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The Decision determined, among other things, that:

- Under HISA Rule 4111, the term “Banned Substances” includes “S0 Non-Approved Substances,” which are defined as:

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.

HISA Rule 4111; Decision ¶ 8.6.

- Hemo 15 is not a vitamin but is an unapproved drug, properly categorized as an S0 Non-Approved Substance. Decision at ¶¶ 8.11, 8.23.

Based on the Decision, HIWU imposed the following sanctions on Shell:

- (1) a period of Ineligibility of two years, as described in ADMC Rule 3223, beginning on January 8, 2024 (the date that a Provisional Suspension was imposed), and continuing through January 7, 2026;
- (2) a fine of \$25,000 in accordance with ADMC Rule 3223;
- (3) payment of \$10,000 of adjudication costs in accordance with ADMC Rule 3223; and
- (4) public disclosure in accordance with ADMC Rule 3620.

Decision ¶ 9.1; June 18, 2024 Notice of Final Civil Sanctions Under the ADMC Program.

Summary of the Parties’ Positions

Shell requests *de novo* review and reversal of the sanctions, asserting that the Authority did not establish that Shell committed an ADMC Rule 3214(c) violation and therefore the sanctions are arbitrary, capricious, an abuse of discretion, prejudicial, and otherwise not in accordance with law.

Shell requests an evidentiary hearing “to contest the facts found by the Authority, legal interpretation, and to supplement the factual record with [two cases, *National Horsemen’s Benevolent and Protective Association v. State of Texas et al.* No. 23-10520 (5th Cir. July 5,

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2024)¹ and *Belle Maer Harbor v. Charter Twp. of Harrison*, 170 F.3d 553 (6th Cir. 1999)], and to argue due process and absence of evidence.” Application for Review at 4.

In its Response to Shell’s Application for Review, the Authority asserts that the FTC should uphold the sanctions based on an ADMC Rule 3214(c) violation, and deny Shell’s request for an evidentiary hearing, as it is unnecessary to contest or supplement the record, and no basis has been demonstrated for doing so.

Determination

Pursuant to the FTC’s Procedures for Review of Final Civil Sanctions Imposed under HISA (“FTC Rules”):

In reviewing the final civil sanction and decision of the Authority, the Administrative Law Judge may rely in full or in part on the factual record developed before the Authority through the disciplinary process under 15 U.S.C. 3057(c) and disciplinary hearings under Authority Rule Series 8300. The record may be supplemented by an evidentiary hearing conducted by the Administrative Law Judge to ensure each party receives a fair and impartial hearing. Within 20 days of the filing of an application for review, based on the application submitted by the aggrieved party or by the Commission and on any response by the Authority, the Administrative Law Judge will assess whether:

- (i) The parties do not request to supplement or contest the facts found by the Authority;
- (ii) The parties do not seek to contest any facts found by the Authority, but at least one party requests to supplement the factual record;
- (iii) At least one party seeks to contest any facts found by the Authority; . . . or
- (v) In the Administrative Law Judge’s view, the factual record is insufficient to adjudicate the merits of the review proceeding.

16 C.F.R. § 1.146(c)(2).

Pursuant to FTC Rule 1.146(c)(2), based on the Application for Review and the Authority’s response, I hereby determine that the parties do not seek to alter the factual record before the Authority. Instead, Shell seeks only to contest the weight given to the evidence in the record and the Arbitrator’s determination that Hemo 15 is a Banned Substance, as charged. Shell’s request to supplement the record with two court opinions, and to argue due process, does not warrant holding an evidentiary hearing. The two court opinions are not evidence, but Shell

¹ Although Shell requested to “supplement the factual record with Exhibit B, the Fifth Circuit Decision in NHPB,” Shell’s Exhibit B is a copy of *Oklahoma v. United States*, 62 F. 4th 221 (6th Cir. 2023). I construe Shell’s request as one to supplement the record with *National Horsemen’s Benevolent and Protective Association v. State of Texas et al.* No. 23-10520 (5th Cir. July 5, 2024).

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may cite them and such other legal authority, as he sees fit, in his briefs.

Accordingly, this appeal will be limited to briefing by the parties. 16 C.F.R. § 1.146(c)(3).

Required Briefing

The parties are directed to concurrently file with the FTC's Office of the Secretary, by **August 14, 2024**:

proposed findings of fact, conclusions of law, and a proposed order, together with a supporting legal brief providing the party's reasoning. Such filings, limited to 7,500 words, must be served on the other party and contain references to the record and authorities on which they rely. Reply findings of fact, conclusions of law, and briefs, limited to 2,500 words, may be filed by each party within 10 days of service of the initial filings.

16 C.F.R. § 1.146(c)(3). In this case, these limits are applied to all of the filings in the aggregate, and **not** individually to each filing listed in FTC Rule 1.146(c)(3).

A subsequent Order will detail further the requirements for these filings.

