue "so clearly arbitrary, and so clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment, that it is unnecessary to do more than refer to decisions of this court which foreclose the question." *Id.* at 311–12 (first citing *Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537 (1935); then citing *Eubank*, 226 U.S. at 143; and then citing *Roberge*, 278 U.S. at 121–22).

In so holding, the Court cited two of the zoning cases premised on the due process concerns of the private nondelegation doctrine, and also *Schecter Poultry*, addressing the separation of powers argument. By doing so, the Court maintained the public versus private

division as opposed to a rationale-based division and endorsed both of the rationales underpinning the private nondelegation doctrine. *See Carter Coal*, 298 U.S. at 311.

The Fifth Circuit, when it ruled recently on the original version of the Act, recognized this ambiguity. *See Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 53 F.4th 869, 881 n.23 (5th Cir. 2022). "Courts and commentators," it wrote, "differ over the locus of the constitutional violation." *Id.* (citing several articles and cases). *Compare U.S. Dep't of Transp. v. Ass'n of Am. R.R.s*, 575 U.S. 43, 46 (2014) ("This argument [regarding private nondelegation] rests on the Fifth Amendment Due Process Clause and the constitutional provisions regarding separation of powers."), *with id.* at 87–88 ("[O]ur so-called 'private nondelegation doctrine' flows logically from the three Vesting Clauses.") (Thomas, J., concurring). But the Fifth Circuit concluded it "need not weigh in" to resolve the question at hand. *Black*, 53 F.4th at 881 n.23. "Whatever the constitutional derivation, all parties and the district court agree that the outcome turns on whether the private entity is subordinate to the agency." *Id.*; *see also Ass'n of Am. R.R.s v. U.S. Dep't of Transp.* (*Amtrak I*), 721 F.3d 666, 671 n.3 (D.C. Cir. 2013), *vacated on other grounds*, 575 U.S. 43 (2015) ("While the distinction [between the due process clause and Vesting Clauses] evokes scholarly interest, . . . our own precedent describes the problem as one of unconstitutional delegation."). When presented with the same ambiguity, the D.C. Circuit also did not decide the issue because the doctrine turns on unconstitutional delegation, regardless of its textual roots, and "neither court nor scholar has suggested a change in the label would effect a change in the inquiry." *Amtrak I*, 721 F.3d at 671 n.3.

Moreover, if we root the private nondelegation doctrine solely in separation of powers concerns, we circumvent our own court's private nondelegation doctrine cases—many of which focus on local regulations, not federal ones, and are grounded in due process rights, as opposed to separation of powers principles. *See Rice*, 30 F.4th at 589–91; *Kiser v. Kamdar*, 831 F.3d 784, 791–92 (6th Cir. 2016); *Stevens v. City of Columbus*, No. 21-3755, 2022 WL 2966396, at *9 (6th Cir. July 27, 2022).

Whatever the exact underpinning of the private nondelegation doctrine, what is clear is that the statute is constitutional if the Authority remains subordinate to the FTC. *See Adkins*, 310 U.S. at 388, 399 (holding a statute constitutional where the private entity is "an aid" to the

agency and is "subject" to the agency's "pervasive surveillance and authority"); *Carter Coal*, 298 U.S. at 310–11 (invalidating a statute where private entities were granted the power to establish the maximum hours of labor without any governmental oversight or approval).

That is the beginning and end of the inquiry as to whether a statute is constitutional under the private nondelegation doctrine. The Supreme Court has never suggested that this is the minimum finding, or that subordination on its own may not suffice to withstand a challenge to a statute on private nondelegation grounds. And so the parties could not have framed the appeal in a different way, because the only private nondelegation test is that of subordination.

Now that the framing and source of the nondelegation doctrine is clear, I apply the existing precedent to HISA, finding that HISA as a whole is facially constitutional because the Authority is subordinate to the FTC in several ways.

B. HISA's Constitutionality

1. Rulemaking Authority

Oklahoma raises several concerns with the Act and its different components. I agree in full with the majority's discussion of section 3053(e)'s amended text, and its conclusion that the amended text indicates that the Authority remains subordinate to the FTC. I diverge in that I find the rest of the Act to be nearly identical to the previously upheld Maloney Act and Coal Act. I also find that the amended text supports the Authority's subordination but does not alone ensure the Act's constitutionality.

To begin, the Authority does not have independent rulemaking power—only the FTC can promulgate regulations with the force of law:

> A proposed rule or proposed modification to a rule cannot take effect unless approved by the Commission. The Commission is authorized to grant such approval if the proposed rule or modification of a rule is consistent with the requirements in this legislation and any applicable rules approved by the Commission. The Commission is granted the authority to prescribe rules and interim final rules to carry out their responsibilities under this section using the rulemaking process under the Administrative Procedure Act.

H.R. Rep. No. 116-554, at 25 (2020).

Like the private entities in the Maloney Act, known as self-regulatory organizations ("SROs"), and the private entity in *Adkins*, the Authority may only "propose[]" rules to the Commission. 15 U.S.C. § 3053(a). The Authority's rule *cannot* go into effect "unless the proposed rule . . . has been approved by the Commission." *Id.* § 3053(b)(2); *accord Adkins*, 310 U.S. at 388 (upholding statute where boards "propose[d]" prices that only took effect once the agency "fix[ed]" them); 15 U.S.C. § 78s(b)(1) (writing that private entities in the securities arena may "propose[]" rules but, generally, "[n]o proposed rule change shall take effect unless approved by the [SEC]"). Here, a rule only goes into effect once the FTC has approved it, and to approve it, the FTC must first ensure that the rule "is consistent with" HISA and other "applicable rules approved by the [FTC]." 15 U.S.C. § 3053(c)(2).

