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.