UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Rebecca Kelly Slaughter
Christine S. Wilson
Alvaro M. Bedoya

ORDER APPROVING THE ANTI-DOPING AND MEDICATION CONTROL RULE PROPOSED BY THE HORSERACING INTEGRITY AND SAFETY AUTHORITY

March 27, 2023

I. Decision of the Commission: HISA's Anti-Doping and Medication Control Rule Is Approved

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. §§ 3051–3060, charges a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority ("Authority"), with developing proposed rules on a variety of subjects. *See, e.g.*, *id.* § 3055(c)(1) (requiring an anti-doping and medication control rule). The Authority's proposed rules and proposed rule modifications take effect only if approved by the Federal Trade Commission ("Commission"). *See id.* § 3053(b)(2). As required by the Act, the Authority submitted and the Commission published for public comment in the Federal Register[1] the text and explanation ("Notice") of a rule proposed by the Authority concerning Anti-Doping and Medication Control ("ADMC"). *See id.* §§ 3053(a), 3053(b), 3055(c)(1). "The Commission shall approve a proposed rule if the Commission finds that the proposed rule is consistent with" the Act and the applicable rules approved by the Commission. *Id.* § 3053(c)(2).[2]

[1] *See* Fed. Trade Comm'n, *Notice of HISA ADMC Proposed Rule* ("Notice"), 88 Fed. Reg. 5070 (Jan. 26, 2023), https://www.federalregister.gov/documents/2023/01/26/2023-00957/hisa-anti-doping-and-medication-control-rule.
[2]

By this Order, for the reasons that follow, the Commission finds that the ADMC proposed rule is consistent with the Act and the Commission's procedural rule, and therefore approves the proposed rule, which takes effect today.

II. Discussion of Comments and the Commission's Findings

Under the Act, the Commission must approve a proposed rule if it finds that the proposed rule is consistent with the Act and "applicable rules approved by the Commission." 15 U.S.C. § 3053(c)(2). Here, the "applicable rules" are the ones issued by Commission that provide the procedures necessary for the Commission's Office of the Secretary to accept proposed rule or rule modification submissions under the Act. *See* 16 C.F.R. §§ 1.140–1.144 (Commission's procedural rule). Among other things, the materials submitted by the Authority for Commission review must explain how the proposal is "consistent with the Act" and "how [the Authority] considered the factors in 15 U.S.C. § 3055." *See* 16 C.F.R. § 1.142(a)(5). As a threshold matter, the Commission finds that the Authority's proposed ADMC rule is consistent with the procedural rule. This finding formally confirms the previous determination made by the Office of the Secretary of the Commission that the Authority's submission of its proposal was consistent with the FTC's procedural rule.[3] The remainder of this Order discusses whether the ADMC proposed rule is "consistent with" the Act.

In deciding whether to approve or disapprove the Authority's proposed rule, the Commission has reviewed the Act's text, the proposed rule's text, the Authority's supporting

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rule is approved and goes into effect, the rule can be modified through a rule modification proceeding by the Authority under § 3053(a); by the Commission itself pursuant to § 3053(e) (in a rulemaking proceeding conducted in accordance with 5 U.S.C. § 553), if the Commission concludes that the Authority's rule does not reflect the policies that the Commission believes would best to protect horseracing integrity or safety; or through a public petition for the amendment of the rule under 16 C.F.R. § 1.31.

[3] *See* Notice, 88 Fed. Reg. at 5070 & n.5. The Secretary's determination that a submission complies with the procedural rule is required before its publication. *See* 16 C.F.R. § 1.143(e) ("The Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing . . . .").

corners of the horseracing industry, advocates, and concerned observers. Most of the comments

standards, or considerations in the text of the Act as well as the Commission's procedural rule."[10] Nevertheless, the Commission received many comments that are unrelated to whether the proposed rule is consistent with the Act or procedural rule, as well as other comments that offer conclusory assertions regarding the proposed rule's consistency with the decisional criteria—*i.e.*, provide no analysis in support of the assertions.[11] Because those comments do not address the statutory criteria that the Commission must use to determine whether to approve or to disapprove the proposed rule, they have little bearing on the Commission's determination.[12] In this Order, the Commission canvasses the most weighty substantive comments it received (including many that do not directly address the statutory criteria), as well as some comments with fewer remarks, and the Authority's responses to these comments, but it does not delve into every issue commenters raise, especially when unrelated to the statutory criteria.

One overarching preliminary issue merits mention at the outset. Some commenters complain that the ADMC rule was not proposed at the same time as other Authority rules, in particular the Racetrack Safety rule. The National Horsemen's Benevolent and Protective Association ("National Horsemen") and the Kentucky Horsemen's Benevolent and Protective Association ("Kentucky Horsemen") assert that Congress intended the ADMC rule to be submitted at the same time as the Racetrack Safety rule so they could "be evaluated together" and that "piecemeal submission makes it impossible for interested parties to know how these

[10] Notice, 88 Fed. Reg. at 5083–84. The Notice also gave guidance to would-be public commenters whose comments would not address the statutory decisional criteria but instead would more generally "bear on protecting the health and safety of horses and jockeys, the integrity of horseraces and wagering on horseraces, and the administration of the Authority itself." *Id.* at 5084.

[11] *See, e.g.*, II.g, *infra*.

[12] This is not to say that such comments are not helpful or productive in the broader effort to improve the safety and integrity of horseracing. In many instances, comments advance specific suggestions for improving the Authority's rules, and the Commission expects that, in appropriate cases, the Authority will consider those comments in proposing rule modifications in the future, and the Commission will also consider them in deciding whether to exercise its discretionary authority to modify the Authority's rules.

rules will be impacted by the additional proposed rules to come."[13] Even if Congress had intended the two rules to be enacted simultaneously, the Authority could not have submitted the ADMC proposed rule at the same time as the Racetrack Safety rule because the anti-doping and medication control enforcement agency ("Agency") had not been selected, and the Act required the input of the Agency (now the Horseracing Integrity & Welfare Unit of Drug-Free Sport International) to develop the ADMC rules as well as the list of prohibited substances. *See* 15 U.S.C. §§ 3054(f)(1)(B), 3055(c)(4)–(5).

Nonetheless, since the Authority's first submissions of proposed rules, the Commission has regularly heard from commenters that they find it difficult to evaluate a proposed rule, such as Racetrack Safety, in isolation, without also knowing the details of an expected later proposal, such as Assessment Methodology. The ADMC proposed rule is the last of the initial rules required by the Act, and although it is proposed against the backdrop of all of the rules of the

Authority [illegible]

§§ 1.140–1.144, the Authority's submissions in support of any proposed rule modification must discuss each of the suggestions made by commenters that the Authority committed to further consider and the reasons that the Authority did or did not adopt the suggestion within the text of the proposed rule modification.[15] In this way, by considering updates to all the rules at once, the Authority, the public, and the Commission will be able to evaluate how the rules interact in practice and to examine both sides of the "cost" and "benefit" ledger at the same time.

a. Rule Series 1000 – General Provisions

The substantive proposed rules are supported by the general rules of interpretation (Proposed Rule 1010) and a list of defined terms (Proposed Rule 1020) to assist with clarity of meaning.

1. Rule 1020 – Definitions

The Authority proposes a list of definitions to be applied to the Rule Series 3000, 4000, 5000, 6000, 7000, and the Protocol, many of which restated or were based on the Act's definitions.[16] Several proposed definitions elicited comments.

