UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
Dr. Scott Shell, DVM	)	Docket No. 9435
Appellant.	)	

ADMINISTRATIVE LAW JUDGE DECISION ON APPLICATION FOR REVIEW

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Table of Abbreviations

AB1 – Appeal Book Part 1

AB2 – Appeal Book Part 2

ADMC – Anti-Doping and Medication Control

ADRV – Anti-Doping Rule Violation

Analogue Act – Controlled Substance Analogue Enforcement Act, 21 U.S.C. § 813 (1986)

AOBr. – Authority's Opening Brief

APFOF – Appellant's Proposed Findings of Fact

ARBr. – Appellant's Reply Brief

AuOBr. – Authority's Opening Brief

AuRBr. – Authority's Reply Brief

HISA – Horseracing Integrity and Safety Act, 15 U.S.C. §§ 3051-60

HIWU – Horseracing Integrity & Welfare Unit

The Authority – Horseracing Integrity and Safety Authority

I. INTRODUCTION

A. Summary of the Case

This decision arises under the Horseracing Integrity and Safety Act ("HISA"), 15 U.S.C. §§ 3051 et seq. and the Rules implementing the Act. Among other things, HISA created the Horseracing Integrity and Safety Authority ("the Authority"), a private, independent, self-regulatory, nonprofit corporation, to "develop[] and implement[] a horseracing anti-doping and medication control program and a racetrack safety program" throughout the United States. 15 U.S.C. § 3052(a). The Authority thus promulgated, and the Federal Trade Commission ("FTC") approved, Rules that include the statutory-required Anti-Doping and Medication Control ("ADMC") Program ("HISA Rules"). *See generally* ADMC Rule 3000 series. The Authority also formed the Horseracing Integrity & Welfare Unit ("HIWU"), as the entity to implement and enforce the ADMC Program on behalf of the Authority. 15 U.S.C. § 3055; HISA Rule 3010(e)(1).

A core principle of the ADMC Program is that "Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and treatment methods that affect their performance." HISA Rule 3010(d)(1); AB1 234-35, at ¶ 21 (HIWU pre-hearing brief). Here, HIWU has charged Appellant Dr. Scott Shell, a veterinarian, with administering, by injection, a substance called Hemo 15, to various racehorses.[1] Dr. Shell provides services to Covered Horses and, therefore, is a Covered Person subject to HISA's Rules

[1] Capitalized terms used, but not defined in this decision, are those defined in HISA Rule 1020 of the General Provisions. Abbreviations are set forth in the Table of Abbreviations.

and to the enforcement system created. 15 U.S.C. §§ 3051(6), (21), 3053(a)(8), 3054(a); HISA Rules 1020, 3040(a)(d); AB2 246 (Shell).[2]

There is no dispute that Dr. Shell injected Hemo 15 into 37 Covered Horses 228 times over a multi-month period. He self-reported all the injections on a HIWU website portal for Veterinarians. HIWU asserts, however, that Hemo 15 is a Banned Substance and that, in consequence, Dr. Shell committed 228 violations of HISA Rule 3214(c). Dr. Shell, on the other hand, contends that Hemo 15 is a vitamin, the injection of which is permissible.

After hearing testimony and receiving evidence from each side, the Arbitrator upheld HIWU's charge. AB1 147-48. The Arbitrator awarded the maximum sanctions against Dr. Shell—two years of Ineligibility and a $25,000 fine—for the first Hemo 15 injection. AB1 148. For the remaining 227 charged violations, the Arbitrator found that Dr. Shell was not at fault, and thus not subject to additional sanctions. AB1 148, 149-50.[3] The Arbitrator further awarded HIWU $10,000 in adjudication costs. AB1 150. Dr. Shell has filed this proceeding to review the Arbitrator's decision.

In this decision, I first summarize the HISA regulatory structure. The relevant facts follow, along with my analysis of HIWU's charge and the sanctions appropriate for the case.[4]

[2] "Attending Veterinarian means a Veterinarian providing treatment or services to Covered Horses hired or otherwise authorized by the Trainer or Owner or his or her respective designee." HISA Rule 1020. The definition covers Dr. Shell. *See, e.g*, AB1 1043, at ¶¶ 1-2; AB2 203-04.

[3] HISA Rule 1020 defines "the penalties resulting from the occurrence of one or more [ADMC] violations" as "Consequences," which parties often refer to as "sanctions," a term also used, but not defined, in the Rules. For simplicity, I use the term "sanctions."

[4] This decision is issued in accordance with an extension for good cause, occasioned by docket demand and prioritization. *See* 16 C.F.R. § 1.146(d)(1).

B. Statutory Coverage, Enforcement, and Review

The Statute: HISA, the federal statute, created and empowered the Authority to develop and enforce rules and sanctions on a variety of industry subjects, including anti-doping and medication for horses, subject to the FTC's oversight. 15 U.S.C. §§ 3053, 3055, 3057. Implementing regulations, effective May 22, 2023, established the ADMC Program's rules, which include, in summary: (1) the persons and animals the Program covers; (2) those substances that are either banned or controlled as medications; (3) the conduct constituting violations and corresponding sanctions; and (4) investigation and enforcement in furtherance of the statute.[5] Rules for FTC oversight of HISA, including review of civil sanctions imposed for rule violations, have also been issued.[6]

Enforcement Authority: HISA Rule 3010(e)(1) assigned HIWU the responsibility to enforce the ADMC Program for the Authority. HIWU charges of ADMC Program rule violations are adjudicated by an arbitrator. HISA Rule 7020.

FTC Review: HISA civil sanctions imposed for rule violations are reviewable by an FTC Administrative Law Judge (ALJ) and thereafter by the Commission itself on a discretionary basis.[7] The ALJ reviews:

> whether—
>
> (i) a person has engaged in such acts or practices, or has omitted such acts or practices, as the Authority has found the person to have engaged in or omitted;

[5] *See generally* 88 Fed. Reg. 5070-5201 (Jan. 26, 2023) (FTC Notice of HISA Proposed Rule and Request for Comment); Order Approving the ADMC Rule Proposed by HISA (Mar. 27, 2023) (available at https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf*);* 88 Fed. Reg. 27894 (May 3, 2023) (FTC Notice of Final Rule, effective May 22, 2023) (available at https://www.federalregister.gov/documents/2023/05/03/2023-09247/horseracing-integrity-and-safety-act-anti-doping-and-medication-control-rule#footnote-1-p27894).

[6] *See* 16 C.F.R. § 1.145 *et. seq.*; *see* 87 Fed. Reg. 60077 (Oct. 4, 2022) (Final Rule).

[7] 15 U.S.C. § 3058(b)-(c); FTC Rules 1.146-1.147.

> (ii) such acts, practices, or omissions are in violation of this chapter or the anti-doping and medication control or racetrack safety rules approved by the Commission; or
>
> (iii) the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

15 U.S.C. § 3058(b)(2)(A); *see also* 16 C.F.R. §§ 1.146(b)(1)-(3).

Review by the ALJ is *de novo,* as though the issue had not been heard before, and no decision had previously been rendered.[8] *See Barrientos v. Wells Fargo Bank, N.A.*, 633 F.3d 1186, 1188 (9th Cir. 2011), and *Aquarius Marine Co. v. Pena*, 64 F.3d 82, 87 (2nd Cir. 1995) (both holding that, on *de novo* review by an appellate court, there is no deference to the district court); *Coalition for Competitive Electricity, Dynergy Inc. v. Zibelman*, 906 F.3d 41, 48 (2d Cir. 2018), and *Freeman v. DirecTV, Inc.*, 457 F.3d 1001, 1004 (9th Cir. 2006) (both describing *de novo* review by appellate court of district court dismissal of complaint under Federal Rule of Civil Procedure 12(b)(6)); *Adirondack Medical Center v. Sebelius*, 740 F.3d 692, 696 (D.C. Cir. 2014), and *Agyeman v. INS*, 296 F.3d 871, 876 (9th Cir. 2002) (both describing scope of *de novo* review of agency's interpretations of statute).

Thus, the ALJ must determine the merits of the Anti-Doping Rule Violation ("ADRV") that HIWU has charged, and whether the sanctions imposed by the Authority were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[9] "[T]o pass muster under the arbitrary and capricious standard," a court must only find a "rational connection between facts and judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56 (1983). "To make this finding the court must consider whether the decision was

[8] 15 U.S.C. § 3058(b)(1); FTC Rule 1.146(b)(3).

[9] 15 U.S.C. § 3058(b)(2)(A); FTC Rule 1.146(b)(1)-(3).

based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Judicial review under the arbitrary and capricious standard looks to ensure that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

Similarly, to find an abuse of discretion, the record must reveal a clear error of judgment. *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 422 F.3d 782, 798 (9th Cir. 2005). "An abuse of discretion is a plain error, discretion exercised to an end not justified by the evidence, a judgment that is clearly against the logic and effect of the facts as are found." *Id.* (cleaned up). Finally, whether the sanctions are in accordance with the law is determined with reference to the substantive law of the HISA statute and the implementing regulations, summarized above.

