INDIANA HORSE RACING COMMISSION
OFFICIAL AGENDA
March 5, 2014
9:00 A.M.
INDIANA STATE LIBRARY - ROOM 211
315 W. OHIO STREET
INDIANAPOLIS, IN 46204

I. **Call to Order**

II. **Approval of minutes of the December 10, 2013 meeting.**

III. **Agenda**

1. Presentation by Centaur regarding 2013 race meets and a 2014 preview.

2. Consideration of emergency rules including Association of Racing Commissioners International's Model Rules regarding medication and penalties – Dr. Dionne Benson, Executive Director, Racing Medication and Testing Consortium.
   a. 71 IAC 1-1-94.1 and 71 IAC 1.5-1-94.1 **"Sample" defined**
   b. 71 IAC 8-1-4.1 and 71 IAC 8.5-1-4.1 **Nonsteroidal anti-inflammatory drugs**
   c. 71 IAC 8-1-4.2 and 71 IAC 8.5-1-4.2 **Threshold levels**
   d. 71 IAC 8-1-5.7 and 7A IAC 8.5-1-5.6 **Anti-ulcer medications**
   e. 71 IAC 8-1-8 and 71 IAC 8.5-1-8 **Androgenic-anabolic steroids**
   f. 71 IAC 8-3-5 and 71 IAC 8.5-2-5 **Out of competition testing**
   g. 71 IAC 8-6-2 and 71 IAC 8.5-5-2 **Prohibited practices**
   h. 71 IAC 8-1-7.1 and 71 IAC 8.5-1-7.1 **Multiple violation rule**

3. Approval of settlement agreement between United Tote and commission staff.

4. Review of Commission Rulings – December 1, 2013 through January 31, 2014.

5. Approval of split sample laboratories for 2014 and beyond pursuant to 71 IAC 8-4-3 and 71 IAC 8.5-3-3.

6. Approval of laboratories for out-of-competition testing for 2014 and beyond pursuant to 71 IAC 8-3-5(h) and 8.5-2-5(h).

7. Waiver of 71 IAC 5.5-3-1(h) **Eligibility**.

8. Consideration of Request to Repeal 71 IAC 10-3-20(b).

9. Consideration of Request to Repeal 71 IAC 1.5-1-40 **"Foreign Substance" defined.**

10. Presentation of the 2014 program by Thoroughbred Breed Development Advisory

Committee and consideration of emergency rules 71 IAC 13.5-3-3 **Out-of-state breeder's awards** and 71 IAC 13.5-3-5 **Purse supplement in open races**.

11. Presentation of the 2014 program by Quarter Horse Breed Development Advisory Committee and consideration of emergency rules 71 IAC 14.5-3-4 **Purse supplement in open races** and 71 IAC 14.5-3-6 **Sired purse supplement**.

12. Consideration of petition from Centaur to expand Fast Bet Mobile to Indiana Downs.

13. Approval of Hoosier Park's 2014 Standardbred racing official list pursuant to 71 IAC 3-1-2.1.

IV. Old Business

V. New Business

VI. Adjournment

Minutes of the Regular Meeting of the
Indiana Horse Racing Commission
December 10, 2013
Indiana State Library, Room 211
315 W. Ohio Street
Indianapolis, IN 46204

Commission members present: William Diener, Chairman; Steve Schaefer, Vice-Chairman; Commissioners Greg Schenkel, Thomas Weatherwax and George Pillow. Also present were Joe Gorajec, IHRC Executive Director; Lea Ellingwood, IHRC General Counsel; Holly Newell, IHRC Deputy General Counsel; IHRC Assistant Executive Director Deena Pitman; Phil Bayt, Ice Miller/Centaur, Robin Babbitt, Ice Miller/Centaur; Brian Elmore, Centaur General Manager of Racing; Tammy Schaeffer, Centaur CFO; Tom Mosley, Quarter Horse Racing Association of Indiana ("QHRAI"); Nat Hill, Indiana Standardbred Association ("ISA"), Jack Kieninger, ISA; Joe Davis, Indiana Horsemen's Benevolent and Protective Association ("IHBPA"); Mike Brown, IHBPA; Chris Duke, QHRAI; Herb Likens, Indiana Thoroughbred Owners and Breeders Association ("ITOBA"); Rod Ratcliff, CEO and Chairman of Centaur; Roger Young, counsel to the ISA; Christina Lawton, Executive Director of ITOBA; Jessica Barnes, IHRC Director of Racing and Breed Development; Jon Schuster, General Manager of Racing at Indiana Downs; and Rick Moore, General Manager of Racing at Hoosier Park.

I. Call to Order

Chairman William Diener called the meeting to order at approximately 9:00 a.m. A quorum was present. Chairman Diener swore in the reporter. Chairman Diener addressed the resignation of Commissioner Jason Barclay and introduced new Commissioner George Pillow.

II. Approval of minutes of the October 29, 2013, meeting.

The Commission unanimously approved the October 29, 2013 minutes.

III. Agenda

Note: All items on the agenda were transcribed by a court reporter from Stewart Richardson. Transcripts are available at www.in.gov/hrc.

1. Discussion Re: Initial Distribution Agreement.

Phil Bayt and Robin Babbitt, Ice Miller/Centaur, partnering with the Indiana Horsemen's Benevolent & Protection Association, the Indiana Standardbred Association, and the Quarter Horse Association of Indiana again presented the petition to request approval of the initial distribution agreement. *Commissioner Weatherwax moved to approve the IDA Commissioner Schenkel seconded. The motion carried 4-0 with Chairman Diener abstaining.*

2. Discussion Re: Survey Results of Purse Monies contractually paid to horsemen's associations (survey results).

All three horsemen's associations reported overwhelmingly that members understood how the associations were using purse monies and had no objections. No further action required by the Commission.

3. **Review of Commission Rulings – October 1, 2013 through December 1, 2013.**

   Deputy General Counsel Holly Newell allowed time to review the rulings and there were no questions from the Commission.

4. **Approval of IHRC complaint policy.**

   After a brief discussion and direction for clarification of the intended scope, *Chairman Diener moved that the policy be approved with the minor word change to the draft. Commissioner Schenkel seconded and the Commission unanimously approved to adopt the policy as amended.*

5. **Consideration of emergency rules re: Complaints.**

   a. 71 IAC 1-1-23 "Complaint" defined
   b. 71 IAC 1.5-1-23 "Complaint" defined
   c. 71 IAC 3-1-5 Complaints against officials
   d. 71 IAC 3.5-1-6 Complaints against officials

   IHRC General Counsel Lea Ellingwood recommended the Commission adopt these rules as emergency rules. *Chairman Diener moved that the Commission adopt the four rules. Commissioner Schenkel seconded. Commission approved, 5-0.*

6. **Request for Approval of Standardbred Breed Development Program Budget for 2014**

   IHRC Director of Racing and Breed Development Jessica Barnes presented the Standardbred Breed Development Program Budget for 2014. *Chairman Diener moved to approve the program budget; Commissioner Weatherwax seconded. The motion carried 5-0.*

7. **Consideration of emergency rule re: 71 IAC 8.5-8.2, Physical inspection of horses.**

   IHRC Equine Medical Director Dr. Angela Demaree presented a request for an emergency rule to require the physical inspection of race horses similar to the ARCI model rule to improve safety and allow for NTRA certification for flat racing. *Chairman Diener moved to approve the proposed rule; Commissioner Pillow seconded. The Commission voted 5-0 to adopt the rule.*

8. **Consideration of the Petition of Hoosier Park, LP in re: The Petition of Hoosier Park to:**

   1) Amend the Final Order of the Indiana Horse Racing Commission Entered on July 14, 1994 to Authorize the Relocation of the Fort Wayne Satellite Facility to 645-821 Lincoln Highway West, New Haven, Indiana 46774; and
   2) Authorize Execution of a Real Estate Lease; and
   3) Authorize the Sale of the Real Estate Upon Which the Fort Wayne Satellite Facility is Located; and
   4) Delegate Authority to the Executive Director to Approve Contracts Related to the Relocation and Construction of the New Haven Satellite Facility; and
   5) Authorize Pari-Mutuel Wagering by means of Fast Bet Mobile.

   John Keeler, vice-president and general counsel of Centaur Holdings, New Centaur, and Hoosier Park, LLC and Jim Brown, president and COO of Centaur Gaming presented the petition to the Commission. *Chairman Diener moved to approve the petition; Commissioner Schenkel seconded. The motion carried 5-0.*

9. **Review of Hoosier Park's permit renewal application and consideration of pari-mutuel permit for 2014 in accordance with 71 IAC 11-1-21 and consideration of Hoosier Park's request for live racing dates for 2014 pursuant to IC 4-31-5-9.**

   Rick Moore, vice president and general manager of racing at Hoosier Park presented the renewal application and request for approval of live racing dates for 2014. *Chairman Diener moved to approve and grant Hoosier Park's permit application for 2014 along with the race dates. Both were approved 5-0.*

10. **Approval of the renewal of Hoosier Park's satellite facility licenses in Merrillville, Fort Wayne and Indianapolis for 2014 in accordance with 71 IAC 12-1-23.**

    Chairman Diener moved to approve the renewal of the satellite facility licenses for 2014. Commissioner Weatherwax seconded. Motion approved 5-0.

11. **Review of Indiana Downs' permit renewal application and consideration of pari-mutuel permit for 2014 in accordance with 71 IAC 11-1-21 and consideration of Indiana Downs' request for live racing dates for 2014 pursuant to IC 4-31-5-9.**

    John Schuster, vice president and general manager of racing, Indiana Grand Racing and Casino, presented the renewal application and live racing dates schedule for 2014 for Indiana Downs. *Chairman Diener moved to approve the renewal application and proposed race dates for Indiana Downs for 2014. The motion was seconded by Commissioner Schenkel and the Commission voted 5-0 to approve.*

12. Approval of the renewal of Indiana Downs' satellite facility license in Clarksville for 2014 in accordance with 71 IAC 12-1-23.

Chairman Diener moved to approve the 2014 renewal application. Commissioner Pillow seconded. Motion passed, 5-0.

IV. Old Business

None

V. New Business

A. Next IHRC meeting will probably be set for some time late February 2014.

B. Chairman Diener indicated that the next meeting would include discussion and consideration of medication rules.

VI. Adjournment

With no further business, Chairman Diener adjourned the meeting at 11:36 a.m.

Respectfully submitted,

Agenda Item #1

Centaur Presentation

Agenda Item #2

Proposed Rules

Thoroughbred & Quarter Horse

February 21, 2014

Proposed Flat Racing Medication Rule Changes Follow:

- Additions are **underlined in bold**
- Deletions are ~~struckthrough~~

71 IAC 1.5-1-94.1 "Sample" defined

Authority: IC 4-31-3-9; IC 4-31-2-23
Affected: IC 4-31-12
"Sample" when used in the context of being removed from or collected from a horse, means any amount of urine, saliva, blood, or other acceptable specimen derived from a horse. All samples become property of the commission at the time they are cleared by the testing laboratory and may be used for research and/or investigative purposes.

71 IAC 8.5-1-4.1 Nonsteroidal anti-inflammatory drugs (NSAIDs)
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 4.1. (a) The use of one (1) of three (3) approved NSAIDs shall be permitted under the following conditions:
(1) Not to exceed the following permitted serum or plasma threshold concentrations which are consistent with administration by a single intravenous injection at the recommended labeled dose at least twenty-four (24) hours before the post time for the race in which the horse is entered:
(A) Phenylbutazone – 2 micrograms per milliliter.
(B) Flunixin – 20 nanograms per milliliter.
(C) Ketoprofen – 10 nanograms per milliliter.
(b) These or any other NSAID are prohibited to be administered within ~~the~~ twenty-four (24) hours before **the** post time ~~for~~ **of** the race in which the horse is entered.
(c) The presence of more than one (1) ~~of the three (3) approved~~ NSAIDs, with the exceptions of phenylbutazone in a concentration below ~~0.5~~ **0.3** micrograms per milliliter **or flunixin in a concentration below 3.0 nanograms per milliliter** ~~or any unapproved NSAID~~ in the post-race serum or plasma sample is not permitted. The use of all but one (1) of the approved NSAIDs shall be discontinued at least forty-eight (48) hours before the post time for the race in which the horse is entered. *(Indiana Horse Racing Commission; 71 IAC 8.5-1-4.1; emergency rule filed Jul 28, 2006, 11:22 a.m.: 20060816-IR-071060279ERA, eff Sep 1, 2006; readopted filed Mar 23, 2007, 11:31 a.m.: 20070404-IR-071070030RFA; emergency rule filed Jan 25, 2012, 12:20 p.m.: 20120201-IR-071120056ERA)*

71 IAC 8.5-1-4.2 Threshold levels
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 4.2. **(a)** The official blood (serum or plasma) **and urine** samples may contain ~~the following drug substances,~~ **only the following therapeutic medications, their metabolites or analogues,** ~~their metabolites or analogs,~~ and **shall** not exceed the threshold concentrations specified in this rule.

(1) **The use of acepromazine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of the metabolite, HEPS, in urine.**
(2) **The use of betamethasone shall be permitted under the following conditions: Not to exceed ten (10) picograms per milliliter of betamethasone in serum or plasma.**
(3) **The use of butorphanol shall be permitted under the following conditions: Not to exceed three hundred (300) nanograms per milliliter of total (free and conjugated) butorphanol in urine or two (2) nanograms per milliliter of free butorphanol in serum or plasma.**
(4) **The use of clenbuterol shall be permitted under the following conditions: Not to exceed one hundred forty (140) picograms per milliliter clenbuterol in urine or the limit of detection (LOD) in serum or plasma.**
(5) **The use of dantrolene shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of 5-hydroxydantrolene in serum or plasma.**

(6) The use of detomidine shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of carboxydetomidine in urine or the LOD for detomidine in serum or plasma.
(7) The use of dexamethasone shall be permitted under the following conditions: Not to exceed five (5) picograms per milliliter of dexamethasone in plasma or serum.
(8) The use of diclofenac shall be permitted under the following conditions: Not to exceed five (5) nanograms per milliliter of diclofenac in plasma or serum.
(9) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO in serum or plasma.
(10) The use of firocoxib shall be permitted under the following conditions: Not to exceed twenty (20) nanograms per milliliter of firocoxib in serum or plasma.
(11) The use of glycopyrrolate shall be permitted under the following conditions: Not to exceed three (3) picograms per milliliter of glycopyrrolate in serum or plasma.
(12) The use of lidocaine shall be permitted under the following conditions: Not to exceed twenty (20) picograms per milliliter of total 3-hydroxylidocaine in serum or plasma.
(13) The use of mepivacaine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of total 3-hydroxymepivacaine in urine or the LOD of mepivacaine in serum or plasma.
(14) The use of methocarbamol shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of methocarbamol in serum or plasma.
(15) The use of methylprednisolone shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of methylprednisolone in serum or plasma.
(16) The use of omeprazole shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of omeprazole sulfide in urine.
(17) The use of prednisolone shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of prednisolone in serum or plasma.
(18) The use of procaine penicillin shall be permitted under the following conditions:
A. Not to exceed twenty-five (25) nanograms per milliliter of procaine in serum or plasma, and
B. Administration of procaine penicillin must be reported to the official veterinarian at the time of administration, and
C. Procaine penicillin must not be administered after the horse is entered to race, and
D. Mandatory surveillance of the horse must occur for the six (6) hours immediately preceding the race for which the horse is entered by association security at the owner's expense.
(19) The use of triamcinolone acetonide shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of triamcinolone acetonide in serum or plasma.
(20) The use of xylazine shall be permitted under the following conditions: Not to exceed one hundredth (.01) of a nanogram per milliliter of xylazine in serum or plasma.

~~(1) The use of clenbuterol shall be permitted under the following conditions:~~
~~(A) Not to exceed the following permitted serum or plasma threshold concentrations of clenbuterol (or its metabolites): Thoroughbred – twenty-five (25) □ictograms per milliliter.~~
~~(B) Not to exceed the following permitted serum or plasma threshold concentrations of clenbuterol (or its metabolites): Quarter horse – two (2) picograms per milliliter.~~
~~(2) The use of firocoxib shall be permitted under the following conditions: Not to exceed forty (40) nanograms per milliliter of firocoxib (or its metabolites) in serum or plasma.~~
~~(3) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO (or its metabolites) in serum or plasma which allows for topical administration of DMSO in accordance with section 1.5 of this rule.~~
(Indiana Horse Racing Commission; 71 IAC 8.5-1-4.2; emergency rule filed Jan 25, 2012, 12:20 p.m.: 20120201-IR- 071120056ERA; emergency rule filed Feb 8, 2012, 12:01 p.m.: 20120215-IR-071120072ERA; emergency rule filed Apr 3, 2013, 10:37 a.m.: 20130410-IR-071130133ERA)

~~**71 IAC 8.5-1-5.6 Anti-ulcer medications**~~
~~Authority: IC 4-31-3-9~~
~~Affected: IC 4-31-12~~

~~Sec. 5.6. The following anti-ulcer medications are permitted to be administered, at the stated dosage, up to twenty-four (24) hours prior to the race in which the horse is entered:~~
~~(1) Cimetidine (Tagamet®) – 8-20 mg/kg PO BID-TID~~
~~(2) Omeprazole (Gastrogard®) – 2.2 grams PO SID~~
~~(3) Ranitidine (Zantac®) – 8 mg/kg PO BID~~
~~*(Indiana Horse Racing Commission; 71 IAC 8.5-1-5.6; emergency rule filed Jul 28, 2006, 11:17 a.m.: 20060809-IR-071060278ERA, eff Aug 1, 2006; readopted filed Mar 23, 2007, 11:31 a.m.: 20070404-IR-071070030RFA)*~~

71 IAC 8.5-1-8 Androgenic-Anabolic steroids (AAS)
Authority: IC 4-31-3-9
Affected: IC 4-31-12

Sec. 8. (a) No AAS (androgenic-anabolic steroid) shall be permitted in test samples collected from racing horses except for **endogenous concentrations** ~~residues~~ of the ~~major metabolite of stanozolol, nandrolone~~, ~~and the~~ naturally occurring substances boldenone, **nandrolone,** and testosterone at concentrations less than the indicated thresholds.
(b) Concentrations of these AAS shall not exceed the following urine threshold concentrations for total (i.e., free drug or metabolite and drug or metabolite liberated from its conjugates) **steroid**:
~~(1) 16β-hydroxystanozolol (metabolite of stanozolol (Winstrol)) – one (1) ng/ml in urine for all horses regardless of sex.~~
(1)~~(2)~~ Boldenone ~~(Equipoise® is the undecylenate ester of boldenone)~~
(A) in male horses other than geldings; – fifteen (15) ng/~~ml~~ **mL** ~~in~~ **of** urine.
(B) ~~No boldenone shall be permitted in geldings or female horses.~~ **In geldings, fillies, and mares – one (1) ng/mL of urine;**
(2) ~~(3)~~ Nandrolone ~~(Durabolin® is the phenylpropionate ester and Deca-Durabolin® is the decanoate ester)~~:
(A) In geldings - one (1) ng/**mL**~~ml~~ ~~in~~ **of** urine.
(B) In fillies and mares – one (1) ng/**mL**~~ml~~ ~~in~~ **of** urine.
(C) In male horses other than geldings – forty-five (45) ng/**mL**~~ml~~ of nandrolone metabolite, 5α-oestrane-3β,17α-diol ~~in~~ **of** urine.
(3) ~~(4)~~ Testosterone:
(A) In geldings – twenty (20) ng/**mL** ~~ml in~~ **of** urine.
(B) In fillies and mares – fifty-five (55) ng/ **mL** ~~ml~~ **of** urine**, unless in foal**.
(C) In male horses other than geldings minimum thresholds will not apply.

(c) Concentrations of these AAS shall not exceed the following free (i.e., not conjugated) steroid concentrations in plasma or serum:
(1) Boldenone: For all horses a confirmatory threshold not greater than 25 pg/mL shall apply;

(2) Nandrolone:
(A) In geldings, fillies, and mares – a confirmatory threshold not greater than 25 pg/mL shall apply;
(B) In male horses other than geldings – nandrolone shall be tested for in urine only;

(3) Testosterone:
(A) In geldings, fillies, and mares-- a confirmatory threshold not greater than 25 pg/mL;
(B) In male horses other than geldings minimum thresholds will not apply.

~~(c)~~ **(d)** All other AAS are prohibited in racing horses.
~~(d)~~ **(e)** ~~Post-race urine samples collected from intact males must be identified to the laboratory.~~ **The sex of the horse must be identified to the laboratory for all samples designated for AAS testing.**
~~(e)~~ **(f)** Any horse to which an anabolic steroid has been administered in order to assist in the recovery from illness or injury may be placed on the veterinarian's list in order to monitor the concentration of the drug or metabolite in urine **or blood**. After the concentration has fallen below the designated threshold for the administered AAS, the horse is eligible to be removed from the list.
~~(f) Implementation of this rule shall commence April 1, 2008.~~

~~(g) During the first ninety (90) calendar days of the first race meet beginning after the implementation date, no positive test establishing the presence of an anabolic steroid shall be considered a violation of this rule and, accordingly, shall not result in a penalty, disqualification, or a forfeiture of any purse, trophy, or award. Trainers shall be notified of any positive test during the ninety (90) day grace period.~~ *(Indiana Horse Racing Commission; 71 IAC 8.5-1-8; emergency rule filed Mar 12, 2008, 1:53 p.m.:20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filingwith the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed May 12, 2008,1:29 p.m.: 20080521-IR-071080353ERA)*

71 IAC 8.5-2-5 Out of competition testing

Authority: IC 4-31-3-9

Affected: IC 4-31-12

Sec. 5. (a) Any horse eligible to race in Indiana under this subsection is subject to testing without advance notice for prohibited substances, practices, and procedures as specified in subsection (f), while the horse is located on the grounds of a racetrack under the jurisdiction of the commission, or stabled off association grounds while under the care or control of a trainer or owner licensed by the commission under the restrictions listed in subsection (e). A horse is eligible to race in Indiana if it is listed:

(1) on an owner's or trainer's license application; or (2) a stall application, nomination list; or

(3) on the horse sign-in sheet at any time during the meet; or

(4) has raced at any Indiana race meet during the calendar year.