This consistency review is no mere rubber stamp. The FTC, under the express terms of the Act, must review the Authority's proposed rules to ensure they are consistent with "the safety, welfare, and integrity of covered horses, covered persons, and covered horseraces[.]" *Id.* § 3054(a)(2)(A). There are certain categories of rules for which Congress explicitly laid out clear boundaries for both the Authority and the FTC, and such rules provide "clearly defined policy" for the Authority and FTC to effectuate. (*See* D. Ct. Opinion, R. 105, PageID 1496.) But even for the ones with fewer constraints, all promulgated rules must abide by Congress's explicit imperative to create rules for "the safety, welfare, and integrity" of covered entities. *Id.* § 3054(a)(2)(A). "[T]o the extent HISA affords rulemaking discretion to advance Congress's broader objectives, such as the requirement that safety standards be 'consistent with the humane treatment of covered horses,' the FTC (not the Authority) ultimately exercises that statutorily conferred discretion—all of which is bound up with 'the policy implications of rules proposed.'" (Authority Br. 41 (citations omitted).)

HISA is remarkably similar to the constitutional Maloney Act, and was so even when assessed irrespective of the amendment. The Maloney Act provides the following parameters regarding the SEC's approval of an SRO's rules. The SEC "shall approve"—meaning it *must* approve—a rule "if it finds that such proposed rule change *is consistent with* the requirements of this chapter and the rules and regulations issued under this chapter that are applicable to such organization." 15 U.S.C. § 78s(b)(2)(C)(i) (emphasis added). Likewise, HISA provides that the

FTC "shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification *is consistent with*—(A) this chapter; and (B) applicable rules approved by the Commission." *Id.* § 3053(c)(2) (emphasis added).

Both the Maloney Act and HISA therefore provide for analogous consistency review: the reviewing agency must approve rules that are consistent with both the statute and previously issued rules. The Supreme Court held that the SEC "has broad authority to oversee and to regulate the rules adopted by the SROs" because rules are not enacted "unless the SEC finds that the proposed rule is consistent with the requirements of the Exchange Act, 15 U.S.C. § 78s(b)[.]" *Shearson/Am. Exp., Inc. v. McMahon*, 482 U.S. 220, 233–34 (1987). If that is true for 15 U.S.C. § 78s(b), then that must also be true of 15 U.S.C. § 3053(c)(2).

And neither agency's review of the respective private entity ends there. Each act also provides additional requirements for the consistency review of proposed rules in specific instances. In the Maloney Act, specifically relating to rules proposed by one specific subset of SROs, the SEC's consistency review includes that the rules be "designed[,] . . . in general, to protect investors and the public interest[,]" as well as not be "designed to permit unfair discrimination . . . among participants[.]" *Id.* § 78q-1(b)(3)(F); *see also Susquehanna Int'l Grp., LLP v. SEC*, 866 F.3d 442, 446 (D.C. Cir. 2017). In the context of another subset of SROs, the SEC must ensure that the proposed rules meet various textual standards, including that they "are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons," and additional standards. 15 U.S.C. § 78f(b)(5).

In HISA, the Authority proposes rules or modifications to rules "relating to" eleven buckets of issues that it then "submits" to the FTC. *Id.* § 3053(a). Some of these include "a list of permitted and prohibited medications"; "standards for racing surface quality maintenance"; and "a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons[.]" *Id.* But in addition to these categories, the Authority may also propose "rule[s], standard[s], or procedure[s] . . . to carry out the horseracing anti-doping and medication control program or the racetrack safety program." *Id.* § 3053(d)(1). For these programs, HISA contains additional requirements and considerations that the FTC

includes as part of its consistency review. *See, e.g.*, *id.* § 3055(b) (listing seven categories of horse-welfare considerations); *id.* § 3055(g)(3)(b).

Both HISA and the Maloney Act therefore provide for similarly broad consistency review, with additional requirements for specific subsets of rules, such that consistency review on its own can ensure that a private authority remains subordinate to a federal agency.

HISA also matches the aforementioned Coal Act's constitutional agency review of private entities' proposed rules. The statute, which the Supreme Court upheld as "unquestionably valid," *Adkins*, 310 U.S. at 399, granted the Coal Commission the power to "approve, disapprove, or modify" the private coal boards' "proposed minimum prices *to conform to the requirements* of this subsection," Bituminous Coal Act of 1937, § 4, pt. II(a), 50 Stat. 72, 78 (emphasis added). Whether providing that the rule must be consistent with a statute, which both the Maloney Act and HISA require, or that the rule must conform to the requirements of a statute, as the Bituminous Coal Act requires, all three statutes properly and constitutionally subordinate the private entity to the federal agency.

And all three statutes provide the agency with independent rulemaking power. The Maloney Act provides that the SEC "may abrogate, add to, and delete from (hereinafter in this subsection collectively referred to as 'amend') the rules of a[n SRO] . . . as the [SEC] deems necessary or appropriate to insure the fair administration of the [SRO], to conform its rules to requirements of this chapter and the rules and regulations thereunder applicable to such organization, or otherwise in furtherance of the purposes of this chapter[.]" 15 U.S.C. § 78s(c). Such review is textually cabined to "Amendment by Commission of rules of self-regulatory organizations," so it applies only to previously enacted rules, not the SRO's proposed rules or its proposed changes to previously promulgated rules. *Id.*

Further still, the Maloney Act provides a separate set of requirements for the SEC to approve an SRO's new rule or rule change. *See id.* § 78s(b). Under this subsection, the SEC may either "approve or disapprove the propos[al,]" or it may "institute proceedings under subparagraph (B) to determine whether the propos[al] should be disapproved." *Id.* § 78s(b)(2)(A)(i). Subparagraph B requires that the SEC "shall provide" the SRO with "notice

of the grounds for disapproval under consideration" and the chance for a hearing on the rule. *Id.* § 78s(b)(2)(B)(i). The other portion of subparagraph B makes clear that within the mandated time frame, the SEC must "issue an order approving or disapproving the" proposed rule. *Id.* § 78s(b)(2)(B)(ii)(I). Notably missing from these procedures? The SEC's ability to itself modify an SRO's proposed rule.

