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November 14, 2022

FTC Office of Secretary
600 Pennsylvania Ave. NW
Ste. CC-5610 (Annex B)
Washington, DC 20580

Re: HISA Anti-Doping and Medication Control Rule (FTC-2022-0062-0001) 87 FR 208

Ladies and Gentlemen:

Every attempt was made to review the over 400 pages of rules and 600 pages of comments made prior to publication on the federal register of the rules proposed for the Commission's final approval with an effective date of January 1, 2023. During the 14-day public comment period, there was only one correction submitted. Vesting federal rulemaking power in a private entity, Congress by enacting HISA provided that the regulations cannot take effect until they are submitted to and approved by the Federal Trade Commission an independent agency with no specialized knowledge or experience with horseracing. The Commission should permit more industry-related guidance in the formulation of these most important rules.

The scope of HISA's regulatory authority extends to all activities related to only Thoroughbred horse racing. Likewise, HISA claims power to regulate racetracks, trainers, owners, breeders, jockeys, racetracks, veterinarians, others licensed by state racing commissions, and agents of any of those persons. The Act does not define "agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training, or racing of covered horses."[1] HISA itself expands this broad classification to include everyone "licensed by a State Racing Commission" and who has "access to restricted areas of a racetrack in the ordinary course of your work."[2] HISA also claims power to regulate the testing laboratories. All activities to be funded not by Congress but by those individuals and entities being regulated while HISA alone sets the regulatory agenda with the FTC having no independent freedom of action for permanent rule-making.

The FTC approved the racetrack safety rules (Rule 2000 series) on March 3, 2022.[3] The FTC provided only a 14-day public comment period while conceding that it "typically provides at least 30 and often 60 days or more for public comment." *Id* at 5. The Act specifies a separate process for "any proposed rule, standard, or procedure developed by" HISA "to carry out the horseracing anti-doping and medication control program or the racetrack safety program."[4] HISA must submit those kinds of proposals to the FTC for public notice and comment, but the Act does not explicitly state whether those proposals are subject to 15 U.S.C. §3053(c)'s requirements, whether the FTC has the power to approve or disapprove them or how they become effective.[5] It is also not clear how the subject matter of proposals submitted under §3053(d) might differ from the types of rules listed in §3053(a).

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[1] 15 U.S.C. §3051(6)
[2] *See* Registration, HOSA (2022), https://bit.ly/3xToEIE.
[3] Fed. Trade Comm'n, Order Approving the Racetrack Safety Rule Proposed by the Horseracing Integrity and Safety Authority (Mar. 3,2022), https://bit.ly/3Nn2ST8.
[4] 15 U.S.C. §3053
[5] *See generally id*. §3053(d)

The following excerpts are from the Fall 2022 Horseman's Journal and the article entitled: "*More Challenges Complicated obstacles await HISA medication regulations due to start Jan. 1."*

> "The mandate for the ADMCI section of the Horseracing Integrity and Safety Act (the Act) can be found in 15 U.S. Code §3055(b) and requires, among other things, that '(1) Covered horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance; (2) Covered horses that are injured or unsound should not train or participate in covered races, and the use of medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited."
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> "The ADMC Committee far exceeded this mandate in creating its regulation. Substances are banned well beyond their ability to 'influence performance' or 'allow unsound horses to train or race'. The term 'covered horse' includes all horses between their first published work and retirement. While many can read the list of prohibited substances and agree that 'yes, that shouldn't be in a racehorse,' a covered horse includes not only racehorses but horses on layup, horses that have had surgery and horses in the recovery period after surgery. Many of the substances that really have no use in a horse actively training and racing have very important value in horses on layup. The many years that have gone into the development and modification of the Association of Racing Commissioners International (ARCI) medication standards, during which numerous veterinary pharmacologists and chemists provided input, have been completely ignored. The ADMC Committee scrapped the ARCI standards in horseracing in favor of a new untested program based on zero tolerance."
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> "Substances are broadly divided into "banned" or prohibited in horses at all times, both in and out of competition, and "controlled" or permitted out of competition. The assignment of any given substances into these categories is presumably based on several factors. The most important factor that the ADMC Committee considered was not the mandated "influence performance" or "allow unsound horses to train or race" but rather whether the substance is FDA-approved."
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> "The S0 category of substance probably intended to be a catch-all category for designer drugs, possibly doping agents imported through covert channels. However, as written, it includes may substances that are in common use, such as vitamin C. In its attempt to close loopholes where true doping could occur, HISA has made the majority of medications currently in use for treating and managing conditions of racehorses illegal."
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> Keypoints of the 3000, 4000, and 7000 rules series are:

1. Everything they can identify in a lab test and a lot of things they cannot are considered a violation at any level in a post-race sample with few exceptions;
2. The identification of any and all substances at any level (with a few exception) in a post-race sample results in disqualification of the horse;
3. The most severe category of substances that are banned, the S0 category includes vitamin C;
4. In addition to potential trainer penalties, an S0 violation can make a horse ineligible to race for 14 months;
5. All supplements are banned within 48 hours of racing or working without any scientific evidence to support the health of the racehorse by such a ban;

6. Any trace of corticosteroids or nonsteroidal anti-inflammatory drugs are banned during works in addition to races, so horses cannot be worked within two or three weeks of most corticosteroid injections or within three to four days of any bute, banamine, Ketofen or DMSO.

