Agenda Item #1

Proposed Rules

Standardbred

April 21, 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.~~ All cleared samples may be used for research and/or investigative purposes by the commission.

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, 2-(1-hydroxyethyl) promazine sulfoxide (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-~~o~~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) A trainer may request that a horse be placed on the veterinarian's list due to medically necessary treatment with AAS. The horse shall remain on the veterinarian's list:**
(1) for 365 days; or
(2) until the concentration of the drug or metabolite in urine or blood has fallen below the designated threshold for the administered AAS; or
(3) until the concentration of the drug or metabolite in urine or blood has fallen below the limit of detection for AAS that do not have a designated threshold.

whichever is longer.~~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 **n**either 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 or AAS in a horse placed on the veterinarian's list in accordance with 71 IAC 8-1-8 (f)** ~~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)*

Proposed Rules

Thoroughbred & Quarter Horse

April 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.~~ All cleared samples may be used for research and/or investigative purposes by the commission.

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, 2-(1-hydroxyethyl) promazine sulfoxide (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) A trainer may request that a horse be placed on the veterinarian's list due to medically necessary treatment with AAS. The horse shall remain on the veterinarian's list:**
(1) for 365 days; or

(2) until the concentration of the drug or metabolite in urine or blood has fallen below the designated threshold for the administered AAS; or
(3) until the concentration of the drug or metabolite in urine or blood has fallen below the limit of detection for AAS that do not have a designated threshold,
whichever is longer. ~~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 or AAS in a horse placed on the veterinarian's list in accordance with 71 IAC 8.5-1-8 (f)** ~~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)

Latest
Industry Comments

Gorajec, Joe

From: John Keeler [jkeeler@centaurgaming.net]
Sent: Monday, April 07, 2014 3:59 PM
To: Gorajec, Joe; Ellingwood, Lea
Cc: Rod Ratcliff; Jim Brown; Brian Elmore; Rick Moore; Jonathan B. Schuster
Subject: Proposed Emergency Rules Implementing Model Rules on Medication and Penalties

Dear Joe, I write on behalf of Hoosier Park and Indiana Grand (collectively, Centaur) regarding the proposed emergency rules on medication. The proposed rules are more particularly identified in Item 2 (a)-(h), inclusive, of the March 5,2014 Commission Meeting Agenda (Emergency Rules). As you may recall, at the last meeting of the Commission, Chairman Diener requested that Centaur advise the Commission in writing of its position on the adoption of the proposed Emergency Rules no later than today.

Centaur and its veterinary medicine professionals have carefully and thoroughly considered the Emergency Rules and have concluded that their prompt adoption is in the best interests of the sport of horseracing. While the adoption of the Emergency Rules may cause Centaur and horsemen some short term economic hardship, especially if surrounding states are slow to timely adopt regulations similar to the Emergency Rules, after weighing all factors, we believe that the delaying the implementation of the Emergency Rules would do more harm than good. If our industry is to succeed and prosper as a popular spectator sport, our fans must be comfortable that all contestants compete on a level playing field and that the welfare of our equine athletes comes first. For many years, Indiana has led the nation in promoting the integrity of horseracing and the safety of human and equine participants. Now is no time to fall behind.

John S. Keeler
Vice President & General Counsel
Centaur Gaming
10 West Market Street, Suite 200
Indianapolis, Indiana 46204
Office Phone: 317-656-8782
Mobile: 317-432-0850
Fax: 317-536-9339
email: jkeeler@centaurgaming.net

U S T A
US Trotting Association

750 Michigan Avenue
Columbus, Ohio 43215-1191

Toll Free 1-877-800-USTA (8782)
(In The USA & Canada)
Phone 614/224-2291
Fax 614/224-4575
www.ustrotting.com

COPY

April 15, 2014

RECEIVED
APR 21 2014
By JE

Mr. William Diener, Chairman
Indiana Horse Racing Commission
1302 N. Meridian St.
Indianapolis, IN 46202

Dear Chairman Diener:

As you are probably aware, the United States Trotting Association (USTA) and most affiliated harness racing horsemen's associations last September went on record opposing parts of the Racing Medication & Testing Consortium's (RMTC) suggested schedule of uniform rules. The rules we opposed have since been addressed at many industry forums. The USTA has appeared at two RMTC meetings, two Racing Commissioners International (RCI) meetings, and several individual state racing commission meetings, including the Pennsylvania Harness Commission, Illinois Racing Board and New York State Racing and Wagering Board.

