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THE LOWDOWN ON OUT-OF-COMPETITION TESTING

WHAT THE RMTC ISN'T TELLING US ABOUT ITS PROPOSED REGULATIONS

By Clara Fenger, DVM, PhD, DACVIM; Tanya Boulmetis, JD; Kim Brewer, DVM; and Thomas Tobin, MRCVS, Phd, DABT; Photos by Denis Blake

The corner office has a beautiful view, with filtered sunlight shining through full plate glass. Grand old oak trees provide shade for much of the year to the building that houses the registry of the American Thoroughbred. Professionals. Many years of experience populate the offices, far from the distinctive scent and dust of the racetrack. Among those distinguished leaders are men who began their careers working up from the mailroom of a racetrack or from the stables of an Arabian horse farm. Many years and miles removed from the actual day-to-day work of sending out a Thoroughbred for a morning workout, mucking stalls or rubbing down

the athlete at the end of the morning, these executives propose to reform medication rules. Their latest initiative to this end is support of an out-of-competition testing regulation promulgated by the Racing Medication and Testing Consortium (RMTC), an organization housed under the same roof, shaded by the same oak trees.

Horse racing is both the Sport of Kings and an economic engine for people across all spectra of socioeconomic status. The reliance on wagering to sustain the sport leads many to suspect that anyone who wins at a high percentage must be using “something” to gain an unfair advantage over his or her



competitors. The perceived potential for such activities has led to a unique and early history of drug testing advances in horse racing, with methods that long predate drug testing in any human sport. This attention to the integrity of the sport has paid off for modern-day horse racing, with fewer than 0.5 percent of all post-race tests returning a positive, and most of those are trace overages of therapeutic medications that would be legal, indeed at times not even tested for, in any human sport. This low violation rate is less than half of the number of violations reported in human sports, and it does not include the widespread practice of approved therapeutic use exemptions in human drug testing, in which otherwise prohibited drugs are permitted during competition for therapeutic use. The only area in which human testing has surpassed equine testing is in its common use of out-of-competition testing.

ERYTHROPOIETIN

Out-of-competition testing is important because some substances can exert an effect on an athlete long after the substance can no longer be detected in the typical post-race drug-testing sample. The poster-child drug for which out-of-competition testing is required is erythropoietin (EPO) and its analogues. EPO is a hormone produced by the kidneys in response to a reduced oxygen environment; it travels from the kidneys to the bone marrow, where it stimulates the production of red blood cells. This hormone is naturally present all the time in all horses, and the balance of EPO, iron and key vitamins folate and B12 combine to maintain a steady level of red blood cell production by the bone marrow.

This balance is important in maintaining the delivery of oxygen to exercising muscles—a key determinant of optimal racing performance. Horses are unique among athletes in that their blood moves with such great speed throughout their bodies and across their lungs during maximal effort that the blood cannot be fully saturated with oxygen as it traverses the pulmonary circulation. This exercise-associated hypoxemia is not observed in other species and likely contributes to the possibility of improvement in performance following EPO administration in horses. If you can increase the oxygen-carrying capacity of the blood, you can deliver more oxygen to the muscles.

What makes EPO a hormone of great threat to the integrity of any sport is that small doses administered at regular intervals will stimulate the production of red blood cells, cells that persist in the bloodstream for months and far outlast the two- to three-day presence of detectable amounts of the EPO hormone in blood. In this way, any performance-enhancing effect of EPO would long outlive the ability of any testing laboratory to actually detect the offending EPO.