A horse shall be presumed eligible if it is a racing breed, at least two (2) years old and an Indiana bred or sired horse. The owner of such an Indiana bred or sired horse may render the horse ineligible for the testing as described in this regulation by indicating in writing the Indiana bred or sired horse is not intended to race in Indiana, pursuant to subsection (b) below provided that the owner of such an Indiana bred or sired horse provides such written notice to the office of the commission thirty (30) days before the horse turns two (2) years old or within thirty (30) days after the owner acquires the horse. In this event, the horse shall be deemed ineligible for racing in Indiana as provided for in subsection (b) below.

(b) If a horse selected to be tested is not covered under subsection (a), the executive director or stewards may nevertheless test any such horse as eligible to race in Indiana for prohibited substances, practices, and procedures specified in subsection (f), unless the owner or trainer or other authorized representative or designee of such horse immediately represents in writing that the horse is not intended to be, and will not be, raced in Indiana for a minimum of three hundred sixty-five (365) days. If the owner, trainer, or other authorized representative or designee so represents, the horse shall be deemed ineligible for racing in Indiana for no less than three hundred sixty-five (365) days from that date. This three hundred sixty-five (365) day ineligibility to race in Indiana shall follow the horse even if sold or transferred to another owner or trainer. An owner or trainer may, however, consent to the collection of a sample from a horse selected for testing under this rule, even if the horse is not presently intended to be raced in Indiana, and if such horse tests negative, it will remain eligible to race in Indiana.

(c) The executive director or stewards may order any horse of a licensed trainer to report to a track under the jurisdiction of the commission for out of competition testing. The trainer is responsible to have the horse or horses available at the designated time and location. In the event that a horse is ordered to report to a track pursuant to the authority granted by this subsection, a licensed trainer is entitled to reimbursement by the commission for mileage (at the current rate paid by the state of Indiana as specified in the current Indiana financial management circular) to and from the location where the horse was stabled when the horse was ordered to report to the track. Under no circumstances will a trainer be entitled to reimbursement for mileage in excess of the actual mileage to the track from the place where the horse was stabled when ordered to report and from the track to the place where the horse is first stabled following the testing. The trainer is not entitled to receive reimbursement from the commission for any other expense relating to any order under this subsection to report to a track for out-of-competition testing.

(d) The official veterinarian, a licensed veterinarian authorized by the commission or a veterinary technician under the direct supervision of the official veterinarian, or a licensed veterinarian authorized by the commission may take a urine, blood, or hair sample from a horse for testing as provided for in this section.

(e) Unless sample collection occurs on the grounds of a racetrack or other location within Indiana under the commission's jurisdiction, the commission's representatives must arrive for the taking of blood, urine, or hair samples from an eligible horse as defined in subsections *[subsection]* (a) or (b), only between the hours of 7:00 a.m. and noon, after announcing their presence at the premises where the horse(s) to be tested is (are) located and showing their credentials to collect samples from the horse(s) selected for testing for prohibited substances,

practices, and procedures as specified in subsection (f). The commission's representatives or designees will request to meet with the trainer or owner of the selected horse(s). If neither is available, the collection will be deferred until the trainer and/or owner, or their representative or designee, becomes reasonably available, but the collection must occur not later than one (1) hour after the commission's designee arrives at the premises in the case of an eligible horse under subsection (a), and not later than two (2) hours in the case of an eligible horse under subsection (b). If the collection does not occur within the time provided for in this subsection, any horse that would have been subject to testing and eligible to race in Indiana will be deemed to be ineligible for racing in Indiana pursuant to the provisions of subsections (a) and (b). In addition, the owner and/or trainer of the horses may be subject to any other sanctions allowed by Indiana law and regulations, including, but not limited to, a fine, suspension, and/or summary suspension. It is a defense to any action brought against an owner and/or trainer for sanctions or as a result of any declaration a horse is ineligible because the sample collection did not occur within the time provided for by this subsection that good cause existed that prohibited the owner, trainer, and/or their representative or designee from complying with the time limits set forth in this subsection. The owner, trainer, and/or their representative or designee has the burden of proving the good cause defense by a preponderance of the evidence.

(f) Prohibited substances, practices, and procedures are defined as the following:

(1) blood doping agents including, but not limited to, erythropoietin (EPO), darbepoetin, Oxyglobin, Hemopure, Aranesp, or any substance that abnormally enhances the oxygenation of body tissues;

(2) gene doping agents or the nontherapeutic use of genes, genetic elements, and/or cells that have the capacity to enhance athletic performance or produce analgesia;

(3) naturally produced venoms, synthetic analogues of venoms, derivatives of venoms, or synthetic analogues of derivatives of venoms;

(4) substances capable of producing a repartitioning effect that are not FDA-approved for use in horses, including, but not limited to, ractopamine, zilpaterol, or any similar agent;

(5) AAS (androgenic-anabolic steroids) other than **endogenous concentrations of the naturally occurring substances as defined in 71 IAC 8.5-1-8** ~~stanozolol, nandrolone, boldenone, testosterone and metabolites thereof~~; and

(6) the presence in a horse of any substance at anytime listed in subdivision (f)(1), (f)(2), (f)(3), (f)(4), or (f)(5) *[subdivision (1), (2), (3), (4), or (5)]* in an eligible as defined in subsections (a) and (b) above is prohibited and is a violation of this rule.

(g) The trainer and/or his/her designees shall cooperate with the official veterinarian, or any licensed veterinarian or licensed veterinary technician authorized by the commission, or any commission employee by:

(1) assisting in the immediate location and identification of the eligible horse selected for out of competition testing; and (2) providing a stall or safe location to collect the samples.

The executive director or stewards may summarily suspend, exclude, and/or otherwise penalize any trainer and/or other authorized representative or designee who does not fully cooperate with a commission employee or representative in assisting and identifying an eligible horse or providing a safe stall to collect samples in a timely fashion. If any such person is summarily suspended, excluded, or otherwise penalized, she/he shall be entitled to a hearing in accordance with Indiana law and regulations. A summary suspension, exclusion, or sanctions for failure to cooperate shall not issue, however, if a horseman meets his or her burden to establish the good cause defense set forth under subsection (e). This provision does not apply to an owner or trainer who timely provides written notice under subsection (a) or (b) that a horse sought to be tested is not intended to be raced in Indiana and thereby renders the horse ineligible pursuant to subsection (b).

(h) The collection of blood, urine, or hair samples under this rule shall be divided in three (3) parts to be analyzed as follows:

(1) approved primary laboratory for screening;

(2) approved primary laboratory for confirmation; and

(3) approved laboratory for split sample testing as chosen by the owner or trainer.

The commission shall approve the laboratories for screening, confirmation, and split sample testing.

(i) In the absence of extraordinary mitigating circumstances, a minimum penalty of a ten (10) year suspension will be assessed for any violation of subsection (f)(1) and (f)(2) of this rule *[subsection (f)(1) and (f)(2)]*. The Association of Racing Commissioners International, Inc. Uniform Classification Guidelines for Foreign Substances and Recommended Penalties and Model Rule will be considered for violations of (f)(3), (f)(4), and (f)(5) of this rule *[subsection (f)(3), (f)(4), and (f)(5)]* with additional penalties for any drug not FDA approved for use in horses.

(Indiana Horse Racing Commission; 71 IAC 8.5-2-5; emergency rule filed Jul 23, 2007, 9:16 a.m.: 20070808-IR-071070461ERA, eff Jul 18, 2007 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #07-461(E) was filed with the Publisher July 23, 2007.]; errata filed Aug 14, 2007,

1:28 p.m.: 20070829-IR-071070461ACA; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA; emergency rule filed Sep 10, 2012, 2:01 p.m.: 20120912-IR-071120525ERA)

71 IAC 8.5-5-2 Prohibited practices

Authority: IC 4-31-3-9

Affected: IC 4-31

Sec. 2. (a) The possession and/or use of a drug, substance, or medication, specified below, on the premises of a facility under the jurisdiction of the commission is prohibited. The following drugs or substances include those which a recognized analytical method has not been developed to detect and confirm the administration of such substance, or the use of which may endanger the health and welfare of the horse or endanger the safety of the rider, or the use of which may adversely affect the integrity of racing:

(1) Erythropoietin.

(2) ~~Darbepoietin~~. **Darbepoetin.**

(3) Oxyglobin.

(4) Hemopure.

(5) Snake venom.

(6) Snail venom.

(7) Ractopamine.

(8) Zilpaterol.

(b) The use of extracorporeal shock wave therapy or radial pulse wave therapy shall not be permitted unless the following conditions are met:

(1) Any treated horse shall not be permitted to race for a minimum of ten (10) days following treatment.

(2) The use of extracorporeal shock therapy or radial pulse wave therapy machines shall be limited to practicing veterinarians.

(3) Any extracorporeal shock therapy or radial pulse therapy machines on the association grounds must be registered with and approved by the commission or its designee before use.

(4) All extracorporeal shock therapy or radial pulse therapy treatments must be reported to the official veterinarian on the prescribed form not later than the time prescribed by the official veterinarian.

(c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United States Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food or nonfood, that is used to treat, cure, mitigate, or prevent a disease, is any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection**, other than vaccines licensed by the USDA**.

(d) While on the premises of a facility under the jurisdiction of the commission, veterinarians may only possess drugs, including compounds as discussed below in subsection (e), in amounts commensurate with the needs of horses with which the veterinarian has a veterinarian-client-patient relationship as that term is defined at 888 IAC 1.1-5-1(2).

(e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below. Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions.

(1) Compounds may only be prescribed to or prepared for horses with which the veterinarian has a veterinarian-client-patient-relationship;

(2) Compounded drugs may only be made from other FDA-approved drugs;

(3) Veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and

(4) Compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).

(f) The possession of any drug not approved by the FDA for distribution in the United States is prohibited, unless the

veterinarian can show proof of prior authorization from the FDA Center for Veterinary Medicine that has been obtained on a single-patient basis only. The authorization must be maintained in the animal health record. A copy of the authorization must be available for immediate inspection.
(g) Extra-label administration of drugs, including use for indication or at dosage levels, frequencies, or routes of administration other than those stated in the labeling, is permitted for FDA-approved drugs only. Extra-label use must meet the prescription labeling requirements in subsections (i) and (j).
(h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).
(i) Drugs possessed by practicing veterinarians on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label which must include:
(1) recommended or usual dosage;
(2) route for administration, if it is not for oral use;
(3) quantity or proportion of each active ingredient;
(4) names of inactive ingredients, if for other than oral use;
(5) an identifying lot or control number;
(6) manufacturer, packer, or distributor's name and address; and
(7) net quantity contents.
If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.
(j) When issuing a prescription for or dispensing a drug to a horse with which the veterinarian has a veterinarian-client-patient relationship, the veterinarian must affix or cause to be affixed a label that sets forth the following:
(1) Name and address of the veterinarian;
(2) Name and address of the client;
(3) Name of the horse;
(4) Date of prescription and/or dispensing of drug;
(5) Directions for use, including dose and duration directions, and number of refills;
(6) Name and quantity of the drug (or drug preparation, including compounds) prescribed or dispensed;
(7) For compounded drugs, the established name of each active ingredient; and
(8) Any necessary cautionary statements.
(k) The practice, administration, or application of a treatment, procedure, therapy, or method identified below, which is performed on the premises of a facility under jurisdiction of the commission or in any horse scheduled to compete in a race under the jurisdiction of the commission and which may endanger the health and welfare of the horse or endanger the safety of the rider or driver, or the use of which may adversely affect the integrity of racing is prohibited: Intermittent hypoxic treatment by external device.

(Indiana Horse Racing Commission; 71 IAC 8.5-5-2; emergency rule filed Aug 20, 2002, 3:00 p.m.: 26 IR 57; emergency rule filed Feb 21, 2003, 4:15 p.m.: 26 IR 2386; emergency rule filed Jan 21, 2004, 2:30 p.m.: 27 IR 1921; emergency rule filed Mar 10, 2006, 11:00 a.m.: 29 IR 2226; errata filed Apr 10, 2006, 2:00 p.m.: 29 IR 2546; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA)

71 IAC 8.5-1-7.1 Multiple Medication Violations
Authority: IC 4-31-3-9
Affected: IC 4-31-12

Sec. 7.1 (a) A trainer who receives a penalty for a medication violation based upon a horse testing positive for a Class 1, 2, 3, 4, or 5 medication with Penalty Class A, B, C, or D, as provided in the Uniform Classification Guidelines of Foreign Substances and Recommended Penalties and Model Rule as revised by the ARCI in August 1996 and any other subsequent revision effective after said date, which are incorporated by reference herein, may be assigned points based upon the medication's ARCI Penalty Guidelines as follows:

Class	Points if Controlled Therapeutic Substance	Points if Non-Controlled Substance
Class A	N/A	6
Class B	2	4
Class C	1	2
Class D	½	1

(b) The points assigned to a medication violation shall be included in the stewards' or Commission Ruling. Such ruling shall determine, in the case of multiple positive tests as described in paragraph (d), whether they shall thereafter constitute a single violation. The ruling shall be posted on the official website of the ARCI. If an appeal is pending, that fact shall be noted in the ruling. No points shall be applied until a final adjudication of the enforcement of any such violation.

(c) Once all appeals are waived or exhausted, the points shall immediately become part of the trainer's official ARCI record and shall then subject the trainer to the mandatory enhanced penalties by the Stewards or the Commission as provided in this rule.

(d) Multiple positive tests for the same medication incurred by a trainer prior to delivery of official notice by the commission may be treated as a single violation.

(e) The official ARCI record shall constitute prima facie evidence of a trainer's past record of violations and cumulative points. Nothing in this Section shall be construed to confer upon a trainer the right to appeal a violation for which all remedies have been exhausted or for which the appeal time has expired.

(f) The stewards or Commission shall include all points for violations in all racing jurisdictions as contained in the trainer's official ARCI record when determining whether the enhancements provided in this regulation shall be imposed.

(g) In addition to the penalty for the underlying offense, the following enhancements may be imposed upon a licensed trainer based upon the cumulative points contained in the trainer's official ARCI record:

Points	Suspension in days
3-5.5	30
6-8.5	60
9-10.5	180
11 or more	360

These points are intended to be an additional uniform penalty when the licensee:
(3) has more than one violation for the relevant time period, and
(4) exceeds the permissible number of points.

(h) The suspension periods in (g) shall run consecutive to any suspension imposed for the underlying offense.

(i) The stewards' or Commission ruling shall distinguish between the penalty for the underlying offense and the enhancement based upon the trainer's cumulative points.

Proposed Rules

Standardbred

February 24, 2014

Proposed Harness Racing Medication Rule Changes Follow:

- Additions are **underlined in bold**
- Deletions are ~~struckthrough~~

71 IAC 1-1-94.1 "Sample" defined
Authority: IC 4-31-3-9; IC 4-31-2-23
Affected: IC 4-31-12
"Sample" when used in the context of being removed from or collected from a horse, means any amount of urine, saliva, blood, or other acceptable specimen derived from a horse. All samples become property of the commission at the time they are cleared by the testing laboratory and may be used for research and/or investigative purposes.

71 IAC 8-1-4.1 Nonsteroidal anti-inflammatory drugs (NSAIDs)
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 4.1. (a) The use of one (1) of three (3) approved NSAIDs shall be permitted under the following conditions:
(1) Not to exceed the following permitted serum or plasma threshold concentrations which are consistent with administration by a single intravenous injection at the recommended labeled doses at least twenty-four (24) hours before the post time for the race in which the horse is entered:
(A) Phenylbutazone – 2 micrograms per milliliter.
(B) Flunixin – 20 nanograms per milliliter.
(C) Ketoprofen – 10 nanograms per milliliter.
(b) These or any other NSAID are prohibited to be administered within the twenty-four (24) hours before post time ~~for~~ **of** the race in which the horse is entered.
(c) The presence of more than one (1) ~~of the three (3) approved~~ NSAIDs, with the exceptions of phenylbutazone in a concentration below ~~0.5~~ **0.3** micrograms per milliliter of serum or plasma **or flunixin in a concentration below 3.0 nanograms per milliliter,** ~~or any unapproved NSAID~~ in the post-race serum or plasma sample is not permitted. The use of all but one (1) of the approved NSAIDs shall be discontinued at least forty-eight (48) hours before the post time for the race in which the horse is entered. *(Indiana Horse Racing Commission; 71 IAC 8-1-4.1; emergency rule filed Jul 28, 2006, 11:22 a.m.: 20060816-IR-071060279ERA, eff Sep 1, 2006; emergency rule filed Jan 25, 2012, 12:20 p.m.:20120201-IR-071120056ERA)*

71 IAC 8-1-4.2 Threshold levels
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 4.2. **(a)** The official blood (serum or plasma) **and urine** samples may contain ~~the following drug substances,~~ **only the following therapeutic medications, their metabolites or analogues,** ~~their metabolites or analogs,~~ and **shall** not exceed the threshold concentrations specified in this rule.

(1) **The use of acepromazine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of the metabolite, HEPS, in urine.**
(2) **The use of betamethasone shall be permitted under the following conditions: Not to exceed ten (10) picograms per milliliter of betamethasone in serum or plasma.**
(3) **The use of butorphanol shall be permitted under the following conditions: Not to exceed three hundred (300) nanograms per milliliter of total (free and conjugated) butorphanol in urine or two (2) nanograms per milliliter of free butorphanol in serum or plasma.**
(4) **The use of clenbuterol shall be permitted under the following conditions: Not to exceed one hundred forty (140) picograms per milliliter clenbuterol in urine or the limit of detection (LOD) in serum or plasma.**
(5) **The use of dantrolene shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of 5-hydroxydantrolene in serum or plasma.**

(6) The use of detomidine shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of carboxydetomidine in urine or the LOD for detomidine in serum or plasma.
(7) The use of dexamethasone shall be permitted under the following conditions: Not to exceed five (5) picograms per milliliter of dexamethasone in plasma or serum.
(8) The use of diclofenac shall be permitted under the following conditions: Not to exceed five (5) nanograms per milliliter of diclofenac in plasma or serum.
(9) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO in serum or plasma.
(10) The use of firocoxib shall be permitted under the following conditions: Not to exceed twenty (20) nanograms per milliliter of firocoxib in serum or plasma.
(11) The use of glycopyrrolate shall be permitted under the following conditions: Not to exceed three (3) picograms per milliliter of glycopyrrolate in serum or plasma.
(12) The use of lidocaine shall be permitted under the following conditions: Not to exceed twenty (20) picograms per milliliter of total 3-hydroxylidocaine in serum or plasma.
(13) The use of mepivacaine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of total 3-hydroxymepivacaine in urine or the LOD of mepivacaine in serum or plasma.
(14) The use of methocarbamol shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of methocarbamol in serum or plasma.
(15) The use of methylprednisolone shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of methylprednisolone in serum or plasma.
(16) The use of omeprazole shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of omeprazole sulfide in urine.
(17) The use of prednisolone shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of prednisolone in serum or plasma.
(18) The use of procaine penicillin shall be permitted under the following conditions:
A. Not to exceed twenty-five (25) nanograms per milliliter of procaine in serum or plasma, and
B. Administration of procaine penicillin must be reported to the official veterinarian at the time of administration, and
C. Procaine penicillin must not be administered after the horse is entered to race, and
D. Mandatory surveillance of the horse must occur for the six (6) hours immediately preceding the race for which the horse is entered by association security at the owner's expense.
(19) The use of triamcinolone acetonide shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of triamcinolone acetonide in serum or plasma.
(20) The use of xylazine shall be permitted under the following conditions: Not to exceed one hundredth (.01) of a nanogram per milliliter of xylazine in serum or plasma.

~~(1) The use of clenbuterol shall be permitted under the following conditions: Not to exceed twenty-five (25) picograms per milliliter of clenbuterol (or its metabolites) in serum or plasma.~~
~~(2) The use of firocoxib shall be permitted under the following conditions: Not to exceed forty (40) nanograms per milliliter of firocoxib (or its metabolites) in serum or plasma.~~
~~(3) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO (or its metabolites) in serum or plasma which allows for topical administration of DMSO in accordance with section 1.5 of this rule.~~
(Indiana Horse Racing Commission; 71 IAC 8-1-4.2; emergency rule filed Jan 25, 2012, 12:20 p.m.: 20120201-IR-071120056ERA; emergency rule filed Feb 8, 2012, 12:01 p.m.: 20120215-IR-071120072ERA; emergency rule filed Apr 3, 2013,10:37 a.m.: 20130410-IR-071130133ERA)

~~**71 IAC 8-1-5.7 Anti-ulcer medications**~~
~~Authority: IC 4-31-3-9~~
~~Affected: IC 4-31-12~~

~~Sec. 5.7. The following anti-ulcer medications are permitted to be administered, at the stated dosage, up to twenty-four (24) hours prior to the race in which the horse is entered:~~
~~(1) Cimetidine (Tagamet®) 8-20 mg/kg PO BID-TID~~
~~(2) Omeprazole (Gastrogard®) 2.2 grams PO SID~~
~~(3) Ranitidine (Zantac®) 8 mg/kg PO BID~~
~~*(Indiana Horse Racing Commission; 71 IAC 8-1-5.7; emergency rule filed Apr 5, 2013, 3:50 p.m.: 20130410-IR-071130135ERA)*~~

71 IAC 8-1-8 Anabolic steroids
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 8. (a) No AAS (androgenic-anabolic steroid) shall be permitted in test samples collected from racing horses except for **endogenous concentrations** ~~residues~~ of the ~~major metabolite of stanozolol, nandrolone~~, ~~and the~~ naturally occurring substances boldenone**,** **nandrolone,** and testosterone at concentrations less than the indicated thresholds.
(b) Concentrations of these AAS shall not exceed the following urine threshold concentrations for total (i.e., free drug or metabolite and drug or metabolite liberated from its conjugates) **steroid**:
~~(1) 16β-hydroxystanozolol (metabolite of stanozolol (Winstrol)) one (1) ng/ml in urine for all horses regardless of sex.~~
(1)~~(2)~~ Boldenone ~~(Equipoise® is the undecylenate ester of boldenone)~~
(A) in male horse**s** other than geldings; -- fifteen (15) ng/ml ~~in~~ **of** urine.
(B) ~~No boldenone shall be permitted in geldings or female horses~~. **In geldings, fillies, and mares – one (1) ng/mL of urine;**
(2) ~~(3)~~ Nandrolone ~~(Durabolin® is the phenylpropionate ester and Deca-Durabolin® is the decanoate ester)~~:
(A) In geldings - one (1) ng/ml ~~in~~ **of** urine.
(B) In fillies and mares – one (1) ng/ml ~~in~~ **of** urine.
(C) In male horses other than geldings – forty-five (45) ng/ml of nandrolone metabolite, 5α-~~e~~estrane-3β,17α-diol ~~in~~ **of** urine.
(3) ~~(4)~~ Testosterone:
(A) In geldings – twenty (20) ng/ml ~~in~~ **of** urine.
(B) In fillies and mares – fifty-five (55) ng/ml **of** urine**, unless in foal**.
(C) In male horses other than geldings minimum thresholds will not apply.