As of this week, two of our four concerns have been resolved. One of our other concerns that limited the acceptable number of medications to twenty-four similarly has been adjusted, and both the RMTC and RCI have stated that the list will be fluid in the foreseeable future. We are grateful for the flexibility displayed.

That leaves harness racing still concerned with the proposed withdrawal and threshold standards for clenbuterol. For many years, clenbuterol has been used appropriately by harness trainers and veterinarians for several days following a race as bronchial dilator and then withdrawn for four days before racing again. Every published study that we have reviewed recommends this drug as very useful for treatment in this manner. Most research also warns that used in larger doses and for a substantial period of time, clenbuterol can produce a repartitioning effect similar to that of anabolic steroids. It is generally estimated that continual treatment can meaningfully affect muscle development, however, at between three- and four-weeks. In order to contain this reported misuse by Quarter Horses and Thoroughbreds, the RMTC recommends a fourteen-day withdrawal time for all breeds. In

effect, this means that Standardbreds, which often race every week, can only benefit from the administration of clenbuterol if they take three weeks between races.

The RMTC said they would find a suitable substitute that would allow for the normal race pattern employed by harness horses. They added albuterol, which behaves similarly to clenbuterol, to their list of approved medications, but everyone, including the drug's proponents, agrees it is both expensive and cumbersome to use.

We ask that you consider the rule adopted in New York that has fashioned a separate standard for harness racing that allows the use of clenbuterol as it has been for years, except in the event a horse hasn't raced for thirty days. In such instances, the horse should be subject to the fourteen-day withdrawal and threshold standards. That rule seems to fairly address the use of clenbuterol.

The USTA would welcome the opportunity to address these medication issues at your upcoming hearing. We believe it is very important to have uniform medication rules, but the different physical characteristics of different breeds should allow for some variation in the respective rules.

Respectfully yours,
The United States Trotting Association

Phil Langley
President

Mike Tanner
Executive Vice President

cc: Joe Gorajec – Indiana Horse Racing Commission
Jack Kieninger – Indiana Standardbred Association
Alan Leavitt – Kentucky Horse Racing Commission

Indiana Horsemen's Benevolent & Protective Association, Inc.

32 Hollaway Boulevard
Brownsburg, IN 46112
(317)-903-4382
www.inhbpa.org

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

Delivered by email
April 7, 2014

Dr. Demaree,

Thank you for the opportunity to share our perspective on contemplated medication rule changes on behalf of the board, officers and members of the Indiana HBPA and all who participate in thoroughbred racing in the state.

The men and women who participate in Indiana thoroughbred racing are not experts in the fields of pharmacology or law – and I am most assuredly not, either. We are generally in favor of the concept of uniform medication policies between jurisdictions, but we have some very real concerns about the ARCI Model Rules and, concomitantly, the rule changes Indiana is considering, for medication and penalties.

We articulated those in our November letter to the Commission, which I believe you have. In general, we have two primary concerns: 1.) we believe that these Model Rules are creatures of policy, fed by imperfect, non-transparent science; and, 2.) since the RMTC Model Rules Committee is considering significant changes (or will have considered, by the time the next IHRC meeting takes place,) to what Indiana proposes to adopt is an indication that adoption of these Model Rules is premature.

The fact that we all agree that the concept is a good idea is not reason enough to adopt these rules prematurely in their current constrictive, fluid and flawed form.

Please keep in mind, these are therapeutic medications. They are not used, nor are they intended, to enhance performance. They – and quite a few other therapeutic medications not included on this list – are used to ensure the health and well-being of our horses. Our

practicing track veterinarians have large trucks stocked with many other medications for a reason – they are needed.

"Policy" should not trump sound practice or good science when it comes to the well-being of our equine athletes.