OUT-OF-COMPETITION TESTING

In 2007 the Association of Racing Commissioners International (RCI) adopted an out-of-competition testing regulation, which, for the first time, instituted a policy for the collection of blood samples for the detection of EPO outside of the post-race testing situation. This regulation represented a significant advance in the ability of racing commissions to address the problem of EPO misuse in horse racing. Since that time, out-of-competition testing has steadily increased, with a high of 3,805 such tests in 2015, of which 45 returned a laboratory finding (a 1.2 percent positive rate). None of those positives actually represented an illegal finding. Cobalt was responsible for 44 of those findings, which did not even represent an illegal finding at the time of the testing and could have resulted from the sampling of a horse shortly after an innocent administration of vitamin B12. The remaining finding was for the dewormer levamisole, a substance of invaluable use in horses as an immune modulator for such diseases as equine protozoal myelitis or Lyme disease. So the 1.2 percent positive rate from 2015 represented not a single real violation. Either racing is doing a great job in controlling illicit substance administrations or we are not testing a sufficient number of horses.

In a recent statement published in *Thoroughbred Daily News*, The Jockey Club President and COO Jim Gagliano challenged the racing industry to adopt the RMTC's far-reaching out-of-competition testing proposal to ensure "the integrity of competition."

Surely, if out-of-competition testing could be expanded, we as an industry could confidently proclaim that all is being done to ensure the integrity of horse

The Jockey Club-supported RMTC regulation would ban some therapeutic medications at any time during the competition life of the horse—on the backside of a racetrack, on farms, even at layup facilities in states in which no racing is held.



racing. As outlined above, EPO poses a substantial threat to the integrity of horse racing, and every stakeholder in the industry should stand firmly behind the expansion of out-of-competition testing. Or should they? First, let's look carefully at the actual RMTC proposal.

THE RMTC PROPOSAL

The RMTC's proposal would expand out-of-competition testing well beyond EPO and related agents and directly into routine practice of veterinary medicine. First, it bans all non-FDA-approved substances, an apparently noble goal on its surface; after all, drug companies have expended millions to demonstrate that their FDA-approved drugs are safe and effective, and our industry should be in support of making sure that our athletes receive only the highest-quality medicines. The first exception is that our federal and state governments have made numerous provisions for the use of medications that were in widespread use at the time that the current system of FDA approval was introduced, as well as for the use of compounded medications, which are legal when there is no FDA-approved alternative available. Strict restrictions are already in place for the control of such substances in post-race testing, but The Jockey Club-supported RMTC regulation would ban them at any time during the competition life of the horse—on the backside of a racetrack, on farms, even at layup facilities in states in which no racing is held. Aside from the negative impact on the athlete itself, when treatment options for any number of conditions would be limited, trainers and owners could be held liable for the actions of any manager or veterinarian, unlicensed by any commission, acting innocently and in good faith in the best interests of the health and welfare of the horse.

The list of prohibited substances appears to have been slightly modified from the list that appears on the World Anti-Doping Agency website (wada-ama.org/en/what-we-do/prohibited-list) and includes cytokines and growth factors, which are specifically used in regenerative medicine, such as Interleukin-1 Receptor Antagonist Protein and platelet-rich plasma, for which, incidentally, no detection technology, out-of-competition testing or otherwise, currently exists. In human sports, such methods of promoting better and faster healing from sports injuries are considered illegal, taking an unfair advantage over competitors. This concept of "cheating" is inappropriate in equine sports, where failing to allow a horse to recuperate to its fullest extent could both predispose the horse and its rider to catastrophic injury and prevent the equine athlete from having a successful second career after racing. The use of such growth factors as targeted therapies for joints, tendons and ligaments should be encouraged in our athletes rather than added to a long list of prohibited substances.

Thyroxine, adrenocorticotropin and human chorionic gonadotropin, substances in common use for the purpose of treating specific conditions in horses, are included on the RMTC's proposed rule. The RMTC provides no evidence that the use of any of these substances poses a risk to the integrity of racing. These substances are currently prescribed pursuant to a specific diagnosis in horses both on and off the track on a daily basis. This regulation seeks to permit the use of thyroxine only after permission is given by the regulatory authority. So if your vet pulls a blood test and determines that the horse has a low level of thyroxine, you cannot supplement the horse until permission is received by the regulatory authority. The RMTC's regulation would put bureaucrats in the place of your own veterinarian in making health and welfare decisions for your horse.