(c) Concentrations of these AAS shall not exceed the following free (i.e., not conjugated) steroid concentrations in plasma or serum:
(1) Boldenone: For all horses a confirmatory threshold not greater than 25 pg/ml shall apply;

(2) Nandrolone:
(A) In geldings, fillies, and mares – a confirmatory threshold not greater than 25 pg/ml shall apply;
(B) In male horses other than geldings – nandrolone shall be tested for in urine only;

(3) Testosterone:
(A) In geldings, fillies, and mares-- a confirmatory threshold not greater than 25 pg/ml;
(B) In male horses other than geldings minimum thresholds will not apply.

~~(c)~~ **(d)** All other AAS are prohibited in racing horses.
~~(d)~~ **(e)** ~~Post-race urine samples collected from intact males must be identified to the laboratory~~. **The sex of the horse must be identified to the laboratory for all samples designated for AAS testing.**
~~(e)~~ **(f)** Any horse to which an anabolic steroid has been administered in order to assist in the recovery from illness or injury may be placed on the veterinarian's list in order to monitor the concentration of the drug or metabolite in urine **or blood**. After the concentration has fallen below the designated threshold for the administered AAS, the horse is eligible to be removed from the list.
~~(f) Implementation of this rule shall commence April 1, 2008.~~
~~(g) During the first ninety (90) calendar days of the first race meet beginning after the implementation date, no positive test establishing the presence of an anabolic steroid shall be considered a violation of this rule and,~~

~~accordingly, shall not result in a penalty, disqualification, or a forfeiture of any purse, trophy, or award. Trainers shall be notified of any positive test during the ninety (90) day grace period.~~
(Indiana Horse Racing Commission; 71 IAC 8-1-8; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed May 12, 2008, 1:29 p.m.: 20080521-IR-071080353ERA)

71 IAC 8-3-5 Out of competition testing
Authority: IC 4-31-3-9
Affected: IC 4-31-12
Sec. 5. (a) Any horse eligible to race in Indiana under this subsection is subject to testing without advance notice for prohibited substances, practices, and procedures as specified in subsection (f), while the horse is located on the grounds of a racetrack under the jurisdiction of the commission, or stabled off association grounds while under the care or control of trainer or owner licensed by the commission under the restrictions listed in subsection (e). A horse is eligible to race in Indiana if it is listed:
(1) on an owner's or trainer's license application; or
(2) a stall application, nomination list; or
(3) on the horse sign-in sheet at any time during the meet; or
(4) has raced at any Indiana race meet during the calendar year.
A horse shall be presumed eligible if it is a racing breed, at least two (2) years old and an Indiana bred or sired horse. The owner of such an Indiana bred or sired horse may render the horse ineligible for the testing as described in this regulation by indicating in writing the Indiana bred or sired horse is not intended to race in Indiana, pursuant to subsection (b) below provided that the owner of such an Indiana bred or sired horse provides such written notice to the office of the commission thirty (30) days before the horse turns two (2) years old or within thirty (30) days after the owner acquires the horse. In this event, the horse shall be deemed ineligible for racing in Indiana as provided for in subsection (b) below.
(b) If a horse to be tested is not covered under subsection (a), the executive director or judges may nevertheless test any such horse as eligible to race in Indiana for prohibited substances, practices, and procedures specified in subsection (f), unless the owner or trainer or other authorized representative or designee of such horse immediately represents in writing that the horse is not intended to be, and will not be, raced in Indiana for a minimum of three hundred sixty-five (365) days. If the owner, trainer, or other authorized representative or designee so represents, the horse shall be deemed ineligible for racing in Indiana for no less than three hundred sixty-five (365) days from that date. This three hundred sixty-five (365) day ineligibility to race in Indiana shall follow the horse even if sold or transferred to another owner or trainer. An owner or trainer may, however, consent to the collection of a sample from a horse selected for testing under this rule, even if the horse is not presently intended to be raced in Indiana, and if such horse tests negative, it will remain eligible to race in Indiana.
(c) The executive director or judges may order any horse of a licensed trainer to report to a track under the jurisdiction of the commission for out of competition testing. The trainer is responsible to have the horse or horses available at the designated time and location. In the event that a horse is ordered to report to a track pursuant to the authority granted by this subsection, a licensed trainer is entitled to reimbursement by the commission for mileage (at the current rate paid by the state of Indiana as specified in the current Indiana financial management circular) to and from the location where the horse was stabled when the horse was ordered to report to the track. Under no circumstances will a trainer be entitled to reimbursement for mileage in excess of the actual mileage to the track from the place where the horse was stabled when ordered to report and from the track to the place where the horse is first stabled following the testing. The trainer is not entitled to receive reimbursement from the commission for any other expense relating to any order under this subsection to report to a track for out-of-competition testing.
(d) The official veterinarian, a licensed veterinarian authorized by the commission, a veterinary technician under the direct supervision of the official veterinarian, or a licensed veterinarian authorized by the commission may take a urine, blood, or hair sample from a horse for testing as provided for in this section.
(e) Unless sample collection occurs on the grounds of a racetrack or other location within Indiana under the commission's jurisdiction, the commission's representatives must arrive for the taking of blood, urine, or hair samples from an eligible horse as defined in subsections *[subsection]* (a) or (b), only between the hours of 7:00 a.m. and noon, after announcing their presence at the premises where the horse(s) to be tested is (are) located and showing their credentials to collect samples from the horse(s) selected for testing for prohibited substances, practices, and procedures as specified in subsection (f). The commission's representatives or designees will request to meet with the trainer or owner of the selected horse(s). If neither is available, the collection will be deferred until

the trainer and/or owner, or their representative or designee, becomes reasonably available, but the collection must occur not later than one (1) hour after the commission's designee arrives at the premises in the case of an eligible horse under subsection (a), and not later than two (2) hours in the case of an eligible horse under subsection (b). If the
collection does not occur within the time provided for in this subsection, any horse that would have been subject to testing and eligible to race in Indiana will be deemed to be ineligible for racing in Indiana pursuant to the provisions of subsections (a) and (b). In addition, the owner and/or trainer of the horses may be subject to any other sanctions allowed by Indiana law and regulations, including, but not limited to, a fine, suspension, and/or summary suspension. It is a defense to any action brought against an owner and/or trainer for sanctions or as a result of any declaration a horse is ineligible because the sample collection did not occur within the time provided for by this subsection that good cause existed that prohibited the owner, trainer, and/or their representative or designee from complying with the time limits set forth in this subsection. The owner, trainer, and/or their representative or designee has the burden of proving the good cause defense by a preponderance of the evidence.
(f) Prohibited substances, practices, and procedures are defined as the following:
(1) blood doping agents including, but not limited to, erythropoietin (EPO), darbepoetin, Oxyglobin, Hemopure, Aranesp, or any substance that abnormally enhances the oxygenation of body tissues;
(2) gene doping agents or the nontherapeutic use of genes, genetic elements, and/or cells that have the capacity to enhance athletic performance or produce analgesia;
(3) naturally produced venoms, synthetic analogues of venoms, derivatives of venoms, or synthetic analogues of derivatives of venoms;
(4) substances capable of producing a repartitioning effect that are not FDA-approved for use in horses, including, but not limited to, ractopamine, zilpaterol, or any similar agent;
(5) AAS (androgenic-anabolic steroids) other than **endogenous concentrations of the naturally occurring substances as defined in 71 IAC 8-1-8** ~~stanozolol, nandrolone, boldenone, testosterone, and metabolites thereof~~; and
(6) the presence in a horse of any substance at anytime listed in subdivision (1), (2), (3), (4), or (5) in an eligible as defined in subsections (a) and (b) above is prohibited and is a violation of this rule.
(g) The trainer and/or his/her designees shall cooperate with the official veterinarian or any licensed veterinarian or licensed veterinary technician authorized by the commission or any commission employee by:
(1) assisting in the immediate location and identification of the eligible horse selected for out of competition testing; and (2) providing a stall or safe location to collect the samples.
The executive director or judges may summarily suspend, exclude, and/or otherwise penalize any trainer and/or other authorized representative or designee who does not fully cooperate with a commission employee or representative in assisting and identifying an eligible horse or providing a safe stall to collect samples in a timely fashion. If any such person is summarily suspended, excluded, or otherwise penalized, she/he shall be entitled to a hearing in accordance with Indiana law and regulations. A summary suspension, exclusion, or sanctions for failure to cooperate shall not issue, however, if a horseman meets his or her burden to establish the good cause defense set forth under subsection (e). This provision does not apply to an owner or trainer who timely provides written notice under subsection (a) or (b) that a horse sought to be tested is not intended to be raced in Indiana and thereby renders the horse ineligible pursuant to subsection (b).
(h) The collection of blood, urine, or hair samples under this rule shall be divided in three (3) parts to be analyzed as follows:
(1) approved primary laboratory for screening;
(2) approved primary laboratory for confirmation; and
(3) approved laboratory for split sample testing as chosen by the owner or trainer.
The commission shall approve the laboratories for screening, confirmation, and split sample testing.
(i) In the absence of extraordinary mitigating circumstances, a minimum penalty of a ten (10) year suspension will be assessed for any violation of subsection (f)(1) and (f)(2) of this rule *[subsection (f)(1) and (f)(2)]*. The Association of Racing Commissioners International, Inc. Uniform Classification Guidelines for Foreign Substances and Recommended Penalties and Model Rule will be considered for violations of (f)(3), (f)(4), and (f)(5) of this rule *[subsection (f)(3), (f)(4), and (f)(5)]* with additional penalties for any drug not FDA approved for use in horses.
(Indiana Horse Racing Commission; 71 IAC 8-3-5; emergency rule filed Jul 23, 2007, 9:16 a.m.: 20070808-IR-071070461ERA, eff Jul 18, 2007 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #07-461(E) was filed with the Publisher July 23, 2007.]; errata filed Aug 14, 2007, 1:28 p.m.: 20070829-IR-071070461ACA; emergency rule filed Mar 12, 2008, 1:53 p.m.:20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing

with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1 establishes the effectiveness of an emergency ruleupon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA; emergency rule filed Sep 10, 2012, 2:01 p.m.: 20120912-IR-071120525ERA)

71 IAC 8-6-2 Prohibited practices

Authority: IC 4-31-3-9

Affected: IC 4-31

Sec. 2. (a) The possession and/or use of a drug, substance, or medication, specified below, on the premises of a facility under the jurisdiction of the commission is prohibited. These drugs or substances include those which a recognized analytical method has not been developed to detect and confirm the administration of such substance, or the use of which may endanger the health and welfare of the horse or endanger the safety of the rider, or the use of which may adversely affect the integrity of racing:

(1) Erythropoietin.

(2) ~~Darbepoietin.~~ **Darbepoetin.**

(3) Oxyglobin.

(4) Hemopure.

(5) Snake venom.

(6) Snail venom.

(7) Ractopamine.

(8) Zilpaterol.

(b) The use of extracorporeal shock wave therapy or radial pulse wave therapy shall not be permitted unless the following conditions are met:

(1) Any treated horse shall not be permitted to race for a minimum of ten (10) days following treatment.

(2) The use of extracorporeal shock therapy or radial pulse wave therapy machines shall be limited to practicing veterinarians.

(3) Any extracorporeal shock therapy or radial pulse therapy machines on the association grounds must be registered with and approved by the commission or its designee before use.

(4) All extracorporeal shock therapy or radial pulse therapy treatments must be reported to the official veterinarian on the prescribed form not later than the time prescribed by the official veterinarian.

(c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United States Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food or nonfood, that is used to treat, cure, mitigate, or prevent a disease, any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection **other than vaccines licensed by the USDA**.

(d) While on the premises of a facility under the jurisdiction of the commission, veterinarians may only possess drugs, including compounds as discussed below in subsection (e), in amounts commensurate with the needs of horses with which the veterinarian has a veterinarian-client-patient relationship as that term is defined at 888 IAC 1.1-5-1(2).

(e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below. Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to~~,~~ mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions.

(1) Compounds may only be prescribed to or prepared for horses with which the veterinarian has a veterinarian-client-patient relationship;

(2) Compounded drugs may only be made from other FDA-approved drugs;

(3) Veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and

(4) Compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).

(f) The possession of any drug not approved by the FDA for distribution in the United States is prohibited, unless the veterinarian can show proof of prior authorization from the FDA Center for Veterinary Medicine that has been obtained on a single-patient basis only. The authorization must be maintained in the animal health record. A copy of the authorization must be available for immediate inspection.

(g) Extra-label administration of drugs, including use for indication or at dosage levels, frequencies, or routes of administration other than those stated in the labeling, is permitted for FDA-approved drugs only. Extra-label use must meet the prescription labeling requirements in subsections (i) and (j).
(h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).
(i) Drugs possessed by practicing veterinarians on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label, which must include:
(1) recommended or usual dosage;
(2) route for administration, if it is not for oral use;
(3) quantity or proportion of each active ingredient;
(4) names of inactive ingredients, if for other than oral use;
(5) an identifying lot or control number;
(6) manufacturer, packer, or distributor's name and address; and
(7) net quantity contents.
If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.
(j) When issuing a prescription for or dispensing a drug to a horse with which the veterinarian has a veterinarian-client-patient relationship, the veterinarian must affix or cause to be affixed a label which sets forth the following:
(1) Name and address of the veterinarian;
(2) Name and address of the client;
(3) Name of the horse;
(4) Date of prescription and/or dispensing of drug;
(5) Directions for use, including dose and duration directions, and number of refills;
(6) Name and quantity of the drug (or drug preparation, including compounds) prescribed or dispensed;
(7) For compounded drugs, the established name of each active ingredient; and
(8) Any necessary cautionary statements.
(k) The practice, administration, or application of a treatment, procedure, therapy, or method identified below, which is performed on the premises of a facility under jurisdiction of the commission or in any horse scheduled to compete in a race under the jurisdiction of the commission and which may endanger the health and welfare of the horse or endanger the safety of the rider or driver, or the use of which may adversely affect the integrity of racing is prohibited: Intermittent hypoxic treatment by external device. *(Indiana Horse Racing Commission; 71 IAC 8-6-2; emergency rule filed Feb 21, 2003, 4:15 p.m.: 26 IR 2385; emergency rule filed Jan 21, 2004, 2:30 p.m.: 27 IR 1920; emergency rule filed Mar 10, 2006, 11:00 a.m.: 29 IR 2220; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1 establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA)*

71 IAC 8-1-7.1 Multiple Medication Violations
Authority: IC 4-31-3-9
Affected: IC 4-31-12

Sec. 7.1 (a) A trainer who receives a penalty for a medication violation based upon a horse testing positive for a Class 1, 2, 3, 4, or5 medication with Penalty Class A, B, C, or D, as provided in the Uniform Classification Guidelines of Foreign Substances and Recommended Penalties and Model Rule as revised by the ARCI in August 1996 and any other subsequent revision effective after said date, which are incorporated by reference herein, may be assigned points based upon the medication's ARCI Penalty Guidelines as follows:

Class	Points if Controlled Therapeutic Substance	Points if Non-Controlled Substance
Class A	N/A	6
Class B	2	4
Class C	1	2
Class D	½	1

(b) The points assigned to a medication violation shall be included in the judges' or Commission ruling. Such ruling shall determine, in the case of multiple positive tests as described in paragraph (d), whether they shall thereafter constitute a single violation. The ruling shall be posted on the official website of the ARCI. If an appeal is pending, that fact shall be noted in the ruling. No points shall be applied until a final adjudication of the enforcement of any such violation.

(c) Once all appeals are waived or exhausted, the points shall immediately become part of the trainer's official ARCI record and shall then subject the trainer to the mandatory enhanced penalties by the judges or the Commission as provided in this Section.

(d) Multiple positive tests for the same medication incurred by a trainer prior to delivery of official notice by the commission may be treated as a single violation.

(e) The official ARCI record shall constitute prima facie evidence of a trainer's past record of violations and cumulative points. Nothing in this Section shall be construed to confer upon a trainer the right to appeal a violation for which all remedies have been exhausted or for which the appeal time has expired.

(f) The judges or Commission shall include all points for violations in all racing jurisdictions as contained in the trainer's official ARCI record when determining whether the enhancements provided in this regulation shall be imposed.

(g) In addition to the penalty for the underlying offense, the following enhancements may be imposed upon a licensed trainer based upon the cumulative points contained in the trainer's official ARCI record:

Points	Suspension in days
3-5.5	30
6-8.5	60
9-10.5	180
11 or more	360

These points are intended to be an additional uniform penalty when the licensee:
(1) has more than one violation for the relevant time period, and
(2) exceeds the permissible number of points.

(h) The suspension periods in (g) shall run consecutive to any suspension imposed for the underlying offense.

(i) The judges' or Commission's ruling shall distinguish between the penalty for the underlying offense and the enhancement based upon the trainer's cumulative points.

Letter From

National Thoroughbred Racing Association (NTRA)

Requesting Approval

Letter Mailed to Horse Racing Commissions in 28 U.S. Jurisdictions

September 30, 2013

Re: Uniform National Medication Rules, Penalties and Laboratory Accreditation

Dear [Chairman]:

As you may be aware, the horse racing industry in the United States has recently developed new uniform model medication guidelines, a penalty system designed to target individuals with multiple medication violations and a requirement for laboratory accreditation and participation in an industry external quality assurance program (the "Reforms"). These Reforms were developed by the Racing Medication and Testing Consortium ("RMTC"), the industry's scientific advisory organization consisting of 25 major racing industry stakeholder organizations and the Association of Racing Commissioners International ("RCI"), the industry's association of state regulatory bodies responsible for the integrity of racing. RMTC recommended the Reforms to RCI and RCI voted to incorporate the Reforms into their official Model Rules earlier this year. Individual regulatory bodies must now move to adopt the Reforms.

In fact, earlier this year eight states in the Mid-Atlantic and Northeast, two regions which comprise the largest concentration of racing on a daily basis in North America and produce about 36% of the daily national handle, jointly agreed to implement the Reforms on January 1, 2014, or when a participating state's live racing begins in 2014. The states committed to implementing the Reforms are Delaware, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, Virginia and West Virginia and several other states are in the process of adopting these Reforms as well. Nationwide adoption of these Reforms is essential to safeguarding horses and riders and providing uniformity to fans and participants alike. If you have not done so already, we ask you to commit to the Reforms and move expeditiously to adopt all aspects of the Reforms without amendment or delay.

The Reforms consist of the following:

1. **The RCI Controlled Therapeutic Medication Schedule** ("Schedule"). The Reforms include a "Schedule of Controlled Therapeutic Medications" which lists medications that have been recognized as necessary for the treatment of illness or injury in the horse on a routine basis. For each medication, the Schedule lists a uniform detection level at which the testing laboratory is to report a positive test and horsemen are provided with guidance for discontinuing treatment to minimize the risk of incurring a violation. The Schedule is based upon years of research by the RMTC and is scientifically supported so

that each level of detection is specifically linked to the concentration above which the drug could affect the horse's performance. Version 1.0 of the Schedule was adopted as part of the RCI Model Rules ("Model Rules") at ARCI-011-020 Section C (1) (b). A copy of Version 1.0 of the Schedule is attached as **Exhibit A** to this letter.

2. **Multiple Medication Violations Penalty System** ("MMV"). The MMV represents an industry-wide plan to provide enhanced penalties for those individuals who accumulate multiple medication violations. Under the new system, each drug or medication violation is assessed points. A trainer's record will be tracked by a central database maintained by RCI and available to state stewards and commissions. A trainer's point record will include violations across all jurisdictions. At certain point total thresholds, the offending trainer will be required to serve an additional suspension. The MMV was adopted as part of the Model Rules at ARCI-011-020 Section B (13) (a)-(j). A copy of the MMV is attached as **Exhibit B** to this letter.

3. **Restrictions on the use and administration of bleeder medications** (the "Furosemide Restrictions"). The Furosemide Restrictions require that Furosemide be the only medication authorized for administration on race day and limit Furosemide administration to no less than four hours prior to post time for the race in which the horse is entered. The Furosemide Restrictions also require that the administration of Furosemide be performed only by third-party veterinarians or veterinary technicians who are prohibited from working as private veterinarians or technicians on the racetrack or with participating licensees. The Furosemide Restrictions were adopted as part of the Model Rules at ARCI-011-020 Section F. A copy of Section F is attached as **Exhibit C** to this letter.

4. **Laboratory Accreditation and Minimum Standards.** The Reforms require that every participating state's drug testing laboratory must be accredited by the RMTC to standards set forth in the RMTC testing laboratory accreditation code of standards ("RMTC Standards"), which are the strictest laboratory standards for equine sport drug testing in the world. RMTC Standards include a requirement for lab accreditation to international laboratory standards known as ISO 17025 accreditation standards. Currently, two labs have been fully accredited to the RMTC Standards and six more labs are undergoing RMTC Standards accreditation review. A copy of the RMTC Standards is attached as **Exhibit D** to this letter.

