No. 23-402

IN THE

Supreme Court of the United States

STATE OF OKLAHOMA, ET AL.,
Petitioners,

v.

UNITED STATES OF AMERICA, ET AL.,
Respondents.

On Petition for a Writ of Certiorari To The United States Court of Appeals For The Sixth Circuit

BRIEF OF THE NORTH AMERICAN ASSOCIATION OF RACETRACK VETERINARIANS (NAARV) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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I. STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus, the North American Association of Racetrack Veterinarians (NAARV)[1], is a professional association of licensed veterinarians specializing in the treatment, health, and welfare of the racehorse. It is a Kentucky based 501(c)(6) non-profit organization established in 2015 dedicated to advancing the health and welfare of the racehorse through evidence-based medicine and the continuing education of the professionals and public involved with the sport. It is the only trade organization that is comprised solely of veterinarians charged with the health and welfare of the equine racing athlete. NAARV represents racetrack veterinary practitioners in all horseracing jurisdictions which are licensed by both state veterinarian licensing agencies as well as state racing commissions and regulators.

NAARV has an interest in this case because its members are "covered persons" pursuant to 15 U.S.C. § 3051(6) that defines "covered persons" as:

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[1] No counsel for a party authored this brief in whole or in part, and no entity or person other than the North American Association of Racetrack Veterinarians (NAARV), its members, its counsel, and Bluestone Farms, LLC, made a monetary contribution intended to fund the preparation or submission of this brief.
Counsel of record for all parties received notice of NAARV's intent to file this brief at least 10 days before its due date pursuant to and in compliance with this Court's Rule 37.2.

> "…all trainers, owners, breeders, jockeys, racetracks, veterinarians, persons (legal and natural) licensed by a State racing commission and the agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training or racing of covered horses."

All racetrack veterinarians are licensed by the State and the Horse Racing Commission of the State. Accordingly, all racetrack veterinarians are directly affected by the defects of the HISA legislation. NAARV is further affected in that its mission of ensuring the health and well-being of the racehorse through the protection and improvement of the veterinary care of the equine athlete is undermined by the limitations of the HISA legislation upon its members and their goal of ensuring the welfare of the equine athlete.

All NAARV veterinarians are bound by the Veterinarian's Oath of the American Veterinary Medical Association as well as state laws applicable to the veterinarian's state license, such as the Code of Ethical Conduct in 201 Kentucky Administrative Regulations 16.500 under the Kentucky Board of Veterinary Examiners.

The Veterinarian's Oath states and obligates all NAARV members to:

> "Being admitted to the profession of veterinary medicine, I solemnly swear to

> use my scientific knowledge and skills for the benefit of society through the protection of animal health and welfare, the prevention and relief of animal suffering, the conservation of animal resources, the promotion of public health, and the advancement of medical knowledge. I will practice my profession conscientiously, with dignity, and in keeping with the principles of veterinary medical ethics. I accept as a lifelong obligation the continual improvement of my professional knowledge and competence." Veterinarian's Oath[2], American Veterinary Medical Association, (2023).

The enactment of the Anti-Doping Medical Control (ADMC) Rules portion of HISA, which became effective on May 22, 2023, severely curtails the racetrack veterinarian's ability to competently care for the equine athlete. These rules place NAARV members in the ethical dilemma of either treating the equine patient appropriately and risk not only themselves, but the horses, trainer, and owner running afoul of the subject regulations or, alternatively, treating the equine patient in a substandard matter in violation of their own Veterinarian's Oath.

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[2] Available at https://www.avma.org/resources-tools/avma-policies/veterinarians-oath. (Last visited November 14, 2023)

In reviewing HISA, it is appropriate for the court to evaluate how its statutory scheme actually works. In doing so, the court can then assess whether the practical consequences of the HISA Authority's interpretation of the statute indicates that it is being interpreted in a manner that aligns with the purpose of HISA. See *Schwegmann Bros. v. Calbert Distillers Corp. 341 U.S. 384 (1951).*

An amicus brief is, therefore, desirable for the Court to hear from this organization and its concerns about the safety and well-being of Thoroughbred racehorses in America, and the extent to which the unconstitutional nature of HISA impairs the profession of racetrack veterinarians.