In exercising its review authority, the ALJ may "affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part" and "make any finding or conclusion that, in the [ALJ's] judgment . . . is proper and based on the record."[10]

II. ANALYSIS

A. The Underlying Facts

Dr. Shell has practiced veterinary medicine for 37 years. AB2 193 (Shell). His practice includes servicing horses at racetracks in northern Ohio and West Virginia. AB1 1043 (Shell wit. state.). On October 4, 2023, HIWU investigators searched a van registered to Dr. Shell, then

[10] 15 U.S.C. § 3058(b)(3)(A); FTC Rule 1.146(d)(3).

located at JACK Thistledown Racino, that one of Dr. Shell's office colleagues was using. AB1 271. The search disclosed a bottle, the label of which stated, among other things:

Rx: 153539 – BB

Hemo 15

This is a compounded drug. Not an FDA approved or indexed drug.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

AB1 1293, 1308, at ¶ 6 (Scollay wit. state.), 1309 (bottle and label). HIWU seized the bottle and had the Pennsylvania Equine Toxicology & Research Laboratory (PETRL) analyze its contents. The lab reported the ingredients found in the bottle's contents. AB1 267, at ¶ 9, 272, 280 (Stormer wit. state.).

HISA Rule 3040(d) requires Veterinarians to keep updated treatment records in an electronic database designated by the Authority. Therefore, after seizing the Hemo 15 from Dr. Shell's truck, HIWU queried the Authority's database of veterinary records for Hemo 15 entries. The search disclosed that, during the period May 29, 2023 through October 19, 2023, Dr. Shell injected Hemo 15 228 times into 37 Covered Horses. AB1 267, at ¶¶ 10, 12 (Stormer wit. state.), 282, 292-402. The entries represent Dr. Shell reporting each injection on HISA's website portal. The May start date reflects the first injection after the ADMC Program became effective, while the October end date is shortly after HIWU's search of Dr. Shell's vehicle. AB1 282, 1362-71 (database results). Dr. Shell admits the 228 injections. AB2 263 (Shell).

In January 2024, HIWU issued an Equine Anti-Doping ("EAD") Notice to Dr. Shell, which stated that "Hemo 15 is an illegally compounded product intended to mimic foreign products that are not approved for use in the United States." AB1 270, 272. Accordingly, HIWU asserted violation of HISA Rule 3214(c), which prohibits "[a]dministration to a Covered Horse

of any Banned Substance . . . .” HIWU further informed Dr. Shell that “each” of the 228 injections “is to be treated as a separate Violation.” AB1 272 (citing HISA Rule 3228(c)). HIWU also imposed a Provisional Suspension on Dr. Shell, which has been in effect since January 2023. AB1 272; HISA Rule 3247(a)(1). After Dr. Shell responded by letter asserting HIWU’s charges lacked merit, in February 2024 HIWU issued its formal charge letter, incorporating the facts from its EAD Notice. AB1 256 (Shell letter), 284 (HIWU charge letter).

An arbitration was convened, which included a hearing conducted in May 2024, after which the Arbitrator found HIWU’s ADMC violation proven and awarded the sanctions summarized above. I turn next to the merits of HIWU’s charge.

B. HISA Rules 3214(c) and 4111 Cover Hemo 15

HISA Rule 3214(c), in pertinent part, prohibits “Administration . . . to a Covered Horse of any Banned Substance . . . .” Banned Substances are those on the Prohibited List, which includes “Prohibited Substances . . . in the Rule 4000 Series.” HISA Rules 1020 (definitions) and 3111.[11] HISA Rule 4111, describing “S0 Non-Approved Substances,” states in part 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.

Although Hemo 15 is not by name included on the Prohibited List, the Authority contends it is covered under HISA Rule 4111 and thus prohibited from use. AuOBr. 16; *see* AB2 110-11 (Scollay).

[11] “Prohibited Substance” includes “any substance or class of substances . . . on the Prohibited List”; and the “Prohibited List” includes “Prohibited Substances . . . in the Rule 4000 Series.”

There is no dispute that HISA Rule 4111(i) and (ii) apply to Hemo 15. The substance "(i) is not addressed by Rules 4112 through 4117, [and] (ii) has no current approval by any governmental regulatory health authority for veterinary or human use." *See* AB1 1292, at ¶¶ 12-14 (Sharlin rep. (FDA public records show no entry for Hemo 15 as an approved animal drug), 408, at ¶¶ 16-17 (Maxwell rep.); AB2 111-12 (Scollay), 303-04, 313-14 (Maxwell), 398-99, 460-61 (Bertone).

Accordingly, the dispute here is over whether Hemo 15 meets subpart (iii), which requires that Hemo 15 not be "universally recognized by veterinary regulatory authorities as a valid veterinary use." In addition, Dr. Shell maintains that because Hemo 15 is a vitamin, HISA Rules 3214(c) and 4111 do not apply at all. I consider this argument first, and thereafter address subpart (iii) of HISA Rule 4111.

1. Hemo 15 is a Compounded Drug—Not a Vitamin Outside the ADMC Program

The Federal Food, Drug and Cosmetic Act defines a drug, in pertinent part, as "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or "(other than food) intended to affect the structure or any function of the body of man or other animals . . . ." 21 U.S.C. § 321(g)(1). A substance that does not make such a "drug claim"—which can be certain vitamins—is not subject to FDA approval and is not covered by the ADMC Program. *See* AB1 1311, at ¶ 13 (Scollay wit. state.); AB2 162 (Scollay) (The FDA "doesn't regulate vitamins, nutritional supplements, unless they meet the definition of a drug.").

Dr. Shell maintains that Hemo 15 is a vitamin and not prohibited for injection into Covered Horses. AOBr. 2; AB2 7-9 (Mollica opening), 240 (Shell). On the other hand, the Authority contends Hemo 15 is a "pharmacological substance" included as a Banned Substance under HISA Rule 4111. AuBr. 8; AB2 531 (Bunting closing).

Horse Necessities, Inc. ("HNI") supplied "all" the Hemo 15 that Dr. Shell obtained, and the product's ingredients "were the same for 37 years" according to Dr. Shell. AOBr. 3; APFOF ¶ 16; AB2 265, 270 (Shell). HNI's Hemo 15 product states on its label that Hemo 15 is a "drug"—a "compounded drug" that is "[n]ot an FDA approved or indexed drug" and whose use "Federal law restricts." Further, the bottle HIWU seized bears a prescription (Rx) number. AB1 1309 (bottle and label). As Dr. Shell's expert, Dr. Bertone, testified regarding HNI, "[t]hat's what they make, is drugs." AB2 451 (Bertone).

Indeed, HNI markets itself as offering "the equine practitioner with the compounded medication they need." https://horsenecessitiesinc.com. The company's pharmacy webpage similarly states that it "compounds prescription medication primarily for horses. Compounding is the creation of a drug to meet the needs of a particular patient. . . . If you have a horse with a specific medication need, give Horse Necessities, Inc. a call https://horsenecessitiesinc.com/pharmacy/. There is no website mention of HNI offering vitamins.

Additional evidence offered corroborates that the substance HIWU seized from Dr. Shell is what HNI described it to be: "a compounded drug," not a vitamin.

There is no vitamin known as Hemo 15. AB2 147 (Scollay). Instead, Hemo 15 "is an internationally produced product that is a combination of vitamins, minerals and other

substances," which is not approved for use in the United States. AB2 110, 147 (Scollay), 303 (Maxwell), 401 (Bertone) (Hemo 15 "is a compounded product."); AB1 413, at ¶ 31 (Maxwell rep.). The combination of ingredients in Hemo 15 is currently approved in Italy, and previously was marketed as Hemo-15® in such countries as Australia and Canada, with drug labels detailing conditions intended to be treated by the product. AB1 408, at ¶ 14 (Maxwell rep.), 1281-84, at ¶¶ 6-8 (Maxwell R-rep.), 1313, at ¶ 17 (Scollay wit. state.) (claims include increasing production of red blood cells by the bone marrow and treating iron deficiency anemia); AB2 303 (Maxwell). However, Hemo-15® has never been FDA-approved, nor have its ingredients been FDA-approved under another name. AB1 408, at ¶ 17 (Maxwell rep.); AB2 403 (Bertone).

In the U.S. pharmaceutical products regulatory scheme, "[c]ompounding combines, mixes, or alters ingredients to create" a new medication. AB1 1295, at ¶ 20 (Sharlin rep.). The Hemo 15 that Dr. Shell injected is made up of various ingredients. AB1 279-80 (lab analysis). That accounts for HNI labeling the Hemo 15 supplied to Dr. Shell as "a compounded drug." Compounded drugs do not go through the FDA approval process. AB1 1295, at ¶ 22 (Sharlin rep.). Thus, HNI stated on the label, "Not an FDA approved or indexed drug." *See* AB2 496 ("[T]hat language is in the guidance document as elements that need to be on the label.") (Sharlin); AB1 1147, 1148 (FDA labeling requirements for compounded drugs).

Reference to Hemo 15 available abroad is probative of the product Dr. Shell obtained. Since there is no approved version of Hemo 15 in this country, the Hemo 15 available in the United States "is intended to be a replicate of the foreign product that is not commercially available in this country. . . . [T]hat's why someone would . . . give it the same name." AB2 187 (Scollay). As Dr. Maxwell similarly put it, Hemo 15 "is a compounded product that is meant to

mimic a foreign substance." AB2 363-64 (Maxwell). That is what a reasonable U.S. customer would think: "[I]f somebody gives it the same name as a product that's not available in this country, my expectation as a consumer would be that . . . it is a replicate of that product, and I think I would be sorely disappointed if I found out that it were not." AB2 190 (Scollay).

Even Dr. Shell's expert, Dr. Bertone accepted that the version of Hemo 15 available in the United States "probably is" "substantially similar" to the formulation of Hemo 15 marketed in Europe. AB2 430-31, 450 (HNI's Hemo 15 would be "substantially similar . . . to the Hemo 15 that's been approved" in Europe) (Bertone).