The Oklahoma Horse Racing Commission ("Oklahoma Commission") wonders whether the definition of *Analytical Testing Restriction* would "disincentiviz[e] labs to develop new methodologies for new substances."[17]

Approving Racetrack Safety Rule Proposed by Horseracing Integrity & Safety Auth. 8 & n.26 (Mar. 3, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/order_re_racetrack_safety_2022-3-3_for_publication.pdf.

[15] If the Authority has no changes that it wants to propose to a given rule, it shall so state in a letter to the Secretary of the Commission that explains the reasons why it does not believe any changes are necessary.

[16] 15 U.S.C. § 3051.

[17] Cmt. of Okla. Horse Racing Comm'n 1 ("Okla. Comm'n Cmt.") (Feb. 7, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0068. The ADMC proposed rule defines *Analytical Testing Restriction* to mean "a restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or on the analysis of a particular class(es) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency." Notice, 88 Fed. Reg. at 5085 (Proposed Rule 1020).

The Texas Racing Commission ("Texas Commission") objects that the definition of *Covered Horse* includes a "loophole" by not including young horses marketed at horse sales that have been the subject of "the rampant use and anabolic effects of beta-agonists, such as albuterol

The Oklahoma Commission remarks that the *Screening Limit* "must be based on objective science and data."[22]

The Authority responds to each of these comments by reference to the statutory definition of the pertinent term or by demonstrating that its definition is proper. Regarding the Texas

of a trainer, the owner, who is strictly liable for rule infractions) can determine a withdrawal interval greater than the Detection Time and “can consider the

As for the Kentucky Commission's comment about no Kentucky breeder being able to become a *Covered Person* under the Act, that complaint is addressed by the Act itself, which provides that breeders (and other racing professionals) "licensed by a State racing commission" are considered a *Covered Person*. *See* 15 U.S.C. § 3051(6). Under the Act, Kentucky can cause Kentucky breeders to become *Covered Persons* by requiring breeders to register with the Kentucky Commission.

As for the Texas Commission's criticism that young horses may be drugged before being sold and becoming protected as a *Covered Horse* under the Act, the Authority correctly notes that its definition is based on the definition in 15 U.S.C. § 3051(4), which provides that a thoroughbred's protected status begins when the horse has its first timed and reported workout at a participating racetrack. If a young horse were found to have albuterol or clenbuterol in its system when first tested after the sale, it would likely not be able to race. The horse, however, might not be barred from racing if the substances were prescribed as allowed under two exceptions in Proposed Rule 4111. Albuterol may be prescribed by a veterinarian as a bronchodilator under Proposed Rule 4111(a). And clenbuterol may be used "when prescribed by a veterinarian . . . for a duration not to exceed 30 days in a 6-month period," although a horse that has been so medicated is placed on the Veterinarians' List and ineligible to participate in any timed workout or covered horserace until urine and blood samples have been found to be free of clenbuterol (or its metabolites or markers).[30]

[30] Notice, 88 Fed. Reg. at 5122 (Proposed Rule 4111(b)).

repeats the complaint about Proposed Rule 3020(b) as "plac[ing] people who are unwittingly treating and caring for Covered Horses in the position of being subject to HISA regulations and penalties."[37]

The Authority responds that it was aware that the void-claim rules differed between Rule 2262 and Proposed Rule 3060, but it states that the solution was already found in its rules.[38] More specifically, if the ADMC proposed rule is approved, "Rule 3060 will supersede the parallel provisions in Rule 2262"—a supersession that stems from language in Rule 3070(c) providing that "[i]n the event of any conflict between the Protocol and any other rules , . . . the Protocol shall prevail."[39] The Authority characterizes Dr. Sivick's complaint (and Dr. Fenger's similar point) as concerning "unregistered veterinarians who have no direct contact with horse racing and are unfamiliar with the Authority's rules [becoming] unfairly punished for violations pertaining to the provision of veterinary care to Covered Horses."[40] In response, the Authority notes that Proposed Rule 3040(b)(4) obligates the Responsible Person to inform all covered persons, including veterinarians, of their "respective obligations under the Protocol" and "to adequately supervise them."[41] The Authority does not respond to the Oklahoma Commission's complaint about Proposed Rule 3040(b)(3) or to the Texas Commission's complaint about Proposed Rule 3010(e)–(f).

The Commission finds that Proposed Rules 3010–3090, which lay out the purpose, scope, and organization of the Protocol, are consistent with the Act. The provisions of Proposed Rule 3010 closely track the statutory language of 15 U.S.C. § 3055(b). As for the conflict between

[37] Cmt. of Dr. Clara Fenger 1 ("Second Fenger Cmt.") (Feb. 6, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0072.
[38] Authority's Response at 21–22.
[39] *Id.* at 22.
[40] *Id*. at 3.
[41] *Id.* at 3–4.

Rule 2262 and Proposed Rule 3060 regarding void claims, the Authority provides a cogent explanation for how Proposed Rule 3060 would supersede Rule 2262 through the preemption terms in Proposed Rule 3070(c). Nonetheless, although that reasoning is correct, it is also complex, and the Commission reco

As for the Kentucky Commission's complaints about Proposed Rule 3040(b)(3), it does appear that, because there is no knowledge requirement, the provision imposes strict liability on the Responsible Person to ensure that no improper medications or methods (including banned substances or methods) are administered. These obligations are consistent with Proposed Rule 3030(a), which imposes personal liability on the Responsible Person for his or her Covered Horse regardless of knowledge or intent. Most important, the Kentucky Commission does not point to any inconsistency between Proposed Rule 3040(b)(3) and the Act. Indeed, strict liability for certain infractions under Proposed Rule 3040(b)(3) is consistent with the strict liability sanctions imposed on trainers under 15 U.S.C. § 3057(a)(2)(A) for, among other things, the presence of a prohibited substance in a horse.

Finally, as for the Oklahoma Commission's point about adding into Proposed Rule 3040(b) that adjudicators can consider the World Anti-Doping Code Program, the Commission does not believe that there is a need to do so because Propose Rule 3070(d) already states that the Code Program may be considered when adjudicating cases.

The Commission welcomes future proposed rule modifications that the Authority decides to submit in response to the useful comment from the Kentucky Commission about the void-claims rule conflict and any other useful comments received.

2. Rules 3110–3140 – Prohibited List, Rules of Proof, and Testing and Investigations

Proposed Rule 3111 describes the Prohibited List, which identifies Prohibited Substances and Prohibited Methods that include both (a) Banned Substances and Banned Methods that are always prohibited as well as (b) Controlled Substances and Controlled Medication Methods that are prohibited only during the Race Period. The Prohibited List is supplemented by the "Technical Document—Prohibited Substances," which provides further guidance on the

Prohibited Substances. Proposed Rules 3121–3122 place the burden on the Agency to prove a violation of the Protocol "to the comfortable satisfaction of the hearing panel" based on facts "established by any reliable means."[42] Proposed Rules 3132–3137 give the Agency broad authority to test Covered Horses, both in and out of competition, mainly to detect the presence of Prohibited Substances. Third parties may request that the Agency conduct enhanced or additional testing, which the Agency may accept or decline in its discretion. Proposed Rule 3140 permits clearance testing (*i.e.*, a request to determine if controlled medication substances have cleared the horse's system) by a laboratory if, before such testing, (1) the Agency approves such request and (2) the Covered Person pays the costs for sample collection and analysis. Further, the Agency may pursue any violation of the Protocol based on the results of such testing.