II SUMMARY OF ARGUMENT

Despite its claim to promote the integrity and safety of horseracing, HISA has created an unconstitutional, private, self-regulating entity (The Authority) which ignores science and undermines the ability of racetrack veterinarians to care for the equine athlete. The actual implementation of HISA is detrimental to racetrack veterinarians. Specifically:

A. The Horseracing Integrity and Safety Act (HISA) fails to safeguard the health and welfare of the racehorse. It includes a provision for the elimination of the race day administration of the Exercise Induced Pulmonary Hemorrhage (EIPH) medication, furosemide, which has been unequivocally shown to be protective of the health of

the racehorse using the highest level of scientific evidence.

B. Further, the regulations promulgated and enforced by the private corporation (the Authority) impose medication regulations that limit the ability of the private veterinary practitioner to appropriately manage the health of the racehorse. These restrictions extend far beyond any possibility of an effect on the horse at the time of the race.

C. The regulations impose penalties upon the veterinarians that include provisional (immediate) suspension from treating racehorses before any due process is afforded to the veterinarian. In practice, this provisional suspension has deprived racehorses of necessary treatment. Veterinarians have been suspended for possession of banned substances that are not banned in the practice of veterinary medicine when the patient is not a racehorse. There is a shortage of veterinarians to provide care for racehorses, so the provisional suspension necessarily results in some horses simply being denied care.

The above deficiencies are directly related to the provisions of HISA and its enacted regulations. This has resulted in the situation that the racetrack veterinarian, who has the most practical understanding of the welfare of the equine athlete, is ignored and forced to practice in a confusing and counterproductive regulatory environment. In other words, the stated purpose of the legislation is not consistent with its implementation.

Accordingly, the Petition for the Writ of Certiorari should be granted, and HISA declared unconstitutional.

III ARGUMENT

A. The Act Fails to Safeguard the Health and Welfare of Racehorses in the Way It Regulates the Administration of Furosemide or Lasix.

The single most investigated equine medication used to ameliorate EIPH (Exercise Induced Pulmonary Hemorrhage) in horses during racing is furosemide, or Lasix. HISA seeks to eliminate the use of furosemide or Lasix on the day of the race for all racehorses within three years of the start date of HISA.

Horses are elite athletes, able to transfer huge volumes of blood to exercising muscles for oxygen delivery and across the pulmonary circulation to release carbon dioxide and take up more oxygen. This efficient and rapid movement of blood creates high pulmonary (lung) blood pressures and predisposes them to injury to the capillary membranes, which results in EIPH, or bleeding in the lungs during exercise. This can range from mild loss of blood in isolated regions of the lungs to the rare occurrence of massive hemorrhage resulting in asphyxiation and death. The possibility of pulmonary injury during high intensity exercise, which includes horse racing, has resulted in veterinarians trying many different therapeutic medications to mitigate this damage.

Anecdotal evidence has supported the use of many different therapies, but only the use of furosemide within four hours of racing has been unequivocally demonstrated with strong scientific evidence to mitigate this disease.[3] In the United States, EIPH has been considered to be a sufficient health risk to the equine athlete that the regulatory provision allowing for the race day use of furosemide has been in place uniformly across all jurisdictions since 1995.[4]

HISA seeks to eliminate this health preserving medication for racehorses. 15 U.S.C. § 3055(d) entitled "Prohibition", states:

> "Except as provided in subsections (e) and (f), the horseracing antidoping and medication control program shall prohibit the administration of any prohibited or otherwise permitted substance to a covered horse within 48 hours of its next racing start, effective as of the program effective date." See 15 U.S.C. § 3055(d).