For a U.S. supplier to create a compounded product for animals —as HNI does—it must "make a copy product of a foreign animal drug. And since a foreign animal drug is an unapproved animal drug in the United States, a copy of an unapproved animal drug is still an unapproved animal drug." AB2 357, 363-64 (Maxwell) ("a compounded product that is meant to mimic a foreign substance" is "a banned substance").

That Hemo 15 is administered by injection supports its classification as a drug. In the FDA's view, an injectable vitamin is "an unapproved animal drug" and when administered intravenously, is regulated. AB2 446-47 (Bertone). Dr. Maxwell thus opines that Hemo 15 "is properly considered a 'new animal drug'" under the Federal Food Drug and Cosmetic Act, and unapproved for use in this country. AB1 412, at ¶ 29 (Maxwell rep.), 1281, at ¶ 4 (Maxwell R-rep.), AB2 303-04 (Maxwell); *see also* AB1 412, at ¶¶ 27-28 (Maxwell rep.), 1294-95, at ¶¶ 16, 18-19 (Sharlin rep.).[12]

[12] Under the Federal Food, Drug, and Cosmetic Act, a "new animal drug" is defined as:

Accordingly, Hemo 15—the compounded product—is a Banned Substance, regardless of whether any of its individual ingredients are prohibited. *See* AB1 413, at ¶¶ 33-34, 414-15, at ¶ 36(a) (Maxwell rep.), 1295-96, at ¶¶ 20-25, 1298, at ¶¶ 31-34 (Sharlin rep.). The very point of having Rule 4111's catch-all for "pharmacological substances" is to enable the ADMC Program to reach products whose ingredients are not already included by name on the Prohibited List. This approach to addressing illicit drug activity is not unique to horseracing or sports in general. *See United States v. Hodge*, 321 F.3d 429, 437 (3rd Cir. 2003) (Congress enacted the 1986 Controlled Substance Analogue Enforcement Act (the "Analogue Act"), amending the Controlled Substances Act, "to make illegal the production of designer drugs and other chemical variants of listed controlled substances that otherwise would escape the reach of the drug laws."). *See also* pp. 26 to 28, below.

Despite his argument in this case, Dr. Shell's own behavior is itself telling. HISA Rule 3040(d) obligates Attending Veterinarians to maintain and retain "treatment records (including, without limitation, records of medical, therapeutic, and surgical treatments and procedures, including diagnostics) . . . ." Although Dr. Shell contends Hemo 15 is "a vitamin supplement to replenish lost vitamins, minerals": (a) he has no record whether "any of these 37 horses ***had*** a vitamin deficiency"; and (b) he never sought "to determine ***if*** they [had] a vitamin deficiency." AB2 223, 281, 282 (Shell) (emphases added).

> any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including such animal feed, -- (1) the composition of which is such that the drug is not generally recognized . . . as safe and effective for the use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .

21 U.S.C. § 321(v).

Similarly, Dr. Bertone's opinion—that HNI's bottle label is "wrong," and that the bottle contains a vitamin despite the company stating it was a "compounded drug"—is entitled to no weight. AB2 451 (Bertone). Dr. Bertone lacks knowledge to assert that HNI publicly represented its own product as something different than what HNI understood it to be, and any opinion he might have in that regard would be pure speculation. Indeed, as Dr. Bertone further testified: "That's what they make, is drugs." AB2 451 (Bertone). The FDA's Guidance for Industry on Compounding Animal Drugs from Bulk Drug Substances instructs specifically that: "The labeling of the compound drug include[] . . . the statement, 'This is a compounded drug. Not an FDA approved or indexed drug.'"—exactly what the Hemo 15 bottle here said. AB1 1147 (label requirements), 1309 (bottle label).

Dr. Shell further contends that, by circulating a December 2023 "reminder" email to Covered Persons shortly before HIWU served Shell with an EAD Notice, the Authority effectively acknowledged a lack of prior notice that Hemo 15 is a Banned Substance. AB1 1044, at ¶¶ 11-12 (Shell wit. state.), 1314-15, at ¶ 23 (Scollay wit. state. quoting email); AB2 13-14 (Shell opening), 239 (Shell). Dr. Scollay, however, explained the reminder. Having identified Dr. Shell's frequent use of Hemo 15, HIWU sought to avoid possible misunderstanding among horse Trainers and Owners in Dr. Shell's Ohio practice area who might otherwise "think that the use of Hemo 15 was permitted when it clearly is not." AB1 1315, at ¶ 25 (Scollay wit. state.); AB2 169-70, 172 (Scollay).

The email represents sound regulatory practice. Its issuance is not a trap that insulates Dr. Shell from responsibility for his prior injections of Hemo 15 into horses. *Cf. Dusenbery v. United States*, 534 U.S. 161, 172 (2002) (upgraded procedures to deliver mail to inmates did not

"necessarily demonstrate the [constitutional] infirmity of those that were replaced."); *Byrd v. District of Columbia*, 297 F. Supp. 2d 136, 140-41 (D.D.C. 2003) (memorandum of agreement to improve policing was not probative of deliberate indifference in civil rights case), *aff'd sub nom. Byrd v. Gainer*, No. 03-7196, 2004 WL 885228 (D.C. Cir. Apr. 26, 2004).

In sum, as Dr. Sharlin testified:

Q. . . . You've confirmed that Hemo 15, in your view, is a drug for the FDA rules?

A. Yes, says so on the label.

AB2 500 (Sharlin). *See also* AB2 496 (Sharlin).

Accordingly, the weight of the evidence does not substantiate Dr. Shell's contention that Hemo 15 is a vitamin. AB1 41, at ¶ 8.11.

2. Hemo 15 is Not "Universally Recognized by Veterinary Regulatory Authorities" for "Valid Veterinary Use"

If Hemo 15 is a drug, Dr. Shell admits it would be a non-approved substance under HISA Rule 4111, ***provided*** it also satisfies Rule 4111(iii), which covers "[a]ny pharmacological substance. . . ***not*** universally recognized by veterinary regulatory authorities as a valid veterinary use . . . ." Emphasis added. *See* AB2 259-60 (Shell). The Arbitrator found no such recognition, thereby holding that Hemo 15 was a Banned Substance. AB1 41, at ¶ 8.11. This finding was correct. The evidence established lack of any such universal recognition.

Dr. Shell testified, in conclusory terms, that other industry veterinarians used Hemo 15 as a vitamin. *See* AB2 226, 238 ("It is widely accepted and used across the United States."), 241. Dr. Bertone, Dr. Shell's expert, gave similarly general testimony, noting that Hemo 15 is "acceptable in the veterinary community," and that "a number of veterinarians use that

compounded product in this country." AB2 380, 382; *see also* AB2 400, 405 (Bertone). This evidence ignores the Rule's requirement, however. The "universal[] recogni[tion]" must be "by veterinary ***regulatory*** authorities"—not by ***veterinarians***. On that score, the evidence did not include approval by ***any*** U.S. regulatory authority and demonstrated, at best, inconsistent treatment of Hemo 15 by regulatory authorities abroad. AB2 303 (Maxwell) (approval withdrawn in Canada and Australia; registered in Italy); AB1 408, at ¶ 15 (Maxwell rep.), 1288, at ¶ 17(c) ("repeatedly in the news for European racing violations") (Maxwell R-rep.); AB2 381, 446 (Bertone) (not approved in Canada; subject of a doping scandal in France).

Even accepting, for argument's sake, that veterinary use could proxy for "regulatory authority" recognition, Dr. Shell's evidence is insufficient.

First, Dr. Bertone's hedged testimony effectively admitted lack of "universal[] recognition." He testified: (1) "The ***substances*** that were in Hemo 15 are, ***by many***, considered a valid veterinary use"; (2) "Hemo 15 is ***not*** universally accepted . . . for a valid veterinarian use[.] That's true, but the ***constituent elements*** are."; and (3) ***"[A]lmost*** all the ***nutrient constituents***" meet "NRC [drug nonconformance report] requirements." AB2 405, 462-63 (Bertone) (emphases added). Dr. Shell, however, bought and injected the compounded product, which "is not universally accepted"; he did not simply administer its "constituents." And acceptance "by many" of the substances that are in Hemo 15 is a far cry from "universal[] recogni[tion]" of the compounded product.

Second, websites offering Hemo 15, which Dr. Shell offered as "demonstrative to show that Hemo 15 is available," refute valid veterinary use. AB1 1051-53 (websites); AB2 115, 272 (Counsel's statement). The cited websites not only make drug claims, but also are obviously

unsuitable for a reasonably prudent U.S. veterinarian to rely on. AB1 1282-84, at ¶¶ 7-8, 1288, at ¶17(d) (Maxwell R-rep.); AB2 307-08, 309-10 (Maxwell) (Equimeds website appears to promote illicit drug distribution and requires payment through Western Union to Ukraine or using Bitcoin), 310-11 (Ukrainian company offering a version of Hemo 15 that cannot be legally imported to the U.S.), 311 (company associated with camel racing offering a powerful pre-race stimulant), 336 (websites "appear to be disreputable"), 435-41 (Bertone) (Equimeds website makes drug claims).

Third, that vitamins generally can be purchased "at a local feed store" or "in a grocery store" is similarly unavailing. *See* AB2 390, 411, 517 (Bertone). There is no evidence that veterinarians purchase Hemo 15 in brick and mortar feed stores.

By contrast, evidence in the arbitration amply refuted "universal[] recogni[tion]" among veterinarians themselves.

HISA Rule 2251(b) requires a Veterinarian who "examines or treats a Covered Horse" to report, among other things:

> (8) any medication, drug, substance, or procedure administered or prescribed, including date and time of administration, dose, route of administration . . . , frequency, and duration (where applicable) of treatment.