There are many issues with this scenario of regulatory permission being required to use a legal medication during training or recuperation. For example, say the state that you requested permission from refuses to allow the medication. After the refusal, you ship to another state, again request

permission, have it granted and medicate your horse. Then the state that refused permission tests your horse out of competition. Obviously, it would be positive. Who is liable? State budgets are constrained enough without looking for lawsuits. Another issue would be the timeframe between requesting permission and receiving it. It would put the commission in the untenable position of being able to refuse or delay approval in order to tacitly punish a horseman who, without any proof, they "felt" was cheating.

Anabolic steroids would be further restricted in this out-of-competition testing regulation well beyond their current restrictions within proximity to racing. Horses are unique among athletes in that we geld our athletes, for which there is no corollary in human sports. Anabolic steroids may be required for normal recovery from injury and disease, and like growth factors, any intervention we can provide to horses that may lead to a fuller and more rapid recovery should be encouraged. Any human bodybuilder or weight lifter can attest that using cycles of anabolic steroids will enhance performance, but the existing minimum withdrawal of 60 days from racing prevents such abuse. This regulation would require placing the horse on the vet's list for six months, which is lightyears in horse racing, and would effectively ban the use of these substances at any time in a racing horse. Further, stanozolol, the only FDA-approved anabolic steroid that provides the benefits of anabolic steroids without the disadvantage of causing studdish behavior, would be banned at all times. This regulation would prevent the beneficial use of anabolic steroids based solely on the premise that it looks good to the public.

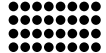
THERAPEUTIC SUBSTANCES

In addition to the restrictions on specific widely used therapeutic substances, an even more sinister provision is hidden within this proposed regulation. A provision calls for out-of-competition testing to be used to police other racing regulations not contained within the language of the out-of-competition testing regulation. On the surface, this sounds innocuous enough, but a careful review reveals the following possible intent in the regulation. If a horse tests positive for a therapeutic substance—for example, methocarbamol or dexamethasone—and there is no vet record or prescription for that substance for that horse, a violation has occurred. In the current environment of picogram identifications at the laboratory, where most methocarbamol and dexamethasone identifications are the result of inadvertent environmental contamination, trainers will be penalized for trace medication levels over which they have no control.

A further issue with this scenario would be for a medication of which trace levels may be found for an extended period of time after the last administration. For example, horses in training can be purchased at auction, leading to the question of who is liable when a horse that recently has been purchased tests positive and only has been in its new barn for a few weeks. New York takes this into account and has a provision through which the new owner may void the purchase within 10 days of notification. However, what if the sale was months ago? The conditions of sale for both Keeneland and Fasig-Tipton do not take a position through which a horse may be returned months later. Again, this could be an expensive litigation scenario for both states and horsemen. There is even a provision in the proposed RMTC regulation for hair testing, in which substances could be found for up to a year later, and other biologic samples as yet undefined.

EXISTING REGULATIONS

A racing commission that is considering adopting the RMTC's recommendation should carefully evaluate the validity of the out-of-competition testing rules; they need to consider whether it falls within the scope of the



jurisdiction conferred by their legislature. Each state has its own enabling statute concerning horse racing. In general, the proposed rule must have a rational and reasonable basis and be based on objective science. It must safeguard the constitutional rights and ensure fairness to all horsemen. In 2006 Ontario was the first jurisdiction to launch an out-of-competition testing program, and many jurisdictions followed suit. These adopted rules range from the very narrow, in which there are defined parameters of which horses are eligible and what is tested for, to extremely broad, in which a state could make a case to test the majority of the horse population in the United States—even if that horse had never been in that specific state.

Some states test only for the blood doping substances and limit the eligible horses to jurisdiction grounds or to horses that are racing in the state. Some test only blood, and others allow urine and hair testing. Other states, however, are testing for a very broad range of substances, some of which include drugs that can be a result of inadvertent environmental contaminations, such as zilpaterol and ractopamine.