The only way that furosemide may be retained for the protection of the equine athlete

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[3] Hinchcliff KW, Morley PS, Guthrie AJ. Efficacy of furosemide for prevention of exercise-induced pulmonary hemorrhage in Thoroughbred racehorses. J Am Vet Med Assoc. 2009 Jul 1;235(1):76-82. doi: 10.2460/javma.235.1.76. PMID: 19566461.

[4] Tobin T, Galley R, Brewer K, Briceno A, Leon DV. Furosemide, the prevention of epistaxis and related considerations: A preliminary evaluation. (2012) Intern J Appl Res Vet Med 10(2):176 – 185.

is discussed in 15 U.S.C. § 3055(3) entitled "Modifications of Prohibition", states:

> (A) In general
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> After receipt of the report required by paragraph (2), the Authority may, by unanimous vote of the Board of the Authority, modify the prohibition in subsection (d) and, notwithstanding subsection (f), any such modification shall apply to all States beginning on the date that is three years after the program effective date.
>
> (B) Condition
>
> In order for a unanimous vote described in subparagraph (A) to affect a modification of the prohibition in section (d), the vote must include unanimous adoption of each of the following findings:
>
> (i) That the modification is warranted.
> (ii) That the modification is in the best interest of horse racing.
> (iii) That furosemide has no performance or enhancing effect on individual horses.
> (iv) That public confidence in the integrity and safety of

> racing would not be adversely affected by the modification.

This requirement for a unanimous vote and the subjective nature of the listed criteria is neither scientifically nor medically based. This provision intentionally ignores the long-established scientific evidence that the health and welfare of the racehorse population is best served with the continued use of furosemide.

B. The Regulations Promulgated by the Authority Limit the Ability of the Private Veterinary Practitioner to Appropriately Manage the Health of the Racehorse by the Way Substances and Medications are Classified and by the Establishment of Zero-Tolerance Levels.

HISA, and specifically the Anti-Doping and Medication Control (ADMC) portion of HISA, severely curtails the ability of racetrack veterinarians to properly care for racehorses. As a practical matter, the ADMC portions of HISA places NAARV and its members in positions of either treating their patients in an appropriate manner and risk placing the horse, its trainer and owner in danger of running afoul of regulations or treating the horse with an alternative or not treating the horse at all in violation of the veterinarian oath.

NAARV members are all practicing racetrack veterinarians who are dedicated to the welfare of the equine athlete. Their ability to treat the equine athlete is based upon long standing experience and science-based techniques and medications that are designed to provide therapeutic treatment to the equine athlete. HISA destabilizes the entire system under which racetrack veterinarians practice their profession. It establishes a confusing regulatory landscape, which leaves the racetrack veterinarian unable to promote the health and welfare of the horse. What constitutes a prohibited substance and what levels of that substance may be a violation of the regulations, is a moving target. The racetrack veterinarian is often forced to make decisions that contradict his or her longstanding experience with regards to what is the best method of treating the horse.

HISA fails to ensure that the decisions affecting the welfare of the equine athlete are based on veterinary medical experience and scientific analysis. The HISA regulatory system lacks transparency and accountability. This can be seen when examining the classification of prohibited substances, approved medications and the detection levels which can lead to potential violations.

(1) The Classification Issue

The practice of veterinary medicine parallels that of human medicine. Medical conditions are identified, differential diagnoses are formulated and considered, and then available treatment options are

offered to the animal owner. HISA classifies both inappropriate treatments that do not belong in the therapeutic arsenal of a veterinarian and accepted and usual therapeutics into a scheme set out in the SO or the Prohibited Substances List, through S7, a Controlled Medication List 15 U.S.C. § 4110. HISA has jurisdiction over what can be used therapeutically in a racehorse throughout its entire career, not just limited to the period right before a race. 15 U.S.C. § 3051.