The Rule is not limited to drugs, but applies to any administered "substance." Yet, during the roughly five-month period following the ADMC Program taking effect in May 2023, Dr. Shell is the ***only*** veterinarian to report using Hemo 15 to the Authority. AB1 1359-60, at ¶¶ 5-6 (Stormer wit. state.), 1362-67 (post-effective date entries). The data refutes the notion that HISA-covered Veterinarians recognize Hemo 15 as having a "valid veterinary use," much less that the use was "universally recognized by veterinary regulatory authorities" throughout the country.

Other evidence confirms lack of "universal[] recogni[tion]" of a valid veterinary use. Witnesses testified concerning cobalt, one of the ingredients in the product Dr. Shell used:

(a) Although a naturally occurring substance, cobalt also is "associated with blood doping in that it basically simulates a condition in the body where the body thinks that it doesn't have enough oxygen, and so the bone marrow produces more red blood cells in response to this sort of artificial hypoxia situation that the cobalt produces." AB2 116 (Scollay); AB1 1313, at ¶ 18 (Scollay wit. state.) (When administered over certain thresholds, cobalt "is associated with efforts at blood doping . . . by overstimulating the bone marrow to produce red blood cells."); *see also* HISA Rule 4121 (banning artificial enhancement of delivery of oxygen).

(b) Excessive levels of cobalt have been documented as not only causing death in horses, but also muscle tremors, pawing, straining to urinate, cardiac arrythmias, hypertension, and laboratory abnormalities. AB1 409, at ¶ 20 (citing sources) (Maxwell rep.); *see also* AB2 314 (Maxwell). Administration by injection, Dr. Shell's method of delivery, is particularly problematic. AB1 409-10, at ¶ 21 (Maxwell rep.).

(c) Cobalt deficiency is not known to occur in horses. AB2 116, 124 (Scollay), 314, 317 (Maxwell). Because horses get enough cobalt in their feed, "there is no justification for administering cobalt to a horse," and "it was quite problematic to me to see it in . . . an injectable product." AB2 116-17 (Scollay); *see also* AB2 121 (Scollay) ("[T]he cobalt [reported in the lab certificate of analysis] was problematic."); AB1 409, at ¶ 20 (Maxwell rep.) ("[C]obalt deficiency has never been diagnosed in this species.").

Another ingredient in the Hemo 15 seized from Dr. Shell is nicotinamide, "a monitoring list" substance. Nicotinamide "is under investigation" to analyze whether "it's an actual

metabolite [of a B vitamin] or a contaminant from the use of [a] bulk drug in formulating some of these vitamin products or compounded drugs." AB2 121 (Scollay).

For all of the above reasons, the weight of the evidence establishes that Hemo 15 does not meet the requirements of HISA Rule 4111(iii).

3. HISA Rule 4111's Carve-out for Compounded Drugs Does Not Apply

In resolving whether Hemo 15 is a Banned Substance, one additional part of HISA Rule 4111 must be considered. The Rule's carve-out for compounded drugs provides:

> 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.

The Arbitrator found this carve-out inapplicable to Hemo 15. AB1 41, at ¶ 8.10. I agree.

The Food Drug & Cosmetic Act and AMDUCA authorize the FDA to regulate animal drugs, including those resulting from compounding, a form of extra-label use. AB1 1295-96, at ¶ 23 (Sharlin rep.); *see* AB2 154 (Scollay), 315-318 (Maxwell). An FDA release, GFI 256, enables compounded substances, which do not require FDA approval, to be administered to meet an animal's medical need. AB2 105, 154 (Scollay), 317-18 (Maxwell), 401 (Bertone). GFI 256 sets out guidance criteria for permissible compounding using bulk drugs and prescribes exercise of FDA enforcement discretion. AB1 1296, at ¶ 24 (Sharlin rep.). In turn, Rule 4111's carve-out permits compounded drugs to be used, so long as they comply with GFI 256. AB1 413, at ¶ 32-34 (Maxwell rep.), 1295, at ¶¶ 23-24 (Sharlin rep.), 1327, 1347 (Scollay slides); AB2 400-01 (Bertone).

Where no FDA approved drug is available to address an animal's particular condition, a compounded drug "may be a medically appropriate treatment" in limited circumstances. AB1

1140 (GFI 256). Thus, GFI 256 fills a potential gap where "the regular drug approval process doesn't always work" due to "special scenarios" confronting veterinarians. . . . [I]f you don't have an approved drug out there, we're going to give you the opportunity to create a compounded drug." AB2 497-98 (Sharlin).

The central elements for approval for compounding are twofold: (1) "medical justification" such as "suffering or death . . . if the animal is not treated" AB2 105-06, 112, 154, 174 (Scollay), 316-17 (Maxwell); AB1 1140, 1141, 1143, 1151 (GFI 256), 1295, at ¶ 20 (Sharlin rep.); and (2) unavailability of an FDA approved drug. *See* AB1 1140-43 (GFI 256), 1297, at ¶ 27 (FDA flowchart) (Sharlin rep.); AB2 319 (Maxwell).

GFI 256 distinguishes between compounding for an individual horse and compounding for inventory ("office" or "bulk" stock). AB1 1142 (GFI 256), 1297, at ¶¶ 27-29 (FDA flowchart) (Sharlin rep.); AB2 318 (Maxwell), 466-67, 468 (Bertone). Where horse-specific compounding is involved, there must be a prescription for the individual horse, and the compounded substance should not be administered to other horses. AB1 1142-43 (GFI 256); AB2 149 (Scollay), 318-19, 323 (Maxwell). The FDA notes explicitly that "the pharmacist should maintain a record of the medical rationale describing the clinical difference" justifying the compound drug for the "identified individual patient." AB1 1144-45 (GFI 256).

Where "office" stock is created, it should be from drugs on the FDA's approved list of drugs whose use for compounding is permitted. AB1 1148 (GFI 256), 1297, at ¶ 27 (FDA flowchart), 1298, at ¶ 32 (Sharlin rep.); AB2 326 (Maxwell). Office stock applies "where there is a rapid or immediate need for the drug to be available," such that the veterinarian does not "have time to acquire a patient specific compound," but must instead use a drug "sitting there in that

shelf. . . .” AB2 319, 320-21 (Maxwell); AB1 1151 (GFI 256: FDA will add drug substances to its approved list where “[u]rgent treatment with the compounded drug is necessary to avoid animal suffering or death, or to protect public safety.”).

Unlike a substance that goes through the FDA approval process, where, as here, the compounded substance is supplied in response to a horse-specific prescription, the product label is ***not*** required to include a claim. “And why is that? Because the compounding was meant for a very narrow, very specific scenario, very specific situation.” AB2 502 (Sharlin); *see also* AB2 329 (While there are label requirements under AMDUCA and GFI 256, “one of those is not that they label any indication.”) (Maxwell); AB1 1147 (GFI 256 label requirements).

Veterinarians who use compounded substances, such as Dr. Shell, have an obligation to know and understand GFI 256. AB2 106-07 (Scollay). Dr. Shell, however, had no apparent understanding of either AMDUCA or the FDA’s guidance document on compounding. *See* AB2 253-55, 256-58 (Shell).

Dr. Shell’s use of Hemo 15 was “not compliant with . . . GFI 256.” AB2 501 (Sharlin). Dr. Shell introduced no significant evidence to rebut these multiple deficiencies:

(1) He produced no evidence of individual prescriptions for the 37 horses he injected. AB2 280 (Shell). As Dr. Maxwell explained: “One prescription should accompany each patient.” AB2 323 (Maxwell). Dr. Shell also failed to maintain specific administration records. AB1 415, at ¶ 36(b) (Maxwell rep.), 1298, at ¶ 30 (Sharlin rep.).

(2) He injected horses with Hemo 15 despite the absence of any medical need, a core feature for using a compounded drug. AB2 112, 152 (Scollay), 286 (Shell); AB1 1285-86, at ¶ 11 (Maxwell R-rep.). Indeed, he never determined whether any of the horses suffered a vitamin

deficiency, but testified that, "I can, as a doctor, assume that a hard working race horse will be deficient in several vitamins, minerals and amino acids." AB2 282 (Shell); *see also* AB2 281-82 (Shell) (no records regarding vitamin deficiency).

(3) Dr. Shell also admitted using the contents of a horse-specific prescription to inject other horses with Hemo 15—essentially applying office stock under non-exigent circumstances. AB2 275-76 (Shell) (the bottle "could be used for multiple horses"), 276 (Shell) ("We would use that bottle for differing horses. And maybe the next time we ordered Hemo 15, we would use a different name of one of the horses that we were treating...medicating . . ."); *see also* AB1 1286, at ¶ 12(b) (Maxwell R-rep.); AB2 150-51 (Scollay), 323-25 (Maxwell). The FDA horse-specific exception—covering "a group of animals in a specific, identified location (e.g., cats in isolation ward X, dogs in kennel Y, or horses in stable Z"—does not envision the assortment of Covered Horses at different racetracks and barns throughout Dr. Shell's practice area. AB1 1142 n.26 (GFI 256).

(4) If the Hemo 15 supplied to Dr. Shell could, somehow, be considered office stock—and not a horse-specific prescription—it needed to be on the FDA's permitted list for bulk drugs, and it is not. AB2 326-27 (Maxwell), 498-500 (Sharlin); AB1 414-15, at ¶ 36(a) (Maxwell rep.), 1298, at ¶ 33 (Sharlin rep.).