The RMTC Model Rules Committee was scheduled to meet April 8 to change their recommendations on Ketoprofin (changes threshold), Flunixin (changes withdrawal time), and to add two medications. In addition, the RMTC is changing its emphasis in the area of multiple medication violations so that its penalty structure "shall be considered," as distinguished from its previous "shall determine" position.

You should also keep in mind, when contemplating the adoption of the Model Rules, that uniformity across jurisdictions will not be achieved through these rules. Racing jurisdictions across the United States have taken varied approaches – adopting some as proposed, altering others, eliminating still others altogether. Some have adopted different rules for standardbreds and flat-racing breeds.

Some jurisdictions have adopted significant portions of the RMTC/ARCI Model Rules, but have left in place existing state-defined thresholds for other medications outside the anointed 24 on the list. Horsemen racing in multiple jurisdictions are still going to be at-risk as they compete in other states.

Therein lies a problem, in an age in which field size, finding new owners and keeping the ones we have is a challenge. Driving owners and trainers out of the state or out of the business after unnecessary positive tests result in forfeited purses and penalties will serve no one well.

If we in Indiana are going to adopt these rules, IN HBPA asks that we also balance the equation by paying close attention to the possibility of endogenous, dietary and environmental substances yielding bad test results.

A major national newspaper surveyed water samples throughout the United States within the last two years. Their finding: We take in all kinds of substances just by drinking the water around us.

Our testing capabilities have evolved to the place where we can test down to the virtual equivalent of two drops of substance in a swimming pool. Adopting a standard that excludes down to the limits of detection – which is, in essence, zero tolerance – without making sufficient provision for additional thresholds that address endogenous, dietary and environmental substances will ultimately result in far too many positives for people who have adhered to the law.

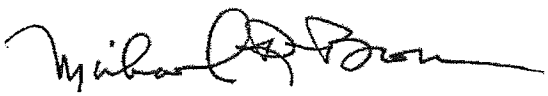
The RMTC and ARCI are working with the National HBPA to develop a more sane and responsive policy toward EDE's. We urge the State of Indiana to pay close attention and to incorporate these policies as they are developed.

Finally, we urge close attention to well-defined dosages and withdrawal times as an important part of adopting these rules. Anyone can set a threshold. Just pick a number. The real science is to create a scientifically valid linked withdrawal time guideline for the racing industry, which also requires that you identify a dose.

The RMTC has consciously moved away from the concept of restricted access times, in favor of withdrawal time guidelines. That only makes sense. But that also means that the existence of scientifically valid withdrawal time guidelines will become that much more important, in that proof of adherence to the guidelines should also be an affirmative defense.

Dr. Thomas Tobin, of the University of Kentucky Gluck Institute, came to the March 5th Commission meeting prepared to discuss many of these issues in more detail. We would like to have him come back for the April 30 Commission meeting. In conjunction with our current response, we are also including the slides he prepared for the previous –and the next – IHRC meeting

Thank you for your time and your consideration on these issues. Please contact me if we can add or clarify anything contained herein.



Michael Brown, executive director
Indiana Horsemen's Benevolent & Protective Association

SCIENTIFICALLY VALIDATED REGULATORY THRESHOLDS FOR USE IN RACING REGULATION

BY
Thomas Tobin, Kimberly Brewer and Charlie G Hughes
Maxwell H. Gluck Equine Research Center
University of Kentucky
First presented at the
2014 National HBPA Winter Meeting
Pasadena, California. Saturday, January 25th, 2014
adapted for
The Indiana Horsemen's Benevolent and Protective Association,
Indianapolis, Indiana

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PUBLISHED RESEARCH BASIS FOR RMTC THRESHOLDS

1/ The HBPA noted lack of published studies supporting the 24 RMTC thresholds.

2/ RMTC, in a Dec. 4th letter to the Ohio State Racing Commission, listed a number of published studies that they presented as supporting the 24 Controlled Therapeutic Medication thresholds.

3/ I will now review the papers relevant to furosemide, flunixin, phenylbutazone, acepromazine.

December 4, 2013
Mr. Bill Crawford
Executive Director
Ohio Racing Commission
77 South High Street, 18th Floor
Columbus, OH 43215

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 HBPA, it is also incorrect. Please see the attached list of research by controlled therapeutic medication.