The ADMC committee of the Authority included on the SO, always banned lists of medications that are FDA Approved, FDA Listed and metabolites of FDA Approved medications in common therapeutic use. Common endogenous and dietary contaminants that may be found in biological samples from competition horses are also included in the SO list, with only a few as substances recognized as requiring a screening limit, or a cut-off level below which a finding would be considered of no significance. Therapeutic medications that are widely used in equine veterinary practice have been inexplicably included on the S0, banned at all times list. For example, Trazodone, an FDA approved sedative and antidepressant, has gained widespread acceptance in horses during periods of stall rest (similar to bed rest in humans) to prevent self-trauma during recovery from illnesses and injuries.[5] This therapeutic medication is on the S0, banned at all

[5] Davis JL, Schirmer J, Medlin E. Pharmacokinetics, pharmacodynamics and clinical use of trazodone and its active metabolite m-chlorophenylpiperazine in the horse. J Vet Pharmacol Ther. 2018 Jun;41(3):393-401. doi:

times list in horseracing, preventing its use in Thoroughbreds during periods of recovery from injury.

The Authority also fails to recognize that substances either legitimately prescribed or illegally used by humans that come in contact with the animals may result in trace positive tests at levels far below any possibility of an effect. In practice, the Authority and its enforcement Agency have penalized horsemen for those positives as if the banned substance (e.g., methamphetamine) were administered to horses in full effective doses on the morning of the race. By way of comparison, the Substance Abuse and Mental Health Service Administration (SAMHSA) establishes a cut-off for methamphetamine in the urine of humans of 500 ng/ml. See Court of Federal Regulations Title 10 Chapter 1 § 26.163. The purpose of this cut-off is to eliminate positive tests from casual contact rather than intentional use of drugs of abuse. Horses are no less susceptible to casual contact with human users, and yet the HISA ADMC has no provision for this method of transfer from their environment.

Furthermore, HISA places great emphasis on the FDA Approval of drugs. This is problematic. Unlike humans, horses represent a very small market for pharmaceutical companies. Most equine infirmities do not have FDA approved drugs available for equine treatment. Medications approved in other species, FDA Listed medications and compounded

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10.1111/jvp.12477. Epub 2018 Jan 14. PMID: 29333613; PMCID: PMC7167085.

medications are used to breach this gap. Federal Law permits veterinarians to possess, prescribe, and administer FDA Approved, FDA Listed and compounded medications in the course of their practice. However, the ADMC regulations do not permit the use of Listed Medications. Common Listed Medications are in daily use for the health and welfare of the horse, and in most cases, there are no FDA approved alternatives. Vitamins, minerals, electrolytes, and sterile intravenous fluids are all FDA Listed but not FDA approved 15 U.S.C § 4111. When specifically questioned about those substances, Authority representatives stated that they would never enforce these provisions. Those representations are inadequate to rely upon when the written regulations say otherwise. 15 U.S.C. § 4111.

Additionally, the regulations provide no reliable withdrawal times for veterinarians and horse trainers to determine when it would be safe to race a horse after administration of therapeutic medications. The Authority has ignored scientific evidence in favor of simply banning every possible medication or any amount of environmental contaminant which may be detected. Horsemen that are concerned about the possibility of a positive test for an innocuous medication have now become less likely to call their veterinarian to treat racehorses. This is because any examination or treatment may result in a positive drug test at an irrelevant concentration in blood or urine. Removing the most highly educated stakeholder, (the racetrack veterinarian), from the care of the horse does nothing to improve the safety or integrity of the sport.