The Kentucky Horsemen argue that "the burdens of proof and presumptions in proposed Rules 3121 and 3122(a), (b), and (c) create a significant (if not insurmountable) hurdle for an accused violator of the [ADMC] rules who seeks to defend him or herself" and that "adequate due process" requires that the "accused *must be afforded* an *unconditional* opportunity to proffer oral and written evidence and other submissions in a full-on arbitral hearing."[43] Along similar lines, the Oklahoma Commission contends that the presumptions in Proposed Rule 3132(a) will "relieve a party from having to actually prove the truth of the fact being presumed [and] may negatively affect integrity of [the Horseracing Integrity & Welfare Unit] testing program."[44] The National Horsemen ask whether, in providing that decisions arising from Proposed Rule 3113 ("Validity of the Prohibited List and Related Technical Documents") "shall not be subject to any challenge," that proposed rule "implies that no mitigating circumstances [will] be allowed."[45]

[42] Notice, 88 Fed. Reg. at 5054 (Proposed Rules 3121–3122).
[43] Second Ky. Horsemen Cmt. at 14 (emphasis in original).
[44] Okla. Comm'n Cmt. at 3.
[45] First and Second Nat'l Horsemen Cmts. at 40.

The National Horsemen further argue that "[n]ot allowing any challenges to analytical methods, screening limits, decision limits and assuming [that those] are scientifically valid is simply wrong" because "[i]f these methods and limits are scientifically valid, they will stand up to legal challenges" and "if they are scientifically flawed then a horseman should not be held responsible for meeting them and they should be allowed to be challenged and subsequently changed."[46] Dr. Fenger likewise complains that "[t]he Prohibited List includes many substances with appropriate use during the out-of-competition period," which the covered person cannot challenge under Proposed Rule 3113.[47]

As to Proposed Rule 3132(e), which states that "[a]ny sample collected following a Vets' List workout constitutes a post-race sample, and, as a result is subject to all of the same requirements that apply to [a] sample collection at covered horseraces," the Kentucky Commission asks whether this provision requires that "post-workout samples will be tested for furosemide (Lasix)."[48]

Although the Kentucky Horsemen complain about the burden of proof and presumptions in Proposed Rules 3121 and 3122, the Agency retains the initial burden of establishing that a violation occurred and for that must satisfy a heightened standard of proof: “comfortable satisfaction of the hearing panel,” which is higher than the “preponderance of the evidence” standard.[56] By contrast, the opposing party‘s showing on rebuttal is subject to the lower preponderance standard.[57] The Oklahoma Commission’s assertion that presumptions “relieve the party from having to actually prove the truth of the fact being presumed” ignores that the same approach is applied under the World Anti-Doping Code, which the Act (15 U.S.C. § 3055(g)(2)(A)(ii)) requires to be considered. Further, the accused person can rebut the presumption by showing “that a departure from the Laboratory Standards occurred that could reasonably have caused the Adverse Analytical Finding.”[58]

The Commission also finds that Proposed Rule 3140 governing Clearance Testing is consistent with the Act. In particular, in developing the ADMC program, the Authority must consider that “[c]overed horses should compete only when they are free from the influence of medications [and] other foreign substances, . . . that affect their performance.” 15 U.S.C. § 3055(b)(1). Clearance testing is one way to ensure compliance with § 3055(b)(1) and allows trainers to use a process to confirm that no banned substances are present in the horse so that it is safe for the horse to participate in races again.

Likewise, the Commission finds that Proposed Rule 3132 (“Authority to Test”) is consistent with the Act. The Commission agrees with the comment from the [illegible] about the [illegible]

With respect to the Kentucky Commission's inquiry about whether Proposed Rule 3132(e) requires testing for Lasix in a post–Vets' List workout sample, the Authority reasonably observes that Proposed Rule 4212(d) allows such use. Regarding the Kentucky Commission's suggestion that post–Vets' List workout samples not be considered post-race samples, it appears that the sampling conducted under Proposed Rule 3132(e) is done at the affirmative request of the Responsible Person to release a horse from the Vets' List so that the horse may enter races again.[59] Thus, the Commission believes that it is entirely appropriate to require a sample collection to be tested like a post-race sample to ensure that the horse enters the race period free of any banned or controlled substances. Furthermore, the Commission notes that Proposed Rule 3132(e) states only that the horse "*may* be required to submit to [a] sample collection," and thus does not require sampling in every instance. As for the Kentucky Commission's question about imposing costs on the owner for Clearance Testing, it seems entirely reasonable to impose such costs on the party asking for the test's benefit—in this instance, the trainer, who is asking for Clearance Testing as a means to reenter her horse in races.

3. Rules 3210–3260 – Equine Anti-Doping Rules

In Proposed Rules 3211–3231, the Authority proposes a list of civil sanctions for Anti-Doping rule violations. Proposed Rules 3212–3214 impose violations for the use, attempted use, possession, trafficking, or administration of Banned Substances or Banned Methods to a Covered Horse, and they impose strict liability on the Responsible Person when a Banned Substance is found in a Covered Horse. Proposed Rules 3215–3216 impose sanctions for refusing or failing to submit a Covered Horse to a sample collection, tampering with doping control, complicity in

[59] Proposed Rule 3132h(e) states in relevant part that "a Covered Horse may be required to submit to Sample collection (at the Owner's cost) following a Vets' List Workout in order to be released from the Veterinarians' List." Notice, 88 Fed. Reg. at 5098.

baseline ADMC rules identified in the Act. *See* 15 U.S.C. § 3055(g)(2)(A)(ii).

4. Rules 3310–3360 – Equine Controlled Medication Rules

In Proposed Rules 3312–3316, the Authority proposes a list of sanctionable violations of the Equine Controlled Medication Rules for conduct involving medication substances and methods. Proposed Rules 3313 and 3315 prohibit the use, attempted use, possession, or administration of Controlled Medication Substances or Controlled Medication Methods to a Covered Horse during the Race Period. Proposed Rules 3315–3316 bar a Covered Person from being complicit in another person's violation or from tampering with medication control. Other violations include the presence of a Controlled Medication Substance in a sample collected from a Covered Horse (Proposed Rule 3312) or the use of a Controlled Medication Substance unjustified by the horse's medical condition or other criteria (Proposed Rule 3314). Strict liability is imposed in Proposed Rules 3312–3314 for presence and use violations. Proposed Rule 3321 automatically disqualifies racing results (but not subsequent results) when the violation is based on a post-race sample or occurs during the Race Period, and irrespective of the reason why the substance was detected or of any degree of fault. Proposed Rule 3322 states that if a violation is based on a Controlled Medication Substance, horses will be race eligible, but if there is a Controlled Medication Method violation, the horse may be ineligible to race. Proposed Rules 3323–3328 and 3331 impose sanctions (*i.e.*, periods of ineligibility, disqualification of results, fines, legal costs, and public disclosure of violation information) on Covered Persons for a rule violation. Those proposed rules allow for the elimination or reduction of the ineligibility period when there is no or little fault or negligence or if the Covered Person has provided investigative assistance—and, conversely, provide for an increase in the ineligibility period where a repeat offense or aggravating circumstances are involved. Proposed Rule 3328 imposes a penalty point

No comments address these provisions. The Authority accordingly provides no response.

