

RCI Model Rules Committee

PETITION FOR NEW RULE OR CHANGE TO EXISTING RULE

Dexamethasone/Betamethasone

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A. Brief Description of the Issue:

There is no ARCI provision for alternative penalties for drug positives that are likely to result from environmental contamination and unlikely to have a relevant effect on the animal. Among the biggest environmental substance offenders are dexamethasone and betamethasone. These corticosteroids represent two of the most common positive tests since the adoption of the 5 and 10 pg/mL threshold. From the ARCI database for dexamethasone:

2014: 55 violations
2015: 78 violations
2016: 131 violations
2017: 153 violations
2018: 140 violations
2019: 112 violations (through September)

It is likely that the lower numbers in the first few years reflects that fewer jurisdictions had adopted the 5 pg/mL threshold. Despite severe penalties, including disqualifications, suspensions and fines, and the low likelihood that dexamethasone administration would actually influence racing performance (Class 4C), the rate of positive tests continues at a high rate, effectively unchanged, reflecting that these are NOT intentional administrations.

Investigation into the sources of these positives has determined that low level positive tests may sporadically persist well beyond the expected withdrawal, and such positives have occurred even in the absence of any known exposure to dexamethasone.

B. Discussion of the Issue and Problem

Provide background on the issue to build context. Address the following:

- What specific problems or concerns are involved in this issue?*

Horsemen and women are being penalized severely for dexamethasone and betamethasone positive tests that (a) result from inadvertent environmental exposure to the drug, (b) at levels well below any possibility of an effect.

Who does the issue affect?

Everyone in horse racing. Horsemen and women who are harmed by being charged with a violation beyond their control, and everyone in horse racing is negatively impacted by the bad press associated with 100-200 positive tests in the sport.

What existing model rules relate to this issue?

Penalty structure associated with positive tests for dexamethasone and betamethasone.

Provide relevant quantitative or statistical information if possible.

The ARCI database was queried in September 2019, which data are presented above. Based on a recent article accepted for publication (attached), at risk horses, including horses administered dexamethasone for any reason, or residing in a stall in which another horse had been administered dexamethasone, have a 1 in 50 chance of a positive test for dexamethasone, and a 1 in 75 chance of a positive test for betamethasone.

C. Possible Solutions and Impact

Provide possible recommendations to solve the problem.

Our recommendation is to offer a penalty classification for inadvertent environmental contamination positive tests, which would be in addition to the regular classification. In no way do we suggest that the 4C classification for dexamethasone or betamethasone be changed, if the level identified exceeds 100 pg/mL. However, based on the high likelihood that levels below 100 pg/mL result from inadvertent environmental transfer, we propose that a different penalty structure for environmental transfer be adopted.

Penalties for environmental transfer should be separate from medication violations, and not be eligible for multiple medication violation points. We recommend that the first environmental transfer positive in a year receive a warning, the second a second tier fine, the third a third tier fine, etc. The actual amount of the fine should be proportionate to the potential purse won. This makes the potential fine for a trainer proportionate to monies (or potential monies) won, so that the winner of a stakes race and the winner of a low level claiming race do not have the identical penalty. The third tier and above should represent substantial proportions of the purse, for the purpose of forcing the trainer to implement management changes that might change the risk of environmental contamination. Further mitigating circumstances, such as specific risks associated with certain racetracks, or barns can be taken into consideration.

Include details on each proposed solution such as

What solution does this proposal provide?

Horsemen and women will no longer be held responsible for circumstances beyond their control with respect to irrelevant concentrations of dexamethasone or betamethasone. Further, this system can be modified going forward to include other substances at risk of environmental contamination.

How will the solution fix the problem?

Rather than change the actual threshold in place, this changes the penalty structure to reflect the lack of culpability on the part of the horsemen/women.

How will the change affect any entities or stakeholders?

- (1) Save reputations of trainers from positives associated with inadvertent environmental transfer
- (2) Save the reputation of the sport, which suffers every time a positive is reported in the media
- (3) Save both horsemen/women and racing commissions the legal expenses associated with fighting/defending these positive tests

How will you or your organization be affected by the proposed change?

Horsemen/women and veterinarians have significant “positive fatigue” resulting from the calling of completely unexplainable positive tests.

What are the benefits of the proposed change?

ARCI medication rules can and should be revised as science is published to support or refute them. Changing this rule indicates that ARCI can and will adjust rules based on evidence.

What are the possible drawbacks of the proposed change?

A threshold change to 100 pg/mL, while accounting for environmental contamination, would permit the administration of dexamethasone less than 48 hours pre-race. However, by leaving the existing threshold intact, and changing the penalty structure to decriminalize the first such test within a year, but ramp up the financial penalty after the second test still provides the deterrent to repeated administrations within the withdrawal period.