Delaware falls into the narrow out-of-competition testing rule category. The state tests for blood doping on any entered horse, any horse that raced there within the past 60 days, any horse that showed the presence of blood doping antibodies at some point, a horse with a trainer who has ever had a horse test positive for EPO and any horse that dies or is euthanized on association grounds for any reason.

Kentucky falls into the latter category; “any horse eligible to race in Kentucky” is its guideline. Kentucky defines this as a horse being eligible if the owner or trainer is licensed in that state, if it is nominated to a race in that state or if it raced in Kentucky within the past 12 months, if it is stabled at a racetrack or licensed training facility or if it is nominated to the Kentucky

Thoroughbred Development Fund. Kentucky testing is supposed to be limited to natural or synthetic types of blood doping substances, venoms and growth hormones.

New Mexico is broader in what it tests for but slightly limited more to horses in its area. The state may test horses on the grounds, horses with papers that are on file, horses nominated to stakes or horses with an owner or trainer licensed in the state. New Mexico also tests for clenbuterol and anabolic steroids in addition to the Kentucky list. It also may test urine and hair, in addition to blood. Illinois tests for blood and gene doping but specifically added the following wording: “This Section does not apply to therapeutic medications approved by the FDA for use in the horse.”

Gagliano, in his statement to the *Thoroughbred Daily News*, bemoaned the fact that only 19 out of 38 states have out-of-competition testing. Perhaps the states that are not currently doing this testing are waiting for a good rule to follow. Racing commissions are woefully underfunded. Adopting a specific rule just because it has the RMTC’s blessing does not mean it will stand up in a court challenge. New York had an expensive, protracted legal fight on this issue, the outcome being that the lawsuit was dropped when New York amended its rule. The states that wait may be better off; they can create a fair and legally validated rule, one that targets the cheaters and only the cheaters, and a rule that will stand up when challenged in court.

All these states have a noble idea—get rid of the cheaters in the industry and make it an even playing field for all horsemen. However, in the RMTC’s quest to make the public think they are getting “tough on racing,” they actually may be diluting the effectiveness of out-of-competition testing.

As it stands, California has the highest percentage of out-of-competition testing, at 10 percent of all drug testing. Contrast this to Kentucky, where




What happens if trace levels of a substance administered before a 2-year-old or horses of racing age sale are found months later after the horse has changed hands?

a generous estimate is 2 percent of all drug testing. The RMTC regulation heralded by Gagliano expands out-of-competition testing to routine therapeutic medications, rather than expanding the number of horses tested for EPO analogues or providing funding to develop testing for designer drugs. In support of its regulation, the RCI recently sent out a survey that asked whether respondents were in favor of expanded testing. What RCI failed to define was “expanded.” Rather than expanding testing for substances that might actually damage the integrity of horse racing, the proposed regulation seeks to expand out-of-competition testing to legitimate therapeutic medications. By expanding this testing to legitimate therapeutic medications, the proposed rule gives chemists something to report in their out-of-competition testing reports and thereby justifies the out-of-competition testing process and the entire regulatory process itself and as such points to the claimed efficacy of the rule. Financially, this approach has only one result. There will be fewer horses tested.

During the 2013 University of Arizona Global Symposium on Racing and Gaming, Alan Foreman, chair of the Thoroughbred Horsemen’s Association, said out-of-competition testing is designed to detect the use of substances like blood-doping agents and “emerging drugs” like peptide venoms that can have pain-killing effects. Testing for these illicit substances is “more important than testing for 24 therapeutic drugs. Those aren’t the drugs compromising racing.”