The Commission finds that it is consistent with the Act and will further the Act's purposes to impose additional disciplinary measures for offenses that adversely affect the activities of the Agency or the

environment, and readily absorbed by the horse), which it names "Environmental Substances," should be considered Specified Substances and, like others in that category, should be recognized by the ADMC Committee as involving inadvertent environmental transfers that can result in positive tests. They therefore contend that "if such inadvertent environmental transfer—rather than intentional administration—to a horse results in an adverse analytical finding, the trainer and the horse should be eligible only for 'a minimal penalty.' "[78] Because "the source of inadvertent environmental exposure often cannot be identified," the National Horsemen contend that Authority investigations of adverse analytical findings involving such substances should involve standard investigative procedures, including providing potentially exculpatory evidence, and must be directed to fact finding.[79] The National Horsemen also recommend screening limits consistent with environmental contamination, similar to the limits they recommend for dietary substances.[80]

Dr. John Sivick (following NAARV's template) likewise contends that "the majority of violations will result from [innocent] transfer of random substances from the environment."[81] Dr. Fenger's comment agrees.[82]

Regarding the limits of detection for substances on the Prohibited List, one commenter complains about "appropriate classifications for substances [and] establishing reasonable thresholds which correlate with the ability to affect performance or endanger the welfare of the horse." Of particular concern to this commenter are findings based on limits of detection that

[78] *Id.*;

contamination, the matter will not be pursued as an Adverse Analytical Finding, and the Atypical Finding will not be publicly disclosed."[90]

The Commission commends the Authority for developing and implementing its Atypical Findings Policy; among other things, the policy takes into account the possibility that a preliminary adverse analytical result may have been caused by innocent environmental contamination, in which case sanctions will not result.[91] The Commission finds that provisions that implement the Atypical Findings Policy are consistent with the Act, particularly the Act's sections governing investigations, testing, and results management.[92]

Regarding the National Horsemen's point about screening limits for endogenous and dietary substances, the Authority states that "[t]hresholds are established in the Technical Document . . . for endogenous substances" and "screening limits are established for dietary substances."[93] As for "Environmental Substances," the Authority notes that the Technical Document characterizes Specified Substances and lists screening limits for environmental substances that are consistent with IFHA Article 6.[94]

The Commission finds that Proposed Rule 4010 is consistent with the Act. The statute requires the Authority to issue "a list of permitted and prohibited medications, substances, and methods."[95] Refinements to the rule suggested by the National Horsemen and other commenters might be considered for future proposed rule modifications, but for purposes of the Commission's current review these constitute mere policy disagreements with the Authority and

[90] Authority's Response at 11–12.
[91] *See* Notice, 88 Fed. Reg. at 5096, 5106, 5115, 5120 (Proposed Rules 3111(d), 3243(c), 3343(c), 3620(b)(5)); *see generally id.* at 5120–21.
[92] *See, e.g.*, 15 U.S.C. §§ 3055(c)(4) (results management and investigations), 3055(c)(1)(A)(ii) (uniform standards for laboratory testing protocols).
[93] Authority's Response at 12.
[94] *Id.*
[95] 15 U.S.C. § 3055(c)(1)(B).

not any inconsistency with the Act. The Commission also finds that adopting limits of detection and omitting withdrawal times are proper methods to ensure the integrity of testing and are consistent with the Act.[96] Finally, the Commission concurs with the Authority that, with respect to drawing medication policies from the states that use policies of ARCI and the Racing Medication and Testing Consortium ("RMTC"), the Act requires instead the adoption of IFHA medication controls.[97]

1. Rule Series 4100 – Banned Substances and Banned Methods

In Proposed Rule Series 4100, the Authority identifies from the Prohibited List those substances and methods that are prohibited at all times ("Banned Substances" and "Banned Methods"). Proposed Rules 4111–4117 list six categories of Banned Substances, and Proposed Rules 4121–4123 list three categories of Banned Methods.

The National Horsemen lodge a series of complaints about Rule 4111.[98] They claim that the rule ignores the statutory standards in 15 U.S.C. § 3055(b)(1) in favor of the Authority's own requirement that medications must be FDA-approved before they are taken off the S0 banned-substances list. Put simply, they contend that "no substances with a valid therapeutic use should ever be in the S0 category"[99] and that there is no justification to bar therapeutic medications that are legal but lack FDA approval.[100] Dr. Fenger makes the similar point that "[t]he Prohibited List

[96] *See id.* §§ 3053(a)(3) (laboratory standards for accreditation and protocol), 3055(c)(1)(A)(ii) (Authority obligated to issue rules concerning "uniform standards for . . . laboratory testing accreditation and protocols"), 3057(b)(1)(C) (Authority responsible for issuing by rule "the standards and protocols for testing such samples").
[97] *See id.* § 3055(b)(4), (g)(2)(A).
[98] Proposed Rule 4111 ("S0 Non-approved Substances") states: "Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117 [other categories of banned substances], (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0." Notice, 88 Fed. Reg. at 5122.
[99] Nat'l Horsemen Cmt. at 6.
[100] The National Horsemen list these substances in Tables 1a and 1b of their comment.

includes many substances with appropriate use during the out-of-competition period" and asserts that "[t]he regulations far exceed their mandate, by regulating therapeutic medications beyond the in-competition period, interfering with the ability of veterinarians to appropriately treat their patients."[101]

The National Horsemen observe that there were several primary metabolites of S7 substances that are included in the S0 list and contend that, if "the S7 substance does not warrant an S0 penalty, then there is no place for its primary metabolites on the S0 list."[102] The National Horsemen also raise concerns about the banning of standard medications required for breeding fillies, as well as anesthesia induction, reversal agents, and long-term tranquilizers used in the post-operation period for horses requiring stall rest.[103] Finally, the National Horsemen complain about imposing a 14-month ineligibility period for using any ADMC medication without a sufficient scientific basis and that doing so could "adversely impact the health and welfare of the horse" by preventing appropriate therapy or by preventing the horse from training because it was "inadvertently administered such a substance."[104] The National Horsemen urge the ADMC committee (1) to consider moving FDA-approved medications or their metabolites from the S0 to the S7 category and (2) to "further reconsider the 14-month ineligibility period" because "it is inappropriate to include in this S0 category, therapeutic substances whose use is Standard of Veterinary Practice."[105] The National Horsemen provide no scientific support for their assertions.