Whether, as Dr. Bertone opined, GFI 256 is "pie in the sky" guidance is beside the point. AB2 401, 473 (Bertone). To invoke Rule 4111's carve-out from prohibition, the "compounded product" must "be compliant." However, Dr. Bertone himself admitted Hemo 15 complies with GFI 256 only "from the standpoint that," as an alleged vitamin, "GFI doesn't even apply to it." AB2 417 (Bertone); *see also* AB2 464 (Bertone) ("neither AMDUCA or GFI 256 apply to Hemo 15").

There similarly is no merit to Dr. Shell's argument that because GFI 256 is "not law," but rather a "guidance" document that publicly states the FDA's enforcement policies, HISA Rule 4111's requirement of "complian[ce]" is meaningless. AOBr. 9. Compounded drug practice that lacks a safe harbor from FDA enforcement policy under GFI 256 simply cannot invoke HISA Rule 4111's carve-out to avoid prohibition as an S0 Non-approved Banned Substance.

* * *

For all these reasons, Hemo 15 is a compounded drug, not a vitamin, and it "is not universally recognized by veterinarian regulatory authorities for valid veterinarian use." Dr. Shell's injection of the substance was not compliant with AMDUCA and GFI 256. HIWU has met its burden of proof under HISA Rule 3121 and established that Dr. Shell violated HISA Rules 3214(c) and 4111 by injecting Hemo 15 into 37 Covered Horses 228 times.

C. Dr. Shell's Defenses Fail

1. There is No "Estoppel" Justification

Dr. Shell's opening papers did not raise the estoppel defense he argued before the Arbitrator. However, his reply brief states, without further elaboration: "HISA [the Authority] should be estopped from asserting that Appellant's Hemo 15, with vitamins, minerals and amino acids and no claims . . . requires government approval under Rule 4111." ARBr. 3 This argument is waived both because raised only on reply and because asserted without any development.[13] The argument is also devoid of factual merit.

[13] *See, e.g., Stewart v. IHT Ins. Agency Group, LLC*, 990 F.3d 455, 457 (6th Cir. 2021) ("[E]ven well-developed arguments raised for the first time in a reply brief come too late."); *Uncommon, LLC v. Spigen, Inc*., 926 F.3d 409, 419 n.2 (7th Cir. 2019) ("As briefed, the argument is terse, free of legal citation, and vague. It is therefore waived."); *Barna v. Bd. of Sch. Dirs. of Panther Valley Sch. Dist*., 877 F.3d 136, 145 (3rd Cir. 2017) ("[W]e have consistently refused to consider ill-developed arguments or those not properly raised and discussed in the appellate briefing.").

HNI supplied Dr. Shell with a product labeled as a "compounded drug," and "not FDA approved." AB1 1309 (bottle and label). Nothing in HISA's rules or Dr. Scollay's 2023 presentations to educate industry participants on the new ADMC Program contradicted that description of Hemo 15, or otherwise identified Hemo 15 as either a vitamin or a substance that was permissible to use. AB2 108-09 (Scollay); AB1 1308, 1310, at ¶¶ 5, 7 (Scollay wit. state.). Dr. Shell attended one of these presentations, and he admits Dr. Scollay never said Hemo 15 was a vitamin. AB2 209, 289-90 (Shell); *see also* AB2 109 (never said "Hemo 15 is a vitamin"), 165-66 (Scollay) ("I never discussed it."). Dr. Scollay did say, during her presentations, that the FDA does not approve vitamins, dietary supplements, and the like. *See* ARBr. 3; AB1 1308, at ¶ 5, 1312, at ¶ 15 (Scollay wit. state.); AB2 108-09, 161-64 (Scollay). But that did not entitle Dr. Shell to ignore multiple "drug" descriptions on HNI's product label for Hemo 15. Just the opposite, at her presentations Dr. Scollay emphasized that veterinarians should "become label readers"—an admonition that Dr. Shell failed to heed. AB1 1312, at ¶ 14 (Scollay wit. state.).

Thus, neither the Authority nor HIWU said or did anything that could form the basis for estoppel. *See, e.g., Ohio State Bd. of Pharmacy v. Frantz*, 555 N.E.2d 630, 633 (Ohio 1990) ("The board cannot be estopped from its duty to protect the public welfare because it did not bring a disciplinary action as expeditiously as possible . . . . To hold otherwise would be to grant defendants a right to violate the law."). *Cf. Heckler v. Community Health Services*, 467 U.S. 51, 60 (1984) (If estoppel were to disable enforcement of law, "the interest of the citizenry as a whole in obedience to the rule of law is undermined.").

2. There Is No Due Process Violation

Dr. Shell argues that, because Hemo 15 is not included on HISA's list of Banned Substances, HISA Rule 4111's "catch all" language, along with its GFI 256 carve-out, fail to give

adequate notice that injecting Hemo 15 could amount to an ADRV. This lack of notice, he contends, violates the Fifth Amendment's Due Process protection and otherwise invalidates the Rule as "arbitrary and capricious." AOBr. 7-11. The Arbitrator declined to reach the Due Process argument as "one that is not properly before this Arbitrator . . . ." AB1 43-44, at ¶ 8.21. However, the Arbitrator also ruled that the absence of any other veterinarian being charged with a Hemo 15-based ADRV demonstrated that "Covered Persons of ordinary intelligence" could understand HISA Rule 4111's operation, thus precluding finding that lack of notice invalidated the Rule as "arbitrary and capricious…." AB1 44, at ¶ 8.22.

The Authority relies on the Arbitrator's rejection of authority to address Dr. Shell's Due Process argument, while responding briefly to the connected arbitrary and capricious point. AuOBr. 11; AuRBr. 6-7. However, the statute, and the HISA and FTC Rules require due process in *de novo* review proceedings. 15 U.S.C. §§ 3057(c)(3), 3058(b)(2)(B) (importing Administrative Procedure Act requirements in 5 U.S.C. § 556); HISA Rule 3122(e); FTC Rule 1.146(c)(1)(ii). In consequence, the Arbitrator's expressed limitation on his own authority does not resolve Dr. Shell's arguments on review, which fail on the merits, however.

First, prior to the ADMC Program taking effect in May 2023, a few veterinarians other than Dr. Shell administered Hemo 15 to horses. But none continued to do so from May 2023 onward. AB1 1359, at ¶¶ 5-6 (Stormer wit. state.), 1367-71 (pre-May 2023 entries). Perhaps some of the others surreptitiously, and in violation of ADMC Program Rules, continued to use Hemo 15, but failed to report its use, or mis-labeled the substance administered in their reports. AB1 16 (Mollica opening). But that all of them did so is not nearly as plausible as the inference—reflected in the Arbitrator's finding—that Veterinarians understood Hemo 15 had

become a prohibited drug. Notice to racetrack Veterinarians was sufficient. This inference, based on "before and after" data, is not mere speculation. *See* AOBr. 10; ARBr. 2, 3.

This evidence, along with abundant other evidence, detailed below, satisfies me that Dr. Shell had ample notice Hemo 15 could not simply be assumed to be a vitamin, and that a reasonably prudent Veterinarian subject to HISA would recognize a need for further inquiry—all the more so for Dr. Shell, who attended a Scollay presentation. *See* AB1 1326 (slide listing Banned Substances categorization, including the S0 catch-all); AB2 99-102 (presentations included substance "stratification," including S0). As applied in this case, HISA Rule 4111 passes constitutional muster.

To satisfy the Constitution's Due Process requirement of fair notice, a regulation must be "reasonably comprehensible to people acting in good faith." *MobileTel, Inc. v. FCC*, 107 F.3d 888, 896 (D.C. Cir. 1997) (cleaned up); *see also, e.g., United States v. Ancient Coin Collectors Guild*, 899 F.3d 295, 321-22 (4th Cir. 2018). This inquiry includes examining "the particular situation of the defendant," and whether, as one to whom the regulation is directed, "it lacked reasonable notice." *Gen. Elec. Co. v. Envtl. Prot. Agency*, 53 F.3d 1324, 1330 (D.C. Cir. 1995). "Words or phrases having a technical or other special meaning" may be "well enough known to enable those within its reach to correctly apply them." *United States v. Weitzenhoff*, 35 F.3d 1275, 1289 (9th Cir. 1993) (cleaned up). Thus, the understanding and practice among those subject to regulation are relevant considerations. *See, e.g., Ohio Cast Prods., Inc. v. Occupational Safety & Health Review Comn'n*, 246 F.3d 791, 799 (6th Cir. 2001).

Horseracing "is a heavily regulated activity . . . ; and it has an unsavory, or at least a shadowed reputation, growing out of a long history of fixing, cheating, doping of horses, illegal

gambling, and other corrupt practices." *Dimeo v. Griffin*, 943 F.2d 679, 681 (7th Cir. 1991) (en banc) (Posner, C.J.). State regulations, prohibiting in general terms administering substances to horses, have long-existed.[14] For private bodies regulating equine sport, a catch-all provision such as HISA Rule 4111, designed to extend prohibition beyond the list of identified banned substances, is similarly commonplace.

HISA Rule 4111 itself closely parallels a British Horseracing Authority ("BHA") rule on Non-Approved Substances:

> 6. Any substance not addressed by any of the other classes of substances, and which has no current approval by any government regulatory authority for veterinary use, or any substance not universally recognised by veterinary regulatory authorities as valid veterinary therapeutic treatment.

BHA Rules of Racing, Code 19 (Prohibited List Code), at ¶ 6 (July 1, 2024).