5. **Reform Adoption Timeline**. Every jurisdiction in the United States that conducts pari-mutuel horse racing is urged to fully and uniformly adopt each of the Reforms without amendment or substantive modification by January 1, 2014, or as soon thereafter as practicable given any legal or procedural limits on adoption or implementation in individual jurisdictions.

6. **Future Modification of the Reforms**. The Reforms process is intended to be ongoing and allows for additional substances to be considered for inclusion in the Schedule, upon recommendation from the American Association of Equine Practitioners (AAEP) and the RMTC. Other aspects of the Reforms may likewise be modified in the future to reflect scientific research and development. States are urged to adopt the Reforms in their entirety without amendment or modification.

These Reforms are in the best interests of the health and welfare of the horse and the safety of the rider, enhance the integrity of our sport, ensure a level playing field for our competitors, assist horsemen who race in multiple jurisdictions and accomplish the uniform regulation of racing in the United States.

To advance the goals and objectives of the Reforms on a uniform basis nationwide, the undersigned, representing a broad cross section of the horse racing industry, hereby formally request that the _____ Commission adopt these Reforms in their entirety and that you schedule a hearing and/or any other official action for the purpose of adopting these Reforms as soon as practicable.

You can expect to be contacted by an industry representative very shortly to determine whether your jurisdiction is committed to the Reforms and your expected timeline for adoption.

To assist you in this process, we have authorized the RMTC to make available to you such scientific expertise and documentation as you may need to fully consider and act upon the Reforms. Feel free to contact Dionne Benson, RMTC Executive Director and COO, at 859-224-2845 or at dbenson@rmtcnet.com for further assistance.

We appreciate your cooperation in this matter and look forward to working with you to achieve national uniformity so that everyone in horse racing will benefit from these critical Reforms.

Sincerely,

Alex Waldrop,
President and CEO, National Thoroughbred Racing Association
Chairman, Racing Medication and Testing Consortium

Additional signatories on attached page.
Exhibits A-D attached and online at http://www.ntra.com/media/Exhibits_to_NTRA_Letter.pdf.

Additional Signatories to September 30, 2013
NTRA Letter to State Racing Commissions

(As of January 2014)

- American Quarter Horse Association
- Arabian Jockey Club
- Arlington Park
- Association of Racing Commissioners International
- Betfair Hollywood Park
- Breeders' Cup Limited
- Calder Race Course
- California Thoroughbred Breeders Association
- Churchill Downs
- Delaware Park
- Del Mar Thoroughbred Club
- Fair Grounds
- Florida Thoroughbred Breeders and Owners Association
- Global Gaming Solutions
    - Lone Star Park at Grand Prairie
    - Remington Park
- Keeneland Association
- Kentucky Downs
- Kentucky Thoroughbred Association
- Monmouth Park
- National Thoroughbred Racing Association (NTRA)
- NTRA Safety & Integrity Alliance
- New York Thoroughbred Breeders, Inc.
- Oak Tree Racing Association
- Penn National Gaming
    - Hollywood Casino, Hotel and Raceway (Bangor, ME)
    - Hollywood Casino at Charles Town Races
    - Hollywood Casino at Penn National Race Course
    - Raceway Park
    - Beulah Park
    - Rosecroft Raceway
    - Sam Houston Race Park
    - Freehold Raceway
    - Zia Park Racetrack and Casino
- Racing Medication and Testing Consortium
- Racing Officials Accreditation Program (ROAP)
- Suffolk Downs
- Sunland Park Racetrack and Casino
- Tampa Bay Downs
- The Jockey Club
- The Jockeys' Guild
- The New York Racing Association, Inc.
    - Aqueduct
    - Belmont Park
    - Saratoga Race Course
- The Stronach Group
    - AmTote
    - HRTV
    - Golden Gate Fields
    - Gulfstream Park & Casino
    - Laurel Park
    - Pimlico Race Course
    - Portland Meadows
    - Santa Anita Park
    - XpressBet
- Thoroughbred Horsemen's Association (THA)
    - Delaware THA
    - Illinois THA
    - Maryland THA
    - New Jersey THA
    - New York THA
    - Pennsylvania THA
- Thoroughbred Owners and Breeders Association
- Thoroughbred Owners of California
- Thoroughbred Racing Associations of North America, Inc.

Staff Recommendation

State of Indiana
Indiana Horse Racing Commission

Michael R. Pence, Governor

www.in.gov/hrc

Staff Recommendation

The Indiana Horse Racing Commission staff recommends approval of the RCI Controlled Therapeutic Medication Schedule, the Multiple Medication Violation Penalty System and related rules.

After careful consideration of all relevant data, the Commission staff concludes that the proposed regulations are in the best interest of racing and will:

1) provide much needed uniformity to the regulation of equine medication;
2) protect the integrity of the sport; and
3) protect the health and safety of our equine athletes.

Ph: 317/233-3119 • Indiana Horse Racing Commission • Fax: 317/233-4470
1302 N. Meridian St., Suite 175, Indianapolis, IN 46202

Status of Rulemaking Process

Phase 1 - Two category drug classification system: Controlled Therapeutic Medications and Prohibited Substances with regulatory thresholds and withdrawal guidelines provided for each of the 24 controlled therapeutic medications

State	Current
California	
Delaware	
Kentucky	
Maryland	
Massachusetts	
Pennsylvania	
Virginia	
West Virginia	
Arizona	
Idaho	
Illinois	
Nebraska	
New Jersey	
New York	
Ohio	
Washington	
Wyoming	
Arkansas	
Florida	
Indiana	
Minnesota	
New Mexico	
Oregon	
Texas	
Colorado	
Iowa	
Louisiana	
Michigan	
Oklahoma	

	Rules Passed
	In Adoption Process
	Under Discussion 2013
	Uncommitted

Under Discussion	races	purse	starters	starts
	39,950	$ 1,015,193,143	78,762	311,567
% of total	89%	90%	87%	87%

Phase 4 - Adoption of the new RCI Penalty Guidelines for Multiple Medication Violations

State	MMV Penalty System
Arizona	
Arkansas	
California	
Colorado	
Delaware	
Florida	
Idaho	
Illinois	
Indiana	
Iowa	
Kentucky	
Louisiana	
Maryland	
Massachusetts	
Michigan	
Minnesota	
Nebraska	
New Jersey	
New Mexico	
New York	
Ohio	
Oklahoma	
Oregon	
Pennsylvania	
Texas	
Virginia	
Washington	
West Virginia	
Wyoming	

	Rules Passed
	In Adoption Process
	Under Discussion
	Uncommitted

Request for Comment

Demaree, Angela

From: Demaree, Angela
Sent: Wednesday, September 18, 2013 3:55 PM
To: Demaree, Angela
Cc: Gorajec, Joe
Subject: IHRC Request for Comment--ARCI New Medication and Penalty Guidelines
Attachments: combined-controlled-therapeutics-v1.0---master-regulatory2.pdf; 2013-07-13-MMV Document.pdf; 2013-07-31-RCI Toughens Penalty Guidelines for Multiple Medication Viola....pdf; 2013-04-02-RCI Gives Final Approval to Uniform Drug Testing Policy and T....pdf

Dear Doctors and Horsemen,

The IHRC is contacting you for feedback regarding the new ARCI medication and penalty proposal. I have attached two documents for comment, the RCI Schedule of Controlled Therapeutic Substances and the Model Rule regarding Multiple Medication Violations.

I have also attached related RCI press releases for your information, if helpful.

The IHRC tentatively plans to include this issue on its December Agenda, please respond with comments no later than noon on November 1st.

Please feel free to contact me via office phone, cell, or email with any questions.

Sincerely,

Angela Demaree, D.V.M.
Equine Medical Director
Indiana Horse Racing Commission
1302 North Meridian, Suite 175
Indianapolis, IN 46202
Office: (317) 233-6895
Cell: 317-260-3529

RACING COMMISSIONERS INTERNATIONAL

Press Release

Tuesday, April 2, 2013
Contact: Ed Martin (859) 224-7070

RCI Gives Final Approval to Uniform Drug Testing Policy and Thresholds

LEXINGTON, KY - Racing Commissioners International (RCI) today gave final approval to the "RCI Controlled Therapeutic Medication Schedule", setting the stage for uniform implementation of racing medication rules in the United States and beyond.

The RCI schedule is intended to be a guide for testing laboratories in determining the level at which the presence of a substance would violate the rules and become a violation. It also creates restrictions on administering medications within times certain prior to a race, creating a clear line that horsemen and veterinarians should not cross.

"For years we have talked about uniformity but today is the first day that we can say there is agreement as to what constitutes a violation," said RCI Chairman Duncan Patterson, who is also the chairman of the Delaware Thoroughbred Racing Commission.

Twenty-four (24) substances deemed appropriate for normal equine care are included on the RCI schedule. Additional substances may be considered for inclusion in the schedule upon recommendation from the American Association of Equine Practitioners or the Racing Medication and Testing Consortium.

According to RCI, approximately 75% of all medication rule violations each year are for overages associated with substances contained on the RCI Schedule.

RCI President Ed Martin said regulators are being encouraged to achieve uniformity by adding the RCI schedule to their rules "by reference", a common way to incorporate a nationally recognized standard into public policy.

"If everyone works from the same schedule, we will have uniformity," Martin said, noting that a movement coordinated by the Thoroughbred Horsemen's Association is already underway in several Mid-Atlantic states to implement the RCI schedule.

Substances not contained on the schedule will be considered "prohibited", meaning they should not be present in a post-race sample at any level or at levels exceeding defined limits found elsewhere in the rules. Patterson indicated that a proposal to address overages that may be caused by environmental contaminants submitted by the National Horseman's Protective and Benevolent Association (NHBPA) will be discussed at the RCI meetings commending in New Orleans on April 23. Also to be discussed will be modifications to the recommended penalty guidelines.

#####

1510 Newtown Pike, Lexington, Kentucky 40511
(859) 224-7070

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Acepromazine	10 ng/ml HEPS in urine	48 hours	Single IV dose of acepromazine at 0.05 mg/kg.	UC Davis project	Applicable analyte is metabolite HEPS
Betamethasone	10 pg/mL of plasma or serum.	7 days	IA administration of 9 mg of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP (American Regent product #0517-0720-01)[1]	RMTC study	IA dosing only - applicable analyte is betamethasone in plasma or serum
Butorphanol	300 ng/mL of total butorphanol in urine or 2 ng/mL of free butorphanol in plasma.	48 hours	Single IV dose of butorphanol as Torbugesic® (butorphanol tartrate) at 0.1 mg/kg.	J. vet. Pharmacol. Therap. doi: 10.1111/j.1365-2885.2012.01385.x	Applicable analytes are total butorphanol (drug and conjugates) in urine and butorphanol in plasma (the drug itself, not any conjugate).

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Clenbuterol	140 pg/mL of urine or LOD in plasma or serum.	14 Days	Oral administration of clenbuterol as Ventipulmin® syrup (Boehringer-Ingelheim Vetmedica Inc., NADA 140-973) at 0.8 mcg/kg twice a day	UC Davis Boehringer-Ingelheim Vetmedica, Inc.	Applicable analyte is clenbuterol.
Dantrolene	100 pg/mL 5-hydroxydantrolene in plasma or serum	48 hours	Oral administration of 500 mg of dantrolene as paste (compounding pharmacy) or capsule formulation (Proctor and Gamble)	J. vet. Pharmacol. Therap. 34, 238–246	
Detomidine	1 ng/mL of carboxydetomidine in urine; LOD for detomidine in plasma.	72 hours	Single sublingual dose detomidine (Domosedan® gel at 40 mcg/kg)	Vet. J. 2012 Oct. 10 http://dx.doi.org/10.1016/j.tvjl.2012.08.016	

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Dexamethasone	5 pg/mL of plasma or serum	72 hours	IM and IV administration of dexamethasone sodium phosphate or oral administration of dexamethasone at 0.05 mg/kg. Regardless of route.	RMTC study	Applicable analyte is dexamethasone in plasma or serum
Diclofenac	5 ng/mL of plasma or serum	48 hours	Five inch ribbon topical application of 1% diclofenac liposomal cream formulation. (Surpass Topical Anti-Inflammatory Cream, IDEXX Pharmaceuticals)	*Veterinary Therapeutics* 6: 57-66 (2005)	Applicable analyte is diclofenac in plasma or serum.
DMSO	10 mcg/mL of plasma or serum	48 hours	Oral or IV	ARCI model rule	Applicable analyte is DMSO in plasma or serum.

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Firocoxib	20 ng/mL of plasma or serum	14 days	Oral administration of firocoxib as EQUIOXX oral paste at a daily dose of 0.1 mg/kg for four days	RMTC study	Applicable analyte is firocoxib in plasma or serum.
Flunixin	20 ng/mL of plasma or serum	24 hours	Single IV dose of flunixin as Banamine® (flunixin meglumine) at 1.1 mg/kg	ARCI model rule	**Secondary anti-stacking threshold**: 3.0 ng/mL in plasma (administration 48 hours prior).
Furosemide	100 ng/mL of plasma or serum	4 hours	Single IV dose of furosemide up to 500 mg	ARCI model rule	Must also have urine specific gravity < 1.010 for a violation.
Glycopyrrolate	3 pg/mL plasma or serum	48 hours	Single IV dose of 1 mg of glycopyrrolate as Glycopyrrolate Injection, USP (American Regent product # 0517-4601-25).	RMTC study; J. vet. Pharmacol. Therap. doi: 10.1111/j.1365-2885.2011.01272.x	Applicable analyte is glycopyrrolate in plasma or serum.

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Ketoprofen	10 ng/mL of plasma or serum	24 hours	Single IV dose of ketoprofen as Ketofen® at 2.2 mg/kg	ARCI model rule	
Lidocaine	20 pg/mL of total 30H-lidocaine in plasma	72 hours	200 mg of lidocaine as its hydrochloride salt administered subcutaneously	ESHLC data; Iowa State.	Applies to total major hydroxylated metabolite
Mepivacaine	10 ng/mL total hydroxymepivacaine in urine or above LOD of mepivacaine in plasma.	72 hours	Single 0.07 mg/kg subcutaneous dose of mepivacaine	EHSLC data	
Methocarbamol	1 ng/mL of plasma or serum	48 hours	Single IV dose of 15 mg/kg methocarbamol as Robaxin® or 5 grams orally.	University of Pennsylvanvia	Applicable analyte is methocarbamol in plasma or serum.

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Methylprednisolone	100pg/mL in plasma or serum	7 days	Total dose of Methylprednisolone acetate suspension in one articular space.[ii] The recommended withdrawal for methylprednisolone acetate is a minimum of 21 days at a 100mg dose.	RMTC February 2013 Directive	Applicable analyte is methylprednisolone.
Omeprazole	1 ng/mL of urine	24 hours	Single oral dose of omeprazole as Gastrogard® at 3.9 mg/kg		Applicable analyte is omeprazole sulfide in urine
Phenylbutazone	2 mcg/mL of plasma or serum	24 hours	Single IV dose of phenylbutazone at 2.2 mg/kg	ARCI model rule	**Secondary anti-stacking threshold**: 0.3 mcg/mL of plasma (Administration 48-hours prior).
Prednisolone	1 ng/mL serum or plasma	48 hours	1 mg/kg orally.		Applicable analyte is prednisolone in plasma or serum.

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0

(Adopted April 2, 2013 by Racing Commissioners International.)

Controlled Therapeutic Substance:	Threshold:	No pre-race treatment within:	Dosing Specifications:	Reference Notes	Note:
Procaine penicillin *(administration must be reported to Commission)*	25 ng/mL Plasma	Following entry to race.	Intramuscular	RMTC – reference notes online.	Mandatory surveillance of horse at owner's expense 6 hours before racing.
Triamcinolone acetonide	100 pg/mL of plasma or serum	7 days	Total dose of 9mg in one articular space.[iii]	RMTC February 2013 Directive	Applicable analyte is triamcinolone acetonide in plasma or serum.
Xylazine	0.01 ng/mg of plasma or serum	48 hours	Intravenous		Applies to any xylazine and xylazine metabolite

[i] **Intramuscular** administration of **Betamethasone** will result in plasma or serum concentrations that will exceed the Regulatory Threshold for weeks or even months, making the horse ineligible to race for an extended period.

[ii] **Intramuscular** administration of **Methylprednisolone** will result in plasma or serum concentrations that will exceed the Regulatory Threshold for weeks or even months, making the horse ineligible to race for an extended period.

[iii] **Intramuscular** administration of **Triamcinolone acetonide** will result in plasma or serum concentrations that will exceed the Regulatory Threshold for weeks or even months, making the horse ineligible to race for an extended period.

RACING COMMISSIONERS INTERNATIONAL

Press Release

Wednesday, July 31, 2013
Contact: Ed Martin (859) 224-7070

RCI Toughens Penalty Guidelines for Multiple Medication Violations (MMV) and Blood Doping

SARATOGA SPRINGS, NY - Racing Commissioners International (RCI) voted today to create a penalty point system and "enhanced" suspensions for trainers with multiple medication violations, strengthening how racing regulators deal with repeat offenders.

The RCI Board, meeting in Saratoga Springs, voted to modify the Model Rules to create an enhanced penalty which would be added to the penalty for an underlying medication rule violation in those instances where the responsible trainer has repeatedly violated medication rules.

"This system is workable and will be a deterrent to those who consistently violate our medication rules," said Duncan Patterson, current Chair of both RCI and the Delaware Thoroughbred Racing Commission.

The RCI Board also voted to require a 10-year suspension and a $100,000 fine for those found guilty of the administration of blood doping agents like EPO.

Under the point system, to be launched in 2014, violations of the medication rule for substances not included on the RCI Schedule of Controlled Therapeutic Substances would earn 1 to 6 points, depending on its official classification as determined by the potential to affect performance. Overages involving the 24 therapeutic medications included on the RCI schedule would earn half as many points, depending on classification.

Depending on the number of points amassed by a repeat offender, the enhanced penalty would be in the form of additional suspension days of between 30 and 360, which would be added to the underlying penalty.

The RCI system is modeled after a similar approach taken in U.S. federal sentencing guidelines.

Although regulatory violations will remain part of a licensee's permanent record, points will be expunged after a period of time based upon the category of punishment deemed appropriate given the substance classification.

RCI President Ed Martin described Tuesday's Model Rules Committee Meeting as "spirited" and noted that there were many regulators who supported the concept of applying points to all regulatory violations.

"I would anticipate that as this system is implemented there will be a desire to expand upon it," Martin said, noting that all racing regulatory entities will expected to submit ruling violation data through a central portal into the RCI database which will track points and their expiration.

The Point System concept has been discussed for over two years and many variations have been proposed as to how it would work. "This has not been an easy project," Martin said, noting that the efforts of various regulatory and industry committees and organizations have been critical in working through the issues.

Specifically, he cited the RCI Drug Testing Standards and Practices Committee, the RCI Regulatory Attorneys Committee, the Racing Medication and Testing Consortium (RMTC), the RMTC Penalty workgroup, the Thoroughbred Horsemen's Association, and The Jockey Club as helping to "tee up" the proposal that was considered and modified by the Model Rules Committee after lengthy debate and discussion.

RCI addressed a concern brought forward by the National HBPA concerning trainers who might be cited for multiple violations involving the same medication on the same day due to changes in testing protocols or equipment. The rule permits Judges, Stewards, or the Commission to consider those a single violation should the facts warrant that treatment.

"This is an important step toward creating an additional deterrent to those who deliberately violate our rules or are persistently sloppy in the administration of medications," Martin said.

"Given the fact that we have created uniform thresholds for controlled therapeutic medications, determined a clear line when those medications should be stopped, and consistent lab standards for all are to follow, there should be no reason for the vast majority of honest trainers to ever come up against this rule. Some will, however, and we believe an enhanced penalty determined by points will be a deterrent to those who have viewed existing penalties as a cost of doing business. It is time for that attitude to stop," he said.

EQUINE VETERINARY PRACTICES, HEALTH AND MEDICATION - CHAPTER 11

ARCI-011-020 Medications and Prohibited Substances

(12) Multiple Medication Violations (MMV)

(a) A trainer who receives a penalty for a medication violation based upon a horse testing positive for a Class 1-5 medication with Penalty Class A-D, as provided in the ARCI Uniform Classification for Foreign Substances, shall be assigned points based upon the medication's ARCI Penalty Guideline as follows:

Class	Points If Controlled Therapeutic Substance	Points If Non-Controlled Substance
Class A[1]	N/A	6
Class B	2	4
Class C	1	2
Class D	½	1

(b) The points assigned to a medication violation shall be included in the Stewards' or Commission Ruling. Such Ruling shall determine, in the case of multiple positive tests as described in paragraph (d), whether they shall thereafter constitute a single violation. The Stewards' or Commission Ruling shall be posted on the official website of the Commission and the official website of the Association of Racing Commissioners International. If an appeal is pending, that fact shall be noted in such Ruling. No points shall be applied until a final adjudication of the enforcement of any such violation.

(c) A trainer's cumulative points for violations in all racing jurisdictions shall be maintained and certified by the Association of Racing Commissioners International. Once all appeals are waived or exhausted, the points shall immediately become part of the trainer's official ARCI record and shall then subject the trainer to the mandatory enhanced penalties by the Stewards or Commission as provided in this regulation.

(d) Multiple positive tests for the same medication incurred by a trainer prior to delivery of official notice by the commission may be treated as a single violation.

(e) The official ARCI record shall constitute prima facie evidence of a trainer's past record of violations and cumulative points. Nothing in this administrative regulation shall be construed to confer upon a licensed trainer the right to appeal a violation for

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[1] Except for Class 1 and 2 environmental contaminants, *e.g.*, cocaine which shall be determined by the stewards based upon the facts of the case.

which all remedies have been exhausted or for which the appeal time has expired as provided by applicable law.

(f) The Stewards or Commission shall include all points for violations in all racing jurisdictions as contained in the trainer's official ARCI record when determining whether the mandatory enhancements provided in this regulation shall be imposed.