HISA's Prohibited Substances Technical Document codified in the enactment is a clear departure from the widely accepted standards for the use of therapeutic medications in the racing industry. 15 U.S.C. § 4000. The racing industry has historically relied upon and used the classification guidelines for foreign substances formulated by the Association of Racing Commissioners International, (ARCI). (See The Uniform Classification Guidelines and Recommended Penalties Model Rule version 16.0-April 2023, ARCI/www.ARCI.com/model-rules-standards/), established scientifically based withdrawal times and thresholds for therapeutic medications that permit their appropriate use to protect the health and welfare of the equine athlete. HISA has, instead, determined that the regulation of most therapeutic medications is to be at the limit of detection by highly sensitive testing instruments. This change in practice fails to place the health and welfare of the horse first and foremost in the development of regulations. Most therapeutic medications may be detected well below their irrelevant plasma concentration, owing to prolonged terminal half-lives and modern high sensitivity drug testing. For example, Aminocaproic Acid, is a substance commonly used to prevent EIPH during workouts. It is thus a lifesaving medication in the event of hemorrhage and can be identified for at least seven days after administration which is at least six days beyond any effect. Regulation at the limit of detection restricts the use of many therapeutic medications. This endangers the health and welfare of the horse, because many horsemen have no choice but to refuse appropriate care if it might prevent the

horse from racing in a reasonably predictable time frame. Furthermore, limit of detection regulations for therapeutic medications are subject to change with technological advances. This is arbitrary and capricious and indicative of a decision-making process that reflects a lack of understanding of the equine athlete and the horseracing industry. This is an example of how, under HISA, subjective opinion can trump science.

Although HISA mandates that as a baseline, it is to rely on the International Federation of Horseracing Authorities International screening limits for urine and plasma, it is unclear from the document upon what scientific basis HISA relies upon for the listed "Detection Times." 15 U.S.C. § 3055 (g)(2)(A). In most cases, the detection times appear to have been taken from the European Horserace Scientific Liaison Committee (EHSLC) detection times. (See Ehslc.com/detection-times/how-detection-safetytimes-are-agreed.) A detection time is defined as the longest time post-administration that the last of an exceedingly small group of horses (usually 4 to 6, but as few as 2 in the HISA Technical Document) no longer tests positive for a substance at a level which is not always defined in the Technical Document. Withdrawal periods are estimated as being anywhere between 2.1 to 2.2 times the length of the detection time,[6] although this provides no reliable guidance for the regulated horsemen or "covered

[6] Toutain PL. How to extrapolate a withdrawal time from an EHSLC published detection time: a Monte Carlo simulation appraisal. Equine Vet J. 2010 Apr;42(3):248-54. doi: 10.1111/j.2042-3306.2010.00028.x. PMID: 20486982.

persons" under the Act. Controlled therapeutic medications have been historically regulated under the ARCI by establishing a withdrawal period representing a balance between appropriate care of the equine athlete and preventing an effect of the medication on the outcome of the race.

Thresholds have been developed based on the withdrawal period. While this approach has its own drawbacks, it is significantly more scientifically rigorous than the HISA/IFHA therapeutic medication guidelines. When detection times are based on only two horses (as HISA proposes for the antihistamine Hydroxyzine), an actual withdrawal period is essentially impossible to determine.

Additionally, the limit of detection of one laboratory may be vastly different from the limit of detection of another laboratory. The European Screening limits (and therefore detection times) were established by seeking to achieve harmonization between their laboratories. The lowest screening limit that all labs could achieve for certain substances was accepted even when some labs were capable of much lower limits. This was intended to avoid a positive test in one lab that could not be confirmed in another. United States labs are capable of much lower detection limits than their IFHA counterparts. Nothing comparable to the European harmonization exists.

For example, EHSLC using IFHA "harmonized" screening limits, lists both Clodronate

and Tiludronate with 30 day detection times.[7] Using higher sensitivity testing methodology, Tiludronate may be detected for over three years beyond the last administration.[8] The lab and lab methodology determine the detection time, and the EHSLC detection times cannot be relied upon for estimating withdrawal times for therapeutic medication when testing is conducted in United States laboratories that may have a higher testing sensitivity. Any publication or use of detection times requires studies to be conducted in the laboratories that will be performing the actual drug testing. Otherwise, publication of detection times determined by less sensitive testing methodology used as guidance for American horsemen and women amounts to entrapment.

