Update on Medication Thresholds

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In an ongoing effort to establish a national uniform medication policy, The Racing Medication and Testing Consortium (RMTC) Controlled Therapeutic Substances List (CTSL) was adopted by Racing Commissioners International (RCI) in April of 2013. At that time, there were 26 substances listed with withdrawal guidelines, thresholds and dosing specifications. This list was created by a scientific committee convened by the RMTC and references were cited for each controlled therapeutic substance. (Ref.1)

On April 28, 2015, the O.S.R.C. received input from a number of OSRC licensed veterinarians, representing both the Thoroughbred and Standardbred racing industry, regarding their views about the possible adoption of the RMTC Controlled Therapeutic Substances List. Collectively, their concerns were:

- 1. Many of the 26 therapeutic substance thresholds referenced unpublished data which could not be reviewed. Summaries of unpublished data provided by RMTC did not allow for scientific scrutiny.
- 2. With some of the substances, data in the published references did not support the threshold established by the RMTC scientific committee. Examples of this, cited by Dr. Clara Fenger of the North American Association of Racetrack Veterinarians, include the thresholds for methocarbamol and dexamethasone.
- 3. The withdrawal times and the thresholds for Clenbuterol and the intra-articular corticosteroids were considered to be too restrictive, particularly for the harness industry. A 14 day withdrawal for Clenbuterol would all but eliminate its use in harness racing. The experimental administration dosages for the intra-articular steroids were impractical (too low to allow for more than one joint to be adequately medicated) for both breeds and the 7 day withdrawal guideline was considered unworkable for harness racing, where many horses race weekly (a view supported by the USTA).
- 4. The thresholds for some of the substances were not appropriate. For example, the thresholds for xylazine and detomidine. The experimental dosages for lidocaine and mepivicaine were seen as impractical.
- 5. Application of the 95/95 Tolerance Interval calculation to establish the thresholds was criticized. (Ref.1,2) There was concern that this type of statictical application was not appropriate for either the experimental models or the limited data sets of many of the referenced publications. 95/95 means that there is 95% confidence that the true withdrawal period is not higher than the estimated withdrawal period in 95% of the population of individual times to a concentration below the established threshold.

Since it was first published in 2013, the RMTC CTS list and associated reference list has been a work in progress - a "living document". Over time, there have been a number of modifications to this list in response to industry needs, input and criticism. More recent examples of CTS list evolution include: amendments to the thresholds and dosing specifications for Omeprazole, xylazine and detomidine and the addition of four therapeutic medications - Cimetidine, Ranitidine, Ceterizine and Guafenesin. All of these recent additions and modifications reference supportive research that has been published. Of the 30 controlled therapeutic substances now on the list, only five reference unpublished data and three of those substances do reference additional scientific publications in addition to the unpublished data reference.

The RMTC defends the statistical methods employed in determining their thresholds. On their website there is an example, using a data set from 20 horses, of how to arrive at a threshold using the 95/95 Tolerance Interval calculation that allows for a reasonable margin of safety even with a horse that is an outlier. They further state that it is erroneous to imply that the application of the 95/95 Tolerance Interval results in a 1 in 20 chance that a horse will have a positive test when the withdrawal guidelines are followed. (Ref. 1)

The major racing states surrounding Ohio have all adopted the RMTC Controlled Therapeutic Substances list - Indiana, Kentucky and Pennsylvania for both Thoroughbreds and Standardbreds and West Virginia for Thoroughbreds as there is no pari-mutuel harness racing in that state. Nationwide, there are 20 states that have adopted the CTS list and these states represent 94% of the national Thoroughbred pari-mutuel handle.

There are a few states, New York and Delaware for example, that have fully adopted the CTS list for Thoroughbreds but not for Standardbreds. They have what might be termed a "bifurcated" medication policy. In New York, for instance, there are noticeable differences between the breeds with regard to the regulation of clenbuterol and intra- articular corticosteroids.

In the months to come, the OSRC will be considering amendments to the current RegulatoryThresholds list and will seek input in doing so. We are currently evaluating specific medication practices in Thoroughbreds and Standardbreds based on medical record evaluations and analytical testing. Proposed changes to our medication policies will be presented at future meetings with an opportunity for public comment.

References:

- 1. **rmtcnet.com** National Uniform Medication Program -- Controlled therapeutic subtances View List + Supporting Research + Explaining the 95/95 threshold
- 2. ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004496.pdf

Ohio State Racing Commission Incident Report -- October 20, 2016

To: William Crawford, Executive Director, Ohio State Racing Commission

From: John Yinger, Presiding Judge, Delaware County Fair, and Steve Zaper, OSRC Investigator,

RE: Controversial activity concerning the Standardbred horse "Betting Line" at the Delaware County Fair on September 22, 2016

Report Details

Betting Line was (#5-horse) in the (first heat-Race 13) and (#2-horse) in the (second heat-Race 18), of the Little Brown Jug at the Delaware County Fairgrounds on September 22, 2016.