(g) In addition to the penalty for the underlying offense, the following enhancements shall be imposed upon a licensed trainer based upon the cumulative points contained in his/her official ARCI record:

Points	Suspension in days
3-5.5	30
6-8.5	60
9-10.5	180
11 or more	360

MMV's are not a substitute for the current penalty system and are intended to be an additional uniform penalty when the licensee:

(i) Has more than one violation for the relevant time period, and
(ii) Exceeds the permissible number of points.

(h) The suspension periods as provided above, shall run consecutive to any suspension imposed for the underlying offense.

(i) The Stewards' or Commission Ruling shall distinguish between the penalty for the underlying offense and the enhancement based upon the trainer's cumulative points.

(j) Any trainer who has received a medication violation may petition the ARCI to expunge the points received for the violation for the purpose of the MMV system only. The points shall be expunged as follows:

Penalty Classification	Time to Expungement
A	Permanent
B	3 years
C	2 years
D	1 year

Industry Comment

Dr. Demaree,

We have forwarded your email and attachments to our directors, officers and horsemen who participate in our program and asked for them to forward to us any questions, comments or other input they might have regarding the ARCI medication and penalty proposals.

We received no responses against the proposals, only a few questions about which jurisdictions this would effect and how Indiana will be interacting with other jurisdictions tracking the "point system".

At this time our recommendation would be to support these initiatives, and go arm in arm with AQHA, ARCI, Keenland Assoc., NTRA, Remington Park, Zia Park, Sam Houston and many other stake holders in our industry. Honestly our horsemen have been accustomed to being on the forefront on many regulatory issues that we believe will lead our industry into a new era of standardization and nearly feel late in boarding the bus carrying this issue forward. We feel very strongly that a uniform threshold and penalty system is not only good for racing in Indiana, but good for the horse racing industry nationally.

Perhaps the answers to a few of the concerns were mentioned in your email text or attachments and we didn't see them, but there are a few areas we would like clarification on to help better address questions and concerns in the future.

- How will Indiana be notified of point violations in other states?
- Will violations in other states who have **not** adopted these guidelines count against a horsemen when he is licensed here? If so, how will the IHRC or Stewards be aware of minor "class D" therapeutic violations?
- How would the IHRC view a case on multiple offenses on a therapeutic drug all with a very small window, and prior to notification of the first offense? I believe this was addressed in section "d" in the attachment dated 7/13.

Again we are very supportive of the IHRC adopting these guidelines and helping move the racing industry as a whole closer to being nationally unified in regards to testing and penaltys.

Our directors and horsemen thank you for taking the time to ask for our input and we look forward to working with the IHRC in not only this standard forward but many others in the future.

Tom Mosley

Director of Industry Relations, Q.H.R.A.I.

10/31/13

Demaree, Angela

From: PHILLIP DYER [pdyereqvet@sbcglobal.net]
Sent: Friday, November 01, 2013 9:01 AM
To: Demaree, Angela
Subject: Re: IHRC Request for Comment--ARCI New Medication and Penalty Guidelines

Comments on RCI schedule of controlled therapeutic substances:

Withdrawal guidelines on IA medications such as methylprednisolone and betamethasone: 7 day intervals between dosing and race day are acceptable,
however it is not logical to dose at 7 days and be concerned about overage under 21 days at a 100 mg dose.Also a 100 mg dose is not adequate for
treatment of bilateral racehorse problems such as tarsitis,which is quite common. Racehorses are an economic entity for owners,trainers,grooms,vets-
extended layoffs between races are a problem,especially for Standardbreds.
Dosage guidelines for DMSO,xylazine,and procaine penicillin would be helpful.
All guidelines for drug medication should recognize that individual differences exist, depending on age,genetics,state of health,etc.

From: "Demaree, Angela" <ADemaree@hrc.IN.gov>
To: "Demaree, Angela" <ADemaree@hrc.IN.gov>
Cc: "Gorajec, Joe" <jgorajec@hrc.IN.gov>
Sent: Wednesday, October 16, 2013 9:16 AM
Subject: FW: IHRC Request for Comment--ARCI New Medication and Penalty Guidelines

Dear Stakeholders,

I wanted to follow up on my request for comment, below. The deadline for comment is noon on November 1st.

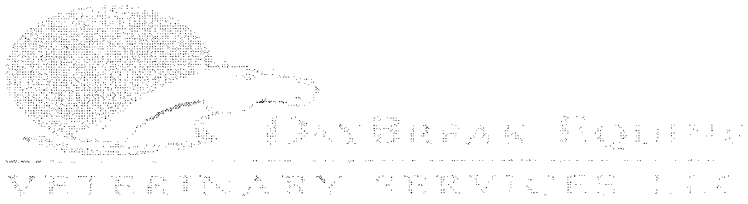
Please feel free to contact me with any questions or concerns. I look forward to hearing from you.

Best,

Angela Demaree, D.V.M.
Equine Medical Director
Indiana Horse Racing Commission
1302 North Meridian, Suite 175
Indianapolis, IN 46202
Office: (317) 233-6895
Cell: 317-260-3529

From: Demaree, Angela
Sent: Wednesday, September 18, 2013 3:55 PM
To: Demaree, Angela
Cc: Gorajec, Joe
Subject: IHRC Request for Comment--ARCI New Medication and Penalty Guidelines

Dear Doctors and Horsemen,



October 31, 2013

Dr. Angela Demaree and Indiana Horse Racing Commission;

I have been a practicing veterinarian at the Indiana Standardbred racetracks since I graduated in 2004. I would like to share my concerns with the new ARCI medication and penalty proposals. My main concerns are with the schedule of controlled therapeutic substances and in particular, the proposed withdrawal time of the intra-articular anti-inflammatory medications and the drug clenbuterol. I agree with the USTA president Phil Langley (see attached pages) on the USTA's views of these issues.

The use of intra-articular anti-inflammatory medications (methylprednisolone, betamethasone, and triamcinolone) have demonstrated and documented safety and effectiveness profiles. They are FDA approved drugs that are available to veterinarians from reputable and regulated manufacturers. The proposed withdrawal time of seven days will have several domino effects on how Standardbred lameness is treated. As I am sure you are aware, most Standardbred horses race on a weekly basis, often on the same night every week. If the withdrawal time is the proposed seven days, the trainer will have several different choices when faced with treating a significant (but minor) lameness. The first option would be to treat the horse with an FDA approved intra-articular anti-inflammatory medication. If this option is chosen, the horse will be forced to miss its next race. Because this is not beneficial to the trainer or the owner of the horse, this will not be a popular choice. The second option would be not to treat the horse and race the horse the following week, which will lead to more lame or sore horses racing. This is not desirable, but in reality that is what will happen due to the economics of having to race on a regular basis. The last option would be to treat the lameness with **non-FDA approved** medications. This is probably the most likely to happen and possibly has the worst potential effect on the horse. These medications are often compounded and readily available to owners, trainers, and veterinarians. Most of these "will not test", and so they become a reasonable alternative in the minds of some owners and trainers. These products have no documented effectiveness and certainly no safety studies or manufacturing / compounding regulations.

I am in favor of and support a withdrawal time of the FDA approved intra-articular anti-inflammatory medications of five days. As a veterinarian, most of the lameness I diagnose is treated one or two days after the horse races. A withdrawal time of five days allows trainers and veterinarians to address any lameness issues after a race while still allowing the horse to be eligible to race the following week. In my opinion, there are much greater concerns in the horse racing industry than whether FDA approved drugs are used five days out instead of seven days.

The proposed change of the withdrawal time of clenbuterol is another concern of mine. I routinely prescribe it for respiratory sickness and lower airway disease. I have never been approached by a Standardbred owner or trainer to use it to build muscle like an anabolic steroid. Indiana currently has different clenbuterol threshold levels for different breeds. I see no need to change the current Standardbred withdrawal time for clenbuterol.

Thank you for your time and consideration.

Andrew G. Hirschy DVM
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Indiana Horsemen's Benevolent & Protective Association, Inc.

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Angela Demaree, DVM
Equine Medical Director
Indiana Horse Racing Commission
1302 N. Meridian Street, Suite 175
Indianapolis, IN 46202

November 1, 2013

Dr. Demaree,

As you know, the Indiana Horsemen's Benevolent and Protective Association (INHBPA) is the state-level affiliate of a national organization. We asked for input from our national organization in preparing our response to the Commission. The information and perspective contained in this document and the accompanying exhibits reflect their considerable expertise and our views on the topics you requested.

We represent thoroughbred owners, trainers, owner-trainers, the people they employ on the backside of Indiana Downs and their Indiana farm employees. Our members are dedicated to the welfare of their horses and to maintaining the integrity of thoroughbred racing. The perspectives we represent in this letter reflect the both the practical experience gained through working with horses, as trainers and owners, and the larger policy concerns that all-too often overshadow practical experience.

As discussed more fully below, our directors and members: (1) generally support the concept of certain medication restrictions; and, (2) generally support the concept of a Multiple Medication Violation ("MMV") Penalty System.

While we believe the recent adoption of Model Rules covering the above subjects by the Association of Racing Commissioners International ("ARCI") was a positive step, as described below there are certain shortcomings regarding each of the Model Rules that must be addressed before Indiana or any State, for that matter, adopts the proposed ARCI Model Rules.

The Approved Therapeutic Medication Schedule

On April 2, 2013 the ARCI adopted its Schedule of Controlled Therapeutic Substances. There are 24 medications set forth on this Schedule. The INHBPA's concerns with this list of 24 medications may be summarized as follows:

1. The Racing Medication & Testing Consortium formulated a list of 51 medications that it "approved" in 2003, as acceptable for therapeutic use and for which regulatory thresholds were going to be developed (**see the attached Exhibit**). However, and without explanation, the RMTC dropped more than half the heretofore acceptable therapeutic medications in its recommendation to the ARCI for a list of 24 medications.

2. The process to come up with the list of 24 was less than scientific and the list of 24 has never been "vetted" by an independent panel of nationally respected racetrack veterinarians. For the most part those individuals doing the picking and choosing of medications were regulatory or academic personnel.

3. The cost of medication was apparently not considered in the final list of 24. For example, ranitidine and cimetidine, commonly used anti-ulcer medications, are not on the list of 24 but have proven to be effective and certainly not performance enhancing. Each is available for about $2 per daily dose. Instead, omeprazole (i.e. Gastrogard), is the only ulcer medication on the list of 24 and costs approximately $30.00 per daily dose.

4. To date, while the proponents of the list of 24 have said the list of 24 is a "living document", not a single medication has been added. Even though to the best of our knowledge, the American Association of Equine Practitioners ("AAEP") has suggested ranitidine, cimetidine, an antihistamine such as hydroxyzine, altrenogest (Regumate) for controlling estrus, an expectorant such as guaifenesin, and isoflupredone (Predef) be added to the list of 24.

5. Other medications not on the list are equally effective therapeutically, yet the list removes a treating veterinarian's discretion regarding which medication is best for the horse. In this regard, the NHBPA is conducting a survey of racetrack veterinarians in order to determine and quantify what additional medications should be added to the list.

6. Limiting the approved list to 24 will discourage research by drug companies to develop new medications.

7. The Model Rule is absolutely unclear regarding what the "penalty" will be if a medication not on list of 24, though on RMTC's former list of 51 (i.e. albuterol), is detected. This dovetails into treatment of such a result in the MVP context.

8. As listed below, the regulatory thresholds for many of the 24 medications are allegedly based on scientific studies yet those studies either: (1) have not been completed, or (2) have not been subject to the normal peer review process and publication in the peer reviewed scientific literature. For that reason such studies are not available to the

scientific (and regulatory) communities for review and analysis ("Secret Science"). We would note that, at a minimum, the IHRC should ask for the background data and information on each of the 24 included items, and their thresholds, before signing onto a regulatory framework that is not publically substantiated.

The RMTC should not serve as its own private peer review board and expect to retain credibility.

A. Acepromazine	No cited peer reviewed published scientific research.
B. Betamethasone	No cited peer reviewed published scientific research.
C. Butorphanol	Cited peer reviewed scientific study has significant shortcomings.
D. Clenbuterol	Recently published paper does not include scientific derivation of presented threshold.
E. Dantrolene	Cited scientific study has shortcomings.
F. Detomidine	Cited scientific study does not include analytical method details.
G. Dexamethasone	No cited peer reviewed published scientific research
H. Diclofenac	No objections at this time.
I. DMSO	No objections at this time.
J. Firocoxib	No cited peer reviewed published scientific research.
K. Flunixin	No cited peer reviewed published scientific research.
L. Furosemide	No objections at this time.
M. Glycopyrrolate	No objections at this time but dose amount was small and the study only involved 6 horses.
N. Ketoprofen	No cited peer reviewed published scientific research.
O. Lidocaine	No cited peer reviewed published scientific research.
P. Mepivacaine	No cited peer reviewed published scientific research.
Q. Methocarbamol[1]	No cited published U. Penn study.
R. Methylprednisolone	No cited peer reviewed published scientific research.
S. Omeprazole	No cited peer reviewed published scientific research.
T. Phenylbutazone	No cited peer reviewed published scientific research.
U. Prednisolone	No cited peer reviewed published scientific research.
V. Procaine Penicillin	No objections at this time.
W. Triamcinolone Acetonide	No cited peer reviewed published scientific research.
X. Xylazine	No cited peer reviewed published scientific research.

9. The list of 24 should be modified to take into account the presence of endogenous, dietary and environmental substances ("EDEs") that unintentionally find their way into a horse's system.

The Multiple Medication Violation Penalty System ("MMV")

The ARCI adopted this Model Rule at its July 2013 Meeting in Saratoga. As an initial matter, the ARCI did not follow its normal adoption process for this Model Rule. The actual process followed did not allow the normal level of industry review and input prior

[1] Rumpler, Colahan & Sams have a published paper (J. vet Pharmocol. Therap.doi:1111/jvp.12068.

to adoption. This resulted in a flawed Model Rule that should not be adopted by Indiana or any State, for that matter, until the Model Rule has been properly reviewed by the industry.

In addition to the procedural shortcomings associated with this Model Rule, the following additional changes are warranted for the reasons noted:

1. Section (1)(a): The chart should be modified to provide that Class B points for non-controlled substances are 3 instead of 4; Class C points for non-controlled substances should be 1.25 points instead of 2 and Class C points for non-controlled substances should be .75 instead of 1. The net effect of these changes is to allow trainers that have Class C or Class D violations one additional violation before the MMV comes into play.

2. Section (1)(d): The "may" should be changed to a "shall". This change will require a corresponding change to Section (1)(b). The whole purpose of the MMV is to remove discretion from the Stewards and Commissions when it relates to an MMV situation. While the INHBPA believes Stewards and Commissions should have discretion in the area of penalties, in order to achieve consistency from State to State, each State should be required to treat such violations as a single violation.

Notwithstanding this position, absent unusual circumstances and normal due process, the INHBPA would not object to the Stewards and Commissions having the ability to treat multiple Class A violations (that are not EDEs) before notice as multiple violations, rather than as a single violation.

3. Section (1)(g)(i) should be modified to read "Has more than one violation, unless the one violation is a Class A violation which is not due to an Endogenous, Dietary and Environmental substance, and".

4. Section (1)(h): The "consecutive" should be changed to "concurrently". It is important to keep in mind that suspensions effectively end the ability of trainers to make a living. Under certain fact pattern, the imposition of the MMVs can have a draconian impact on a trainer.

5. Section (1)(j): The text as written should be deleted in its entirety and replaced with the following language, "Points shall be automatically expunged by the Commission from the trainer's licensing record when the below-listed time(s) expire." The MMV has been compared to "points" that are given for automobile driving violations. Taking this comparison one step further, an individual does not have to contact the Department of Motor Vehicles to have points removed from her/his driving record; the points are automatically removed when the applicable time period expires. Similarly, the points should be automatically removed from a trainer's record.

6. Section (1)(j): The chart should be modified to provide that the expungement period for Class C violations is 1 year and the expungement period for Class D violations is 6 months.

7. A new Section (1)(k) should be added that provides "The time for expungement shall begin to run on the date the underlying violation becomes final regardless of when the violation is entered into the ARCI's trainer database."

8. A new Section (1)(l) should be added that provides "No multiple violation penalty points shall be imposed for Restrictive Timeline violations."

9. A new Section (1)(m) should be added that provides "In the event a trainer is suspended, the time for expungement shall continue to run and shall not be tolled during the suspension."

Conclusion

The INHBPA commends the ARCI and other industry participants and organizations for their efforts to date with regard to medication related issues. These efforts are important to the long-term health of our industry. As noted in this letter, various changes to the Model Rules should be carefully considered by the Indiana Horse Racing Commission before these Model Rules are adopted.

If you, or any member of the Commission, have any questions about the information contained in this letter, please do not hesitate to contact me at 317-903-4382, or at brownpreston@indy.rr.com.

Thank you, for your consideration in allowing us to contribute our perspective in this discussion.

Michael R. Brown, executive director
Indiana HBPA

RMTC Therapeutic Medications Routinely Used and Identified as Necessary by the Veterinary Advisory Committee

This table is reproduced courtesy of Dr. Scott Waterman and the Racing Medication and Testing Consortium. For each of these therapeutic medications, the RMTC is developing appropriate regulatory thresholds in plasma or urine and also associated withdrawal time guidelines (Communicated September, 2011).

First Priority Group
(Currently in Research)
1. Acepromazine
2. Butorphanol
3. Detomidine
4. Glycopyrrolate
5. Lidocaine
6. Mepivacaine
7. Methocarbamol
8. Pyrilamine

Second Priority Group
9. Boldenone
10. Dantrolene
11. Dexamethasone
12. Firocoxib
13. Fluphenazine
14. Hydroxyzine
15. Nandrolone
16. Stanozolol
17. Testosterone

Third Priority Group
18. Albuterol
19. Betamethasone
20. Diclofenac
21. Methylprednisolone
22. Reserpine
23. Triamcinolone
24. Trichlormethiazide
25. Xylazine

Fourth Priority Group
26. Atropine
27. Beclomethasone
28. Buscopan
29. Cromolyn
30. Isoxsuprine
31. Pentoxyfylline
32. Phenytoin
33. Prednisolone

Fifth Priority Group
34. Diazepam
35. Dipyrone
36. Fluorprednisolone
37. Guaifenesin
38. Isoflupredone
39. Prednisone

Research Already Under Way
40. Aminocaproic Acid
41. Carbazochrome
42. Clenbuterol
43. Procaine Penicillin

Already in Body of Model Rules
44. Cimetidine
45. DMSO
46. Flunixin
47. Furosemide
48. Ketoprofen
49. Omeprazole
50. Phenylbutazone
51. Ranitidine

2014 FEB 21 A 10:46

Angela Demaree
Equine Medical Director
Indiana Horse Racing Commission
1302 North Meridian suit 175
Indianapolis Ind. 46202

Dear Angela

The ISA at this time would not be in favor of enacting the ARCI medication and penalty proposal. We do think their some good parts to the proposal, however on the hole we apose the rule. The model rule on multiple medication violations is a good step in the right direction. We think more discussion should be had on both rules. Thank you for the opportunity to discus that important matter.

Thank You
Jack Kieninger
President ISA.

RMTC
Racing Medication &
Testing Consortium

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November 25, 2013

Joe Gorajec
Executive Director
Indiana Horse Racing Commission
1302 N. Meridian Street, Suite 175
Indianapolis, IN 46202

Dr. Angela Demaree
Equine Medical Director
Indiana Horse Racing Commission
1302 N. Meridian Street, Suite 175
Indianapolis, IN 46202

Mr. Gorajec and Dr. Demaree:

Thank you for your inquiry regarding the National Uniform Medication Program. RMTC is happy to respond to the concerns raised in the Indiana Horsemen's Benevolent and Protective Association's (IHBPA) letter. The RMTC welcomes the opportunity to explain the program and to resolve any concerns about it.

The National Uniform Medication Program is the result of a decade or more of work in the areas of medication policies, laboratory testing, and increased penalties for multiple medication violators. The medication policies proposed for the National Uniform Medication Program have been reviewed at the national level by multiple industry stakeholders including the National HBPA and other horsemen's groups. These policies represent an attempt to reach long awaited uniformity in the horse racing industry.

Approved Medication Schedule

The Controlled Therapeutic Medication schedule is a list of medications which are allowed to be present in test samples on race day if they are present at concentrations less than the applicable threshold. This list is the result of many hundreds of thousands of dollars of research funded by the RMTC as well as other industry groups. The IHBPA raises a number of issues regarding the providence and composition of this list. For clarity's sake, RMTC will address each issue in turn.

Issue #1
The IHBPA initially raised concerns regarding limiting the list to 24 therapeutic medications in lieu of a 51 medication list first developed in 2001. The characterization of the initial list of 51 medications by the HBPA as approved therapeutic substances is specious at best. The original genesis of the 51 medication list was a survey of practicing veterinarians compiled by RMTC. This list is the compilation of responses by 78 veterinarians surveyed. Those veterinarians were asked to list all medications that they used in 2001.

The original reason for producing the list was not to create an "end all/be all" for therapeutic medications. The goal was simply to prioritize the administration studies based on the drugs practitioners relied on the most at that time as well as which ones caused the most violations.

Looking, however, at the list provided by the IHBPA, there are several medications that are not appropriate for approval of thresholds in 2013. For brevity's sake, I will attempt to group these medications.

Anabolic Steroids

The IHBPA's list includes boldenone, nandrolone, testosterone, and stanozolol. The first three are endogenous anabolic steroids with existing thresholds in the RCI regulations designed to reflect naturally occurring concentrations of these substances in the horse. Stanozolol is only available as a compounded pharmacy product giving rise to concerns regarding concentration of drug and purity of the active ingredient. As such the RMTC board unanimously voted to remove a regulatory threshold for this substance.

Medications Lacking Efficacy

Several of the medications on the list are not efficacious in the horse. Specifically, research completed in Dr. Tobin's laboratory has shown that oral pyrilamine and isoxsuprine lack efficacy due to poor oral bioavailability as a result of a high first pass effect.[1]

Long Term Tranquilizers

The IHBPA's list includes fluphenazine and reserpine. These drugs are long-acting tranquilizers that can have substantial central nervous system effects for up to 30 days. These were considered and quickly rejected due to the safety and welfare concerns associated with training horses at speed and racing horses on long term tranquilizers.