Best regards,
Dionne Benson, DVM
Executive Director

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SUMMARY

1/ FLUNIXIN:

NO RELEVANT DATA POINTS IN STUDY.

2/ PHENYLBUTAZONE:

PENNSYLVANIA ANALYSIS OF RMTC STUDY SUGGESTS 10% OR SO OVERAGE RATE.

3/ ACEPROMAZINE:

SIX HORSES, DOSE ORAL, NOT IV, THREE TIMES THE RMTC DOSE, NO DATA IN PAPER RELEVANT TO RMTC THRESHOLD

 © Thomas Tobin 2012

FIRST, A THANK YOU TO RMTC: THE FUROSEMIDE THRESHOLD

First, I must acknowledge RMTC recognition of this Chay et al 1983 paper, research supported by HBPA as the scientific basis for the Salix threshold in American racing.

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)

FUROSEMIDE THRESHOLD HISTORY

1/ Dosed **47 horses** with AAEP/Dose/ Route/Lasix and quantified plasma furosemide at 1 and 4 hours.

2/ At 1 hour the plasma distribution was "normal" i.e., a bell curve.

2/ **At 4 hours the plasma distribution curve was SKEWED TO THE RIGHT [LOG NORMALLY DISTRIBUTED].**

REGULATORY THRESHOLD FOR FUROSEMIDE [1983]

Four hour rule required detention barns. Kentucky HBPA asked us to develop a regulatory threshold, so we dosed 47 horses with 250 mg furosemide I/V.

The figure above right shows the raw data, clearly skewed to the right.

A LOG TRANSFORMATION NORMALIZED THIS DISTRIBUTION AND WE ESTIMATED THAT 1/1,000 HORSES WOULD EXCEED ABOUT 27/30 NG PER ML.

Adjusted upward, this became the current regulatory threshold, 100 ng/ML in plasma /serum, linked, courtesy of Dr. Sams, to a 1.010 urinary specific gravity "cut-off".

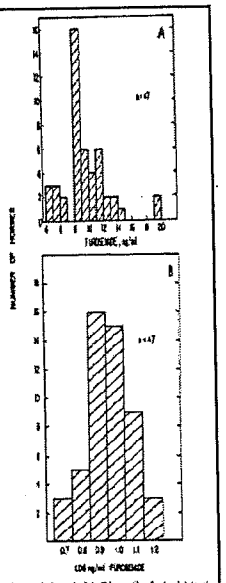

FIG. 4. Furosemide plasma levels in 47 horses 4 hr after iv administration of 4.5 mg/kg furosemide.

A, the vertical bars represent the number of horses found within the indicated ranges of furosemide plasma levels; B, the vertical bars represent the number of horses found within the indicated ranges of the log of furosemide plasma levels.

 © Thomas Tobin 2014

FUROSEMIDE THRESHOLD HISTORY

This threshold was based on:

1.1/ **Defined formulation**, **Specific dose** and a **specific route of administration**.

2/ Administered to a **significant number of animals [47].**

3/ Our **analytical method was capable of quantifying ALL OF THE SAMPLES.**

4/ Did not have samples that were below our limit of quantification [LOQ] and **we did not eliminate any high samples.**

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FUROSEMIDE THRESHOLD HISTORY

1/ In 1998 Dr. Sams suggested adding the 1.010 specific gravity screening level.

2/ Now the RMTC rule, urine specific gravity less than 1.010, plasma furosemide above 100ng/ml = violation.

3/ This threshold is widely in place in North America.

 © Thomas Tobin 2014

FUROSEMIDE THRESHOLD HISTORY

First scientifically based threshold developed and applied in racing chemistry.

GOOD MATH,

LONG IN PLACE NATIONAL THRESHOLD

 © Thomas Tobin 2014

FLUNIXIN

RMTC 20 ng/ml flunixin threshold,

dose 1.1 mg/kg IV,

24 hr. withdrawal time guideline

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FLUNIXIN: THE RMTC CITED PAPER:

1/ RMTC presented Soma et al., 1988, AJVR, V49 #11, p 1894-1898, as supporting the RMTC **20ng/**ml flunixin threshold/24 hr. withdrawal time guideline.