The Coal Act also provided the Coal Commission limited modification power. Much like the review described in the Maloney Act, the Coal Commission's power to modify rules was not all-encompassing: it could only be done to conform the proposal to the requirements of the statute. § 4, 50 Stat. at 78. The importance of this power is that the Coal Commission could ensure that proposed rules that did not align with, or were inconsistent with, the statute's purpose did not become promulgated rules with the power of law.

Both before and after the amendment, the FTC has had, and continues to have, independent rulemaking power. Prior to the amendment, section 3053(e) provided that the FTC could issue an interim final rule, which carries the power of law, under the standards articulated in the Administrative Procedures Act, 5 U.S.C. § 553(b)(B)—if "necessary to protect" "(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces." 15 U.S.C. § 3053(e) (2020). 5 U.S.C. § 553(b)(B), known as the APA's good-cause provision, allows agencies to issue rules where regular notice-and-comment procedures are "impracticable, unnecessary, or contrary to the public interest." This section provided the FTC with broad rulemaking power without the need for notice-and-comment rulemaking that could be used beyond the emergency context, such as when notice and comment was "unnecessary"—for example, if there had already been sufficient notice-and-comment procedures regarding various alternative options presented in a proposed rule. *See* 16 C.F.R. § 1.142(a)(3) (requiring the Authority to include a discussion of "any reasonable alternatives" to the proposed rule and explain why the specific proposal was chosen); *Mobil Oil Corp. v. United States EPA*, 35 F.3d 579, 584 (D.C. Cir. 1994) ("If the original record is still fresh, a new round of notice and comment might be unnecessary."); *Priests for Life v. United States Dep't of Health & Human Servs.*, 772 F.3d 229, 276 (D.C. Cir. 2014) (similar), *vacated on other grounds by Zubik v. Burwell*, 578 U.S. 403 (2016).

Now, with the amendment, the FTC can utilize proper procedures under the APA, including either regular notice-and-comment procedures or the good-cause provision, to "abrogate, add to, and modify the rules of the Authority" whenever the FTC "finds necessary or appropriate to ensure the fair administration of the Authority, to conform the rules of the Authority to the requirements of this Act and applicable rules approved by the Commission, or otherwise in furtherance of the purposes of this Act." 15 U.S.C. § 3053(3). Just as the Maloney Act and the Coal Act allow the agency to amend the private entity's proposed rules in certain circumstances, so does HISA. Ultimately, none of Oklahoma's arguments regarding the unlawfulness of HISA's rulemaking structure carry substantial weight.

One final note about the private nondelegation doctrine and the cases that have formulated the subordination test. I have noted the numerous ways in which HISA—both with and without the amendment—is nearly identical to the unquestionably constitutional Maloney Act. But even if there are slight differences between the two statutes, no case has ever said that the Maloney Act in its current form is a floor for private nondelegation purposes. In other words, it is not true that a statute must be identical to the Maloney Act, or provide more oversight than the SEC, to be a constitutional delegation. The private entity simply must be subordinate to the agency. The Authority is subordinate to the FTC, and so HISA remains facially constitutional.

2. Enforcement Authority

Oklahoma also challenges HISA's enforcement structure. The Supreme Court has not ruled on this precise issue, but other circuit courts have relied upon Supreme Court precedent to do so in a way that supports the enforcement structure's constitutionality. Courts' review of the Maloney Act is once again instructive. All circuits that have ruled on the issue have held that the Maloney Act's enforcement scheme is constitutional where, as here, a private entity (the National Association of Securities Dealers ("NASD")) brought enforcement actions against covered entities. *See, e.g.*, *Sorrell v. SEC*, 679 F.2d 1323 (9th Cir. 1982); *First Jersey Sec., Inc. v. Bergen*, 605 F.2d 690 (3d Cir. 1979), *cert. denied*, 444 U.S. 1074 (1980); *R.H. Johnson & Co. v. SEC*, 198 F.2d 690 (2d Cir. 1952), *cert. denied*, 344 U.S. 855 (1952).

The Second Circuit held that because of "the [SEC's] review of any disciplinary action" taken by the NASD, there is "no merit in the contention that the Act unconstitutionally delegates power to the association." *R.H. Johnson & Co.*, 198 F.2d at 695. The Ninth Circuit, citing to Second and Third Circuit decisions upholding the constitutionality of NASD's enforcement powers, noted that "[petitioner's] claim of unconstitutional delegation appears to rest on his mistaken idea that the SEC does not engage in an independent review of NASD decisions. As we stated in *Sartain v. SEC*, 601 F.2d 1366, 1371 n.2 (9th Cir. 1979), SEC review is de novo." *Sorrell*, 679 F.2d at 1326 n.2. The unanimous principle from the circuit decisions—which the Supreme Court has not disturbed despite repeated opportunities to do so—is that so long as the agency retains de novo review of a private entity's enforcement proceedings, there is no unconstitutional delegation of legislative or executive power, even if the agency does not review the private entity's initial decision to bring an enforcement action. The consistency of this principle reinforces the constitutionality of HISA's enforcement scheme.