The parties are also directed to confer and file, no later than **August 8, 2024**, a joint Appeal Book containing the evidentiary record presented below, including without limitation all hearing video and transcripts, and all documentary and video exhibits. A courtesy copy should also be submitted to OALJ@ftc.gov.

II. Application for a Stay

Shell also filed an Application for Stay of Final Civil Sanction during the pendency of review, to which the Authority filed its Response.

Under the FTC Rules, an application for a stay of the sanctions imposed by the Authority "must provide the reasons a stay is or is not warranted by addressing the [following] factors . . . and the facts relied upon":

- (1) The likelihood of the applicant's success on review;
- (2) Whether the applicant will suffer irreparable harm if a stay is not granted;
- (3) The degree of injury to other parties or third parties if a stay is granted; and
- (4) Whether the stay is in the public interest.

16 C.F.R. § 1.148(c)-(d).

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Summary of the Parties' Positions on the Stay Factors

First, Shell asserts he has a strong likelihood of success on *de novo* review because (1) the Authority did not meet its burden to show Hemo 15 is a Banned Substance in order to prove a violation of ADMC Rule 3214(c); (2) HISA Rule 4111, the charges and the sanctions violate Shell's Fifth and Fourteenth Amendment constitutional due process rights to fair notice of prohibited behavior; and (3) *National Horsemen's Benevolent and Protective Association* shows that enforcement of HISA Rules by the Authority unconstitutionally violates the private nondelegation doctrine. The Authority responds that the likelihood of Shell's success on review is low because the requirements of the ADMC Rules were appropriately followed by both HIWU and the Arbitrator below.

Second, Shell asserts he will suffer irreparable harm absent a stay, as the sanctions, including his ineligibility period and the publication of the violation on HIWU's website, have harmed his reputation and engendered loss of goodwill of clientele and business opportunities. The Authority responds that the public disclosure has already occurred, as, pursuant to ADMC Rule 3620, HIWU is required to publicly disclose a final decision made by the Arbitral Body within twenty days of the issuance of a decision.

Third, Shell asserts there is no risk of injury to other parties or third parties if a stay is granted because Shell is already currently provisionally suspended in another case and thus the Authority cannot claim harm to the public on a track under the Authority's purview. The Authority responds that granting the stay will undermine the Authority's efforts to protect the integrity of horseracing and will harm Responsible Persons² and the betting public by permitting Shell's participation therein.

Fourth, Shell asserts a stay is in the public interest because it prevents enforcement of sanctions that are arbitrary, capricious, and unconstitutional. The Authority responds that the public interest is served by compliance with the rules and regulations validly promulgated by federal agencies.

Determination

First, Shell has not shown a sufficient likelihood of prevailing on the merits to warrant a stay. Shell's stay application is itself too conclusory to present a basis for determining, at this point, that Hemo 15 is not a Banned Substance under HISA Rules, or that Shell has been deprived of due process. The Authority's opposition confirms that this factor supports denying a stay.

Shell's argument that the Fifth Circuit's decision in *National Horsemen's Benevolent and Protective Association*, ruling that HISA is unconstitutional under the private nondelegation doctrine, affords no basis for stay relief. The Sixth Circuit rejected this same argument and upheld HISA's constitutionality in *Oklahoma v. United States*, 62 F.4th 221 (6th Cir. 2023), *cert.*

² "Responsible Person" means "the Trainer of the Covered Horse. If the Covered Horse does not have a Trainer, the Responsible Person shall be the Owner of the Covered Horse." ADMC Rule 3030.

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denied, 2024 U.S. LEXIS 2724 (June 24, 2024). The effect of these conflicting decisions is more appropriately resolved after considering the parties' briefs on the merits of this case.

Second, ADMC Rule 3620 requires public disclosure of the Decision. Resulting reputational harm therefore cannot itself justify a stay absent special facts not shown here. Any arguable harm has already occurred and thus would be unaffected by issuing a stay. In addition, because Shell is currently under a Provisional Suspension for additional charges related to the Possession of Banned Substances, issuing a stay in this case would not alleviate harm to Shell. Furthermore, the Arbitrator determined that Shell need not pay the fine until the end of his period of Ineligibility. Thus, the second factor similarly weighs against granting the stay request.

The third and fourth factors also weigh against stay relief. Based on the record evidence cited in the Decision, Shell appears to be an outlier in administering Hemo 15 to his equine patients, as no other veterinarian has reported administrations of Hemo 15 or been similarly charged for its administration. Decision ¶¶ 6.2(s), 8.19. Granting the stay request could send a potentially wrong message regarding the interpretation and application of HISA Rule 4111. The implication – that Hemo 15 may not be banned – could unsettle industry understanding, thereby harming others and the public interest generally as well as jeopardizing the well-being of Covered Horses.

For these reasons, Shell has not met the burden set forth in 16 C.F.R. § 1.148 to grant a stay during the pendency of this review proceeding. Accordingly, Shell's request for a stay is **DENIED**.

ORDERED:

Jay L. Himes

Jay L. Himes
Administrative Law Judge

Date: August 5, 2024