2/ **FIVE** mares, 8-12 years old, no mention of training.

3/ Limit of Quantitation of method **50 ng/ml.** 3/ 1.1 mg/kg samples only collected for 10 hours. **NO 24 HOUR SAMPLES.**

 © Thomas Tobin 2014

FLUNIXIN:
THE RMTC CITED PAPER:

1/ 1.1 mg/kg samples only collected for 10 hours.

2/ NO 24 HOUR SAMPLES.

CONCLUSION:

NO DATA POINTS WHAT-SOEVER IN THIS PAPER EVEN CLOSE TO THE 24 HOUR TIME POINT OR THE 20NG/ML THRESHOLD.

 © Thomas Tobin 2014

PHENYLBUTAZONE

 © Thomas Tobin 2014

RMTC CITED PHENYLBUTAZONE STUDY

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)

1/ This 30 year old paper cited by the RMTC in support of the phenylbutazone threshold is authored by Soma and Tobin, among others.

2/ However, RMTC has ignored the RMTC phenylbutazone study carried out in Florida 26 years later, in or about 2010, which samples were analyzed in Pennsylvania and Florida.

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RMTC BUTE PA ANALYSIS

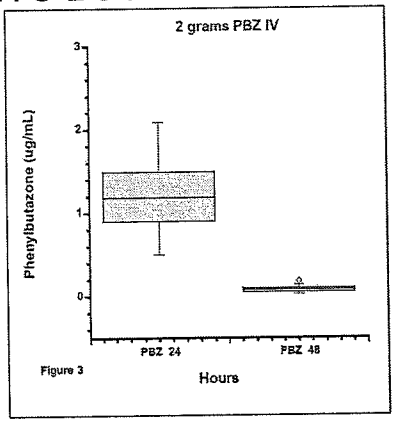

Figure 3

These data indicate that even with no prior administrations of PBZ a dose of 2 grams 24 hours prior to post-time may produce a violation of the 2 µg/ml threshold. It is suggested that if a dose of 4.4 mg/kg is to be administered that the weight of the horse be taken into consideration or PBZ be administered at 36 hours prior to race time.

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RMTC BUTE PA ANALYSIS

Figure 3 shows the results of a single IV administration of 2 grams (??4.4mg/kg??) of phenylbutazone (PBZ). This group of 20 horses did not have prior administration of PBZ.

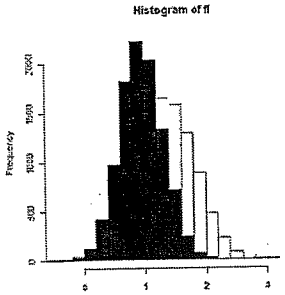
The 24 hour mean post-administration plasma concentration was 1.2 **(range of 0.5 to 2.1) µg/ml** and mean 48 hours plasma concentration was 0.08 (range of 0.02 to 0.18) µg/ml.

These data indicate that even with no prior administrations of PBZ a dose of 2 grams 24 hours prior to post-time may produce a violation of the 2 µg/ml threshold. It is suggested that if a dose of 4.4 mg/kg is to be administered that the weight of the horse be taken into consideration or PBZ be administered at 36 hours prior to race time.

Phenylbutazone IV administration to 20 horses (courtesy of the Drs Sams and Callahan of the University of Florida).

MATH & PA SAYS DANGEROUS THRESHOLD

2UG/ML PHENYLBUTAZONE Statistical Projections



POPULATION PLOT FL vs/PA (red=FL, white=PA)

# horses out of 17,500	2~3(ug/ml)	3~4(ug/ml)	4~5(ug/ml)	>5(ug/ml)
PA	1,400	3.5	0	0
FL	30-8	0	0	0

© Thomas Tobin 2012

2UG/ML PHENYLBUTAZONE

Plan for approximately 10% overages, at least

Pennsylvania: A 36 hour rule, or reduce the dose

ACEPROMAZINE

RMTC: 10ng/ml regulatory threshold, HEPS in urine.