In fact, the enforcement scheme in HISA is even more constitutionally sound than that found in the Maloney Act. The Maloney Act was amended in 1975, and, in relation to the enforcement scheme, the amendment may have constrained the SEC's power to review the disciplinary proceedings the NASD pursued. *See Bergen*, 605 F.2d at 697. Nonetheless, this did not change the court's analysis:

> We need not now decide whether this statutory change effects a significant alteration in the SEC's power to review NASD disciplinary proceedings. It suffices to say that to the extent the amendment restricts the SEC's ability to receive additional evidence not presented below, this does not alter our conclusion in Todd [*Todd & Co., Inc. v. SEC*, 557 F.2d 1008 (3d Cir. 1977)] that there is no unconstitutional delegation of legislative authority.

Bergen, 605 F.2d at 697. HISA, unlike the Maloney Act, unambiguously empowers the FTC to obtain additional evidence not in the record below and to review the proceeding de novo. *See* 15 U.S.C. § 3058(c)(3)(C). The enforcement scheme in HISA, including two levels of de novo review and allowing the FTC to review evidence not in the record, ensures that HISA is soundly in the company of previously upheld enforcement mechanisms, and is thus not an unconstitutional delegation of power to a private authority.

* * *

Although the majority and I take different paths in our analysis, I fully agree that HISA is constitutional under Supreme Court precedent as well as the majority of federal court caselaw.

EXHIBIT C

Caution
As of: July 13, 2024 2:18 PM Z

Belle Maer Harbor v. Charter Twp. of Harrison

United States Court of Appeals for the Sixth Circuit

September 24, 1998, Argued ; March 1, 1999, Decided ; March 1, 1999, Filed

No. 97-1596

Reporter
170 F.3d 553 *; 1999 U.S. App. LEXIS 3127 **; 1999 FED App. 0075P (6th Cir.) ***

BELLE MAER HARBOR, a Michigan limited partnership and MARC HOWARD, Plaintiffs-Appellants, v. CHARTER TOWNSHIP OF HARRISON, a Michigan municipal corporation; PAMELA A. WEEKS, Trustee, Harrison Township Board of Trustees; RONALD J. NOWAKS, Trustee; JAMES P. SENSTOCK, Trustee; BARBARA C. URBAN, Trustee; Individually and in their Official Capacity; BARBARA CASEY, Harrison Township Ordinance Enforcement Officer, in her Official Capacity, Defendants-Appellees.

Prior History: [1]** Appeal from the United States District Court for the Eastern District of Michigan at Detroit. No. 96-70614. Horace W. Gilmore, District Judge.

Disposition: REVERSED and REMANDED.

Core Terms

Ordinance, Township, vagueness, feet, radius, criminal sanction, inspecting, bubbling, waterways, rights, criminal penalty, summary judgment, facial, width

Case Summary

Procedural Posture
Plaintiffs, a marina operator and its manager, appealed from a decision of the United States District Court for the Eastern District of Michigan, which upheld an ordinance passed by defendant township regulating the marina's use of mechanical agitators and a tugboat used to keep the waterway from freezing around its boats and structures.

Overview
Plaintiffs, a marina operator and its manager, used mechanical agitators and a tugboat to keep the waterways from freezing around the marina's boats and structures. Defendant Township passed an ordinance regulating the use of such equipment and limiting plaintiffs' use, stating that plaintiffs' current use was causing excessive bubbling. The trial court dismissed plaintiffs' complaint that the ordinance lacked sufficient definiteness to provide township residents with adequate notice of the proscribed conduct under the ordinance. Plaintiffs voluntarily dismissed the remainder of their complaint and filed an appeal to the partial summary judgment order. On appeal, the court looked at the face of the ordinance to determine whether it lacked sufficient definiteness to meet the requirements of due process. The court held that a person of ordinary intelligence could not determine the proscribed conduct that could lead to criminal sanctions. Therefore, the court held that the final sentence in the ordinance was void for vagueness and was severable. The court reversed the lower court's grant of summary judgment and remanded for further proceedings.

Outcome
The court reversed in favor of plaintiffs, a marina operator and its manager, holding that part of an ordinance passed by defendant township was void for vagueness.

LexisNexis® Headnotes

Constitutional Law > ... > Fundamental Freedoms > Judicial & Legislative Restraints > Overbreadth & Vagueness of Legislation

Governments > Legislation > Vagueness

Constitutional Law > ... > Fundamental Rights > Procedural Due Process > Scope of Protection

Governments > Legislation > General Overview

HN1[] **Judicial & Legislative Restraints, Overbreadth & Vagueness of Legislation**

A vague ordinance violates the United States Constitution in two significant respects: such an ordinance fails, (1) to define the offense with sufficient definiteness that ordinary people can understand prohibited conduct, and (2) to establish standards to permit police to enforce the law in a non-arbitrary, non-discriminatory manner. The second prong -- providing minimal guidelines to govern the conduct of law enforcement -- constitutes the more important aspect of the vagueness doctrine. This reflects the common sense understanding that the average citizen does not read, at his leisure, every federal, state, and local statute to which he is subject. An enactment imposing criminal sanctions or reaching a substantial amount of constitutionally protected conduct may withstand facial constitutional scrutiny only if it incorporates a high level of definiteness.