The Oklahoma Commission recommends adding ammonium sulfate as an S6 miscellaneous substance (from its current S0 classification), because when "[w]hen fed orally" it

[101] Second Fenger Cmt. at 1, 2.
[102] Nat'l Horsemen Cmt. at 6.
[103] *Id.* at 2, 6.
[104] *Id*. at 7.
[105] *Id.*

acts as a "urinary acidifier in horses" and, in compounded injectable form, "may be used as a regional or local anesthetic on horses for race day purposes."[106]

The Authority responds to criticisms regarding its FDA-approval requirement by stating that, if a substance is not legally required to have FDA approval, "then lack of FDA approval does not disqualify it from use."[107] On the other hand, "if a substance meets the FDA criteria for a 'Drug' and it does not have FDA approval, it is a Banned Substance."[108] The Authority further notes that "there are FDA approved medications that have no legitimate use in the horse; therefore, they are designated as Banned Substances," a conclusion it supports.[109] The Authority further notes that the S0 designation can be revised based on a substance's evolving use as recognized by international regulators and veterinary colleges.[110] As for the primary metabolites of S7 substances being on the S0 list, the Authority replies that "the Technical Document provides for penalty mitigation when an S0 substance is determined to be present in a sample as a consequence of a documented administration of an S7 substance.[111] Regarding the National Horsemen's complaint about prohibiting the use of standard medications necessary for breeding fillies, the Authority notes the National Horsemen's failure to identify any such medications and states further that medications conventionally used for pregnancy purposes are all classified as S7 substances and therefore permitted for use in fillies and mares under specified conditions. As for the use of anesthesia induction agents, the Authority says that conventional agents have been classified as S7 substances based on advice from veterinary specialists.[112] Regarding the asserted bar on long-term tranquilizers, the Authority replies that several long-term tranquilizers are S7

[106] Okla. Comm'n Cmt. at 4.
[107] Authority's Response at 10.
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.* at 11.

substances, so veterinarians are able to use those to control horse activity in the peri-operative period.[113] Finally, the Authority disagrees with the National Horsemen's comment about the 14-month ineligibility period, asserting that there simply "is no period of ineligibility" for a horse that was given an S7 controlled substance.[114] As for S0 violations, the Authority agrees that there is an ineligibility period for "up to 14 months" but notes that the prohibited list will be reviewed annually based on science and evolving use.

The Commission finds that Proposed Rule 4111 is consistent with the Act. Proposed Rule 4111's ban on S0 substances that have "no current approval by any governmental regulatory health authority for veterinary or human use" or are "not universally recognized by veterinary regulatory authorities as a valid veterinary use" is certainly consistent with the Act's requirement that the medication must "represent[ ] an appropriate component of treatment." 15 U.S.C. § 3055(b)(5). As the Authority states, the designation of a banned substance on the S0 category was based on a robust scientific record that included research findings and input from veterinary specialists and research findings, and these sources informed the Authority's decision to designate a substance in the S0 category due to the health risk it poses to horses.

By contrast, as the Authority points out, the National Horsemen fail to back up many of their claims with scientific evidence. The National Horsemen rely heavily on a provision in the Act that bars medication that "affect[s] [the horse's] performance." 15 U.S.C. § 3055(b)(1). But that phrase is susceptible to different interpretations, and the Authority's determination of banned substances falls comfortably within the scope of § 3055(b)(1). As the Authority points out, the designation of a substance as Banned or Controlled cannot be based solely on individual practitioners' preferences or beliefs that particular therapeutic substances

or restricted—particularly in the absence of supporting scientific literature.[115] Commenters are incorrect when they assert that the Authority requires FDA approval for a substance to be used. As the Authority replies, if a substance is not legally required to have FDA approval, "then lack of FDA approval does not disqualify it from use."[116] Conversely, "there are FDA approved medications that have no legitimate use in the horse; therefore, they are designated as Banned Substances."[117] Such a reading is entirely consistent with the Act.

As for the Oklahoma Commission's suggestion to add ammonium sulfate as an S6 miscellaneous substance, the Authority states that, like other ammonium salts, "[a]mmonium sulfate would fall under category S0 of the Prohibited List" as not approved for any veterinary use and thus banned at all times.[118] The substance "can be added to the Technical Document when it undergoes annual review," says the Authority, but until then remains banned.[119] The Oklahoma Commission's suggestion to reclassify ammonium sulfate as a S6 miscellaneous substance under Proposed Rule 4117 and the Authority's reasoned response that it remains for now an S0 "non-approved substance" under Proposed Rule 4111 might reflect different approaches, but they do not reveal any inconsistency with the Act. The Authority has the power to determine, with the approval of the Commission, what are permitted and prohibited substances and medications.[120] The Authority's current determination to keep ammonium sulfate as an S0 substance falls clearly within its power under the Act.

Finally, the Commission notes the Authority's statement that the Prohibited List is reviewed annually and can be revised based on "new science, evolving trends in medication use,

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[115] *Id*.
[116] *Id*. at 10.
[117] *Id*.
[118] *See* Notice, 88 Fed. Reg. at 5127 (Proposed Rule 4111 ("S0 Non-Approved Substances")).
[119] Authority's Response at 26.
[120] *See* 15 U.S.C. §§ 3055(c)(1)(B), 3055(c)(5).

changes to FDA approvals, and input provided by stakeholders and veterinary experts."[121] The Commission encourages the Authority to submit a proposed rule modification as necessary if any

substance."[124] The AWI notes that the United States was the only major racing jurisdiction in the world to permit the race-day use of Lasix and, while appreciating the Authority's work, hopes for an eventual prohibition on the race-day use of Lasix in the United States.[125] Although recognizing the therapeutic role Lasix can play to treat exercise-induced pulmonary hemorrhage, the AWI notes that such treatment "affects only a small percentage of horses," whereas the overreliance on Lasix in the lead-up to a race has long been a serious concern; indeed, it cites research that approximately 95% of starters in the United States receive Lasix. As a powerful diuretic, Lasix can cause horses to lose 20 to 30 pounds of fluid, enabling them to run faster but also causing severe dehydration, which in turn can be linked to electrolyte imbalance, muscle fatigue, and overall exhaustion. AWI recognizes that resistance to barring or even limiting the use of Lasix exists in the United States. AWI characterizes as important first steps the Agency's position that Lasix should be categorized as a controlled medication category and its four-hour race day prohibition, but nevertheless notes that "workouts pose just as much risk for horses as racing." Other commenters express opposition to any restrictions on the use of furosemide.[126]

The Texas Commission states that "[s]ince feed is undefined in the HISA regulations, the provision [Proposed Rule 4211] may or may not make complete feed illegal in the last 24 to 48 hours."[127] It also suggests changing Proposed Rule 4211(b) to the language used in Texas rules that prohibit the use of substances for 24 hours before post time, which allows "treatments that are necessary for horse welfare" without any ill effects "on the safety or integrity of the sport."[128]

[124] Second AWI Cmt. at 3.
[125] *Id.*; *see also* First AWI Cmt. at 2–3.
[126] Cmt. of Joseph Bahadoor (Jan. 29, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0008; Cmt. of Gerald Bergsma Cmt. (Jan. 30, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0015; Cmt. of Cindy Murphy Cmt. (Feb. 8, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0092.
[127] First Tex. Comm'n Cmt. at 4.
[128] Second Tex. Comm'n Cmt. at 2–3.

The Authority takes issue with the Texas Commission's comment to change Proposed Rule 4211(a), suggesting that such a change would allow the use of banned substances and would allow more than only feed, hay, and water to be given to the horse during the last 48 hours before race time. In response to AWI's Rule 4212 proposal, the Authority notes that the 4-hour window is solidly grounded in science and based on the period of time required for furosemide's dilution effect on the urine to resolve.[129] The Authority explains that the risk of a masking effect from the use of diuretics is based on the production of dilute urine below the laboratory's sensitivity to detect that substance.