PROPOSED RMTC THRESHOLD, ACEPROM AZINE

RMTC proposes 10ng/ml HEPS regulatory threshold in urine

RCI SCHEDULE OF CONTROLLED THERAPEUTIC SUBSTANCES - Version 1.0
(Adopted April 2, 2013 by Racing Commissioners International)

Controlled Therapeutic Substance:	Threshold:	No post-race treatment within:	Dosing Specifications	Reference Notes	Notes
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 00517-0725-01)	RMTC study	IA dosing only - applicable analyte is betamethasone in plasma or serum
Butorphanol	100 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.	Lab. Pharmacol. Therap. doi: 10.1177/1535370X12461955	Applicable analyte are total butorphanol (drug and conjugates) in urine and butorphanol in plasma (the drug itself, not any conjugates).

4/21/2014 © Thomas Tobin 2014 21

THE RMTC ACEPROMAZINE THRESHOLD

1/ RMTC proposes a 10ng/ml HEPS regulatory threshold in urine.

2/ April 2nd RMTC document cites "UC Davis project"

3/ 10ng/ml HEPS first appeared as an *"in house"* Ohio threshold in 1999, [Tom Journell], less than the previously in place 25ng/ml California threshold.

3/
4/21/2014

4/21/2014 © Thomas Tobin 2012 22

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)

THE WIEDER PAPER:

- Acepromazine as **"Sedalin"** an **ORAL formulation.**
- Dose; **0.15 mg/kg, THREE TIMES** the RMTC IV dose.
- **Number of horses SIX**, a very small number for a threshold study.
- Nowhere in the study can I find a regulatory threshold or a withdrawal time guideline for acepromazine.

THE WIEDER ACEPROMAZINE PAPER

I quote from the Wieder study, page 641:

"Once again it must be noted that the windows of quantification are derived from use of a highly sensitive targeted method. Therefore, they do not necessarily reflect a routine screening situation and consequently do not reflect detection time advice that may be offered by official regulatory bodies."

NO MATH, NO THRESHOLD

SUMMARY

FLUNIXIN:

NO RELEVANT DATA POINTS IN STUDY

PHENYLBUTAZONE:

PENNSYLVANIA ANALYSIS OF RMTC STUDY SUGGESTS 10% OVERAGE RATE

ACEPROMAZINE:

DOSE ORAL, NOT IV, THREE TIMES THE RMTC DOSE, NO DATA IN PAPER RELEVANT TO RMTC THRESHOLD

TAKE HOME MESSAGE

Ronald Reagan: "TRUST BUT VERIFY"

Verify: Ask for the Data; if they can show you a valid statistical probability, then we all know exactly where we are.

Not good to regulate or to be regulated if neither the regulators or the regulated know where they are.

Acknowledgements

This research has been supported by ongoing research support from The National Horsemen's Benevolent and Protective Association and the Alabama, Arizona, Arkansas, Canada, Charles Town (West Virginia), Florida, Iowa, Indiana, Kentucky, Louisiana, Michigan, Minnesota, Nebraska, Ohio, Oklahoma, Ontario (Canada), Oregon, Pennsylvania, Tampa Bay Downs (Florida), Texas, Washington State, and West Virginia Horsemen's Benevolent and Protective Associations and the Florida Horsemen' s Charitable Foundation, the Oklahoma Quarter Horse Racing Association and the Neogen Corporation. The continuing support of the Director, Faculty of the Gluck Equine Research Center, the University of Kentucky Gluck Equine Research Foundation, the administration of the College of Agriculture and the University of

Kentucky are gratefully acknowledged .

Gorajec, Joe

From: swiftyfarms@frontier.com
Sent: Thursday, March 27, 2014 2:24 PM
To: Gorajec, Joe
Cc: darlenelikens@yahoo.com
Subject: ITOBA stance on proposed medication rules

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Indiana Horse Racing Commission,

The Indiana Thoroughbred Owners and Breeders association supports the proposed rule changes of the Association of Racing Commissioners International's Model Rules, regarding medication and penalties that were proposed at the March 5, 2014 Indiana Horse Racing Commission Meeting. ITOBA believes these rules being set in place are the best thing for the Thoroughbred Industry as a whole and the best thing for the animal itself.