Constitutional Law > ... > Fundamental Freedoms > Judicial & Legislative Restraints > Overbreadth & Vagueness of Legislation

Governments > Legislation > Vagueness

Constitutional Law > Bill of Rights > Fundamental Freedoms > General Overview

Constitutional Law > ... > Fundamental Freedoms > Judicial & Legislative Restraints > General Overview

HN2[] **Judicial & Legislative Restraints, Overbreadth & Vagueness of Legislation**

In examining a facial challenge, the court must first determine whether the enactment reaches a substantial amount of constitutionally protected conduct. Where the enactment does not reach constitutionally protected conduct, the complainant may succeed in a vagueness claim only if the enactment is impermissibly vague in all of its applications. Therefore, vagueness claims not involving *U.S. Const. amend. I* freedoms must be examined in light of the facts of the particular case at hand and not as to the statute's facial validity. However, even in cases not involving *First Amendment* rights, courts may engage in a facial analysis where the enactment imposes criminal sanctions.

Constitutional Law > ... > Fundamental Freedoms > Judicial & Legislative Restraints > Overbreadth & Vagueness of Legislation

HN3[] **Judicial & Legislative Restraints, Overbreadth & Vagueness of Legislation**

To withstand a facial challenge, an enactment must define the proscribed behavior with sufficient particularity to provide a person of ordinary intelligence with reasonable notice of prohibited conduct and to encourage non-arbitrary enforcement of the provision.

Constitutional Law > ... > Fundamental Freedoms > Judicial & Legislative Restraints > Overbreadth & Vagueness of Legislation

HN4[] **Judicial & Legislative Restraints, Overbreadth & Vagueness of Legislation**

Although courts do not require impossible clarity in standards governing conduct, the court must apply a relative strict standard of scrutiny where criminal sanctions apply.

Counsel: ARGUED: Bruce T. Leitman, Bloomfield Hills, Michigan, for Appellants.

ARGUED: Robert J. Seibert, ANTHONY, SEIBERT & DLOSKI, P.L.L.C., Mt. Clemens, Michigan, for Appellees.

ON BRIEF: Bruce T. Leitman, Bloomfield Hills, Michigan, for Appellants.

ON BRIEF: Robert J. Seibert, ANTHONY, SEIBERT & DLOSKI, P.L.L.C., Mt. Clemens, Michigan, for Appellees.

Judges: Before: NORRIS, BATCHELDER, and BRIGHT *, Circuit Judges.

Opinion by: MYRON H. BRIGHT

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* The Honorable Myron H. Bright, Circuit Judge of the United States Court of Appeals for the Eighth Circuit, sitting by designation.

Opinion

[*2] [*555] OPINION**

BRIGHT, Circuit Judge. This action for injunctive relief and declaratory judgment by Belle Maer Harbor, a marina operator on Lake St. Clair in Harrison Township, Macomb County, Michigan ("Township") and its manager Marc Howard (collectively "Belle Maer") attack as vague an ordinance of the township which regulates the marina's use of mechanical agitators and a tugboat **[**2]** used to keep the waterway from freezing around its boats and structures. From an adverse judgment, Belle Maer appeals. We determine the **[***3]** ordinance, in the part challenged, to be invalid and reverse and remand. [1]

I. BACKGROUND

In 1988, the Township enacted the "Boat Bubbling Ordinance" ("Ordinance 239") to protect the safety of property owners living along the Township's waterways and to ensure unimpeded access to Lake St. Clair and other frozen waterways within the Township for winter recreational activities. Ordinance 239 established various safety requirements for the use of mechanical devices known as bubbling devices, [2] which protect docks and other structures in the Township's waterways from ice damage during the **[**3]** winter and spring seasons. Most important for purposes of this appeal, Ordinance 239 set strict limits on the size of open water areas which bubbling devices could create: the open water area could not exceed a five-foot radius from the protected object, or an area "determined by the inspecting officer to be a reasonable radius." This prohibition applied only to canals with widths of 110 feet or less. [3] Violation of **[***4]** the ordinance carried criminal penalties: a maximum of a $ 300 fine and a thirty-day period of incarceration.

[4]** Belle Maer owns and operates Belle Maer Harbor Marina ("Marina"), a private for-profit marina located in the Township on Lake St. Clair. Navigable canals connecting to Lake St. Clair border the Marina on the west and south, and Lake St. Clair abuts the Marina on the north. The canals vary in width from 148 feet to 200 feet, with over 200 docks located along their banks. To protect its docks, pilings and sea walls from ice damage during the winter months, the Marina operates a tugboat to break up the ice within the Marina's interior basin and uses bubbling devices to melt ice around its structures within the canals. The Marina complied with the safety requirements of Ordinance 239, although the open water restriction did not apply to Belle Maer because the Marina's canals exceeded 110 feet in width.

In 1996, the Township adopted Ordinance 303, an amendment to Ordinance 239, which removed the exception to the open water restriction for canals exceeding 110 feet in width. The Township contends that excessive bubbling had created hazardous conditions for Township residents using the frozen waterways. These conditions justified increasing the Ordinance's safety requirements and expanding **[**5]** the open water restriction from "canals one hundred ten (110') feet or less in width" to "any canal or waterway" in the Township. [4]

[*5]** Ordinance 303 brought the **[*556]** Marina within the ambit of the open water restriction set forth in

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[1] At the outset, we note that Belle Maer challenges the ordinance's provision governing the use of mechanical agitators, otherwise known as bubbling devices, not the other safety requirements in the ordinance. Belle Maer states that it complies with these safety requirements.

[2] Bubbling devices extract relatively warmer water from the bottom of a waterway and bring that water to the surface, creating an area of open water which otherwise would be covered by ice.