The Authority also discusses its obligations under 15 U.S.C. § 3055(e)–(f) to convene an advisory committee to study the use of furosemide on horses during the 48-hour period before post time, and that the committee's findings must be submitted within three years of the program's effective date. During the three-year period, state racing commissions are permitted to request an exemption for furosemide from the prohibition in 15 U.S.C. § 3055(d) (an exemption that may not be requested for two-year-old Covered Horses or Covered Horses competing in stakes races). In the meantime, as the Authority observes, there is a sound scientific basis for the provisions proposed by the Authority concerning furosemide; moreover, "much of the international racing community conducts racing without the use of race-day furosemide and has done so for decades," which shows that "horses can race safely and successfully without furosemide administration."[130]

The Authority disagrees with the Texas Commission's assertion that Proposed Rule 4211 might make feed illegal up to 48 hours before race time. It states that "[f]eed is clearly permitted

[129] Authority's Response at 4.
[130] *Id*. at 4–5.

in Rule 4211."[131] The Authority also takes issue with the Texas Commission's comment to change Proposed Rule 4211(a) because it believes that Texas's suggested changes would allow the use of banned substances and would allow many more substances to be given to the horse in the 48 hours prior to post time beyond only feed, hay, and water during the 48-hour race period.

The Commission finds that Rule Series 4200 is consistent with the Act. As for furosemide (Lasix), the Commission finds that the limited (and temporarily three-year-excepted) use of Lasix under Proposed Rule 4212(d) is consistent with the Act.[132] Regarding whether feed is barred during the race period, Proposed Rule 4211(a) expressly states that "feed, hay, and water are permitted during the Race Period."[133] Although the Texas Commission is not exactly clear on what changes it seeks to Proposed Rule 4211(a), the Commission believes that the proposed provision (along with the exceptions in Proposed Rule 4212) strikes an appropriate balance by prohibiting all banned substances at any time and restricting the abuse of any controlled medical substances in the two days before race time, after which only feed, hay, and water can be given to the horse; Proposed Rule 4211(a) is consistent with the Act's requirements to protect the health and wellbeing of racehorses.

resulting from a violation involving a prohibited substance; it states that there is no period of ineligibility resulting from a violation involving an S7 controlled medication substance, but that the covered horse "may be placed on the Veterinarian's List, and, if so, then a subsequent Vets' List Workout must be scheduled [and] [a] post-Vets' List Workout Sample may be required."[134]

The Oklahoma Commission suggests that the rule specify that the Regulatory Veterinarian possesses discretion to place a horse on the Vets' List after an S7 substance violation even if the horse were eligible to compete, out of concern for "NSAIDs & corticosteroids (among other substances) possibly masking lameness & welfare issues."[135] The Authority agrees, with the desirability of such discretion, stating that "[t]he horse may be placed on the Vets' List to verify its fitness to race if warranted in the opinion of the Regulatory Veterinarian."[136]

The Commission agrees with both the comment and the Authority that, even when a horse could return to racing after a finding of an S7 controlled-medication violation, the Regulatory Veterinarian has the discretion to postpone such return and place the horse on the Vets' List until the horse's condition improves. Proposed Rule 4310 as applied is consistent with—indeed, mandated by—the Act.[137]

4. Rule Series 4000 Appendix: Technical Document—Prohibited Substances

The Proposed Rule Series 4000 Appendix lists those prohibited substances falling within the general categories in the Prohibited List and sets forth their detection times, screening limits, and thresholds.

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[134] *See id*. at 5124.
[135] Okla. Comm'n Cmt. at 4.
[136] Authority's Response at 26–27.
[137] *See* 15 U.S.C. § 3055(b)(2) (requiring the Authority to consider, in developing its ADMC program, that "covered horses that are . . . unsound should not . . . participate in covered races, and that "the use of medications [and] other foreign substances . . . that mask or deaden pain in order to allow . . . unsound horses to . . . race should be prohibited").

The Authority's Prohibited Substances—Technical Document elicited many comments. The National Horsemen and Kentucky Horsemen (using identical language) argue that the Technical Document "completely reorganizes the existing [ARCI] Uniform Classification Guidelines" for "no good reason"; they describe the Guidelines as having "been developed and refined over many years," and as based on peer-reviewed, veterinary science–based research concerning "the potential for a substance to affect racing performance or endanger the welfare of the horse."[138] The National Horsemen and Kentucky Horsemen also raise concerns about blank spots in the Prohibited Substance list that would default to the limit of detection without regard for a substance's ability to be transferred from the environment or to have a very long terminal half-life.[139] They claim that 12% of substances on the list are at risk of environmental transfer either from common, legal use as an oral medication or from stability in the environment. Further, they express the concern that veterinarians will need to be careful about using therapeutics with extremely long terminal half-lives.[140]

The National Horsemen also complain about the Authority's handling in the Prohibited Substances—Technical Document of S7 therapeutic medications,[141] which they deem a clear departure from the original ARCI goal of establishing scientifically based withdrawal times and thresholds for therapeutic medications. The National Horsemen claim (as does a nearly identical comment from K. Myrick) that the Authority has determined the regulation of most therapeutic medications to be at limit of detection, which they claim restricts the use of many therapeutic

[138] Second Nat'l Horsemen Cmt. at 3; First Nat'l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. at 1 & Att. (Hiles Cmt.).
[139] Second Nat'l Horsemen Cmt. at 3; First Nat'l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. at 1 & Att. (Hiles Cmt.).
[140] Second Nat'l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. Attach. (Hiles Cmt.) at 2; First Nat'l Horsemen Cmt. at 1, 3.
[141] Second Nat'l Horsemen Cmt. at 2–4, 28.

5320(c)–(e) and 5420–5440 set forth a

provide “the most conclusive evidence there is” of what happened there.[161] They assert that these provisions hamstring their ability to contest “the Agency’s ECM rule violation charge [as] incorrect due to non-compliance with a key sample collection, handling, or testing protocol.”[162] The Oklahoma Commission expresses the same concern regarding the prohibition on photography/videography of the sample collection session, stating that the provision “decreases testing integrity and transparency” and that—especially given the Responsible Person’s potential liability—“recording of [a] sampling session should be a reserved right.”[163]

standards "governing investigations or sample collection[s]" were followed properly.[168] The Kentucky Horsemen assert that the accused must be able to supplement the record created in the adjudicatory stage if review of the final decision and sanction is sought from the Commission under § 3058.[169]

Dr. Sivick complains that the proposed rule provisions "permit laboratories to call positive tests at their limits of detection, which may vary widely from lab to lab."[170] "The end result of this regulation," Dr. Sivick asserts, "is to have completely different rules depending upon which laboratory is testing the samples," such that "[t]he approval of these regulations will result in differing violations from jurisdiction to jurisdiction depending on the laboratory limits of detection."[171] Finally, the Texas Commission criticizes Proposed Rule 5450(b)(2)(i) as "prohibiting individuals from performing the duties of Sample Collection Personnel if they are involved in the administration of horseracing." The Texas Commission claims this restriction will essentially "exclude any Association Veterinarian from collecting samples . . . [and] will put the Association in the untenable position of being required to obtain a sample for injured or euthanized horses but unable to do so because of the lack of authorized personnel on site."[172]

As for Kentucky Commission's comment about sample collection packaging under Proposed Rule 5320, the Authority notes that "[b]ulk packaging only ensures the first container retrieved from the sealed package is 'clean and

bulk packaging meets the requirements of Proposed Rule 5320(b). With respect to the Oklahoma Commission's complaint about testing laboratories' purported lack of storage space due to housing samples and related documents, the Authority's response shows that in fact laboratories

Scrivener's errors were found in Proposed Rules 5430(e) and 5510(b)(1). The Commission deems the errors to be corrected in the final rule.[181]

2. Rules 5600–5700 – Investigations

Proposed Rules 5610–5640 require the Agency to obtain, assess, and process anti-doping and medication control intelligence from all available sources so as to detect and deter doping and medication abuse, develop effective test planning, and conduct investigations. Proposed Rules 5710–5740 require the Agency to conduct efficient and effective investigations into (among other things) atypical findings and other sample abnormalities, and to scrutinize other information or intelligence, in order to determine whether there has been an anti-doping or controlled medication rule violation or other rule violation. The Agency must use all available investigative resources, including obtaining information from law enforcement authorities and other regulators. The investigative powers provided to the Agency by Proposed Rule 5730 include inspection, examination, seizure, production of documents, subpoenas, and interviews. Proposed Rule 5720(f) requires all covered person to cooperate with the Agency's investigations and provides that failure to do so may result in the imposition of sanctions.