The science behind all the EHSLC detection times, most importantly, the limit of detection or screening limit that was used in determining these detection times, is not disclosed by HISA. Unlike the European countries from which these limits were obtained, American citizens are accustomed to transparency in regulations. Penalties and fines

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[7] Popot MA, Jacobs M, Garcia P, Loup B, Guyonnet J, Toutain PL, Bailly-Chouriberry L, Bonnaire Y. Pharmacokinetics of tiludronate in horses: A field population study. Equine Vet J. 2018 Jul;50(4):488-492. doi: 10.1111/evj.12789. Epub 2018 Jan 9. PMID: 29194746.

[8] Riggs CM, Thompson SL, So YM, Wong JKY, Wan TSM, Robinson P, Stewart BD, Ho ENM. Tiludronic acid can be detected in blood and urine samples from Thoroughbred racehorses over 3 years after last administration. Equine Vet J. 2021 Nov;53(6):1287-1295. doi: 10.1111/evj.13395. Epub 2020 Dec 23. PMID: 33247964.

should not be assigned to individuals based on inaccurate, unknown, or undisclosed scientific bases.

The ARCI thresholds have been developed over the course of years, with the input of chemists and scientists, and input from the horseracing industry in open meetings. The ARCI thresholds for substances for which no IFHA Screening Limit exists are ignored in the Prohibited Substances Technical Document. 15 U.S.C. § 1206(b)(1) requires: "…Covered horses … compete only when they are free from the influence of medications, other foreign substances, and method that affect their performance…" and 15 U.S.C. § 1206(g)(A) states: "...the baseline anti-doping and medication control rules described in this paragraph are… the lists of permitted and prohibited substances…in effect for the International Federation of Horseracing Authorities for urine and …plasma." Therefore, there was no reason for the Authority to abandon the in-place ARCI thresholds for substances not included in the IFHA screening limits.

(2) The Detection Issue in Relation to Environmental Substances

The issues related to the detection of environmental substances are of particular concern to the racetrack veterinarian and their clients. Environmental substances include veterinary pharmaceuticals, human pharmaceuticals, human recreational drugs and even by-products of manufacturing. For drugs or medicines taken or administered to humans or animals, substances that are: (1) eliminated in the urine at an elevated level;

(2) stable in the environment; and, (3) readily absorbed by the mucus membranes or gastrointestinal tract are classified as environmental substances[9].

Additionally, environmental substances may be in human or animal topical products or administered by mouth to horses which makes them highly susceptible to being absorbed or taken up by horses in trace amounts close to racing[10]. This is because of their presence on feed tubs, hay nets and even the cobwebs of the barn.[11] Based on the establishment of the "specified substances" category by HISA, the Authority's ADMC fully recognizes that inadvertent environmental transfer can and does occur, resulting in positive tests. What the ADMC fails to recognize is the extent to which this cross-contamination may occur. In addition to the limited recognition by the ADMC of a small number of "Specified Substances," medications that are equine therapeutics, human therapeutics and human recreational substances may be identified in ground

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[9] Brewer K, Machin J, Maylin G, Fenger C, Morales-Briceño A, Tobin T. Gabapentin, a human therapeutic medication and an environmental substance transferring at trace levels to horses: a case report. Ir Vet J. 2022 Oct 4;75(1):19. doi: 10.1186/s13620-022-00226-5. PMID: 36192810; PMCID: PMC9531455.

[10] Ibid.

[11] Russell CS, Maynard S. Environmental contamination with Isoxsuprine. In RB Williams, E Houghton, JF Wade (Eds) (2000) Proceedings of the 13th International Conference of Racing Analysts and Veterinarians (pp. 381 – 383) Cambridge, United Kingdom.

water at levels in the ng/ml range,[12] exceeding the levels at which a positive may be called in a racehorse. Common substances highly stable in the environment include the common diabetes drug Metformin, and blood pressure medications, Metoprolol and Atenolol, and despite no evidence that these medications can have any effect on a horse race at any level, they are included in the S0, banned at all times lists. Additional substances highly stable in the environment cut across all HISA schedules (SO-S7)[13]. Trace levels of these substances consistent with inadvertent environmental transfer in racehorses have been penalized under HISA as if horse trainers have administered full therapeutic doses on race day.