[3] Ordinance 239 provided in relevant part:

> D. The amount of open water created by a bubbling system shall be controlled as follows:
>
> 1. In canals one hundred ten (110') feet or less in width, a person choosing to bubble shall operate, maintain and periodically inspect the bubbling system apparatus so as to maintain an open water radius surrounding the bubbled object not to exceed five (5') feet, or as determined by the inspecting officer to be a reasonable radius.

Jt. App. at 223.

[4] Ordinance 303 provides in relevant part:

> In any canal or waterway a person choosing to bubble shall operate, maintain and periodically inspect the bubbling system apparatus so as to maintain an open water radius surrounding the bubbled object, not to exceed five (5) feet, or as determined by the inspecting officer to be a reasonable radius.

Jt. App. at 229.

Ordinance 239. [5]

In response, Belle Maer filed a seven-count complaint, seeking, *inter alia*, a preliminary injunction **[**6]** to prevent the Township from enforcing the open water restriction against Belle Maer. At the outset, the parties stipulated to the entry of a temporary restraining order, enjoining enforcement of the Ordinance pending the conclusion of the proceedings before the court. At the close of discovery, the Township filed a partial motion for summary judgment as to Belle Maer's federal preemption and vagueness claims, and Belle Maer responded with its own motion for summary judgment for declaratory and injunctive relief.

After hearing oral argument concurrently on both motions, the district court ruled from the bench, granting the Township's partial motion for summary judgment and denying Belle Maer's motion for declaratory and injunctive relief. The next day the parties stipulated to an order dismissing the remaining counts of the complaint. The order also stayed enforcement of the Ordinance pending the outcome of this appeal. Belle Maer timely filed the appeal before this court. We have jurisdiction under *28 U.S.C. § 1291* and review a decision granting summary judgment de novo. *See Davis v. Sodexho, Cumberland College Cafeteria, 157 F.3d 460, 462 (6th Cir. 1998)*. **[**7]** T**II. DISCUSSION**

Turning to the specific arguments presented on appeal, Belle Maer asserts that the Ordinance lacks sufficient definiteness to provide Township residents with adequate notice of the proscribed conduct under the Ordinance. In **[***6]** addition, they contend that the Ordinance's imprecision precludes Township inspection officers from uniformly enforcing the Ordinance's open water restriction. Belle Maer also argues that the Township's five foot radius requirement violated their substantive due process rights on grounds that the Ordinance constituted an unreasonable means of advancing a governmental interest. [6] **[**8]** In short, Belle Maer asserts that it can only comply with the Ordinance by ceasing to use its bubblers and tugboat which would result in extensive damage to its facilities and substantial financial injury. Because we conclude that the Ordinance is void-for-vagueness, the court does not reach Belle Maer's substantive due process argument. [7]

A. *Void-for-Vagueness*

The *Due Process Clauses of the Fifth* and *Fourteenth Amendments* provide the constitutional foundation for the void-for-vagueness doctrine. *See United States v. Haun, 90 F.3d 1096, 1101 (6th Cir. 1996)*; *Columbia Natural Resources, Inc. v. Tatum, 58 F.3d 1101, 1104 (6th Cir. 1995)*. ***HN1***[] A vague ordinance violates the Constitution in two significant respects: such an ordinance fails, (1) to define the offense with sufficient definiteness that ordinary people can understand prohibited conduct, and (2) to establish standards **[**9]** to permit police to enforce the law in a non-arbitrary, **[***7]** non-discriminatory manner. *See Kolender v. Lawson, 461 U.S. 352, 357, 75 L. Ed. 2d 903, 103 S. Ct. 1855 (1983)*. The second prong -- providing minimal guidelines to govern the conduct of law enforcement -- constitutes the more important aspect of the **[*557]** vagueness doctrine. *See Smith v. Goguen, 415 U.S. 566, 39 L. Ed. 2d 605, 94 S. Ct. 1242 (1974)*. "This reflects the common sense understanding that the average citizen does not read, at his leisure, every federal, state, and local statute to which he is subject." *Tatum, 58 F.3d at 1105*. An enactment imposing criminal sanctions or reaching a substantial amount of constitutionally protected conduct may withstand facial constitutional scrutiny only if it incorporates a high level of definiteness. *See Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 494, 71 L. Ed. 2d 362, 102 S. Ct. 1186 (1982)*; *Kolender, 461 U.S. at 357*.

HN2[] In examining a facial challenge, this **[**10]** court must first "determine whether the enactment reaches a substantial amount of constitutionally protected conduct." *Hoffman Estates, 455 U.S. at 494*. Where the enactment does not reach constitutionally protected conduct, the complainant may succeed in a vagueness claim "only if the enactment is impermissibly

[5] For clarity's sake, we will refer to Ordinance 239, as amended by Ordinance 303, as "the Ordinance."

[6] According to Belle Maer's expert, Professor C. Allen Wortley, the unpredictability of such factors as the weather, underwater currents and other environmental variables, and the current state of the art of bubblers prevent operators from controlling the size of an area of open water created by bubblers with any degree of accuracy.