The Fédération Equestre Internationale ("FEI") rules similarly prohibit use of not only listed substances, but also ones that have "a similar chemical structure or biological effect." FEI Equine Anti-Doping and Controlled Medication Regulations, Appendix 1, at 94 (3rd ed. 2023) (defining the "Equine Prohibited Substances List" to include "[s]ubstances with the same biological or chemical effect as a Prohibited Substance . . . , even if they are not specifically listed by name"); *see also* BHA Rules of Racing, Code 19, at ¶ 5 (Non-approved substances

[14] *See, e.g., Hubel v. West Virginia Racing Comm'n,* 513 F.2d 240, 241 n.1 (4th Cir. 1975) (state law prohibiting "any narcotic, stimulant, depressant, or local anesthetic"); *Suarez v. Administrador Del Deporte Hipico de Puerto Rico*, 354 F. Supp. 320, 322 n.1 (D.P.R. 1972) (Territorial law prohibited "any drug or substance that stimulates, depresses or alters the natural condition of the horse."); *DeGroot v. Arizona Racing Comm'n*, 686 P.2d 1301, 1311 (Ariz. Ct. App. 1984) (State law prohibited administering "any drug, medicine or other substance foreign to the horse's . . . body which does or could affect the racing condition of a horse . . . includ[ing] but . . . not limited to stimulants, depressants, local anesthetics, narcotics and analgesics."); *Vitale v. State Racing Comm'n*, 433 N.E.2d 914, 915 (Mass. App. Ct. 1982) (State law prohibited administering any drug to a horse "for the purpose of retarding, stimulating or in any other manner affecting . . . (its) speed") (parenthetical in original); *State v. Baldwin*, 31 So. 2d 627, 629 (Fla. 1947) (State law prohibited "administer[ing] . . . to any horse . . . any stimulant, depressant, hypnotic or narcotic drug, of any kind or description . . . .").

include "Other substances with a similar chemical structure or similar biological effect to those set out in paragraphs 1 to 4 above."); Australian Rules of Racing, AR 2, at 20 (2024) ("Prohibited substance" means "a substance specified in these Australian Rules to be a prohibited substance, or which falls within any of the groups or categories of substances specified in these Australian Rules to be prohibited substances, unless it is specifically exempted."); *Ali Alabbar v. FEI*, CAS 2013/A/3124, at ¶ 3.7 (Sept. 27, 2013) (DHEA, while "not specifically listed," is prohibited); *Deutsche Reiterliche Vereinigung e.V. v. FEI*, CAS 2008/A/1700, 1710, at ¶¶ 83, 87 (Apr. 30, 2009) (FEI rule prohibiting, among other substances, "[a]gents, cocktails or mixtures of substances that may affect the performance of a horse; masking agents; substances with no generally accepted medical use in competition horses; substances which are usually products prescribed for use in humans or other species; agents used to hypersensitise or desensitise the limbs or body parts," including, although not named capsaicin).

In the sports world generally, this same approach to substance prohibition is pervasive. As the Panel in *Carter v. International Olympic Committee (IOC)* noted: "There is a great number of stimulants, and they cannot all be listed by name. Therefore, the list of prohibited stimulants provides a list of named stimulants, which are typically the ones often detected, as well as a 'hold all basket'." CAS 2017/A/4984, at ¶ 152 (May 31, 2018). The decision in *Bastianelli v. Comitato Olimpico Nazionale Italiano (CONI*) is similar:

> [T]here is a significant record of CAS tribunals finding athletes to have committed doping offences based on positive tests resulting from substances not included on the Prohibited List. The rationale for these decisions is clear: failing to prohibit substances with a similar chemical structure or biological effect to those already included in the Prohibited List would hinder the fight against doping in sports and detract from the unequivocal warning set out in the Introduction to the WADA Code: "Doping is fundamentally contrary to the spirit of sport."

CAS 2008/A/1712, 1742, at ¶ 18 (May 29, 2009) (footnote citing decisions omitted).[15]

As these rulings reflect, "[t]he fight against doping is arduous . . . ." *USA Shooting v. Union Internationale de Tir (UIT)*, CAS 94/129, at ¶ 34 (May 23, 1995). Hemo 15 in particular is strongly disfavored for use in race horses. Readily available industry understanding and practice, included in the evidence in this case, inform the fair notice analysis of HISA Rule 4111. Yet, Dr. Shell seemingly was oblivious to the storm warnings swirling around Hemo 15. For example:

(1) There is no approval or registration of Hemo 15 with the FDA in the United States, while registration in other countries has declined. AB2 336 (Maxwell); AB1 408, at ¶ 15 (Maxwell rep.: "Hemo 15 is no longer marketed and produced for the Canadian and Australian veterinary markets, where it is no longer registered.").

(2) Versions of Hemo 15 offered abroad were and currently are registered as a drug. AB2 336 (Maxwell); AB1 1281, at ¶ 6 (Maxwell R-rep.: "[T]he foreign product sold in other countries as Hemo-15® was formerly or is currently registered as a pharmaceutical agent, with standard drug labels in multiple countries, such as Australia, Canada, and Italy."); AB2 443-45 (Bertone) (Shown a website stating "buy Hemo 15 online," "used to treat animal suffering from anaplasmosis and babesiosis," Dr. Bertone testified the substance makes claims that, if "marketed in the US, . . . would be considered a drug.").

(3) Online websites offering Hemo 15 are obviously disreputable—requiring payment abroad via Western Union or using Bitcoin, and touting improved racing performance in camels,

[15] *See also Wawrzyniak v. Hellenic Football Federation (HFF)*, CAS 2009/A/2019, ¶ 25 (May 21, 2010) (Although not explicitly prohibited, "Methylhexaneamine must be considered as a prohibited substance similar to the Tuaminoheptane, a specified prohibited stimulant specifically mentioned in the 2008 Prohibited List."); *IAAF v. RFEA & Onyia*, CAS 2009/A/1805, 1847, at ¶ 56 (Sept. 22, 2009) ("[N]ot only are the stimulants specifically listed . . . prohibited, but so are all related substances with a similar chemical structure or similar biological effect(s)."); *M. v. IOC*, CAS 2002/A/374, at ¶ 15 (Jan. 24, 2003) (Although not expressly identified, under the catch-all classification, aranesp "is an analogue and mimetic of a Prohibited Substance."); *L v. IOC*, CAS 2002/A/370, at ¶ 8 (Nov. 29, 2002) ("Although darbepoetin is not specifically listed as a prohibited substance . . . it is an analogue or mimetic of erythropoietin.").

for example. AB1 1051-53 (websites), 1282-84, at ¶¶ 7-8 (Maxwell R-rep.); AB2 309-12 (Maxwell).

(4) Dr. Scollay's pre-HISA launch presentations, referred to earlier, discussed the S0 classification for non-approved substances, embraced in HISA Rule 4111, as well as FDA treatment of compounded drugs. AB2 101-06 (Scollay); AB1 1326, 1327 (slides regarding S0 classification and compounded substances). Dr. Shell attended one of Dr. Scollay's 2023 presentations. AB2 209 (Shell). He also received from HNI a product described as a "compounded drug." AB1 1309 (bottle and label). A reasonably prudent Veterinarian would have inquired, regardless of how long he had used Hemo 15. Dr. Shell made no such inquiry. *See* AB2 336 (Maxwell) (Dr. Shell's failure to secure written advice from HISA indicates lack of prudence as a veterinarian); AB1 1288, at ¶ 17(e) (Maxwell R-rep.).

Moreover, Dr. Shell testified that he never (a) "Googled Hemo 15," (b) "read any news articles on the internet" about it, (c) "came across any information about doping allegations involving Hemo 15 in other jurisdictions," or (d) navigated to the websites offering Hemo 15 that his own counsel identified in the case. AB2 270-73 (Shell). While implausible, in all events Dr. Shell's testimony demonstrates his failure to exercise due diligence as a practicing horserace industry veterinarian subject to state regulation, pre-HISA, and, to the Authority's Rules, once effective.

Readily accessible online websites report horseracing violations and highlight risks associated with Hemo 15. AB2 336 (Maxwell); *see also* AB1 1288, at ¶ 17(c) (Maxwell R-rep.); AB2 441, 443, 446 (Bertone). Again, to illustrate:

- Hemo 15, a possible source of cobalt, "is a prescription only veterinary medicine which is not licensed for use in the UK but may be imported into the UK and used by veterinarians under licence."

  - BHA, John Ryan (Oct. 24, 2022), https://judicialpanel.britishhorseracing.com/results/result/?id=2301.

- "Hemo-15, which is not licensed for use in horses in the U.K., may be prescribed by veterinary surgeons under the 'Cascade' legislation. Cobalt is a threshold substance prohibited on raceday by the Rules of Racing at a concentration exceeding 0.01 micrograms total cobalt per millilitre in urine. It is possible that exposure to significantly increased levels of cobalt may have welfare implications for the horse."

  - Rebecca Bastiman, Robin Bastiman (Aug. 28, 2018) (Sanctions for injection of Hemo 15 imposed), https://judicialpanel.britishhorseracing.com/results/result/?id=1794.

- "[A]mong the products seized in the raid were Hemo-15 and DMSO . . . . Compared to similar products which are authorized in France, Hemo 15 is very highly dosed in cobalt. The administration of cobalt in such doses is believe[d] to stimulate erythropoiesis, i.e. the formation of red blood cells in the bone marrow."

  - Thoroughbred Daily News, Three Indicted in French Doping Investigation (Mar. 25, 2022) (internal quotation marks omitted), https://www.thoroughbreddailynews.com/three-indicted-in-french-doping-investigation/.

- "There are four injectable veterinary products that have been either previously or currently registered and/or available for use in horses that contain cobalt salts.