"The entire S0 category of substances reflects a gross misunderstanding of what is legal to administer to an animal. FDA approval does not indicate whether a drug is legal to use, dispense or administer if they are manufactured in facilities registered with the FDA and listed with the FDA or compounded and labeled according to the pharmacy board regulation of the state in which they are sold. By the inclusion of FDA-listed products in the S0 category, almost all vitamins and many drug products in common use are suddenly categorized alongside some of the most egregious forms of doping. Substances that are common components of feed and many contaminants of hay also fall into this category. Despite the emphasis on FDA approval, 109 FDA-approved substances are in the HISA S0 category. Of these 15 FDA-approved substances are in therapeutic use in equine practice. Based on the severe proposed penalty of 14-month ineligibility period for any horse demonstrated to have been administered an S0 substance, no substances with a valid therapeutic use should ever be in the S0 category. A short layup could inadvertently turn into the retirement of an otherwise sound and healthy horse."

"Several primary metabolites of controlled therapeutic substances from the S7 category are included in the S0 list. If the S7 substance does not warrant an S0 penalty, there is no place for its primary metabolites on the S0 list. The scheduling of many substances as S0 that are commonly used in the breeding process is troubling. Female racehorses are commonly bred and then continue to race up to four months of pregnancy. The scheduling of all breeding-associated medications such as deslorelin into the S0 category would effectively bring this practice to a halt after the consequences befall those in the industry as proposed."

"A simple surgery to remove a chip fracture, usually accompanied by a six-to eight-week respite from racing, could readily be turned into a 14-month ineligibility period because of an innocuous administration of a therapeutic medication for the purpose of maintain the health and welfare of a race animal. The 14-,month racing ineligibility period for a horse administered any substances in this S0 category is particularly severe. This provision adversely impacts the health and welfare of the horse by either preventing the horse from receiving the most appropriate therapy or preventing the horse from being in training for 14 months after being inadvertently administered one of these common, legal substances. Training during the critical 2- and 3-years-old years of a horse is essential to build the proper bone density and strength to withstand the rigors of racing. This time frame places that horse at higher risk of catastrophic injury by at least preventing training with fast workouts for a protracted period and possibly even delaying the horse's starting age to 4 years or older. Further there is no evidence that any doping substances have any effects that persist beyond, at most, about four months."

"Screen limits adopted by HISA are taken from the International Federation of Horseracing Authorities, but additional screening limits could have been adopted from jurisdictions in the U.S. HISA goes beyond what any sports regulatory body imposes on its participants. Rule 4211 restricts the administration of all substances other than "feed, hay and water" (which are undefined) within the "race period," or 48 hours before racing, with only a few exceptions. The exceptions up to 24 hours before racing are orally administered vitamins, anti-ulcer medications,

> licensed vaccines, unsupplemented isotonic electrolyte solutions (electrolyte pastes prohibited), antimicrobials, antiparasitics and altrenogest (Regu_Mate) in fillies."
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> "HISA recognizes the importance of controlling the horse's reproductive behavior by permitting altrenogest in fillies and mares up to 24 hours before racing. It fails to recognize that sexual behavior on the part of the male horse is equally disruptive and even dangerous in the racing environment. The application of menthol (Vicks VapoRub) to a stallion's nares is a commonplace practice of good horsemanship to prevent him from detecting and reacting to pheromones from mares. This practices in banned in the HISA regulations. Supplements or feed additives during the 48 hours pre-race are prohibited. Since feed is undefined in the HISA regulations, the provision may or may not make complete feed illegal in the last 24 to 48 hours. Oats are a great source of vitamins, minerals and antioxidants, but even oats within 24 hours of a race is a HISA violation. Health conditions of horses that are managed through nutrition include anhidrosis, tying up, allergies and even exercised-induced pulmonary hemorrhage. Preventing the management of a horse's health in the last 48 hours before racing does nothing to protect the integrity of racing or the health and welfare of the horse."

The Rule 7000 series contains no provision for mediation. Litigation as proposed is cost prohibitive and unduly burdensome. Rule 3139 states the agency may at any time, with or without prior notice, take physical possession of any Sample collected by or on behalf of the Agency and any related analytical date or information in the possession of a Laboratory. Upon request by the Agency, the Laboratory in possession of the Sample or related data shall grant access to and enable the Agency to take physical possession of the Sample or data as soon as possible. This rule ignores the valid subpoena power and enables the Agency to disregard the reasonable expectation to privacy and scientific methodologies employed for the integrity and credibility of the industry.

Very truly yours,

Va. Fields

Virginia S. Fields
General Counsel
Texas Racing Commission