



U.S. Trotting Association Harness Racing Medication Collaborative

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via email

Dear Ed:

At the upcoming April meeting, the USTA hopes to persuade the ARCI decision makers to confer true parity, for purposes of ARCI processes and model rulemaking, on the Standardbred breed. A necessary result of this parity will be evaluation of HRMC recommendations on a par with RMTC recommendations. All entities concerned will gain from this advance, including RMTC.

Many of the regulators themselves are using separate rules for separate breeds, RMTC's position notwithstanding, because they recognize that it is irrational not to do so. This is the case, for example, in New York. For the reasons stated below, a thoughtful and complete understanding of the role of regulators in medication regulation requires different rules for different breeds in certain circumstances, when the physiology and the performance models of the different breeds are taken into account.

Regulators are not concerned with the horse solely as an organism, although the horse's health and welfare are of paramount importance. They are also concerned with the horse as a performing athlete. Medication rules must strike a balance between therapeutic effects of medication administered according to certain limits and performance-enhancing effects that may occur when those limits are exceeded.

On the frontier where therapy meets performance enhancement, rule makers cannot legitimately mark out a boundary without accounting for the performance model itself. Established veterinary practice in Standardbreds furnishes a good example. As Dr. Vincent R. DiCicco relates in his letter to the USTA dated 19 March 2019, betamethasone treatment in Standardbreds virtually always involves multiple joints, and often multiple limbs. The Standardbred performance model involves a trot or a pace, which means two feet down, as distinguished from a gallop, which involves one foot down. Two feet down implies multiple joints receiving concurrent stress, therefore there will be both primary and compensatory inflammation.

For example, if the left front ankle is the primary injury, then it is to be expected (in the Standardbred) that the right front ankle, the right knee, or even the contralateral hock will be overloaded, and

therefore also compromised. This scenario does not occur in Thoroughbred racing. The current RMTC rule . . . does not fit the performance model in Standardbred racing. This restriction on treating Standardbreds, in my opinion, cuts the harness horse short for proper therapeutic treatment.

The veterinary professional standard of care is another important consideration for regulators. The importance of standard of care to the health and welfare of the horse is obvious. But when a medication regulation conflicts with a standard of care, it must be possible to articulate why the rule should take precedence, taking all available scientific information plus the performance model into account. If this is not possible, then perhaps the regulation is irrational.

Consideration of the performance model is fundamental to safeguarding the health and welfare of the horse. The reason that therapeutic medications are permitted at all in the National Uniform Medication Program is that they contribute to the health and welfare of the horse. Otherwise, it would be a simple matter to ban all medication. But there must be a rational connection between the standards for allowed use of a medication and its therapeutic effect. For example, Dr. DiCicco's explanation of the use of betamethasone in Standardbreds illustrates the necessity of treating multiple joints, hence a quantity larger than RMTC's permitted amount is necessary to achieve any truly therapeutic result. When we speak of the health and welfare of the horse, advances in human knowledge, rational regulatory principles, and established standards of veterinary practice must all be taken into account, otherwise that phrase becomes a mere incantation.

Neither RMTC, nor ARCI, nor the USTA, nor the racing commissions themselves are the final authority in disputes concerning the legal validity of medication regulations. The courts will strike down administrative action based on medication rules found to irrationally ignore the performance model of the racing breed, or found to arbitrarily restrict their foundation to questionable or insufficient science. The USTA is presently involved in a Massachusetts case involving a betamethasone test result that came in above the RMTC level but below the level we are now recommending. The aggrieved parties intend to vigorously dispute the application of a betamethasone level that is inappropriate for the Standardbred breed.

The Massachusetts matter is an example of the unnecessary strife that a one-breed approach inevitably causes. Likewise, important projects like the National Racing Compact are hindered by an exclusively Thoroughbred focus. The gains in horsepower, brainpower, and working capital that will result from the adoption of a true and explicit multi-breed approach at ARCI will make ARCI a stronger and better institution.