Identify possible fiscal impact of the recommended change.

This would save Commissions and Horsemen/women hundreds of thousands in legal fees.

D. Please identify any affected stakeholder groups that expressed support or opposition. (These stakeholders may include the racetracks, breed registries, owners, trainers, jockeys, veterinarians, or others.)

For those stakeholder groups that have expressed an opinion, please list the points on which they agree or disagree, and the arguments they have expressed.

NAARV is the sponsor of this proposal, USTA and HBPA are in agreement on all points expressed.

At previous meetings, the RMTC has argued against this based on the possibility of administration of dexamethasone within 48 hours. However, we have revised our position to leave the threshold intact, and change only the penalty structure to reflect the new information revealed by the recent acceptance of our paper to a peer reviewed journal.

Are there any affected stakeholder groups that have not been consulted on this proposal?

The RMTC has not reviewed this current proposal, the Jockey's Guild has also not been consulted.

Please submit any formal letters of support or opposition by stakeholder groups.

To Follow.

E. Attach the model rule language you are proposing. Please show new language with underlined text. If you are proposing that current model rule language be eliminated, please strikeout the language to be deleted.

**Uniform Classification Guidelines for Foreign Substances
And Recommended Penalties Model Rule.
September, 2020 (V.14.3)**

Dexamethasone	<i>Azium, etc</i>	4	C	*for levels in excess of 100 pg/mL
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Harness

Controlled Therapeutic Medication	Threshold	Withdrawal Guideline	Dosing Specifications	Reference Notes	Note
Dexamethasone	5 pg/mL of plasma or serum	72 h	Intramuscular and intravenous administration of dexamethasone sodium phosphate or oral administration of	<u>McClure et al.</u> <u>(Comparative Exercise Physiology, In Press)</u>	<u>Also environmental substance, see Environmental substance Chart</u>

			dexamethasone at 0.05 milligrams per kilogram regardless of route		
Betamethasone	10 pg/mL of plasma or serum	7 days	Intra-articular administration of 9 milligrams of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP (American Regent prod	<u>McClure et al. (<i>Comparative Exercise Physiology, In Press</i>)</u>	<u>Also environmental substance, see Environmental substance Chart</u>

Thoroughbreds/Quarter Horses

Controlled Therapeutic Medication	Threshold	Withdrawal Guideline	Dosing Specifications	Reference Notes	Note
Dexamethasone*	5 pg/mL of plasma or serum	72 h	Intramuscular and intravenous administration of dexamethasone sodium phosphate or oral administration of dexamethasone at 0.05 milligrams per kilogram regardless of route	<u>McClure et al. (<i>Comparative Exercise Physiology, In Press</i>)</u>	<u>Also environmental substance, see Environmental substance Chart</u>
Betamethasone*	Limit of detection plasma or serum	14 days	Intra-articular administration of	<u>McClure et al. (<i>Comparative Exercise</i></u>	<u>Also environmental substance, see Environmental</u>

			9 milligrams of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP (American Regent prod	<i>Physiology, In Press)</i>	<u>substance Chart</u>
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*Prohibition on stacking pursuant to ARCI 011-020(F)

Environmental Substance Chart

<u>Controlled Therapeutic Medication</u>	<u>Environmental Threshold</u>	<u>Reference Notes</u>
<u>Dexamethasone</u>	<u>100 pg/mL</u>	<u>McClure et al. (Comparative Exercise Physiology, In Press)</u>
<u>Betamethasone</u>	<u>100 pg/mL</u>	<u>McClure et al. (Comparative Exercise Physiology, In Press)</u>

Environmental Transfer Penalty Structure

<u>First Offense</u>	<u>Second Offense</u>	<u>Third Offense</u>	<u>Fourth and higher Offense</u>
<u>Warning</u>	<u>\$250 fine</u>	<u>5% value of the race</u>	<u>10% value of the race</u>

F. Do any racing jurisdictions currently have a version of this rule in effect? If yes, please attach copies of those rules.

No

G. Review the RCI Model Rules and identify any other Model Rules this change would affect and submit proposed amendments to those rules to comply with changes that would be made by this proposal.

FILING THIS REQUEST WITH RCI DOES NOT GUARANTEE YOUR PROPOSAL WILL BE CONSIDERED BY THE MODEL RULES COMMITTEE. IF YOU HAVE OPPOSITION FROM AN INTERESTED PARTY, YOU ARE STRONGLY ENCOURAGED TO TRY TO REACH CONSENSUS PRIOR TO FILING THIS FORM.