With the ever-increasing sensitivity of drug testing in horse racing, environmental substances that are readily detected in water, reflecting stability in the environment or commonly present in human topical products should all be included as specified substances. This is because their identification as trace contaminants in the blood or urine of a horse reflects neither an effect on the animal, nor intent of the horse caretaker to take an unfair advantage. Further, in the adjudication resulting from an

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[12] Bexfield LM, Toccalino PL, Belitz K, Foreman WT, Furlong ET. Hormones and Pharmaceuticals in Groundwater Used as a Source of Drinking Water Across the United States. Environ Sci Technol. 2019 Mar 19;53(6):2950-2960. doi: 10.1021/acs.est.8b05592. Epub 2019 Mar 5. PMID: 30834750.

[13] Bexfield LM, Toccalino PL, Belitz K, Foreman WT, Furlong ET. Hormones and Pharmaceuticals in Groundwater Used as a Source of Drinking Water Across the United States. Environ Sci Technol. 2019 Mar 19;53(6):2950-2960. doi: 10.1021/acs.est.8b05592. Epub 2019 Mar 5. PMID: 30834750.

adverse analytical finding for a specified substance, at a level consistent with inadvertent environmental transfer rather than intentional administration should not constitute a penalty for the trainer and the horse. Such adverse analytical findings are randomly occurring and have no impact on the performance of the horse[14]. This serves only to fuel bad publicity for the industry by creating a sensational headline asserting that a horse has tested positive for a banned substance, but, in reality, in an amount so miniscule so as to be clinically ineffective.

The HISA Authority requires that the responsible person must investigate and provide evidence for the source of Adverse Analytical Findings. 15 U.S.C. § 3121 and 15 U.S.C. § 7250. This violates the due process of affected persons. The Authority and its enforcement Agency provide only investigations of adverse analytical findings as violations, and do not include procedures that allow for the discovery of potentially exculpatory evidence. 15 U.S.C. § 7260. The Authority and Agency prevent the accused horseman from access to information that could aid in determining the source of the violation. 15 U.S.C. § 7260. For example, in some cases, identifying substances and their metabolites in both blood and urine may provide evidence as to the dose and timing of the exposure. In the case of a prohibited substance, the Authority and Agency will not provide

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[14] Fenger C, Sacopulos P, Brewer K, Machin J, Tobin T. More Challenges: Complicated obstacles await HISA medication regulations due to start Jan 1. The Horseman's Journal Fall 2022: 24-30.

the laboratory data for urine if the medication was found in blood and vice versa, preventing the accused horseman from using that information to determine when the exposure occurred. 15 U.S.C. § 7260 (d)(1-5). In many cases the source of the inadvertent environmental exposure simply cannot be identified. Adverse Analytical Findings may be communicated to responsible persons after the last batch of hay, straw or feed has been consumed or the employees have moved on.

Some classified substances are of endogenous origin, produced by the animal's own body, but could also be exogenously administered. Thresholds for these endogenous thresholds must be regulated by identification of a normal threshold by testing many horses within a normal population. 15 U.S.C. § 4000.

Dietary substances are those that can be detected in the animal's blood or urine from its natural presence in hay or feed. There are thirteen dietary substances in the HISA SO category of which two are associated with screening limits. There are sixteen dietary substances in the HISA S7 category of which only ten are associated with a threshold. 15 U.S.C. § 4000.

The Authority could have and should have readily adopted screening limits for these substances from existing sources. For example, there are in house screening limits for Glaucine and Lobeline at the Pennsylvania Equine Toxicology and Research Laboratory, (PETRL). Provisional screening limits exist in the scientific literature for others, including

aminorex (75 mg/ml urine),[15] and synephrine (50 ng/ml urine).[16]

C. The Provisional Suspension of Veterinarians Without Due Process Negatively Impacts the Health and Welfare of the Racehorse.