  - Hemo-15 Vitamin-Amino Acid Injection."

  - Racing Queensland, Ban on injectable products containing cobalt salts (May 4, 2021), https://www.racingqueensland.com.au/news/2021/05-may/ban-on-injectable-products-containing-cobalt-salts.

- "The unlicensed substances to which the vet pleaded guilty to having in his possession were . . . Hemo 15, a supplement that contains cobalt, a naturally occurring trace mineral for which there are established thresholds."

  - Racing Medication & Testing Consortium, Racing vet facing fitness hearing after pleading guilty over remedies (Nov. 15, 2017), https://rmtcnet.com/racing-vet-facing-fitness-hearing-pleading-guilty-remedies-racing-post-11-15-17/.

- "Stephen McConville, the trainer of Anseanachai Cliste, and his son Michael, who was due to ride the 33-1 outsider at Cheltenham, injected the horse with Hemo 15, a compound containing the banned substance cobalt . . . ."

- The Guardian, McConvilles given three-year bans after injecting horse at Cheltenham (Sept. 19, 2017), https://www.theguardian.com/sport/2017/sep/19/mcconvilles-three-year-doping-ban-cheltenham-anseanachai-cliste.

Recognizing the horseracing law context, HISA Rule 4111's contents are not vague. Indeed, none of the witnesses here disputed that subparts (i) and (ii) applied to Hemo 15. While Dr. Shell disputed subpart (iii)'s applicability, identifying "veterinary regulatory authorities" that recognize Hemo 15 as "a valid veterinary use"—if such bodies exist—should not be arduous, nor subject to uncertain interpretation. Yet, the evidence of veterinary regulatory recognition, noted earlier, is nowhere near universal. The carve-out for using compounded substances similarly is adequately specified by the FDA. Dr. Shell offered no evidence Veterinarians regard the FDA's guidance to be inadequate.

Dr. Shell's professed claim to have lacked fair notice is toothless. Moreover, none of the Due Process authorities he relies on arise from fact settings related to the rules addressing use of drugs and other substances in the horseracing industry, or in the sports world generally. By contrast, well-established industry context demonstrates fair notice to horseracing veterinarians, among other industry participants.

Finally, the disagreement among experts here concerning Hemo 15 does not amount to a Due Process violation. *See* AOBr. 8, 9-10; ARBr. 3-4. If that were the test, few laws would survive—and so, it is not. *See, e.g.*, *United States v. Long*, 15 F. Supp. 3d 936, 942 (D.S.D. 2014) (Analogue Act, reaching pharmaceutical analogs to scheduled substances, was not unconstitutional despite expert disagreement over the similarity of substances.); *see also United States v. Williams*, 106 F.4th 639, 651-53 (7th Cir. 2024) and *United States v. Galecki*, 89 F.4th 713, 730-33 (9th Cir. 2023) (Analogue Act does not violate Due Process).

HISA Rule 4111, as applied to Hemo 15, is not unconstitutional. The existence of adequate notice similarly precludes finding imposition of liability under the Rule either arbitrary or capricious. Dr. Shell's contention that HISA Rule 4111 is itself arbitrary and capricious is not a ground for review under either 15 U.S.C. § 3058(b)(2)(A) or FTC Rule 1.146(b)(1)-(3).

3. Prosecution of this Case by the Authority and HIWU is Not Unconstitutional

Relying on the Fifth Circuit's decision in *Nat'l Horsemen's Benevolent and Protective Ass'n v. Black,* 107 F.4th 415 (5th Cir. 2024), Dr. Shell argues that HIWU's enforcement proceeding here violates the private nondelegation doctrine and thus is unconstitutional. AOBr. 11-12. The Sixth Circuit, however, rejected this same argument and upheld HISA's constitutionality, as did an Eighth Circuit majority in a recent decision affirming denial of a preliminary injunction. *Oklahoma v. United States*, 62 F.4th 221 (6th Cir. 2023), *cert. denied*, 144 S. Ct. 2679 (2024); *Walmsley v. FTC*, 117 F.4th 1032 (8th Cir. 2024).

The Authority maintains that this argument, too, is "outside the scope" of this proceeding. AuRBr. 7. I reject the Authority's position. An FTC ALJ reviewing the Authority and HIWU's enforcement activity may appropriately consider the possible impact of federal courts of appeals rulings dealing with whether these two entities may, consistent with the Constitution, prosecute and discipline Dr. Shell at all. *See* 15 U.S.C. § 3057(c)(3); HISA Rule 3122(e); FTC Rule 1.146(c)(1)(ii) (ALJ review authority extends to due process protection).

Although Dr. Shell contends that *National Horsemen's* is the "better reasoned" decision, the Sixth Circuit's ruling applies to this case. AOBr. 12. The Sixth Circuit's geographic scope includes Ohio, and Dr. Shell is himself an Ohio-based and licensed veterinarian, whose practice

is concentrated in Northeast Ohio. AB1 1043, at ¶ 1 (Shell wit. state.); AB2 199, 207 (Shell). The Hemo 15 giving rise to this case was found during HIWU's search of a truck at JACK Thistledown Race Track, located near Cleveland, Ohio. APFOF ¶ 2; AB1 155 (EAD Notice); AB2 7 (Shell opening). The truck, registered to Dr. Shell, bore an Ohio tag number. AB1 155 (EAD Notice). The horses receiving Hemo 15 injections were overwhelmingly stabled at racetracks in Ohio, Kentucky, and Michigan, all states within the Sixth Circuit. AB1 292-402. Thus, the contacts with the Sixth Circuit are clear. By contrast, this case has no apparent connection to horseracing within the states covered by the Fifth Circuit.

The "presumption of constitutionality" instructs that a federal law may be invalidated "only upon a plain showing that Congress has exceeded its constitutional bounds." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *see also Turner Broadcasting System, Inc. v. FCC*, 507 U.S. 1301, 1301 (1993) (A federal statute "is presumptively constitutional.") (Rehnquist, C.J., in chambers). Bearing in mind both the presumption and the particular facts here, I follow the Sixth Circuit's ruling upholding the Authority and HIWU's authority. Thus, Dr. Shell's argument fails.

D. Sanctions

Dr. Shell asserts that he is "faultless" and that, therefore, the sanctions imposed are arbitrary and capricious. AOBr. 11. The Authority describes the Arbitrator's sanctions rulings as "unusual," but urges that they be "affirmed" nonetheless. AuOBr. 20. I find the Arbitrator's rulings too vulnerable to uphold on the Arbitrator's stated rationale. However, I conclude that the sanction award is appropriate for other reasons.

1. Sanction Elimination or Reduction Under the HISA Rules

Since the two principal bases for eliminating or mitigating the ADRVs proven against Dr. Shell underlie reviewing the sanctions imposed, I set forth the pertinent parts the Rules, covering: (1) eliminating sanctions under No Fault or Negligence (NF) analysis; and (2) reducing sanctions under No Significant Fault or Negligence (NSF) analysis. HISA Rules 3224 and 3225.

The HISA Rules define "No Fault or Negligence" as requiring the Covered Person to establish 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 . . . a Banned Substance . . . , or that he or she had . . . otherwise committed an Anti-Doping Rule Violation. . . ." HISA Rule 1020. Under HISA Rule 3224(b), a NF finding "only applies in exceptional circumstances."

The stringent "utmost caution" standard required to show NF is relaxed when the defense raised is NSF. NSF requires the Covered Person to establish 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 . . . ." HISA Rule 1020 (emphasis added). As one leading decision notes, "a claim of NSF is (by definition) consistent with the existence of some degree of fault and cannot be excluded simply because the athlete left some 'stones unturned'. . . . To find otherwise would render the NSF provision . . . meaningless." *Sharapova v. International Tennis Federation (ITF),* CAS 2016/A/4643, at ¶ 84 (Sept. 30, 2016); *see also Ali Alabbar*, CAS 2013/A/3124, at ¶ 12.17(1).

2. The Arbitrator's Sanctions Rulings

The Arbitrator divided HIWU's charge of 228 injections into "the first ADRV" and the "remaining 227 violations." AB1 46, at ¶ 8.30. The Arbitrator held that, in making his first injection of Hemo 15 after the ADMC Program became effective in May 2023, 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.

AB1 46, at ¶ 8.30. The Arbitrator thus rejected Dr. Shell's NSF argument, which also necessarily precluded Dr. Shell from satisfying the even more rigorous NF requirements.

For this first ADRV, the Arbitrator directed a two-year period of Ineligibility and $25,000 fine, both the maximums under HISA Rule 3223(b). The Arbitrator further required Dr. Shell to pay $10,000 in adjudicative costs. AB1 46, at ¶¶ 8.31, 47-48, at ¶ 9.1(a)-(c); HISA Rule 3223(b) (authorizing payment of "some or all of the adjudicative costs and the Agency's legal costs").

As I have detailed above, rejection of Dr. Shell's NSF argument is fully warranted on the facts. *See, e.g., Ali Alabbar*, CAS 2013/A/3124, at ¶ 12.38 (NSF rejected where "the very words

and phrases used to market the Supplement set the red flags waving," and the owner-trainer failed to "do an internet search . . . , which would have instructed him that the Supplement did contain a prohibited substance"); *Carriere Zwei, FEI Tribunal Decision*, Case No. 2007/08, at ¶ 4.1x (Aug. 10, 2007) (despite assurances of stable veterinarian that supplement with a "suspicious name" would not increase testosterone level, horse rider "acted with gross negligence and disregard to the risks" by not "receiving written advices from renowned veterinarians").