[7] The parties continue to dispute whether this court can consider Professor Wortley's expert testimony. Although Belle Maer introduced this evidence into the record, Belle Maer did not direct the court's attention to this evidence in its response to the Township's motion for summary judgment. This evidence goes principally to the substantive due process argument. The district court did not address this issue; neither do we.

vague in all of its applications." *Id. at 495*. Therefore, vagueness claims not involving *First Amendment* freedoms must be examined in light of the facts of the particular case at hand and not as to the statute's facial validity. *See Tatum, 58 F.3d at 1109 n. 6* (limiting vagueness challenge to an "as applied" analysis since the case did not implicate *First Amendment* rights); *United States v. Avant, 907 F.2d 623, 625 (6th Cir. 1990)* (reviewing vagueness challenge to statute not involving *First Amendment* rights on the facts of that specific case) (citing *United States v. Mazurie, 419 U.S. 544, 42 L. Ed. 2d 706, 95 S. Ct. 710 (1975)*). However, even in cases not involving *First Amendment* rights, we have recognized that courts may engage in a facial analysis where the enactment imposes criminal **[**11]** sanctions. *See Springfield Armory, Inc. v. City of Columbus, 29 F.3d 250, 252-254 (6th Cir. 1994)* (rejecting district court's "as applied" analysis of statute with criminal penalties, and concluding that the particular statute was unconstitutionally vague on its face).

[*8]** Applying these principles to this case, we conclude first that the Ordinance does not threaten to inhibit the exercise of protected *First Amendment* rights. *See Hoffman Estates, 455 U.S. at 495-96*. Neither party contends that *First Amendment* rights were at issue in this case, and our review of the Ordinance supports this conclusion. But the Ordinance does impose criminal penalties, including incarceration and fines, for its violation. "When criminal penalties are at stake, as they are in the present case, a relatively strict test is warranted." *Springfield Armory, Inc., 29 F.3d at 252* (citing *Hoffman Estates, 455 U.S. at 499*). Given the criminal sanctions resulting from violations of the Ordinance, we must examine the Ordinance on its face to determine whether it lacks sufficient definiteness to meet the requirements of the Due Process Clause. *29 F.3d at 254*. **[**12]**

HN3[⬆] To withstand a facial challenge, an enactment must define the proscribed behavior with sufficient particularity to provide a person of ordinary intelligence with reasonable notice of prohibited conduct and to encourage non-arbitrary enforcement of the provision. *See Kolender, 461 U.S. at 357*. Here, Belle Maer complains that the Ordinance fails to meet both prongs of the vagueness doctrine. Nevertheless, Belle Maer focuses the court's attention principally on the unlimited discretion afforded by the Ordinance to enforcement officers in determining whether an area of open water violates the Ordinance's dictates. We, therefore, begin our discussion of the Ordinance with this aspect of the vagueness doctrine.

The Ordinance provides that an operator of a bubbling system may maintain an area of open water around a protected object "not to exceed five . . . feet, or as determined by the inspecting officer to be a reasonable radius." Belle Maer identifies two problems with the language of the Ordinance as it pertains to the inspector's enforcement decisions. First, the Ordinance **[**13]** in no way limits the imposition of criminal penalties on operators for maintaining an area of open water of *less than* five feet in radius, as long as the shorter radius is **[***9]** determined not to be a "reasonable" radius. Second, if the area of open water exceeds five feet in radius around the protected object, the sole restriction governing **[*558]** the inspector's enforcement decision is what that officer deems to be "reasonable." The failure to include a definition of "reasonable" compounds the definitional slipperiness of this Ordinance. With these arguments in mind, we must discern whether the reasonableness standard in the Ordinance bounds the inspection officer's enforcement decisions sufficiently to prevent ad hoc, discriminatory enforcement of the open water restriction. *See Kolender, 461 U.S. at 358* ("Where the legislature fails to provide such minimal guidelines, a criminal statute may permit 'a standardless sweep [that] allows policemen, prosecutors, and juries to pursue their personal predilections.'") (quoting *Smith, 415 U.S. at 575*).

Facing a similar definitional question in *Haun*, we reaffirmed the general principle **[**14]** that a failure to define a term within a statute or ordinance does not render the statute unconstitutionally vague, where the common meaning of the word provides both adequate notice of the conduct prohibited and of the standards for enforcement. *Haun, 90 F.3d at 1101* (citing *United States v. Kaylor, 877 F.2d 658, 661 (8th Cir. 1989)*). Referencing Webster's Third New International Dictionary, we then held that an ordinary person would understand the import of the word "proceeds" in the context of a money laundering statute and, therefore, the statute did not qualify as unconstitutionally imprecise. *Id.*

Unlike *Haun*, however, this court cannot say that a commonly accepted meaning exists for the term "reasonable" which would provide an inspection officer with guidance in interpreting the Ordinance and in executing his or her enforcement duties with any uniformity. As a threshold point, the court finds support for this conclusion in Black's Law Dictionary which uses

terms and phrases like "fair, proper, just, moderate, suitable under the circumstances" and "fit and appropriate to the end in view" to define the term reasonable. Black's definition **[**15]** demonstrates that a standard **[***10]** grounded on reasonableness in this context is susceptible to a myriad of interpretations conferring on the inspectors "a virtually unrestrained power to arrest and charge persons with a violation." *Kolender, 461 U.S. at 360* (citation omitted).

The Township counsel's comments at the hearing before the district court on the motions for summary judgment also support our determination: "I would agree that in the text of the ordinance, there are not articulated standards as to what what [sic] factors would determine reasonableness[.]" [8] **[**17]** Jt. App. at 297. The deposition testimony of the officer charged with enforcement of the Ordinance substantially undercuts the Township's position. Enforcement Officer Barbara Casey testified in her deposition that she could not discern an intelligible standard in the Ordinance to govern the performance of her duties: "one persons idea of a reasonable radius would vary from another's." [9]

[*559] Constrained only by this **[***11]** reasonableness standard, an inspector could impose criminal sanctions for an area of open water of six, seven or ten feet, and perhaps even less than five feet. **[**16]** [10] Discretion of this magnitude furnishes Township inspectors with a "convenient tool for 'harsh and discriminatory enforcement against particular groups deemed to merit their displeasure.'" *Papachristou v. City of Jacksonville, 405 U.S. 156, 170, 31 L. Ed. 2d 110, 92 S. Ct. 839 (1972)* (quoting *Thornhill v. Alabama, 310 U.S. 88, 97-98, 84 L. Ed. 1093, 60 S. Ct. 736 (1940)*).