Thank You

Christina Lawton, ITOBA Executive Director

Herbert Likens, ITOBA President

Dear Joe

April 7, 2014

I am writing on behalf of the Indiana Standardbred Association regarding the proposed Emergency medication rules. The ISA. Oppose the adoption of these Emergency Rules. Implementing all these rules will be a hardship on standarbred racing. The ISA believe there is a deference between the way the two breeds race. The Standarbreds race much more often than flats, once a week opposed to once or twice a month. This would be hardship especially if the surrounding states have different rules than ours; we depend a lot on the surrounding states to help fill our fields. A lot of the better horses from other states come to Indiana to race witch has a big economic impact on our racing and also the quality. This could be a hardship for the horsemen with the possibility of unintentional positives, because of different rules in other state for Standardbreds. We all know that there is different rules for flats and standardbreds not all rules apply to both breeds equally .The welfare and safety of both equine and human participants Is our top priority. Along with integrity and quality for the better and a level playing field for all horsemen.

Thank You

Jack Kieninger
President
Indiana Standardbred Association

Gorajec, Joe

From: melracing@aol.com
Sent: Tuesday, April 08, 2014 10:44 PM
To: Gorajec, Joe
Cc: wdiener@hrc.in.gov
Subject: Medication

Joe-

I don't quite understand the urgency to jump into the medication rules, as there are only 4 states that have implemented it in one way or another. None of the surrounding states to Indiana have put it in effect. If I am not mistaken the IHRC just changed the rules in 2011-12.

What is wrong with the present drug rules? Last year Indiana only had 5 positives in all three breeds and 2 or 3 of those were "minor overages" in the words of Dr. Demeree. I would think other states should be looking to adopt Indiana's present medication rules.

As Indiana is getting more new owners, trainers and veterinarians, late drug rule changes will only serve to confuse. The whole thing reminds me of what I know of Obamacare..... it is thrown out there and nobody really knows what it is or the ramifications. Rushing into it is not the answer.

Regards,

Michael E. Lauer

Commissioners and Commission Staff:

Please consider the following comments from Indiana Breeder & Protection, Inc. (IBOP) regarding proposed emergency rules **'71 IAC 8-1-4.2 and 71 IAC 8.5-1-4.2 Threshold levels'** as dated February 21, 2014.

The proposed threshold emergency rules differ greatly from the ARCI Model Rules on two key issues; structure and withdrawal times. From a structure perspective, the ARCI Model Rules take a very simplistic approach by incorporating by reference their ARCI Controlled Therapeutic Medications Schedule as can be seen in C(1)(b). In this particular case, this would be Version 1.0 dated April 1, 2013. This is a similar approach to the commission's initial proposed rules on the subject.

This type of incorporation by reference by the ARCI, which we encourage, does include a violation for any treatment within stated withdrawal times. Yet, the proposed threshold rules do not which may require further explanation by commission staff.

Page 275 and 428 from Version 5.6 of the ARCI Model Rules approved by the ARCI Board of Directors on December 13, 2013 read as follows:

C. Medication Restrictions

(1) A finding by the commission approved laboratory of a prohibited drug, chemical or other substance in a test specimen of a horse is prima facie evidence that the prohibited drug, chemical or other substance was administered to the horse and, in the case of a post-race test, was present in the horse's body while it was participating in a race. Prohibited substances include:

  (a) Drugs or medications for which no acceptable threshold concentration has been established;

  (b) Controlled therapeutic medications in excess of established threshold concentrations or administration within the restricted time period as set forth in the ARCI Controlled Therapeutic Medication Schedule, Version _____;

  (c) Substances present in the horse in excess of concentrations at which such substances could occur naturally; and

  (d) Substances foreign to a horse at concentrations that cause interference with testing procedures.

(2) Except as otherwise provided by this chapter, a person may not administer or cause to be administered by any means to a horse a prohibited drug, medication, chemical or other substance, including any restricted medication pursuant to this chapter during the 24-hour period before post time for the race in which the horse is entered.

On a technical basis, the proposed threshold rules, as is, use the term 'HEPS' which we believe should be spelled out. We would also suggest that a definition for 'limit of detection (LOD)' be established, especially considering that a limit of detection may not be able to provide a specific concentration, or limit of quantification (LOQ), for a particular medication or substance. Imagine a scenario where a lab states that that they believe there is a positive test (LOD), but can't quantify any specific amount (LOQ). Given that, would any LOD without an LOQ meet the preponderance of evidence required of the commission by Indiana statute? We don't believe so.