RMTC states that "[t]he dose in the [betamethasone] proposal exceeds the manufacturer's recommended dose In fact, a recent study showed that

‘maximum anti-inflammatory activities for the glucocorticoids were observed at in vitro concentrations below manufacturer recommended levels.’” The “study” cited is a 2015 doctoral dissertation that has attracted no peer review since its publication. *In vitro* experiments are of minimal relevance to processes in a live animal, and are therefore of dubious value to medication regulators. The horses used for the dissertation were normal, therefore the dissertation lacks relevance to horses with joint disease, and no one is suggesting injecting normal joints with betamethasone. No control without any injection was used in the study. There are a number of other problems with the experimental method and conclusions drawn in the dissertation, but the essential problem has been aptly stated by Dr. Clara Fenger, a member of HRMC:

Used in the manner in which the RMTC has interpreted this dissertation, the argument could be made that no horses . . . should ever be injected with corticosteroids, because they cause death of cartilage cells. What is not discussed, because only normal horses were used in this study, is that inflammation causes profound and severe elaboration of inflammatory mediators, which are the underlying cause of not simply short term lameness and performance issues, but also progressive arthritis. Inflammation poses a considerably greater threat to the health of joints than our therapeutic medications for its treatment.

The above quote also responds to RMTC’s next point concerning extended duration of effect.

The primary reason for the 30 mg recommended betamethasone dose is that the stifle joint is very large, and the RMTC-recommended dose of 9 mg is not therapeutic in this large joint. The primary clinical researcher on the BetaVet product, Dr. Gary White, has recommended a dosage of 18 mg in one stifle joint. Therefore, considering that horses typically require treatment of bilateral joints, the recommendation of 15 mg per stifle joint is conservative.

RMTC cites the Nolen-Watson paper as its support for its claim that clenbuterol has “documented anabolic-like effects.” When this paper was submitted to AJVIM, Dr. Kenneth McKeever (a recognized authority on clenbuterol and a member of the HRMC panel) reviewed it. The paper was rejected due to a series of methodological problems. The investigators used Thoroughbreds and polo ponies rather than Standardbreds. They did not have a scale to weigh most of the horses and thus could not document changes in body mass. Measurement of rump fat thickness provides only speculation about total fat mass. Accordingly, the investigators were unable to calculate fat free mass, which represents muscle mass. The investigators were unable to demonstrate an anabolic effect that would affect performance.

To the contrary, as Dr. McKeever has explained, it has been

unequivocally demonstrated that clenbuterol administration impairs the performance of horses trained in a style similar to that of Standardbred racehorses The purported anabolic effects of clenbuterol are limited to increasing the cross-sectional area of Type IIX fibers, decreasing mitochondrial density and enzyme activity, directly antagonistic to the purpose of training and raising a Standardbred. . . .

In summary, there is no possibility of performance enhancement with clenbuterol use in Standardbreds, and any use of clenbuterol beyond a short term aid for horses with inflammatory airway disease is associated with decreased performance and adverse health effects.

We stated at the beginning of this letter that according HRMC equal dignity and status to that of RMTTC as a source of guidance to the regulators would be an advance that would benefit all parties, including RMTTC. By this point in the discussion, the reason for this is becoming clear. HRMC is composed of eminent veterinarians from the academic, practicing, and regulatory disciplines. It is an invaluable resource for any association seeking to make models rules in an area so wholly dependent on veterinary science. HRMC brings a tremendous amount of learning and experience to the table.

If the USTA's presentations at this conference prove nothing else, they will certainly prove that there is a wealth of valuable scientific and practical knowledge that has not been available to ARCI heretofore. Indeed, RMTTC and the USTA have had several amicable conversations, in which we recognized the value of cooperation and the importance of achieving the broadest possible base of scientific knowledge. Moreover, we touched upon the possibility of joint ventures that would contribute to the health and welfare of the horse and to the work of ARCI. The principle stands out that cooperation of all the breeds in this regard will benefit all of us. A corollary to this principle is that different breeds must be treated fairly.

Respectfully,



Russell C. Williams, President



Joe Faraldo, Esq., HRMC Chair