No comments were received about these proposed rules and thus the Authority provided no response.

The Commission finds that these rules are consistent with the Act. Investigations of potential ADMC rule violations play a central part in the program and are required to be conducted pursuant to several statutory provisions.[182]

e. Rule Series 6000 – Equine Standards for Laboratories and Accreditation

[181] In the final rule, the words "within the kit" will be deemed as stricken from Rule 5430(e). The Notice explained this change, stating that "it was not consistent with collection kits available in the industry." *See* 88 Fed. Reg. at 5083. In Rule 5510(b)(1), the word "refigerator" will be deemed to be corrected as "refrigerator" in the final rule.
[182] *See, e.g.*, 15 U.S.C. §§ 3054(c)(1)(A), 3054(e)(1)(E), 3055(c)(4).

Proposed Rule Series 6000 establishes "Laboratory Standards" to govern the accreditation of laboratories used to test samples obtained from Covered Horses, the process for achieving and maintaining such accreditation, and the standards and protocols for testing the recovered samples. Its "main purpose . . . is to ensure that Laboratories report valid test results based on reliable evidentiary data and to facilitate harmonization in Analytical Testing of Samples by Laboratories."[183] Proposed Rule Series 6100 prescribes the standards and procedures under which a laboratory can obtain and maintain HISA Equine Analytical Laboratory ("HEAL") accreditation. Proposed Rule 6130 deals specifically with a laboratory's efforts to maintain HEAL accreditation, while Proposed Rule 6140 addresses the Agency's monitoring of laboratories' accreditation status. Proposed Rule 6500 sets forth the circumstances that may lead to suspension, revocation, or restriction of a laboratory's HEAL accreditation. Proposed Rule Series 6200, 6400, and 6600 establish procedures for monitoring the quality of laboratories' performance. Under Proposed Rule 6210, the Agency will distribute samples used to monitor laboratories' capabilities and performance. Proposed Rule Series 6400 sets forth the procedures that will be used by the Agency to inform laboratories of deficiencies in their testing operations and results and to monitor the laboratories' corrective efforts. Proposed Rule Series 6300 includes standards for the analysis of samples as well as criteria to govern the withdrawal of HEAL accreditation if a laboratory falls short of those standards.

The American Association for Laboratory Accreditation ("A2LA") "commend[s]" the Authority "for developing a robust program concerning Anti(Doping and Medication Control" and "support[s] . . . the laboratory testing requirement": "specifically[,] the inclusion of the requirement to be ISO 17025 accredited by an accreditation body who is an [International

[183] Notice, 88 Fed. Reg. at 5171 (Proposed Rule 6010(a)).

"to avoid manifest injustice" (Proposed Rule 7310). Proposed Rule 7340 sets forth the timing for issuing a final decision, and Proposed Rule 7350 authorizes arbitrators and IAP members to "grant any remedy or relief authorized by the Act" or its rules. Under Proposed Rule 7400, final decisions of the Arbitral Body or the IAP are subject to review pursuant to 15 U.S.C. § 3058.

The Kentucky Horsemen challenge multiple rule provisions in Rule Series 7000. They first contend that the Act created a "separation of powers" framework in which the Authority has been given "legislative-like functions" while the Agency has been provided both law enforcement and adjudicative authority.[195] For enforcement duties, they cite to the Act's directive that the Agency "shall . . . serve as the independent [ADMC] enforcement organization."[196] They assert that the Agency's adjudicative functions derive from its statutory mandate to "conduct and oversee [ADMC] results management, including independent investigations, charging, and adjudication of potential [ADMC] rule violations."[197] This mandate, the Kentucky Horsemen contend, gives the Agency the exclusive right to choose members of the Arbitral Panel and the IAP.[198] According to the Kentucky Horsemen, such an arrangement—embodied in Proposed Rules 7020, 7030, and 7040, which allow the Authority to enter "mutual agreements" with the Agency in the selection and appointment of arbitrators and adjudicators who serve on those panels—violates the Act by improperly (*i.e.*, without statutory authorization) giving "the Authority a role in 'adjudication.' "[199]

The Kentucky Horsemen further contend that "Sections 3054(a), (e)(1) and 3055(c)(4)(B) of the Act *do not permit the Authority* to have any say or input—by 'mutual agreement' or

[195] First Ky. Horsemen Cmt. at 2–3.
[196] *Id.* at 1; *see* 15 U.S.C § 3054(c)(1)(E)(i).
[197] First Ky. Horsemen Cmt. at 2–3 (citing 15 U.S.C.§ 3055(c)(4)(B); *see also* 15 U.S.C. § 3054(e)(1)(E) (providing duties of the Agency).
[198] First Ky. Horsemen Cmt. at 3.
[199] *Id.*

otherwise—in selecting or appointing *independent* arbitrators or adjudicators, or pools of same, to adjudicate ADMC rule violations or sanctions."[200] The Kentucky Horsemen contend that the Act structurally walls off the Authority from exercising any role in the Agency's "conduct and over[sight of] . . . results management," including the Agency's oversight of "independent . . . adjudication." 15 U.S.C. § 3055(c)(4)(B). The Kentucky Horsemen assert that this structural wall assures "Covered Persons" that the Agency alone exercises the power to select and appoint arbitrators or adjudicators, who are independent of influence or manipulation by the Authority, to hear charges and consider sanctions.[201] The Kentucky Horsemen argue that each of the contested rules breaches the Act's exclusive assignment of "results management" functions to the Agency to "conduct and oversee . . . independent . . . adjudication."[202]

The Authority rejects these arguments on the grounds that "[t]he Act does not establish a system of separation of powers within the Authority."[203]

The Commission finds that Proposed Rules 7020, 7030, and 7040 are consistent with the Act. The Kentucky Horsemen fail to show that allowing the members of the Arbitral Body and the IAP to be selected by "mutual agreement of the Authority and the Agency" violates the Act's provision for the Agency to "conduct and oversee antidoping and medication control results management, including . . . adjudication."[204] Adjudications are the central element in disciplinary proceedings brought under the Act, and the Act empowers both the Agency and the Authority to play a role in that process. Indeed, the Authority is given broad powers to establish the overall ADMC program itself, including specifying the persons and horses to be covered by the ADMC

[200] *Id.* at 4.
[201] *Id*. at 3–8.
[202] *Id*. at 7.
[203] Authority's Response at 2.
[204] 15 U.S.C. § 3055(c)(4)(B); *see also id.* § 3054(e)(1)(E)(iii) (power to "implement anti-doping . . . adjudication programs").