Casie Coleman is both the trainer (OSRC 2496) and co-owner (OSRC 2495) of Betting Line. The assistant trainer is Mark McKinnon (OSRC 0665) and the groom is Jeffery Kemp (OSRC 0676).

Assistant trainer Mark McKinnon either lost his cell phone or it was stolen on the night of September 21, 2016, and later was retrieved by an unknown person.

On McKinnon's phone there were text messages reading: "where is the shit for Betting Line," "anytime between 8:30-10:30 am range," "when it's clear safely get his treatments into him," "how's b line this am," and "were the guys able to laser." These text messages were photographed and sent to the phone of Delaware County Fair Presiding Judge, John Yinger, who immediately contacted trainer Ms. Coleman for an explanation of those texts.

Ms. Coleman explained that the "shit" was yogurt she gives to Betting Line every day to help maintain his "gut" stomach.

On this race day (September 22, 2016) Ms. Coleman wanted to give Betting Line his yogurt six to eight (6-8) hours prior to the race.

Ms. Coleman added that Betting Line received a laser treatment on Tuesday, September 20, 2016 and Wednesday, September 21, 2016, under the supervision of the veterinarian John Reichert (OSRC 0109).

This veterinarian-supervised treatment is permitted under the allowable times veterinarians can be in the Jug barn (noon -1:30 pm).

The text messages were not conclusive and the judges took no action at that time, which was approximately 10:30 am (September 22, 2016).

At approximately 2:00 pm Presiding Judge John Yinger was called to the Jug Barn by the Delaware County Fair officials who had received complaints by other horsemen with entries in the Little Brown Jug race. Tom Wright, Director of Racing, and Mr. Yinger listened to the complaints of the horsemen and proceeded to stalls 16 and 17 of the Jug Barn where Casie Coleman's horses were stabled.

Steve Zaper arrived at this time. Mr. Yinger again asked Ms. Coleman for an explanation of the text messages and questioned the security personnel to ascertain if there had been any unauthorized activity in the Jug Barn on either September 21 or 22, 2016. Greg Keidel, Jug Barn Co-Supervisor, stated that the log reflects that there were no unauthorized activities on the night of September 21, 2016. Casie Coleman repeated that the intent of the "treatment" was to give the horse his daily yogurt and that the laser treatment was allowed under the restrictions of the Jug Barn detention procedures.

Ms. Coleman added that the yogurt was not given to Betting Line on September 22, 2016 because the assistant trainer, Mark McKinnon was late to work. The laser treatment was not administered on September 22, 2016 because the groom did not bring the charger cord and the laser machine battery was low.

Mr. McKinnon stated he did not give Betting Line his yogurt due to the rumors surrounding the horse. The yogurt is given with the dose syringe and he did not want to further the rumors. Mr. McKinnon said he lost his phone he had too much to drink on the night of September 21, 2016.

Groom Jeff Kemp stated that the term "shit" he used in his text was "just the way I talk."

Ms. Coleman, Mr. McKinnon and Mr. Kemp were asked by Ohio State Racing Commission investigators Steve Zaper and Christy Hanks to submit a written statement explaining the texts.

Mr. Yinger asked track veterinarian Scott McQuinn to examine Betting Line for needle marks on the horse and none were found.

OSRC Investigators, aided by Doug Murray of the TRPB, conducted a search of all areas under Ms. Coleman's control in the Jug Barn, as well as Ms. Coleman's private vehicle, her truck and horse trailer, which had been used by Ms. Coleman, Mr. McKinnon and Mr. Kemp, and no violations were found. A report on the search is attached. The full yogurt container was examined but not confiscated.

Dr. Mitchell, the state veterinarian, was notified that Betting Line would be "specialed"--meaning the horse would be sent to the test barn no matter where he finished. Betting Line also received TCO2 testing and one additional tube of blood was taken.

A review of the Jug barn detention policies and procedures was conducted with Greg Keidel, Jug Barn Co-Supervisor. A copy of the Delaware Fair and Little Brown Jug Society detention policies and procedures is available.

There were four security people in the Jug Barn on Tuesday, September 20, 2016 and Wednesday, September 21, 2016 and seven security people on Thursday, September 22, 2016. Security people escort Jug horses to and from the track when warming up. Security persons check everything brought into the Jug Barn and patrol the Jug Barn stalls.

Mr. Zaper again interviewed Ms. Coleman and assistant Mr. McKinnon on September 26, 2016 concerning the yogurt and dose syringes. Ms. Coleman stated that she bought three or four one liter tubs of yogurt in Ohio on Monday, September 19, 2016.