Adjunct Bleeder Medications

The IHBPA's list includes two drugs that have been characterized as adjunct bleeder medications for use with furosemide. However, there is significant evidence that adjunct bleeder medications are not efficacious. Moreover, the Association of Racing Commissioner's International (RCI) has determined that the only appropriate race-day medication is furosemide. Consequently, use of any adjunct bleeder medication on race day is prohibited.

Other Concerning Medications

A number of drugs with significant pharmacologic effects were reviewed but not included in the controlled therapeutic medication list. They are as follows:

1. Hydroxyzine – an antihistamine drug with significant side effects (tranquilization); cetirizine, an active metabolite of hydroxyzine without these side effects, is being considered for inclusion as an orally effective antihistamine as an alternative to hydroxyzine;
2. Trichlormethiazide – a weak diuretic which the AAEP has advised is normally administered at 24 hours in combination with dexamethasone. But now that dexamethasone cannot be used at 24 hours, AAEP veterinarians indicated no interest in pursuing a threshold for it;
3. Atropine – has significant cardiovascular and respiratory system effects associated with its use – ocular use is appropriate but would require significant time off as the eye is dilated for several weeks after use;
4. Buscopan – smooth muscle relaxant, usually used in cases of colic;
5. Beclomethasone – inhaled corticosteroid that is not FDA approved for use in the horse, limited research completed on this medication in horses;
6. Cromolyn – mast cell stabilizer that is not FDA approved for use in the horse, questions regarding efficacy;
7. Pentoxifylline – vasodilator usually used in laminitic horses;
8. Phenytoin – anti-epileptic medication in humans – not FDA approved for use in the horse;
9. Diazepam – a benzodiazepine drug that is used for induction to surgery;

10. Dipyrone – not permitted by the FDA for any use in the United States.

Other Medications

Finally, there are a group of medications that either are being considered or could be considered for inclusion in the list. They are as follows:

1. Albuterol – currently undergoing review for possible inclusion on the list with a threshold that would permit use closer to race time than that permitted for clenbuterol. Anticipate having a proposal before the RMTC board in late 2013/early 2014;
2. Isoflupredone – currently completing research for this medication. Anticipate having a proposal before the RMTC board in late 2013/early 2014;
3. Ranitidine – administration study in progress for this medication;
4. Cimetidine – administration study in progress for this medication;
5. Cetirizine – administration study to be completed for this medication in early 2014;
6. Altrenogest – while not on the original list of 51, this drug is being considered for an administration study when funding is available.

Issue #2

The current list of 24 medications has been reviewed by the AAEP Racetrack Veterinarians subcommittee. Current research efforts reflect their input into the list. We consider them an "independent panel of nationally respected racetrack veterinarians."

Issue #3

As for a concern regarding cost, while it was not a primary concern, we are in the process of administration studies for ranitidine and cimetidine. The focus of the group choosing medications was to look to those drugs that had significant research reflecting their safety and efficacy in the horse. Therefore, preference has been given to those drugs and medications approved by the FDA for use in the horse. Additional considerations were to give priority to those that had the fewest side effects that could affect racing integrity.

Issue #4

The list has been in place for less than 6 months. In that time we have initiated research projects for at least 5 additional medications. These projects are expensive and our budget will not allow for expenditures in this area. If there are concerns regarding the speed of this work, we invite the IHBPA to contribute funds to assist with completion of the projects.

Issue #5

The existence of controlled therapeutic medications does not affect the ability of a veterinarian to use any other appropriate therapeutic medication. Any appropriate therapeutic medication may be administered to horses on the backside of a race track. The only difference between these drugs and the controlled therapeutic medications is they cannot be present in a horse's system at detectable concentrations on race day. Moreover, the RMTC will not provide any information to practitioners regarding appropriate withdrawal times, doses, and routes for these substances.

Issue #6

This allegation is unsupported. Simply put, this regulation does not discourage the development of new drugs. Instead it encourages drug companies to work with RMTC and horse racing commissions on appropriate and responsible use of medications. Moreover, as there is a preference for medications approved for use in the horse by the FDA, it will, if anything, encourage companies to perform this extra research so that their products will be considered for inclusion on the list of controlled therapeutic substances.

Issue #7
The penalties for all medications are at the discretion of the stewards – the same system that currently exists. The Multiple Medication Violation Penalty System (MMV) assigns points clearly to each RCI Penalty Class of medications.

Issue #8
This allegation is patently false. All substances on the list of 24 have significant scientific research supporting the threshold and withdrawal guidelines. Moreover, the research for these has been vetted by private veterinarians, regulatory veterinarians, analytical chemists, laboratory directors, and veterinary pharmacologists and toxicologists. While the supporting data have not been made public for some of these thresholds, summary reports have been available to the regulatory community prior to adoption of each threshold. As for the list provided by the IHBPA, it is also incorrect. Please see the attached list of research by controlled therapeutic medication.

Issue #9
The RMTC has, at the request of RCI, provided technical assistance on a National HBPA proposal regarding environmental, endogenous, and dietary substances. These are being presented to RCI by the HBPA in December.

Multiple Medication Violation (MMV) Penalty

The MMV is a system that is designed to address the serious issue of repeat drug and medication regulation violators. Very few individuals will ever be subjected to penalties as a result of multiple medication violations. Those few individuals with multiple violations are, however, responsible for forming the negative public perception of medication and horse racing.

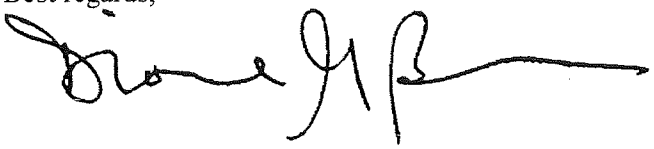
The IHBPA raises a myriad of issues regarding the MMV. These issues are identical to those raised by the National HBPA before the RCI. Each of these issues was discussed and considered by the regulators prior to enacting the current regulation. The IHBPA's proposal would in essence eviscerate the MMV – by allowing trainers more violations in a shorter period of time and have their suspensions run concurrently with any suspension for the underlying punishment.

To address a few points specifically, however, the IHBPA would like all violations occurring within a period of time prior to notification to be considered as one for the purpose of MMV. This would require medication violations such as dermorphin to be treated as a single violation regardless of the number of positive findings. The IHBPA states that it would not object to Class A violations being treated separately – but even this provision would allow a trainer to have multiple stanozolol positives and require the stewards treat them as one violation. Giving stewards the discretion to treat these violations separately does not alter the discretion they currently have under the rule. The IHBPA states that this is not uniform – it would be just as uniform to treat each medication violation as separate for the MMV. Removing discretion here is not appropriate.

The IHBPA wants to place the responsibility for expunging records for multiple medication violations on the individual racing commissions. It is unrealistic to require commissions to track the multitude of licensed trainers under their jurisdiction – when it is appropriate for a trainer, who is most familiar with his or her own record, to track these points and request an expungement.

I hope this information is of assistance as you review the National Uniform Medication Program. I am happy to speak with you at any time regarding these issues or any other questions you may have. Please feel free to contact me at your convenience. Thank you.

Best regards,



Dionne Benson, DVM
Executive Director

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[i] Dirikolu, L., *et.al, Pyrilamine in the horse: detection and pharmacokinetics of pyrilamine and its major urinary metabolite O-desmethylpyrilamine*, J. Vet. Pharacol. Ther., 32(1): 66-78 (2009); Harkins, J.D., *et.al, Absence of detectable pharmacological effects after oral administration of isoxsuprine*, Equine Vet. J., 30(4): 294-99 (1998). Harkins JD, Mundy GD, Stanley S, Woods WE, Sams RA, Richardson DR, Grambow SC, Tobin T,.*Absence of detectable pharmacological effects after oral administration of isoxsuprine.* Equine Vet J. 1998 Jul;30(4):294-9.

Racing Commissioners International, Inc.

December 20, 2013

Mr. Joe Gorajec, Executive Director
Indiana Horse Racing Commission
1302 North Meridian Street - Suite 175
Indianapolis, IN 46202

Dear Mr. Gorajec:

Thank you for your letter and the opportunity to provide input to the Commission.

There are some statements in the letter you received from the Indiana HBPA that I must take issue with and I would hope would not be viewed as cause for non-action by the Indiana Horse Racing Commission in considering adoption of the thresholds for the twenty four substances included on the Schedule of Controlled Therapeutics.

The National HBPA has been an active participant in the RCI Model Rules process and we make every effort to consult with industry constituent organizations in the assessment of issues that come before the association, prior to action on items that we will recommend to our regulatory members to enact. In addition, organizational members of the Racing Medication and Testing Consortium (RMTC), have additional opportunities to impact on proposals before they even come to the RCI for consideration.

Version 1.0 of the RCI Schedule of Therapeutic Substances contains twenty four substances with recommendations for testing thresholds and restrictive administration times. The thresholds are supported by the work of the Scientific Advisory Committee of the Racing Medication and Testing Consortium and are based on the professional scientific review and analysis of all available research, studies and literature. In some cases, proprietary research was made available to the members of this group under a non-disclosure agreement. To argue that the recommended thresholds are not science based is not accurate and every step has been taken to involve the country's leading authorities in this area in the formation of the recommendations that you have before you.

It is important to note that the American Association of Equine Practitioners has been represented in this assessment. The AAEP represents practicing racetrack veterinarians who treat every breed. While this schedule contains twenty-four substances, there is no prohibition on a practicing veterinarian using any other legal medication to treat a horse. In doing so, they do run the risk of a post race positive - as they currently do now - as various jurisdictions may deploy different approaches to these substances. The Model Rule proposal addresses only 24 substances at this time.

The adoption of the schedule is essential and in the interest of horsemen who have consistently complained over the years about the lack of uniformity from one jurisdiction to another. The substances included on the schedule account for the vast majority of post race positives and medication rule violations in North America. This is an important step forward and should not be delayed.

Additional medications may be added to subsequent versions of the schedule. The RMTC is currently considering additional substances requested by the AAEP. RCI will consider their recommendations once the work of the Scientific Advisory Committee and any associated scientific studies are completed.

The National HBPA has requested that a list of environmental contaminants be assessed and thresholds be determined. This request has been assessed by the RMTC and they have made recommendations concerning some of those substances which have just been adopted by RCI. These are posted on the RCI website at http://arcicom.businesscatalyst.com/model-rules---standards.html.

The RCI Drug Testing Standards and Practices Committee did not recommend going beyond the recommendations of the RMTC at this time. Other substances requested to be considered by the National HBPA are still pending and RCI looks forward to subsequent submissions from the RMTC.

Regarding the Multiple Medication Violation (MMV) model rule, it's adoption was consistent with how we have developed model rules in the past, although this rule was developed in an active work session of the committee and involved various industry representatives, including the National HBPA and the Thoroughbred Horsemen's Association. (Standardbred horsemen's groups are invited to participate in RCI meetings, but usually do not with the exception of the breed registry.)

The Model Rule Penalty Guidelines (including the MMV provision) are general recommendations and are not intended to inhibit commission consideration of specific facts in individual cases. The development of a "point system" to assist commissions in assessing a licensee's performance in adhering to medication rules was a long process that involved both the RCI and a working group within the RMTC headed up by a horsemen's organization representative. While there have been many different opinions as to how this should work, the Model Rule represents the majority point of view of your fellow regulators after assessing the real time input from the National HBPA and other organizations participating in the discussion. Just as in a legislative mark-up, the Model Rules process that resulted in the current MMV Model Rule was dynamic, with many opinions and options expressed, some adopted, some rejected. There is no requirement on RCI to have consensus from anyone other than the member regulators as to the recommendations we make to our members.

Certainly any organization representing a segment of the racing industry reserves the right to continue arguing issues before individual commissions. But having said that, the number of licensees who may ultimately be affected by an enhanced penalty based upon a pattern of regulatory non-compliance is relatively small. RCI has consistently urged racing officials to consider a licensee's regulatory compliance record as a factor in determining appropriate penalties or whether to issue a license renewal. The failure of some officials to do so has brought considerable criticism on racing regulators by Congress. The MMV Model Rule is an attempt to provide some guidance to

racing officials in an easy to understand way as to when a licensee's non-compliance with medication rules may warrant consideration as an aggravating factor in a specific case justifying an enhanced penalty.

We do anticipate that the exact wording of the MMV Model Rule may undergo revision, but the substance of what is being recommended in terms of an enhanced penalty if repeat violations exist for a licensee do not appear to be items the RCI member regulators intend to modify.

I hope this information assists the Indiana Commission in assessing these matters.

Ed Martin
President/CEO.

cc: Duncan Patterson

RMTC/RCI Controlled Therapeutic Substances

Reference Chart

Controlled Therapeutic Substance	Reference
Acepromazine	Wieder, M.E., *Identification of acepromazine and its metabolites in horse plasma and urine by LC-MS/MS and accurate mass measurement*, Chromatographia, 75:635-43 (2012)
Betamethasone	HFLSS Study – pre publication
Butorphanol	Knych, H., *Pharmacokinetics and pharmacodynamics of butorphanol following intravenous administration to the horse*, J. vet. Pharmacol. Therap. 36(1):21-30 (Feb. 2013)
Clenbuterol	Knych, H., *Detection, pharmacokinetics and cardiac effects following administration of clenbuterol to exercised horses*, Equine Vet Journal, 2013 June. doi: 10.111/evj.12118 [Epub ahead of print]
Dantrolene	Knych, H., *Pharmacokinetics and metabolism of dantrolene in horses*, J. vet Pharmacol. Therap., 34: 238-46 (June 2011)
Detomidine	L'ami, J.J., *Sublingual administration of detomidine in horses: Sedative effect, analgesia and detection time*, Vet. Journal, 2012 Oct 10. pii: S1090-0233(12)00363-2. doi: 10.1016/j.tvjl.2012.08.016. [Epub ahead of print]
Dexamethasone	Soma, L., *Pharmacokinetics of dexamethasone following intra-articular, intravenous, intramuscular, and oral administration in horses and its effects on endogenous hydrocortisone*, Journal of Veterinary Pharmacology and Therapeutics, 36: 181–191 (April 2013)
Diclofenac	Anderson, D., *Urinary and serum concentrations of diclofenac after topical application to horses*, Vet. Ther., 6(1): 57-66 (2005)
DMSO	Blythe, L.L., *Pharmacokinetic disposition of dimethyl sulfoxide administered intravenously to horses*, Am. J. Vet. Res., 47(8): 1739-43 (Aug. 1986)
Firocoxib	University of Florida – HFLSS Lexington preparing publication
Flunixin	Soma, L.R., *Disposition and excretion of flunixin meglumine in horses*, Am. J. Vet. Res., 49(11): 1894-98 (Nov. 1988)
Furosemide	Chay, S., *The pharmacology of furosemide in the horse. V. Pharmacokinetics and blood levels of furosemide after intravenous administration*, Drug. Metab. Dispos., 11(3): 226-31 (May/June 1983)
Glycopyrrolate	Rumpler, M., *Pharmacokinetics of glycopyrrolate following intravenous administration in the horse*, J. vet Pharmacol. Therap., 2012 0.1111/j. 1365-2885.2011.01272.x [Epub ahead of print]

Controlled Therapeutic Substance	Reference
Ketoprofen	Sams, R., *Pharmacokinetics of ketoprofen after multiple intravenous doses to mares*, J. Vet. Pharmacol. Ther., 18(2): 108-16 (April 1995)
Lidocaine	EHSLC Data, Iowa State; *see also*, Sillence, M., *The pharmacokinetics of equine medications*, RIRDC publication (January 2012), available online at http://researchdata.ands.org.au/pharmacokinetic-data-for-twelve-therapeutic-equine-medications
Mepivacaine	EHSLC Data; *see also,* Sillence, M., *The pharmacokinetics of equine medications*, RIRDC publication (January 2012), available online at http://researchdata.ands.org.au/pharmacokinetic-data-for-twelve-therapeutic-equine-medications
Methocarbamol	Rumpler, M., *et* al, *The pharmacokinetics of methocarbamol and guaifenesin after single intravenous and multiple-dose oral administration of methocarbamol in the horse*, J. Vet. Pharmacol. Therap., 2013 doi: 10.1111/jvp.12068 [Epub ahead of print], University of Pennsylvania – pre-publication
Methylprednisolone	Soma, L. R., *Pharmacokinetics of methylprednisolone acetate after intra-articular administration and its effect on endogenous hydrocortisone and cortisone secretion in horses*, Am. J. Vet. Res. 67(4): 108-16 (April 2006); University of California – Davis pre-publication
Omeprazole	ARCI Rule
Phenylbutazone	Chay, S., *Population distributions of phenylbutazone and oxyphenbutazone after oral and i.v. dosing in horses*, Am. J. Vet. Res., 67(4): 654-62 (Dec. 1984)
Prednisolone	Peroni, D.L., *Prednisone per os is likely to have limited efficacy in horses*
Procaine Penicillin	Kuchembuck, N.L, *Plasma Concentration and Local Anesthetic Activity of Procaine Hydrochloride Following Subcutaneous Administration to Horses,* American Journal of Veterinary Research 68(5): 495-500 (2007)

Controlled Therapeutic Substance	Reference
Triamcinolone acetonide	Knych, H., *Pharmacokinetics of triamcinolone acetonide following intramuscular and intra-articular administration to exercised Thoroughbred horses*, Equine Veterinary Journal. doi: 10.1111/evj.12059 [Epub ahead of print]; Soma, L.R., *Pharmacokinetics of intra-articular, intravenous, and intramuscular administration of triamcinolone acetonide and its effect on endogenous plasma hydrocortisone and cortisone concentrations in horses*, Am J Vet Res., 72(9):1234-42 (Sept. 2011)
Xylazine	Laboratory derived interim recommendation based upon Limit of Detection

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September 27, 2013

Mr. Ed Martin, President
Association of Racing Commissioners International
2343 Alexandria Drive
Suite 200
Lexington, KY 40504-3283

Dear Ed:

On Wednesday, the Executive Committee of the United States Trotting Association (USTA) voted unanimously to not support the recent medication proposals advocated by the Association of Racing Commissioners International and the Racing Medication & Testing Consortium. After much study, it is our feeling that those changes address the concerns of Thoroughbred racing and disregard harness racing entirely. The USTA hereby requests leaving the harness rules as they are now constituted.

The USTA feels there are too many differences in the breeds to have rules common to both. Therefore, we encourage separate sets of rules for Thoroughbreds and Standardbreds, respectively. We firmly believe that this will work best for all parties.

Obviously, the proposed change in the administration times for both clenbuterol and corticosteroids brought this situation to a head. In effect, these proposals took the use of those therapeutics away from the Standardbred horsemen while not at all impacting the ability of Thoroughbred horsemen to employ the medications. What strikes us as ironic is that there is no evidence to suggest that Standardbred horsemen are using clenbuterol for anything other than its intended purpose – as a

bronchodilator – while testimony given at the most recent RMTC meeting suggests that Quarter Horse and Thoroughbred horsemen are "stacking" the drug in order to use it as a substitute for anabolic steroids. Your own statement from September 26 indicates the RCI policy recognizes that with regard to clentbuterol AAEP states "use of these drugs in a limited way can be helpful to the horse but overuse can be detrimental." We agree. Think about what the rule proposal does. It eliminates the limited user and encourages steroidal abuse. Several weeks of intense treatment followed by 14 days off and then followed by several more weeks of intense treatment sounds like abuse to us.

There are many protocols employed by the harness racing industry to ensure integrity that our Thoroughbreds counterparts do not follow. For example, harness racing administers Lasix at a state-supervised location and horses receiving it must stay there or in the paddock until race time. All horses are required to be in the paddock two to four hours before race time and need to exercise on the track for veterinarian observation during that time. In addition, in most jurisdictions horses racing in stakes events need to be in some sort of detention facility from twelve hours to several days before they race. The Thoroughbred industry claims its horses can't tolerate such a disruption in their routines.

Standardbreds are different from Thoroughbreds. Our horses race on a weekly basis, often for many years. Thoroughbreds do not. Catastrophic breakdowns in our sport are exceedingly rare. Sadly, this is not the case in the Thoroughbred industry. Further evidence of the difference in durability is reflected by the fact that on a yearly basis, there are more harness races than Thoroughbred contests, despite the fact that the annual Standardbred foal crop is approximately one-third the size of the yearly Thoroughbred yield.

The USTA is very much in favor of uniform rules, but by breed. We support "out of competition testing", reasonable withdrawal times, the seeking out and elimination of blood doping and EPO, testing to identify improper Shock Wave Therapy use, and developing tests for presently unknown drugs.

Funding sources much larger than available to RMTC have been made available to Dr. Soma in Pennsylvania to accomplish these goals. Harness racing will continue with its other safeguards on Lasix, paddock times, detention barns, etc.

It is our opinion that there are now more separate rules than common ones, so going all the way with different rules for different breeds is a small step.

We fail to understand how a Thoroughbred problem of steroidal abuse can be solved by these rules. The fact they have a negative effect on Standardbreds for no apparent reason only adds to our resolve.

Hopefully we can work together to accomplish "uniform rules" by breed.

Sincerely,

Phil Langley
USTA President

RACING COMMISSIONERS INTERNATIONAL

Press Release

Thursday, September 26, 2013
Contact: Ed Martin (859) 224-7070

Statement from Racing Commissioners International on Recent Decisions by the United States Trotting Association

Official Statement from Edward Martin, President and CEO, The Association of Racing Commissioners International (RCI):

RCI continues to rely on the scientific review process at the Racing Medication and Testing Consortium involving key regulatory advisors who are actively involved with the regulation of both Standardbred and Thoroughbred racing as well as the American Association of Equine Practitioners (AAEP). Unfortunately the United States Trotting Association has removed itself from discussions involving those recommendations before they are sent to the RCI.