rules,[205] the ADMC program's "disciplinary process," the "[h]earing procedures" for [ADMC] rule violations,[206] and the rules and procedures for access to relevant facilities and the issuance of subpoenas.[207] The Authority also may submit for Commission approval numerous rules pertaining to nearly all aspects of the ADMC program, including provisions pertaining to the "process or procedures for disciplinary hearings,"[208] provisions describing ADMC rule violations and imposing sanctions for violations,[209] and provisions governing ADMC "results management."[210]

210 The Agency does not have "exclusive" authority over the adjudicati The Authority DMC 89A7ces.4ibing

Second, the Kentucky Horsemen complain that Proposed Rules 3361, 7060(b), 7110(b), and 7180, which concern the adjudication of alleged controlled medication rule violations, fail to provide the "adequate due process" required under 15 U.S.C. § 3057(c)(3) because they allow the IAP to rely solely on the parties' written submissions instead of holding an evidentiary hearing where adverse witnesses can be cross-examined. Cross-examination, the Kentucky Horsemen claim, is required under § 3057(c)(2)(B).[214] The Kentucky Horsemen further assert that an in-person hearing is required at the adjudicative stage because there is no assurance that there will be an evidentiary hearing before an Administrative Law Judge when the final sanction is reviewed by the Commission under 15 U.S.C. § 3058.[215] The Kentucky Horsemen also contend that proposed Rules 7180(c) and 7180(d) fail to provide due process by presumptively disallowing reply briefs.[216] Lastly, say the Kentucky Horsemen, the rules impose "disparate subpoena power" by allowing the Agency to seek relevant information during the investigation and again during the adjudicatory proceeding, whereas the accused may seek relevant information only during the adjudicatory proceeding.

The Authority responds that its proposed ADMC rules were "fully compliant" with its due-process obligations under 15 U.S.C. § 3057(c)(3) and that a hearing was also available before the Commission under 15 U.S.C. § 3058.[217]

The Commission finds that Proposed Rules 3361, 7060(b), 7110(b), and 7180 confer sufficient due process protections to satisfy the criteria in § 3057(c)(3). The Rules allow the

[214] First Ky. Horsemen Cm1the

parties to submit "all supporting documentation" on which they seek to rely[218] and permit adjudication on written briefs alone *only* if the IAP determines that it will be "sufficiently well-informed to render a decision" without a hearing.[219] Written submissions could include, for example, documentation from the sample collection session reflecting the results of the collection and the integrity of the procedures employed, relevant materials received from third parties by IAP order,[220] and information or documents obtained from the other party.[221]

The procedures employed in IAP proceedings to resolve medication control rule charges were deliberately made simpler and less costly "partly in response to requests by commenters to provide for a simplified hearing process for Covered Persons charged with a violation."[222] "The procedure allows the adjudication process to dispense where appropriate with certain of the more formal and costly aspects of legal proceedings." *Id.* The submissions also fit comfortably within the Act's command that "adequate due process" be "commensurate with . . . the possible civil sanctions for such violation." 15 U.S.C. § 3057(c)(3). Infractions of the Authority's medication control rules result in fines and do not lead to periods of ineligibility. If the only available sanction in the Authority's proposed rules were a lifetime ban from the industry, "adequate due process" would likely require more. But with the sliding-scale approach to discipline evidenced in its proposals, the Authority's medication control rule violation procedures provide "adequate due process" that is "commensurate" with the available sanctions. This process is therefore fully consistent with long-standing Supreme Court precedent recognizing that due process does not

[218] Notice, 88 Fed. Reg. at 5199 (Proposed Rule 7180(e)).
[219] *See id.* at 5118, 5197 (Proposed Rules 3361, 7060(b)).
[220] *See id.* at 5199 (Proposed Rule 7260(b)).
[221] *See, e.g.*, *id.* at 5165 (Proposed Rule 5410) (providing detailed procedures for sample collection, including presence of horse trainer or owner to ensure the integrity of the sample); *id.* at 5199 (Proposed Rule 7190) (allowing for "the exchange of information between the parties" and authorizing the adjudicator to "resolve any disputes" that might arise from that exchange); *id.* (Proposed Rule 7260(b)) (permitting party to request IAP member(s) to order production of any document which the party believes to be "relevant and material to the dispute").
[222] *Id.* at 5083.

As to Proposed Rule 7130(b), the Authority responds that the panel will consist of "qualified individuals" who volunteer for a position and that "no steward will be required to serve on the Panel."[237] The Authority does not respond to the inquiry about Proposed Rule 7190.

The Commission finds that Proposed Rule 7130 is consistent with the Act. Proposed Rule 7130 governs the appointment of administrative hearing panels to adjudicate cases arising from alleged violations of the anti-doping and controlled medication rules. Under Proposed Rule 7020(b), a charge resulting from an alleged controlled medication rule violation is adjudicated by members of an IAP, the new name for the pre-existing National Stewards Panel.[238] Proposed Rule 7040(f) specifically allows stewards to se

addressed the private nondelegation concern by amending 15 U.S.C.§ 3053(e) to give the Commission the power to "abrogate, add to, and modify the rules of the Authority."[246] Indeed, the Sixth Circuit has addressed and upheld the amended statute as constitutional.[247] The many (mostly duplicative) comments maintaining that legal uncertainty remains either fail to provide an explanation or erroneously base it on a second ruling by the Fifth Circuit that remanded the case for further proceedings in light of the statutory amendment.[248] Commenters have also claimed, with little support, that the Act violates other constitutional[249] and statutory[250] provisions.

The Commission discerns no persistence of "legal uncertainty" following the statutory amendment. In any event, these comments do not relate to the statutory decisional criteria and thus are irrelevant to the Commission's decision whether to approve or disapprove the ADMC proposed rule.

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[246] Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, 136 Stat. 4459, 5231–32 (2022).
[247] *Oklahoma v. United States*, No. 22-5487, 2023 WL 2336726 (6th Cir. Mar. 3, 2023) (upholding the law against non-delegation and anti-commandeering challenges).
[248] *See, e.g.*, Cmt. of U.S. Reps. Lance Gooden and Jake Ellzey (Feb. 9, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0102 (maintaining that the amendment to 15 U.S.C. § 3053(e) did not cure the statute's constitutional infirmity and recommending that the Commission disapprove the proposed ADMC rules); Cmt. of U.S. Trotting Ass'n (Feb. 8, 2023) (same); Cmt. of K. Myrick (same); Ky. Horsemen Cmt. at 1 (Att. 1) (same); Cmt. of Kim Williams (Feb. 8, 2023), https://www.regulations.gov/comment/FTC-2023-0009-0086 (noting that ARCI has asked the Commission to refrain from approving the ADMC proposed rules until resolution of the Act's constitutionality was resolved); Cmt. of Jared Easterling, General Counsel, Global Gaming Solutions, LLC (Feb. 9, 2023) ("Global Gaming Cmt."), https://www.regulations.gov/comment/FTC-2023-0009-0101 (discussing Fifth Circuit's decision in January 2023 not to withdraw its original holding); Tex. Comm'n Cmt. at 1 (claiming that "the Authority as private actorp.

For the preceding reasons, the Commission finds that the Horseracing Integrity and Safety Authority's ADMC proposed rule is consistent with the Horseracing Integrity and Safety Act of 2020 (as amended) and the Commission's procedural rule governing submissions by the Authority. Accordingly, the Anti-Doping and Medication Control rule is APPROVED.