CONCLUSION

As Gagliano suggests, the expansion of out-of-competition testing is a goal worthy of widespread industry support. However, the details of the current RMTC proposal, supported by The Jockey Club, fall short of actually improving the integrity of horse racing. There are currently more than 80 EPO analogues, and technology is only capable of identifying a handful. Designer anabolic steroids and peptides can only be detected in limited numbers, because the technology for finding anything is only now being developed. There is a need for expanded out-of-competition testing and more widespread adoption of the current regulations by racing jurisdictions but not for expanding this testing into the administration of legitimate therapeutic medications. The proposed regulation only criminalizes legal activity without providing even the tiniest of steps toward addressing the true threats to the integrity of horse racing. In the meantime, horsemen and vets have to waste precious resources and time fighting the implementation of overly broadly drafted rules when our efforts, one and all, would be better spent focusing as a united industry on ways to identify true cheating. The mission of The Jockey Club would be better served if its executives would emerge from their offices in the shade of the oak trees and walk the backside of our racetracks talking to the actual people who keep them in their jobs. 

UPDATE: NATIONAL HBPA WORKING HARD FOR POSITIVE CHANGE

Immediately following the Global Symposium on Racing and Gaming in Tucson, Arizona, the Association of Racing Commissioners International (RCI) scheduled meetings on December 8 and 9 at the Omni Resort, also in Tucson. The National HBPA was present and represented by Dave Basler, executive director of the Ohio HBPA, along with National HBPA President and Chair Leroy Gessmann and CEO Eric Hamelback. The RCI Model Rules Committee met first, followed by the RCI Board of Directors.

The RCI Model Rules Committee convened to discuss several topics. One of those was the proposed changes submitted by the Racing Medication and Testing Consortium (RMTC) to the current Multiple Medication Violation (MMV) phase of the National Uniform Medication Program (NUMP). Significant work went into reevaluating the current MMV phase by a subcommittee of the RMTC, which was composed of a wide array of industry stakeholders. Following the subcommittee’s changes and recommendations, the RMTC board approved the amendments, which were then proposed in writing to the RCI with the intention to amend the current model rule.

The changes that were amended to the MMV allowed for decreases in the amount of time that points remain on a trainer’s record as well as a decrease in the number of points assigned for medications that are not performance-enhancing. More importantly, the changes would allow stewards to have discretion in how many—if any—points are awarded in cases where a positive test is the result of contamination and proven through mitigating circumstances.

The significant progress made to improve the MMV component of the NUMP now allows for support given to this phase by the NHBPA.

The changes were supported by a wide range of industry participants, including the NHBPA and RMTC. The only opponent of the changes was The Jockey Club.

“With the sensitivity of today’s testing, trainers are at a constant risk of having a positive test from a miniscule amount of a substance a horse

might have ingested through contaminated feed, hay or other environmental factors or through human contact,” said Hamelback. “Furthermore, these positives are sometimes called at levels and for medications that could not possibly affect performance on the track, so this is certainly a step in the right direction. We thank the RCI, RMTC and all the other industry groups who came together to improve the MMV and make it a fair system for all.”

Another topic discussed by the RCI Model Rules committee was the proposed model rule discussed in this article to allow for out-of-competition testing. While the NHBPA has been on the record supporting out-of-competition testing, it was important to note horsemen’s concerns related to the drafted proposed model rule. The intention of the NHBPA’s presence at the meeting was to state the organization’s opposition to the current content and to express apprehension regarding the overreaching intent, which would cause concern for horsemen’s rights.

Working together with Alan Foreman of the Thoroughbred Horsemen’s Association, the NHBPA was successful in presenting opposition to the original proposed model rule and thus initiating significant changes. While concerns can still be voiced, the changes initiated by the Model Rules Committee were very much in the favor of horsemen’s rights. Of particular importance was the change made to the new out-of-competition testing draft going before the RCI full board that involved the exclusion of results found regarding therapeutic medications as non-relevant findings.

The NHBPA believes the progress made in the past few months has been very encouraging. While it is important to say that we are working together with many other stakeholders to initiate uniformity, it is also very important to note that the voices and concerns identified for many years by the NHBPA are finally getting proper recognition and orchestrating positive change for our industry.