We understand that there is a debate over Clenbuterol, but note that there are alternatives to treat a Standardbred horse post-race that will better accommodate the Standardbred business model without creating a back door to steroidal-type effects. We have also heard that some are advocating a liberalization of the recommended policy pertaining to corticosteroid use. The AAEP has advised that the use of these drugs in a limited way can be helpful to the horse but the overuse may be detrimental. The policy we have recommended recognizes this.

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Racing Medication & Testing Consortium News Release

RMTC: CURRENT THRESHOLD LEVELS FOR CORTICOSTEROIDS, CLENBUTEROL SHOULD REMAIN

RMTC
Racing Medication &
Testing Consortium

NEWS RELEASE

November 26, 2013
Contact: Hallie Lewis (859) 224-2848

RMTC: CURRENT THRESHOLD LEVELS FOR CORTICOSTEROIDS, CLENBUTEROL SHOULD REMAIN

The Racing Medication & Testing Consortium (RMTC) is releasing two position papers which stated that no physiologic difference among the various racing breeds exists to justify changing regulatory thresholds from those recently established by the Racing Medication & Testing Consortium (RMTC) for the use of corticosteroids and clenbuterol.

The recommendations were made by a panel comprised of recognized laboratory directors, veterinary pharmacologists, practicing veterinarians, regulatory veterinarians, and veterinary surgeons with extensive experience in Thoroughbred, Standardbred, Quarter Horse and Arabian racing. The panel was established by the RMTC in response to a request by the United States Trotting Association (USTA) at the September 2013 RMTC board meeting to establish more liberal thresholds for the use of intra-articular corticosteroids and clenbuterol in the Standardbred breed.

The panel included the following individuals:

Rick Arthur, DVM – Equine Medical Director, California Horse Racing Board
Larry Bramlage, DVM, DACVS – Rood and Riddle Equine Hospital
Tom Brokken, DVM – Teigland, Franklin, and Brokken DVMs, PA
Lynn Hovda – RPH, DVM, MS, DACVIM – Chief Commission Veterinarian – Minnesota Racing Commission
Heather Knych, DVM, MS, PhD – University of California, Davis
Bobby Lewis, DVM – Elgin Veterinary Hospital
Wayne McIlwraith, BVSC, PhD, DACVS – Surgeon and Professor, Colorado State University
Paul Nolan, DVM – Equine Sports Medicine Associates
Mary Robinson, VMD, PhD – University of Pennsylvania School of Veterinary Medicine
Rick Sams, PhD – HFLSS – Lexington

The Corticosteroid Position Paper outlines the concerns regarding both short term pain masking effects of corticosteroids as well as long term damage caused by injudicious use of these medications. The panel affirmed the thresholds originally proposed by the RMTC.

"The benefit of the intra-articular corticosteroid thresholds as enacted by RMTC is to allow sufficient time between treatment and racing to allow the veterinarian to evaluate the effects of such treatment," stated panel member Dr. Wayne McIlwraith of Colorado State University. "Moreover, by providing a significant separation between intra-articular corticosteroid treatments and race-day,

we minimize the potential for those treatments obscuring a more serious injury and compromising pre-race examinations."

The Clenbuterol Position Paper provides a review of both the legitimate beneficial effects and potential integrity issues associated with clenbuterol use. Ultimately, the panel determined that the original threshold recommended by RMTC should be upheld.

"We believe that protecting the integrity of horse racing is paramount and, therefore, there should be a sufficient separation between the administration of clenbuterol and race day for all horses which is supported by the existing threshold," stated RMTC board member and panel member Dr. Bobby Lewis. "We do, however, acknowledge the need to provide options to veterinarians that allow them to appropriately treat horses which is why we recommended researching albuterol and guaifenasin as alternative treatments to clenbuterol."

Full copies of these documents are available at:
http://www.rmtcnet.com/resources/RMTC%20Position%20Paper%20on%20Clenbuterol.pdf and
http://www.rmtcnet.com/resources/RMTC%20Position%20Paper%20on%20Corticosteroids.pdf.

The RMTC consists of 23 racing industry stakeholders and organizations that represent Thoroughbred, Standardbred, American Quarter Horse and Arabian racing. The organization works to develop and promote uniform rules, policies and testing standards at the national level; coordinate research and educational programs that seek to ensure the integrity of racing and the health and welfare of racehorses and participants; and protect the interests of the racing public.

For additional information, visit the RMTC website at rmtcnet.com or contact Hallie Lewis, RMTC director of communications, at (859) 224-2848.

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Racing Medication & Testing Consortium

White Paper

Corticosteroids

RMTC
Racing Medication &
Testing Consortium

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RMTC Position Statement on Corticosteroids

Introduction

Synthetic corticosteroids are important therapeutic drugs that are widely used in human and veterinary medicine for a number of indications including treatment of inflammation and pain associated with joint disease and arthritis. Corticosteroids were originally identified in the 1930s as the hormones produced by the adrenal gland that are necessary for the maintenance of metabolism, water balance, and electrolyte balance in mammals.[i] The anti-inflammatory properties of corticosteroids and their utility for the treatment of rheumatoid arthritis were discovered in the late 1940's. The 1950 Nobel Prize in Physiology or Medicine was awarded to researchers for the discovery of these hormones, their structure, and function.[ii]

Chemistry

Synthetic corticosteroids are structurally similar to hydrocortisone (cortisol) and cortisone that are produced primarily in the *zona fasciculata* and *reticularis* of the adrenal cortex of mammals. Hydrocortisone is released in response to stress and low concentrations of glucocorticoids in the blood. These substances possess increased glucocorticoid potency and efficacy and less mineralocorticoid activity compared to the endogenous hormones. Therefore, a smaller dose of synthetic corticosteroid needs to be administered and compared to administration of hydrocortisone or cortisone. Additionally, derivatives have been modified to produce long-acting formulations that enable less frequent dosing.

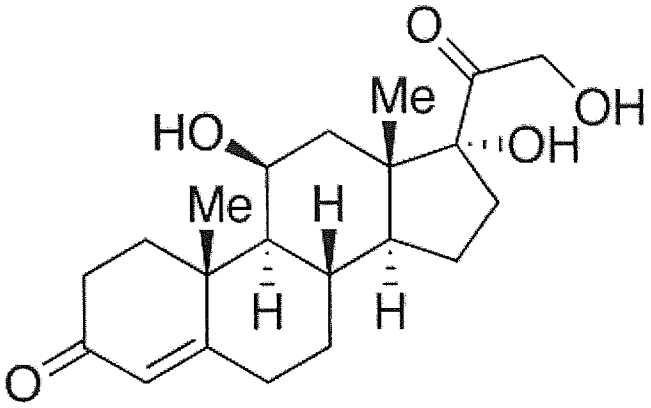

Figure 1. Chemical structure of hydrocortisone.

Corticosteroids with FDA-approved formulations available for intra-articular administration to the horse include methylprednisolone acetate, betamethasone acetate and phosphate, and triamcinolone acetonide.[iii] These products are administered as aqueous suspensions (methylprednisolone acetate and betamethasone acetate and phosphate) or solution (triamcinolone acetonide). Once solubilized in an aqueous environment, the ester must be hydrolyzed before the corticosteroid can cross the cell

membrane and bind to the appropriate receptors. Methylprednisolone is formulated as an acetate ester, which provides the longest duration of effect due to its poor solubility. Betamethasone is formulated as a mixture of the acetate ester and phosphate ester to produce immediate as well as long-lasting effects. Triamcinolone acetonide also provides long lasting effect. Of these, methylprednisolone acetate has been found to persist for the longest period of time in the equine joint. However the prolonged effects of corticosteroids need to be recognized as potentially negative as well as positive effects can occur.

Pharmacokinetics

The elimination of synthetic corticosteroids following intra-articular administrations varies by steroid and can be vastly different from the rate of elimination following other administration routes.

Methylprednisolone Acetate

Research regarding the pharmacokinetics of methylprednisolone acetate was recently completed at the University of California – Davis. The research evaluated administration of methylprednisolone as its acetate ester in suspension into a single articular space at a total dose of 100 mg to a group of 16 exercised Thoroughbreds.[iv] Methylprednisolone reached maximum plasma concentration in an average of 0.273 days. Based upon this dosing regimen, plasma concentrations were below the limit of detection at 10 days in all horses with the average being 5.53 days and the range being 1.5-10 days. The limit of detection for methylprednisolone in plasma was 50 pg/mL. Urine concentrations resulting from dosing according to this protocol were measurable in some horses for more than 17 days.

In another study completed at The Ohio State University, researchers investigated the pharmacokinetics of a 100 mg or 200 mg dose of methylprednisolone as the acetate ester in suspension divided among several intra-articular spaces.[v] In this study, five exercised Thoroughbreds were administered a 100 mg intra-articular total dose then, after a washout period, were administered a 200 mg intra-articular dose. The 100 mg intra-articular dose was divided between the tarsometatarsal joint (60 mg) and the metatarsophanlangeal joint (40 mg). Based upon this dosing protocol, plasma concentrations were below 50 pg/mL at an average of 7 days. The higher dose of 200 mg was divided between the contralateral tarsometatarsal joint (80 mg), the contralateral metatarsophalangeal joint (60 mg), and one metacarpophalangeal joint (60 mg). The researchers found a statistically significant longer time between administration with the higher dose and the time that plasma concentrations were below 50 pg/mL. With a 200 mg total dose, the plasma concentrations were below 50 pg/mL at an average of 18 days.

Triamcinolone Acetonide

In a study published in 2013, researchers at the University of California – Davis reported on the pharmacokinetics of triamcinolone acetonide in 12 exercised Thoroughbred horses.[vi] In this study, researchers administered 9 mg of triamcinolone acetonide into the right antebrachiocarpal joint. Plasma concentrations after administration were below the limit of quantification (100 pg/mL of plasma) at 2.92 days in all horses studied and below the limit of detection (50 pg/mL of plasma) at 7 days in all horses.

In a 2011 study, researchers at the University of Pennsylvania investigated the pharmacokinetics of intra-articular injections of triamcinolone acetonide in 4 Thoroughbred horses.[vii] Each horse received a 0.04 mg/kg (30 mg) intra-articular dose of triamcinolone acetonide in the left carpal joint. Plasma concentrations after administration were quantifiable in plasma for 102 hours post-administration.

Betamethasone

Intra-articular (fetlock) administration of 9 mg of a mixture of betamethasone sodium phosphate and betamethasone acetate to twenty Thoroughbred horses was investigated at the University of Florida and HFL Sport Sciences, Inc. in 2012. The study revealed that plasma concentrations of betamethasone peaked rapidly within 8 hours after administration due to the high aqueous solubility of the phosphate ester and that plasma concentrations remained detectable for ten days after administration. The method was characterized by a lower limit of quantification of 5 pg/mL and a limit of detection of 1 pg/mL. Plasma concentrations were less than the limit of quantification by five days after dose administration.

Pharmacodynamics

Corticosteroids are responsible for a variety of effects in the horse. Generally speaking, corticosteroids exert their effects by binding to receptors in the cytoplasm of cells that are present in many cell types throughout the body. The binding of a corticosteroid to a steroid receptor usually begins a sequence of events affecting gene transcription and the synthesis of proteins. Examples are:

- Potential alteration of the G protein-coupled receptors to interfere with intracellular signal transduction pathways
- Enhanced transcription in many genes, especially those involving suppression of inflammation.
- Inhibition of gene transcription – including those that encode pro-inflammatory substances.

The last two in this list are considered genomic effects. This type of corticosteroid effect usually occurs within hours to days after administration. The genomic effects outlast our ability to measure the synthetic corticosteroid in plasma, as evidenced by persistent suppression of the normal production of hydrocortisone following synthetic corticosteroid administration.[viii]

Therapeutic Use

Corticosteroids are used to reduce pain and swelling due to inflammation, and to alleviate allergic symptoms. It is to be recognized, however, that they do not correct any structural, anatomic change such as intra articular fractures that also initiate potent inflammation. Moreover, by removing the mediators of, and therefore the signs of, inflammation corticosteroids inhibit host defense and repair processes – thus interfering with the horse's natural identification of the need for healing if there is an anatomic reason for the joint inflammation, such as an injury to the bone or ligaments that must heal before normalcy can return. The corticosteroids can restore normal function to physiologic processes such as joint lubrication when disruptions of these normal self-defense mechanisms are initiated by trauma or overuse.[ix] They are also very effective at mitigating inflammation in cases of contact allergy such as contact dermatitis or lower airway disease; however they should not be used in lieu of removal of the primary cause.

Corticosteroids are often used in combination with other corticosteroids, hyaluronic acid, and other intra-articular treatments. The number of different protocols used by race track practitioners is extensive. There is concern that repeated corticosteroid injections of certain corticosteroid products can affect the articular surfaces of joints. In a 2010 paper, Dr. McIlwraith observed that intra-articular methylprednisolone acetate caused deleterious effects to articular surfaces.[x] Moreover, Dr. McIlwraith observed that there may be some benefit to a period of rest occurring between intra-articular injections with any corticosteroid and racing.

AAEP Position on Use of Intra-Articular Corticosteroids in Performance Horses
The American Association of Equine Practitioners (AAEP) has adopted the following statement regarding the use of intra-articular medications in non-racing performance horses:

> *The AAEP recognizes that the judicious use of intra-articular medications with a valid veterinarian-patient relationship is appropriate treatment and can benefit a horse's health and well being. The AAEP defines this relationship to be a clinical or lameness examination with appropriate diagnostic tests prior to initiation of a therapeutic plan. Clinicians treating performance horses in the competitive environment are encouraged to develop treatment regimens, particularly with reference to the use of IA corticosteroids, which allow adequate evaluation of the horse's response to treatment prior to competition.*[xi]

RMTC Recommendations Regarding Use of Intra-Articular Corticosteroids
The RMTC invited a group of veterinarians and racing laboratory director with considerable expertise and experience in issues related to corticosteroids and horse racing in November 2012 to review the use of intra-articular corticosteroids in race horses. The goal of this meeting was to address concerns that had been raised by various groups regarding the potential overuse of corticosteroids in race horses. Paramount among the issues raised at this meeting was the need to curtail the practice of injecting one or more joints in a horse within a few days of racing. Accordingly, the group determined that it was desirable to set plasma or serum thresholds which would allow the practitioner to determine the horse's response to treatment prior to racing. The current ARCI Model Rule incorporates not only those thresholds but also a Restricted Administration Time (RAT). That RAT is based loosely upon the RMTC's recommended withdrawal guidelines.

The RMTC has recommended thresholds and withdrawal times for commonly used intra-articular corticosteroids that permit their use in accordance with the principles articulated by the AAEP in the above referenced position paper specifically with regard to the requirement to allow adequate evaluation of the horse's response to treatment prior to competition. Accordingly, the RMTC recommended a sufficient withdrawal period that the response to treatment could be evaluated before racing. This withdrawal period should be long enough that the systemic concentrations of the medication have dropped below the threshold and the amounts in the joint have declined enough that the horse will have time to again manifest signs of significant anatomic injury that might be dangerous during performance and that might be masked by the treatment. Seven days is a recommended safe withdrawal period with limited doses of intra-articular corticosteroids.

The necessary withdrawal period to stay under the plasma or serum threshold is lengthened with increased dosages and shortened with lower dosages. If the dosage used is higher (as with treatment of multiple joints) the withdrawal period must be lengthened to assure that threshold concentrations will not be violated. The recommended thresholds are based on scientific studies of the disposition of clinically used doses of the intra-articular corticosteroids that are commonly used to treat performance horses in the United States. The products, doses investigated, and their corresponding plasma or serum thresholds are as follows:

Product	Dose*	Threshold
Methylprednisolone acetate (*e.g.*, Depo-Medrol™)	**100 mg**	**100 pg of methylprednisolone per milliliter of serum or plasma**
Triamcinolone acetonide (*e.g.* Vetalog™)	**9 mg**	**100 pg of triamcinolone acetonide per milliliter of serum or plasma**
Betamethasone sodium phosphate and betamethasone acetate	**9 mg**	**10 pg of betamethasone per milliliter of serum or plasma**

*These are not clinical dosage recommendations; rather the dosages used represent those administered when making threshold recommendations

As noted in the specific sections regarding research on each of these intra-articular formulations above, the recommended withdrawal times generally exceed the time for the plasma or serum concentration in any horse to fall below the recommended threshold. Often the recommended withdrawal time exceeds the time to fall below the recommended threshold by several days. To determine RMTC withdrawal times, the European Milk withdrawal guidelines have been followed.

The purpose of using these guidelines is to provide a very conservative and safe threshold to trainers and veterinarians using approved therapeutic medications. This is a very robust statistical approach to determining withdrawal times and provides a wide margin of safety. The goal is to provide a safe withdrawal time to trainers and veterinarians which will provide a very small likelihood of a violation if dosing guidelines are followed and to assure that corticosteroid concentrations within joints have dropped below those that could mask anatomic injury that may be dangerous to the horse or rider/driver.

Genesis of the Issue

The use of corticosteroids in performance horses is, in some circumstances, dictated by trainers and based upon the entry of a horse in a race. This scenario emphasizes the masking of clinical signs rather than the mitigation of disease. However, it is undesirable to have treatment too close to the performance event in which the response to treatment and the, resolution of clinical signs, and clarification that there is no serious anatomic disruption being masked. Our primary concern must be for the safety of the horse and rider.

Representatives of the United States Trotting Association (USTA) and some other individuals recently raised the concern that use of the one-week RAT rather than threshold concentrations prevents therapeutic treatment of horses that race on a weekly basis – this includes some Thoroughbreds and Quarter Horses as well as most Standardbred horses. Representatives of the USTA requested that RMTC review the one-week RAT and related corticosteroid recommendations as they relate to the Standardbred business model of weekly races. The USTA has requested that the RMTC consider separate medication rules for Standardbred horses which allow them to be treated with corticosteroids within seven days of racing.

In response, the RMTC convened another meeting of experts with experience in treating and regulating the various breeds. The panel included practicing veterinarians in the Standardbred and Thoroughbred racing circuit; surgeons who treat a variety of racing breeds; and regulatory veterinarians with responsibility for regulating a variety of breeds in their jurisdictions. This white

paper was produced by this second panel of experts to address the questions and concerns raised regarding corticosteroid use in the horse and the RMTC threshold recommendations.

Corticosteroid Concerns

Though needless degeneration of joints aided by injudicious use of corticosteroids is a long-term concern with the use of corticosteroids, it is the masking of the pain by the presence of pharmacologic concentrations of corticosteroids sufficient to hide early anatomic disruption that is of most concern. Use of corticosteroids close to time of the event in sufficient doses to hide these predisposing disruptions of bone and cartilage puts horses and people at increased risk of serious injury. It is this concern that drives the need to move treatment time and medication doses far enough away from the event to assure the horse is performing without joint concentrations of corticosteroids high enough to hide impending structural failure and its potentially catastrophic consequences for the horses and people involved.

The threshold recommendations were chosen to assure this level of safety for the horse and rider/driver. Were this not a concern, the threshold concentrations could be more easily adjusted to accommodate different entry times and times between starts. But, concern for horses and people have dictated that the joint concentrations of the medication fall to those that give the horse the chance to show that there is more than just an inflammatory component to the injury in the evaluation of the response to treatment before performance recommended by the AAEP. This overriding concern, not laboratory limits of detection, was the basis for the selection of threshold concentrations recommended by the panel of veterinarians in 2012. This recommendation is based on current available science and needs to be assessed in light of practical application to the racing situation. This is the genesis for the concurrent recommendation of an implementation period for the new regulatory thresholds.

Summary of the Panel's Review of Key Discussion Points

1. **Are there physiologic differences between Standardbred and other breeds with regard to corticosteroids?**

The consensus of the group was that there are insufficient physiologic differences between Standardbred horses and other breeds to justify different regulations for use of the intra-articular corticosteroids based on breed. While these horses, because of their racing gait, tend to have fewer catastrophic musculoskeletal injuries than some other racing breeds, they nonetheless experience career -ending fractures and osteoarthritis that, similar to other breeds, can be linked to excessive or injudicious corticosteroid use. The objective of the regulations is to protect the welfare of the horses and the integrity of the racing product. As such, the concerns extend beyond catastrophic injury and joint disease to the protection of the horse.

2. **Corticosteroids and Restricted Administration Times (RAT)**

The panel did recognize that RATs prohibit treatments with smaller doses of corticosteroids which would remain below the recommended thresholds but occur within 7 days of racing. This is not an issue that is unique to Standardbreds. Emphasis on thresholds rather than treatment times may be sufficient to allow a practitioner to observe a horse after treatment but prior to racing even without a bright line of a RAT. Practitioners must still allow several days between treatment and racing to avoid a high probability of a threshold violation. RATS that cannot be enforced by thresholds or other laboratory testing put trainers and veterinarians who attempt to abide by the medication rules at a competitive disadvantage and may put horses at risk. This conundrum warrants consideration in the final establishment of recommendations of thresholds or treatment times.

3. **Corticosteroids and Thresholds**

The RMTC has developed thresholds for regulating the intra-articular administration of the corticosteroids methylprednisolone acetate, betamethasone acetate and betamethasone sodium phosphate, and triamcinolone acetonide. Additionally, it is in the process of developing a threshold for regulating use of isoflupredone acetate. These thresholds have been reviewed by a variety of experts and were introduced to veterinarians at the AAEP Racing Committee meeting in December of 2012. At that meeting, several practitioners from Pennsylvania – including practicing Standardbred veterinarians - indicated that the thresholds were similar to those in effect in Pennsylvania and that veterinarians were using corticosteroids in accordance with the rules. Additionally, Minnesota has had similar thresholds for intra-articular corticosteroids in place since 2009 and the equine medical director has indicated compliance with their rules and a general ability to control excessive or injudicious use of corticosteroids.

4. **Implementation Period**

The RMTC Corticosteroid Experts previously recommended a corticosteroid rule implementation period during which trainers and veterinarians would be provided feedback regarding concentrations of corticosteroids in post-race samples before enforcement of corticosteroid thresholds would begin. The length of this implementation period may vary because different jurisdictions have different race meet schedules which may require a variety of time periods to implement the new thresholds. Ideally, the implementation period would be between three and six months in duration.