On the remaining 227 injections of Hemo 15—each of which similarly authorized maximums of a two-year period of Ineligibility and a $25,000 fine—HIWU sought "significant" sanctions. AB1 46, at ¶ 8.32. Although the Arbitrator found these remaining 227 injections were ADRVs, he ruled that "Dr. Shell is not at Fault" due to the following "exceptional circumstances":

> (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.

AB1 47, at ¶¶ 8.33- 8.34.

The Arbitrator further wrote that, in charging and seeking "significant" penalties for each of Dr. Shell's 228 Hemo 15 injections, HIWU sought "disproportionate and excessive" sanctions. AB1 148, at ¶ 8.32. Thus, to order multiple additional sanctions "would not be an accurate reflection of the unique circumstances of this case . . . ." AB1 46, at ¶ 8.32. Based on this NF finding, the Arbitrator awarded no additional sanctions for the remaining 227 ADRVs. AB1 at 46-47, at ¶¶ 8.33, 48, at ¶ 9.1(d).

Dr. Shell challenges as "illogical" the Arbitrator's ruling awarding maximum sanctions on the first Hemo 15 injection. AOBr. 10. Just as the Arbitrator found NF on the remaining 227 injections, so too, Dr. Shell contends, "he is faultless for the first administration because he had no notice Hemo 15 was banned." AOBr. 10 (emphasis deleted); ARBr. 6. Thus, the Arbitrator's failure to find NF for the first injection, Dr. Shell argues, is "arbitrary and capricious." AOBr.10-11; ARBr. 6-7. There is illogic here, but it will not support Dr. Shell's argument that he is "faultless." *See* AOBr. 11; ARBr. 2, 6, 7. The Arbitrator's reasoning leading to his NF ruling on the 227 injections fails to withstand *de novo* review for other reasons.

The facts the Arbitrator relied on in rejecting NF for Dr. Shell's initial Hemo 15 injection did not change once Dr. Shell made that first injection. Quite the opposite: they apply equally to the other 227 injections and should, therefore, have precluded finding this an "extreme and exceptional case" for NF purposes. *See* AB1 46, 47, at ¶¶ 8.30, 8.34. In finding NF for the 227 injections, the Arbitrator faulted HIWU for not detecting Dr. Shell's use of Hemo 15 earlier. In the Arbitrator's view, despite no affirmative expression of approval, by its inaction HIWU essentially lulled Dr. Shell into a false sense of security that it was okay for him to continue injecting Hemo 15 into horses. *See* AB1 46-47, at ¶¶ 8.33- 8.34.

However, by blaming HIWU for taking roughly six months to act on the Hemo 15 entries Dr. Shell reported, the Arbitrator failed to appreciate HISA Rule 4111's industry context and misapplied the evidence. "There are," Dr. Scollay testified, "many things that are not on the [Banned Substance] list . . . ." AB2 177 (Scollay). HISA Rule 4111's catch-all exists for that very reason: "[t]here is a great number of stimulants, and they cannot all be listed by name." *Carter*, CAS 2017/A/4984, at ¶ 152. Not only are stimulants "numerous," but "new stimulants can easily be developed." *Id.* at ¶ 67; *see also RFEA & Onyia*, CAS 2009/A/1805, 1847, at ¶ 91 ("It would be impractical to cite all stimulants because of the large numbers of compounds available on the market. Further, an open list allows the inclusion of those designer drugs created only for doping purposes.").

In view of the numerous substances potentially subject to the catch-all, HIWU cannot be expected to be on the lookout for any particular substance among the "[l]iterally hundreds of thousands of records" entered by Veterinarians on a continuous basis in the Authority's database. AB2 34 (Stormer). Until you know there's a needle to look for, no one would expect you to hunt through the haystack. HIWU's seizure of Hemo 15 from Dr. Shell's van in October 2023 identified the needle that enabled HIWU to do a focused database search.

In addition to misapplying the evidence, the Arbitrator's NF ruling on the remaining 227 injections is inconsistent with his finding that Dr. Shell's estoppel defense was meritless—a holding that I agree with. Rejecting estoppel, the Arbitrator found, correctly, that: (1) "there was no misrepresentation by Dr. Scollay regarding the categorization of Hemo 15"; (2) "at no time did the Agency [HIWU] take a contradictory position regarding the application of the ADMC program"; and (3) "[t]here 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." AB1 43, at ¶¶ 8.18-8.19. Dr. Shell, however, "never altered his practice, 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." AB1 43, at ¶ 8.18. Instead, by continuing to inject Hemo 15 into horses, Dr. Shell committed one ADRV after another.

Under HISA Rules 1020 and 3224, NF requires that Dr. Shell "not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she administered to the Covered Horse . . . a Banned Substance . . . ." The facts detailed above establish his inability to satisfy this standard. And while Dr. Shell may not have sought to "cheat," and may subjectively have believed injecting Hemo 15 was permitted, such facts are insufficient to show the "exceptional circumstances" required for a NF finding under HISA Rule 3224(b). *See, e.g., International Ski Federation (FIS) v. Johaug*, CAS 2017/A/5015, at ¶¶ 180-83,185, 192-94, 201-02, 206 (Aug. 21, 2017) (Although the athlete followed a doctor's advice to treat lip sores with a product that included a prohibited substance and had no intent to improve performance, by failing to make "even a cursory check of the label" or to do "a simple internet search," the athlete did not exercise the utmost caution required for NF.); *Baxter v. IOC*, CAS 2002/A/376, at ¶ 3.33 (Oct. 15, 2002) (By failing to read the package label or to consult his team doctor before using a Vicks inhaler that included a prohibited substance, a "sincere and honest" athlete committed a doping violation.). *Cf. In re Perez*, FTC No. 9420 at 9 (ALJ Decision on Application for Review, Feb. 7, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/609612_d09420-administrative_law_judge_decision_on_application_for_review_-_public.pdf (Veterinarian's lack of wrongful intent in continuing to possess a Banned Substance did not

satisfy "compelling justification" required to negate a HISA Rule 3214 possession violation), *review denied*, 2024 WL 3824065 (F.T.C. Aug. 8, 2024).

On the facts of this case, Dr. Shell simply cannot satisfy the requirements of the NF defense. Therefore, I find, based on my *de novo* review, that neither elimination nor reduction of sanctions on the basis of NF or NSF is available to Dr. Shell.

That said, the Arbitrator had the right idea in mind in recognizing that awarding sanctions for each ADRV would be disproportionately punitive on the facts of this case. "[I]t is a widely accepted general principle of sports law that the severity of a penalty must be in proportion with the seriousness of the infringement." *W. v. FEI*, CAS 99/A/246, at ¶ 31 (May 11, 2000). "[T]he substance and the possible application of the [proportionality] principle are not in doubt." *Klein v. Australian Sports Anti-Doping Authority (ASADA) and Athletics Australia (AA)*, CAS A4/2016, at ¶ 232 (May 25, 2017).[16]

The Authority, however, obviates any need for me to apply the proportionality principle to appropriately deal with all of Dr. Shell's ADRVs. The Authority asserts that, "consider[ing] the unusual circumstances of this case," the Arbitrator's sanctions award should be "affirmed." AuOBr. 19-20; AuPFOF ¶ 17.

In light of this concession, even though Dr. Shell failed to prove either NF or NSF for any of his ADRVs, I adopt the sanctions award from the arbitration. But my doing so covers all the

[16] *See also Sport Lisboa e Benfica SAD v. Federation Internationale de Football Association (FIFA)*, CAS 2021/A/8076, at ¶ 131 (Oct. 10, 2022) (reducing a "manifestly disproportionate" sanction); *I. v. Federation Internationale de l'Automobile (FIA)*, CAS 2010/A/2268, at ¶¶ 133-43 (Sept. 15, 2011) (discussing arbitration proportionality rulings); *Puerta v. ITF*, CAS 2006/A/1025, at ¶ 88 (July 12, 2006) ("[T]he war against doping . . . is a hard war, and to fight it requires eternal vigilance, but no matter how hard the war, it is incumbent on those who wage it to avoid, so far as is possible, exacting unjust and disproportionate retribution.").

228 ADRVs, not just the first one. *See* 15 U.S.C. § 3058(b)(3)(A)(iii), and FTC Rule 1.146(d)(3) (the ALJ "may make any finding or conclusion that, in . . . [my] judgment . . . is proper and based on the record.").[17]

III. CONCLUSION

Shell injected a Banned Substance into 37 Covered Horses 228 times in violation of HISA Rules 3214(c) and 4111. Except as to finding NF for the 227 injections, (a) the Arbitrator's Decision does not reveal any "plain error," *Nat'l Marine Fisheries Serv.*, 422 F.3d at 798; and (b) the Arbitrator "acted within a zone of reasonableness . . . , reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. Accordingly, the sanctions of: (1) a two-year period of Ineligibility; (2) a $25,000 fine payable by Dr. Shell; and (3) a $10,000 contribution by Dr. Shell towards HIWU's adjudication costs are **AFFIRMED**.

ORDERED:

Jay L. Himes
Jay L. Himes
Administrative Law Judge

Date: October 31, 2024

[17] There may be tension between the Authority's position here on sanctions and HIWU's assertion, in charging and prosecuting Dr. Shell, that it "ha[d] no discretion" under HISA Rule 3228(c)(1) but to "treat[]" each injection "as a separate anti-doping violation. . . ." AB2 538 (closing statement); AB1 230, 242, 244 (prehearing brief), 272 (EAD Notice); AuOBr 7. In light of the Authority's concession, I express no opinion on HIWU's prior position.