Ms. Coleman explained that normal yogurt treatment for Betting Line is one-half liter of yogurt, administered twice-a-day via dose syringe. Betting Line will not eat yogurt mixed with his regular food. One tub of yogurt was brought with everything associated with the horse on Tuesday, September 20, 2016 at Noon when Ms. Coleman brought her horses into the Jug Barn. All of the items were inspected by the Jug Barn security people.

According to Ms. Coleman more than one security person looked at her items and nobody objected to the yogurt or dose syringe that she brought with the horse. The rest of the yogurt was kept refrigerated at the hotel and brought one tub Wednesday, September 21, 2016 and Thursday, September 22, 2016. Ms. Coleman did not know if the yogurt was checked when brought in on those days.

According to Mr. McKinnon, he was in charge of the yogurt, which was kept at the hotel, and which was brought to the Jug Barn on Tuesday, September 20, 2016 with the feed and was checked by security. Mr. McKinnon stated he brought another tub of yogurt into the Jug Barn on Wednesday, September 21, 2016 and Thursday, September 22, 2016, and no security check on the yogurt tubs was performed on those two days. Mr. McKinnon did not give the horse yogurt on Thursday, September 22, 2016 because of the controversy.

Chip Hastings, Jug Barn Co-Supervisor was interviewed by Steve Zaper on September 27, 2016. Mr. Hastings stated that not all of the feed items needed to be sealed when brought into the Jug Barn on Tuesday, September 20, 2016, which is contradictory to the aforementioned policies and procedures. Security did search the feed if a bag was open. According to Mr. Hasting, dose syringes are not allowed in the Jug Barn according to the policies and procedures, however, at the suggestion of Jug Barn Co-Supervisor Greg Keidel, the dose syringes were allowed until race day. Mr. Hastings said Mr. McKinnon could have brought the yogurt in each day without security checking.

On October 14, 2016, an affidavit was filed by trainer Anthony Alagna (OSCR 2016). In this affidavit, Mr. Alagna stated that he witnessed two individuals performing a laser treatment to Betting Line on Wednesday, September 21, 2016 at around Noon. This information is consistent with the confirmed laser treatment of Betting Line stated earlier in this report (between Noon & 1 pm) on September 20 and 21, 2016, and as such, would not be a violation of OSRC Rules or Jug Barn detention rules or procedures.

Report Summary

The contents of the text messages are not conclusive and the explanations contained in the written statements do not offer any evidence to be conclusive in regard to a plan to give the horse an illegal substance or treatment.

There were no objections by security when the dose syringes and the yogurt were brought in to the Jug barn on Tuesday, September 20, 2016 by Ms. Coleman. The Jug Barn detention policies and procedures were not followed to the letter by security and this caused confusion as to what the rules were. Possession of a dose syringe is not a violation of OSRC rules.

It is our opinion that yogurt is not a classified substance and can be fed on race day. This opinion is supported by Dr. Richard Sams and Dr. Mary Scollay. Both individuals are on the RMTC advisory committee.

Race #13, September 22, 2016, the first division of the Little Brown Jug, was reported as cleared by the Department of Agriculture Toxicology Laboratory. There were no violations.

Race #18, September 22, 2016, the final division of the Little Brown Jug, was reported as cleared by the Department of Agriculture Toxicology Laboratory. There were no violations.

~Attachments available upon request~ -- e-mail requests to marty.evans@racing.ohio.gov

Ohio Common Sense Initiative –Business Impact Analysis

Agency Name: Ohio State Racing Commission

Regulation/Package Title: Chapter 2 New Rule 2016

Rule Number: 3769-2-43

Date: July 2016

This rule may also be found by accessing LAWriter at http://codes.ohio.gov/oac/3769.

Rule Type: New

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language. Proposed rule 3769-2-42 is statutorily mandated by R.C. 3769.087(C) and provide that permit holders licensed by the Ohio State Racing Commission who are also video lottery sales agents who have not entered into an agreement with the recognized horsemen's association shall pay to the respective horsemen's group between 9 (nine) and 11 (eleven) percent of the video lottery terminal income. The OSRC will determine the specific percentage. The monies must be

for the benefit of breeding and racing in Ohio. The rules are identical with the exception that 3769-2-42 apples to thoroughbred racing permit holders and 3769-12-43 apples to standardbred racing holders.

- 2. Please list the Ohio statute authorizing the Agency to adopt this regulation. Ohio Revised Code Sections 3769.03 and 3769.087 (C).
- 3. Does the regulation implement a federal requirement? No
- 4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement. Not Applicable.
- 5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)? The rules are required pursuant to R.C. 3769.087 (C).
- 6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes? OSRC permit holders who are video lottery sales agents and the respective horsemen's associations will enter into mutually beneficial agreements that will benefit breeding and racing in Ohio.