During this implementation period, trainers would not be assessed penalties for exceeding corticosteroid thresholds. Instead, both the veterinarian and trainer would be notified of the concentration(s) of corticosteroid(s) in each test sample in order to provide feedback to the veterinarian regarding which protocols comply with the regulations. This would allow veterinarians to adjust their practices and modify their protocols without risk of a positive finding, keeping in mind that the end goal is the safety of the horse and people.

Similar programs have been used in both Pennsylvania and Minnesota. In Pennsylvania, practitioners have also been permitted to submit unofficial samples for specific corticosteroid testing after the rule went into effect for purposes of determining whether a protocol is acceptable. The results from these samples are reported directly to the submitting veterinarian. In Minnesota, practitioners were allowed to submit unofficial samples to the racing laboratory for analysis after corticosteroid administration. The practitioners were required to submit treatment records for the horse along with the sample. The laboratory would then screen the sample for the specific corticosteroid and inform the equine medical director for the commission and the veterinarian if the sample exceeded the threshold (concentrations were not provided). In 2013, after the practitioners adjusted their intra-articular corticosteroid treatment protocols, there were a total of 2 corticosteroid overages – one at the harness track and one at the Thoroughbred/Quarter Horse track. This was true despite the fact that many horses at both of these tracks compete every week.

California and Virginia have similar programs underway involving feedback to practitioners of results of tests performed on official samples. The equine medical directors are working with practicing veterinarians to evaluate withdrawal times for a variety of corticosteroid dosages and protocols for intra-articular injections completed as a part of routine practice.

Recommendations of the Panel

1. Corticosteroid thresholds should remain as recommended by the RMTC and enacted by the ARCI. This will protect horses, jockeys, and drivers by allowing veterinarians to evaluate the effects of treatment before racing.
2. RMTC should recommend that the ARCI remove the Restricted Administration Times from the regulations. The existing thresholds will prevent intra-articular administrations close to the race while allowing appropriate treatment with smaller doses of corticosteroids.
3. A commission-determined implementation period of approximately three to six months with feedback of laboratory results to practitioners is strongly recommended before any corticosteroid medication violations are prosecuted. This will allow veterinarians to adjust their protocols and adapt to changes in the regulations.
4. Continuing education should be provided to practitioners. Commissions are encouraged to direct practitioners to resources at the AAEP, RMTC, and the jurisdiction's Equine Medical Director.

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[i] Sneader, W., *Drug Discovery. A History*, John Wiley & Sons Ltd., West Sussex, England (2005).
[ii] Available online at: http://www.nobelprize.org/nobel_prizes/medicine/laureates/.
[iii] Available online at: http://www.accessdata.fda.gov/scripts/animaldrugsatfda/.

[iv] Knych, H.K., *et al, Disposition of methylprednisolone acetate in plasma, urine, and synovial fluid following intra-articular administration to exercised thoroughbred horses*, J. vet Pharmacol. Therap. 2013 June 20. doi: 10.1111/jvp.12070 (2013) [Epub ahead of print].

[v] Menendez, M.I., *et al, Pharmacokinetics of methylprednisolone acetate after intra-articular administration and subsequent suppression of endogenous hydrocortisone secretion in exercising horses*, AJVR 73:1453-61 (2012).

[vi] Knych, H.K., *et al, Pharmacokinetics of triamcinolone acetonide following intramuscular and intra-articular administration to exercised Thoroughbred horses*, EVJ 2013 January 27, doi: 10.1111/evj.12059 [epub ahead of print].

[vii] Soma, L.R., *et al, Pharmacokinetics of intra-articular, intravenous, and intramuscular administration of triamcinolone acetonide and its effect on endogenous plasma hydrocortisone and cortisone concentrations in horses*, AJVR 72(9): 1234-42 (2011).

[viii] *Veterinary Pharmacology and Therapeutics, Ninth Edition*, p. 783.

[ix] *See generally,* Frisbie DD, Kawcak C, Trotter GW, Powers BE, Walton RM, McIlwraith CW. *Effects of triamcinolone acetonide on an in vivo equine osteochondral fragment exercise model.* Equine Vet J 1997;29:349-359; Kawcak CE, Norrdin RW, Frisbie DD, McIlwraith CW, Trotter GW. *Effects of osteochondral fragmentation and intra-articular triamcinolone acetonide treatment on subchondral bone in the equine carpus*. Equine Vet J 1998;30:66-71.

[x] McIlwraith, C.W., *The use of intra-articular corticosteroids in the horse: What is known on a scientific basis?* EVJ 42(6): 563-71 (2010).

[xi] American Association of Equine Practitioners, *Clinical guidelines for veterinarians treating the non-racing performance horse*, (2011).

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Clenbuterol

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RMTC Position Statement on Clenbuterol

Introduction

Clenbuterol is a relatively selective β_2 adrenergic receptor agonist used for bronchodilation and increasing mucociliary clearance in the horse. In contrast to other β_2 adrenergic receptor agonists such as albuterol and terbutaline, clenbuterol is rapidly and extensively absorbed after oral administration without extensive first-pass metabolism so that clinically effective serum or plasma concentrations are achieved.

Chemistry

Clenbuterol (Figure 1) is 4-amino-alpha-[(tert-butylamino)methyl]-3,5-dichlorobenzyl alcohol (IUPAC) typically marketed as the hydrochloride salt. Clenbuterol has one chiral center at the benzylic carbon and is administered as the racemate although most of the pharmacologic activity is attributed to the levorotatory isomer.

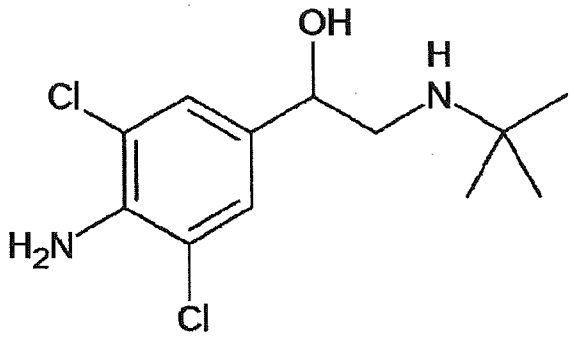

Figure 1. Chemical structure of clenbuterol.

Clenbuterol was first reported from Boehringher Ingelheim laboratories in the early 1970s and marked the end result of a search for an orally effective and longer lasting bronchodilator than had been available previously. Increased oral bioavailability was achieved by substituting halogens (chloride) for protons to the aromatic ring. A longer duration of effect and increased β_2 adrenergic receptor selectivity was achieved primarily by substituting the tertiary butyl group for a methyl group on the secondary amine group.

Ventipulmin® is the only formulation of clenbuterol approved by the US Food and Drug administration for use in the horse. The approved product is a viscous liquid sold by Boehringher Ingelheim Vetmedica, Inc. at a concentration of 72.5 micrograms per milliliter. No parenteral forms of clenbuterol are approved for use in any species in the US.

Pharmacokinetics

The pharmacokinetics and disposition of clenbuterol in the horse after single and multiple dose administrations have been reported in numerous publications.[i] After oral administration clenbuterol is rapidly and nearly completely absorbed, reaching peak blood concentrations within a few hours of administration.[ii; iii]

Research regarding the pharmacokinetics of clenbuterol was recently completed at the University of California – Davis. The research indicated that it was readily absorbed when administered orally.[iv] At the low dose recommended by the manufacturer of 0.8 mcg/kg clenbuterol reached maximum plasma concentration in an average of 1.42 hours. Based upon a 30 day regimen of 0.8 mcg/kg twice daily, plasma levels were below detection using LC-MS at 7 days in all 22 horses sampled. Urine levels using this protocol were measurable for over 20 days.

Pharmacodynamics

Clenbuterol is a selective β_2 adrenergic receptor agonist. It works through receptors in the lungs that are coupled through G proteins to increase intracellular cyclic AMP which produces smooth muscle relaxation. The desirable actions of clenbuterol are produced by stimulation of these receptors in the airways and lungs, resulting in bronchodilation and an increase in the clearance of mucus and debris. Therefore, it is used therapeutically for the management of acute and chronic respiratory disorders in horses. It may also cause a reduction in release of allergic and inflammatory mediators from mast cells in the lungs.[v]

All drugs have side effects that can affect other body functions. In the horse, concentrations of clenbuterol can be found in all vital organs, including the heart and brain. Side effects can occur in the horse within 5 to 10 minutes following oral administration of clenbuterol and are due to the activation of β_2-adrenergic receptors in these organ systems. Moderate sweating, an increase in heart rate, nervousness, and pacing have been reported, and suggest a greater sensitivity of the horse to clenbuterol than other species in which higher doses were administered before these effects were observed.[vi]

Therapeutic Use

In recent promotional material, the manufacturer of Ventipulmin™ specifically lists Recurrent Airway Obstruction and Inflammatory Airway Disease as diseases that clenbuterol is intended to treat. The FDA approved information provided by the manufacturer states that the indications for use of this medication are "the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD)." A copy of this material is attached to this document.

The makers of Ventipulmin™ publish the following twice daily administration regimen for clenbuterol:

- Initial dosage: administer 0.5 mL/100 lbs (0.8 mcg/kg) for 3 days (6 treatments);
- If no improvement, administer 1.0 mL/100 lbs (1.6 mcg/kg) for 3 days (6 treatments);
- If not improvement, administer 1.5 mL/100 lbs (2.4 mcg/kg) for 3 days (6 treatments);
- If no improvement administer 2.0 mL/100 lbs (3.2 mcg/kg) for 3 day (6 treatments); If no improvement, horse is non-responder to clenbuterol and treatment should be discontinued.

Based upon these dosing recommendations, the minimum length of time for effective treatment is three days with dosing twice daily and the maximum duration of treatment is twice daily for 30 days. More recently, evidence of tachyphylaxis, specifically regarding its bronchoprotective properties, was apparent by 21 days. These observations suggest that prolonged and continuous use of clenbuterol as a bronchodilator may be unjustified.[vii]

RMTC Recommendations Regarding Use of Clenbuterol

The use of clenbuterol in performance horses has come under criticism because it is a β_2 - adrenoreceptor agonist and because it produces a repartitioning effect. Clenbuterol is a banned

performance-enhancing substance in all sanctioned human athletic competitions. The crux of the issue is that while clenbuterol does provide for bronchodilation, clenbuterol also has repartitioning effects on skeletal muscle which mimic the anabolic effects of androgenic/anabolic steroids. WADA lists clenbuterol as a banned anabolic agent along with other β_2 agonists. [viii] As discussed below, clenbuterol administration has been shown to increase muscle mass and decrease fat when used – even at therapeutic doses.

In a recent report out of New York, a task force identified clenbuterol as a major safety and integrity issue in racing. The task force reported that a significant number of horses at NYRA tracks were being administered clenbuterol – many of which were not receiving it to treat airway disease.[ix] Similar findings have been reported throughout the United States. Prior to the CHRB suspending authorization of clenbuterol in California, the equine medical director reported that 58% of thoroughbred horses in training and 100% of quarter horses nominated to major stakes showed detectable levels of clenbuterol in plasma samples. After much discussion, and in light of these concerns, the RMTC board voted to set the thresholds listed above with a 14 day recommended withdrawal guideline.

An important note regarding the RMTC clenbuterol recommendations is that the withdrawal guidelines only apply to the FDA approved product Ventipulmin.™ Other clenbuterol containing products are not FDA approved and have been shown to have varying amounts of clenbuterol when analyzed which can affect both the pharmacokinetics and pharmacodynamics. Second, the RMTC recommended that clenbuterol use be subject to a 140 pg/mL threshold in urine and the limit of detection in plasma or serum. The two-prong threshold was recommended to prohibit race day administration of a small amount of clenbuterol. Along with this recommendation, the RMTC provided withdrawal guidance of 14 days. These recommendations are based on scientific studies of the disposition of the lowest clinical dose of clenbuterol that can be used to treat performance horses in the United States.

This recommendation was forwarded to the Association of Racing Commissioners, International who adopted the urine and plasma thresholds recommended by RMTC. In addition, they converted the 14 day withdrawal guideline to a 14 day Restricted Administration Time (RAT).

Request for Further Discussion

Recently, the United States Trotting Association (USTA) and some individuals raised the concern that the 14 day RT prevents treatment of horses that race on a weekly basis – this includes some Thoroughbreds and Quarter Horses as well as many Standardbred horses. The USTA requested that RMTC review the 14 day RT and related clenbuterol threshold recommendations as they relate to the Standardbred business model of weekly races. The USTA has requested that the RMTC consider separate medication rules for Standardbred horses that would permit clenbuterol treatment within five or fewer days of racing.

In response, the RMTC convened a discussion among experts with experience in treating and regulating the various breeds. The panel included practicing veterinarians in the Standardbred and Thoroughbred racing circuit; surgeons who treat a variety of racing breeds; and regulatory veterinarians with responsibility for regulating a variety of breeds in their jurisdictions.
More restrictive thresholds for clenbuterol are currently in place in California (21 days) and New Mexico (termed "zero tolerance").

Clenbuterol Pharmacodynamic Research

A significant amount of research has been done regarding the effects of clenbuterol on exercised horses. The vast majority of the pharmacodynamic research has been done on Standardbred horses at Rutgers University. In those studies, researchers used a 5 day on- 2 day off-treatment model at a 2.4 mcg/kg dose. Control horses and some of the horses treated with clenbuterol were exercised 3 times per week.

In one of the first studies to be published regarding repartitioning and clenbuterol, researchers measured rump fat and fat free mass in Standardbred mares.[x] At the first measurement – two weeks into the trial, they found a statistically significant difference in horses in the clenbuterol treatment groups regardless of exercise status. A statistically significant difference was not observed within the exercised only horses until week 4. Essentially, researchers observed a statistically significant increase in fat free mass two weeks prior in the group with clenbuterol plus exercise when compared to the group that was only exercised. Simply put – horses on clenbuterol achieve more fitness faster.

In another research paper from Rutgers, researchers examined the effect of clenbuterol on aerobic performance in horses.[xi] The researchers observed that treated horses experienced sweating and severe agitation beginning on day 1 of administration and continuing until day 10. In addition, researchers documented:

- a decrease in VO_{2max} in horses treated with clenbuterol and exercised and a corresponding increase in horses that were only exercised
- a decrease in time to fatigue in horses treated with clenbuterol while horses only exercised had a corresponding increase in time to fatigue
- a decrease in plasma volume in clenbuterol treated horses with a corresponding increase in exercised only horses

These changes occurred over an eight week period with intermittent clenbuterol treatment.
Researchers have also examined clenbuterol's effect on cardiac function. In yet another study from Rutgers University, researchers examined the effect of chronic low dose clenbuterol use on echocardiography results in trained Standardbred horses.[xii] Researchers determined that chronic clenbuterol administration caused statistically significant changes in cardiac function – particularly post exercise. Specifically, the researchers observed:

- significant stroke volume increase with accompanying increase in left ventricle internal dimension for treated horses versus non-treated horses (regardless of exercise status)
- significant increases in aortic root dimension for treated horses after 8 weeks versus untreated horses regardless of exercise status
- significant increases in left ventricular internal dimension at both systole and diastole in treated horses versus non-treated horses (regardless of exercise status)

Again, these changes were observed in eight weeks using intermittent treatment.
In 2003, researchers at Rutgers University examined histologic samples of muscle fibers taken from Standardbred horses administered clenbuterol (exercised and not exercised) and compared them to control horses (exercised and not exercised).[xiii] These investigators observed a decrease in type IIA muscle fibers with an increase in type IIX muscle fibers in all horses administered clenbuterol. Type IIX muscle fibers increase in horses that are in detraining. Thus, these investigators concluded that administration of clenbuterol was detrimental to exercise performance "in horses running races comparable to Standardbreds."

Also, in a 2013 poster presented to the American College of Veterinary Internal Medicine diplomats, researchers from the University of Pennsylvania found a significant decrease in the percent of rump fat thickness after administration of clenbuterol at the low therapeutic dose of 0.8 mcg/kg for as few as 6 days.[xiv] In this limited study of six Standardbred horses, tracheal mucociliary clearance rate increases were not observed until day 6. In a separate study, reversal of the effects of clenbuterol on rump fat required a minimum of 11 days following completion of a 21 day administration of 0.8 mcg/kg twice daily.[xv]

Physiologic Differences Between Standardbred and Other Breeds

The consensus of the group is that there is nothing physiologically unique about Standardbred horses that justifies different regulations. Given this and the potential risks of long term chronic administration of clenbuterol as well as the potential for abuse, the RMTC elected to consider the welfare of all horses in its threshold determination. Moreover, while a greater majority of Standardbreds race more often than other breeds, allowing a five day withdrawal time for Standardbreds (or any breed) will allow for a horse to take several weeks off of training and benefit from the anabolic effects of clenbuterol for approximately 11 days. Furthermore, in one jurisdiction, a Standardbred racing weekly could conceivably be administered clenbuterol up to 5 days a week. Absent weekly testing of out of competition horses, it would be impossible to regulate these issues.

Airway Disease and Thresholds

While clenbuterol is a useful drug when used appropriately, even a short period of use within a few days of racing is a threat to integrity and the safety of the horse. As such, it is necessary to find other alternatives. In addition to clenbuterol, RMTC placed glycopyrrolate on the list of therapeutic medications. Glycopyrrolate is used to decrease bronchial secretions in the horse. It has a recommended withdrawal time of 48 hours.

In addition to glycopyrrolate, RMTC is investigating the possibility of adding nebulized albuterol (another β_2 adrenergic receptor antagonist) and guaifenesin (an expectorant). Considerable research is published on albuterol; very little is published on the pharmacokinetics of guaifenesin.

Recommendations

The recommendations of the panel are as follows:

1. Clenbuterol thresholds should remain as recommended by the RMTC and enacted by the ARCI.
2. RMTC should recommend that the ARCI remove the Restricted Administration times from the clenbuterol regulations.
3. The RMTC should work to add albuterol and guaifenesin to the list of controlled therapeutic medications as soon as possible.

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[i] Kallings, P., Ingvast-Larsson, C., Persson, S., Appelgren, L.E., Forster, H.J. & Rominger, K.L. Clenbuterol plasma concentrations after repeated oral administration and its effects on cardio-respiratory and blood lactate responses to exercise in healthy Standardbred horses. *Journal of Veterinary Pharmacology and Therapeutics* **14**, 243– 249 (1991); Harkins, J.D., *et al, Clenbuterol in the horse: urinary concentrations determined by ELISA and GC/MS after clinical doses*, J. vet. Pharmacol. Therap., **24**: 7-14 (2001); Knych, H.K., *et al, Detection, pharmacokinetics and cardiac effects following administration of Clenbuterol to exercised horses, Equine Vet J.* 2013 Jun 17. doi: 10.1111/evj.12118. [Epub ahead of print]

[ii] Soma L.R., Uboh C.E., Guan, Moate, F.P., Luo, Y., Teles, D., Li, R, Birks, E.K., Rudy, J.A., & Tsang, D.S.. Pharmacokinetics and disposition of clenbuterol in the horse. *Journal of Veterinary Pharmacology and Therapeutics* **27**: 71-77 (2004).

[iii] Kallings, P., Ingvast-Larsson, C., Persson, S., Appelgren, L.E., Forster, H.J. & Rominger, K.L. Clenbuterol plasma concentrations after repeated oral administration and its effects on cardio-respiratory and blood lactate responses to exercise in healthy Standardbred horses. *Journal of Veterinary Pharmacology and Therapeutics* **14**, 243– 249 (1991).

[iv] Knych, H.K., *et al, Detection, pharmacokinetics and cardiac effects following administration of Clenbuterol to exercised horses, Equine Vet J.* 2013 Jun 17. doi: 10.1111/evj.12118. [Epub ahead of print].

[v] Dixon, P.M., *Respiratory mucociliary clearance in the horse in health and disease, and its pharmaceutical modification.* Veterinary Record, 131(11), 229-235 (1992); Erichsen, D.F., Aviad, A.D., Schultz, R.H. & Kennedy, T.J. *Clinical efficacy and safety of clenbuterol HCl when administered to effect in horses with chronic obstructive pulmonary disease (COPD).* [see comments.]. Equine Veterinary Journal, 26(4), 331-336 (1994).

[vi] Read JR, Boston RC, Abraham G, Bauquier SH, Soma LR, Nolen-Walston RD., Effect of prolonged administration of clenbuterol on airway reactivity and sweating in horses with inflammatory airway disease. *Am J Vet Res.* 2012 Jan;**73**(1):140-145.

[vii] Read JR, Boston RC, Abraham G, Bauquier SH, Soma LR, Nolen-Walston RD., Effect of prolonged administration of clenbuterol on airway reactivity and sweating in horses with inflammatory airway disease. *Am J Vet Res.* 2012 Jan;**73**(1):140-145.

[viii] Available at: http://www.wada-ama.org/Documents/World_Anti-Doping_Program/WADP-Prohibited-list/2013/WADA-Prohibited-List-2013-EN.pdf

[ix] New York Task Force on Racehorse Health and Safety, *Investigation of Equine Fatalities at Aqueduct 2011-2012 Fall/Winter Meet* (2012).

[x]Kearns, C.F., *et al, Chronic administration of therapeutic levels of clenbuterol acts as a repartitioning agent*, J. Appl Physiol, **91**:2064-70 (2001).

[xi] Kearns, C.F. and McKeever, K.H., *Clenbuterol diminished aerobic performance in horses*, Medicine and Science in Sports and Exercise, 2002 doi: 10.1249/01.MSS.0000038973.96796.1E .

[xii] Sleeper, M.M., Kearns, C.F., and McKeever, K.H., *Chronic clenbuterol administration negatively alters cardiac function*, Medicine and Science in Sports and Exercise, (2002).

[xiii] Beekley, M.D., *et al, Chronic clenbuterol administration alters myosin heavy chain composition in standardbred mares, The Veterinary Journal*, **165**:234-39 (2003).

[xiv] Barr, C.A., *et al, The effect of chronic clenbuterol administration on mucociliary clearance and body fat in adult horses*, ACVIM Poster (2013).

[xv] Personal communication by Dr. Mary Robinson with Dr. Rose Nolen-Waltson.