[18]** Thus, ***HN4***[⬆] although we do not require impossible clarity in standards governing conduct, *Kolender, 461 U.S. at 361*, the court must apply a relative strict standard of scrutiny here where criminal sanctions apply. *See Springfield Armory, Inc., 29 F.3d at 252*. We conclude after a close examination of the Ordinance that the reasonableness standard entrusts the enforcement decision regarding the open water restriction "to the moment-to-moment judgment of the policeman on his beat." *Smith, 415 U.S. at 575* (quoting *Gregory v. City of Chicago, 394 U.S. 111, 120, 22 L. Ed. 2d 134, 89 S. Ct. 946 (1969)*). In addition, the court cannot conclude that a person of ordinary intelligence could determine from this standard the proscribed conduct which **[***12]** could lead to criminal sanctions. Therefore, we hold that the final clause in the Ordinance, namely, "or as determined by the inspecting officer to be a reasonable radius," is void for vagueness, and is severable according to the severability clause contained in the Ordinance. [11] **[**19]** CHARTER TOWNSHIP OF HARRISON, MICH., BOAT BUBBLING ORDINANCE § 20.185 (1989).

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[8] Having made this sweeping comment, the Township's counsel still maintained at the hearing that the Ordinance's imprecision does not render it unconstitutionally vague, arguing that the reasonableness standard simply put the burden on the Township to show that the standards were reasonable. This does not satisfy the demands of due process. *See Kolender, 461 U.S. at 358 n.7* (citing *United States v. Reese, 92 U.S. 214, 221, 23 L. Ed. 563 (1876)*) ("It would certainly be dangerous if the legislature could set a net large enough to catch all possible offenders, and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large.").

[9] Casey stated the following during an interchange with Belle Maer's counsel in her deposition:

> Q. Now, I would like you to take a look at exhibit two there again which is the proposed, the amendment to the bubbling ordinance. Again, I would like to go back to this language which states ["]or as determined by the inspecting officer to be a reasonable radius.["] Have you been given any kind of standards or any kind of guidelines as to how to make that determination?
>
> A. No.
>
> Q. Okay. Do you know of any standards or any guidelines that you would use as to make this determination?
>
> A. No, I don't. I think it's a little vague in it's [sic] writing because it says or as determined to be reasonable. One person['s idea of a reasonable radius would vary from another's, that's why I'm not going to make the determination. When it comes to it[,] I'll take pictures again, I will see what we have out there, I will show the supervisor and they can make the judgment calls.

Jt. App. at 254-55.

[10] Although counsel for the Township interprets the Ordinance not to apply to open water less than five feet, the Ordinance is susceptible to a contrary construction, and we must determine validity and invalidity on the basis of the language itself.

[11] Belle Maer also claims that the language of the open water restriction -- "bubbler system or mechanism" -- failed to provide notice of whether this provision applied to Belle Maer's tugboat. Having declared the open water restriction in the Ordinance void-for-vagueness on other grounds, we decline to reach this issue.

But the Township argues to the contrary, relying heavily on *Tatum* for the proposition that "gray areas" necessarily arise in interpreting words used "to govern human conduct." [12] *Tatum, 58 F.3d at 1109*. Building on this principle, the Township insists that its inspectors would not make enforcement decisions in a vacuum. Rather, decisions to prosecute would be constrained by the reasonableness standard in relation to the stated purpose of the Ordinance: to protect the health and safety of Township residents from excessive use of bubblers and the safety hazards resulting from such use.

[20]** This court does not disagree with the Township that many ordinances, statutes and other enactments have "gray areas" requiring use of an officer's discretionary judgment in their enforcement. However, due process requires at least sufficient exactness to prevent arbitrary enforcement and give notice of what an individual must do to comply with the enactment. Construing the open water restriction in conjunction with the Ordinance's stated purpose does not save this enactment from Belle Maer's vagueness challenge.

[*13]** Under the present scheme, neither the enforcement officer nor the bubbler operator can ascertain by examining the language of the Ordinance alone whether criminal sanctions will result from one foot or ten feet of open water created by a bubbler around a protected object. This level of imprecision cannot withstand a due process challenge on vagueness grounds. The people of Harrison are entitled to more definiteness in the Township's law making than illustrated by the language in question of the Ordinance. Therefore, we conclude that the final clause of the Ordinance, which reads "or as determined by the inspecting officer to be a reasonable radius," fails because **[**21]** of vagueness. [13]

[12] The *Tatum* court rejected a vagueness challenge to the RICO statute, exclaiming that nothing "startling" existed in that statute to render it unconstitutionally vague.

[13] We further question whether the Ordinance's requirement that an operator "periodically inspect" his or her bubbling device "so as to maintain an open radius . . . not to exceed five feet . . ." might also be unconstitutionally vague. An operator laboring under this mandate might be required to monitor an area of open water almost constantly because of the ever-changing weather conditions and the unpredictable timing of the inspections. This language, therefore, may vest too much discretion in the enforcement authority. We decline to address this issue, however, as the Ordinance will be redrafted, clarified and made more specific in response to this opinion.

[*560] III. CONCLUSION

Accordingly, we REVERSE the district court's decision granting summary judgment and dismissing this cause, and we REMAND for further proceedings consistent with this opinion.

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