Development of the Regulation

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation. The permit holders and the respective horsemen's association have been intimately involved in the implementation of R.C. 3769.087(C) from enactment to the present.
- 8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency? The rule provides that the respective permit holder and horsemen's association will have an opportunity to provide input regarding the implementation of the specific percentage contemplated by the statute.
- 9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed? Not applicable.
- 10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? None. R.C. 3769.087(C) specifically lays out the requirement.
- 11. Did the Agency specifically consider a performance-based regulation? Please explain. Not applicable.
- 12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation? Not applicable.
- 13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community. The regulation is very specific and limited by statue. The affected permit holder and horsemen's association will be able to fully and transparently participate in determining the requisite percentage.

Adverse Impact to Business

- 14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
 - a. Identify the scope of the impacted business community. The impacted businesses are the racetrack permit holders and the respective horsemen's association.
 - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance). None.
 - c. Quantify the expected adverse impact from the regulation. None.
- 15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community? The rule was statutorily mandated by R.C. 3769.087(C) and the Commission is required to implement this rule.

Regulatory Flexibility

- 16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain. Not applicable.
- 17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation? Not applicable.
- 18. What resources are available to assist small businesses with compliance of the regulation? The Commission website at www.racing.ohio.gov; The Commission main office at 77 S. High Street, 18th Floor, Columbus, Ohio 43215; The Commission phone number at 614-466-2757; and The Commission facsimile number at 614-466-1900.

Ohio Common Sense Initiative –Business Impact Analysis

Agency Name: Ohio State Racing Commission

Regulation/Package Title: Chapter 2 New Rule 2016

Rule Number: 3769-12-43

Date: July 2016

This rule may also be found by accessing LAWriter at http://codes.ohio.gov/oac/3769.

Rule Type: New

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

- 19. Please briefly describe the draft regulation in plain language. Proposed rule 3769-2-42 is statutorily mandated by R.C. 3769.087(C) and provide that permit holders licensed by the Ohio State Racing Commission who are also video lottery sales agents who have not entered into an agreement with the recognized horsemen's association shall pay to the respective horsemen's group between 9 (nine) and 11 (eleven) percent of the video lottery terminal income. The OSRC will determine the specific percentage. The monies must be for the benefit of breeding and racing in Ohio. The rules are identical with the exception that 3769-2-42 apples to thoroughbred racing permit holders and 3769-12-43 apples to standardbred racing holders.
- 20. Please list the Ohio statute authorizing the Agency to adopt this regulation. Ohio Revised Code Sections 3769.03 and 3769.087 (C).
- 21. Does the regulation implement a federal requirement? No
- 22. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement. Not Applicable.
- 23. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)? The rules are required pursuant to R.C. 3769.087 (C).
- 24. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes? OSRC permit holders who are video lottery sales agents and the respective horsemen's associations will enter into mutually beneficial agreements that will benefit breeding and racing in Ohio.

Development of the Regulation

- 25. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation. The permit holders and the respective horsemen's association have been intimately involved in the implementation of R.C. 3769.087(C) from enactment to the present.
- 26. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency? The rule provides that the respective permit holder and horsemen's association will have an opportunity to provide input regarding the implementation of the specific percentage contemplated by the statute.
- 27. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed? Not applicable.
- 28. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? None. R.C. 3769.087(C) specifically lays out the requirement.
- 29. Did the Agency specifically consider a performance-based regulation? Please explain. Not applicable.
- 30. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation? Not applicable.
- 31. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community. The regulation is very specific and limited by statue. The affected permit holder and horsemen's association will be able to fully and transparently participate in determining the requisite percentage.

Adverse Impact to Business

- 32. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
 - a. Identify the scope of the impacted business community. The impacted businesses are the racetrack permit holders and the respective horsemen's association.
 - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance). None.
 - c. Quantify the expected adverse impact from the regulation. None.
- 33. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community? The rule was statutorily mandated by R.C. 3769.087(C) and the Commission is required to implement this rule.

Regulatory Flexibility

- 34. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain. Not applicable.
- 35. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation? Not applicable.
- 36. What resources are available to assist small businesses with compliance of the regulation? The Commission website at www.racing.ohio.gov; The Commission main office at 77 S. High Street, 18th Floor, Columbus, Ohio 43215; The Commission phone number at 614-466-2757; and The Commission facsimile number at 614-466-1900.

*** DRAFT - NOT YET FILED ***

3769-2-43 Commission to determine distribution percentage of video lottery terminal income

(A) Permit holders licensed by the state racing commission who are video lottery sales agents of the Ohio lottery who have not entered into an agreement with the applicable state racing commission recognized horsemen's association in accordance with section 3769.087(C) of the Revised Code shall pay not less than nine per cent or more than eleven per cent of the video lottery terminal income for the benefit of breeding and racing in Ohio. The specific percentage will be determined by the commission after a hearing where the commission will consider relevant factors including but not limited to capital expenditures.