To be a racetrack veterinarian, members of NAARV must secure two licenses. First, they must secure a license issued by the state, typically the state veterinarian licensing board which entitles members to practice general veterinarian medicine. A second license is also required to practice veterinary medicine on the restricted access stabling area of the racetrack where many thoroughbred horses are stabled. This second license is issued by state regulators authorized to govern horse racing, such as the state racing commissions or authorities.

When a veterinarian is provisionally (immediately) suspended, his/her ability to treat racehorses is immediately halted. The dual system of licensure prevents another veterinarian, unlicensed

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[15] Maylin G, Fenger C, Machin J, Kudrimoti S, Eisenberg R, Green J, Tobin T. Aminorex identified in horse urine following consumption of Barbarea vulgaris; a preliminary report. Ir Vet J. 2019 Dec 23;72:15. doi: 10.1186/s13620-019-0153-5. PMID: 31890155; PMCID: PMC6929286.

[16] Brewer K, Machin JJ, Maylin G, Fenger C, Morales-Briceño A, Neidhart MM, Tobin T. Case report: Synephrine, a plant substance yielding classic environmental clusters of hay related identifications in equine urine. Drug Test Anal. 2022 Apr;14(4):774-780. doi: 10.1002/dta.3212. Epub 2022 Jan 28. PMID: 35088566.

by the Racing Commission, from taking over the care of that veterinarian's patients. If a horse is in the middle of a course of antibiotics for an infection, or other critical treatments, it is simply out of luck. There is no surplus of equine veterinarians to cover these horses. HISA provides no system of due process to determine if the alleged violation is significant enough to threaten the health and welfare of the veterinarian's patients. In practice, the Authority has provisionally suspended several veterinarians for possession of substances deemed to be banned for use in a racehorse but perfectly legal for use in any other kind of horse. Considering that all racetrack veterinarians also treat non-racehorses, possession alone is not sufficient to endanger a subset of racehorses by eliminating their medical care.

The absence of the veterinarian's right to due process not only negatively impacts the health and welfare of the racehorse population, but also subjects racetrack veterinarians to two parallel systems of review. The first system governs any allegations of wrongdoing involving medication and/or track safety violations that will be adjudicated before the authority of the Federal Trade Commission. All allegations other than medication and track safety violations remain subject to adjudication pursuant to state law and before state regulators.

This is significant because all allegations or initial findings of wrongdoing by a member of NAARV, pursuant to HISA, result in a report to the Federal Trade Commission, and, therefore, a federal violation. A federal violation may result in the loss of

not only the NAARV member's track license, but also threaten the member's professional license to practice veterinarian medicine. Therefore, members of NAARV are not able to "take the deal" in a minimum violation, but instead are forced to defend their positions to maintain their license and their livelihood. Prior to the implementation of HISA, NAARV members were able to negotiate a state violation without necessarily risking their general veterinary license. Under HISA they are forced to do so in a system, created under HISA 3000 and 7000 Rules (See 15 U.S.C. § 3000 and 15 U.S.C. 7000), which deprives them of both substantive and procedural due process.

HISA 3000 and 7000 Rules violate NAARV members substantive and procedural due process rights. It does so by establishing a closed system of self-review that provides no guarantees to review by the Federal Trade Commission (hereinafter, "FTC") and a cost prohibitive appeal process directly to the United States Court of Appeals. NAARV members, as covered persons under the act, are therefore denied both substantive and procedural due process rights by 15 U.S.C. § 305(A) because this system in application subjects the covered person to a different adjudication the consequences for them are severe than exists under state-based systems. Additionally, HISA adjudication system denies and violates NAARV member's rights to trial by jury as guaranteed by the Seventh Amendment of the United States Constitution. *George R. Jarkesy, Jr.; Patriot28, L.L.C. v. Securities and Exchange Commission*, 51 F4th 644 *(2022)*.

IV CONCLUSION

For the reasons stated above, the Petition's Writ of Certiorari should be granted.

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Respectfully submitted,

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