We would also suggest that any use of the term 'limit of detection' for any medication in serum or plasma is not a threshold, so both proposed rules are misnamed.

Thank You

Jim Hartman
IBOP Vice-President

Commissioner and Commission Staff:

Please consider the following comments from Indiana Breeder & Protection, Inc. (IBOP) regarding the proposed repeal of **'71 IAC 8-1-5.7 and 71 IAC 8.5-1-5.6 Anti-ulcer medications'** as dated February 21, 2014.

The ARCI has only repealed the anti-ulcer medications rule in their flat racing rulebook. Per the footnote on page 280 of the ARCI Model Rules, "Version 5.5 to 5.6 ARCI Board 12/9/13 deleted ARCI-011-022 Anti-Ulcer Medications." However, the ARCI has not repealed the anti-ulcer medications rule in their standardbred rulebook.

Page 431 from Version 5.6 of the ARCI Model Rules approved by the ARCI Board of Directors on December 13, 2013 reads as follows:

H. Anti-Ulcer Medications

The following anti-ulcer medications are permitted to be administered, at the stated dosage, up to 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

Overall, we object to the elimination of any threshold for cimetidine and ranitidine as anti-ulcer medications. Testimony at the March 5, 2014 indicated that in the past the commission worked with the labs to determine threshold levels based upon available science. If the work product of those efforts established threshold levels and a withdrawal time, why change? Also, when was the last time any of the anti-ulcer medication thresholds were violated? In consulting the commission's annual reports back to 2009 and the commission rulings for 2013, we don't see any violations for anti-ulcer medications.

Thank You,

Jim Hartman
IBOP Vice-President

Commissioners and Commission Staff:

Please consider the following comments from Indiana Breeder & Protection, Inc. (IBOP) regarding proposed emergency rules **'71 IAC 8-3-5 and 71 IAC 8.5-2-5 Out of competition testing'** as dated February 21, 2014. These administrative rules have never followed the ARCI Model Rule and neither do the proposed changes as the ARCI Model Rules have no mention of androgenic-anabolic steroids. Therefore, we are questioning the use of an emergency rulemaking process, especially for a change that would make the practice of using FDA-approved therapeutic medications while a horse is out of competition a prohibited practice.

Page 281 and 433 from Version 5.6 of the ARCI Model Rules approved by the ARCI Board of Directors on December 13, 2013 read as follows:

ARCI-011-022 & ARCI-025-022 Out of Competition Testing for Blood and/or Gene Doping Agents

(1) Any horse on the grounds at a racetrack or training center under the jurisdiction of the commission; or under the care or control of trainer or owner licensed by the commission is subject to testing for blood and/or gene doping agents without advance notice. This rule does not apply to therapeutic medications approved by the FDA for use in the horse.

(2) Horses to be tested may be selected at random, with probable cause, or as determined by the commission;

(3) The Commission Veterinarian, or any licensed veterinarian or licensed veterinary technician authorized by the commission, may at any time, take a urine, blood or hair sample from a horse for this purpose.

(4) Prohibited substances, practices and procedures are defined as:
   (a) Blood doping agents including, but not limited to Erthropoietin (EPO), Darbepoetin, Oxyglobin, Hempure, Aransep or any substance that abnormally enhances the oxygenation of body tissues.
   (b) Gene doping agents or the non-therapeutic use of genes, genetic elements, and/or cells that have the capacity to enhance athletic performance or produce analgesia.

(5) Cooperation with the Commission Veterinarian, or any licensed veterinarian or licensed veterinary technician authorized by the commission, includes:
   (a) Assisting in the immediate location and identification of the horse selected
   (b) for out of competition testing;
   (c) Providing a stall or safe location to collect the samples;
   (d) Assisting the veterinarian in properly procuring the samples;
   (e) Split samples will be collected as per PMRMR-025-023-C.

(6) Out of competition samples will be sent to the official laboratory of the commission, or other laboratory as designated by the commission with reports made in accordance with the provisions of these medication rules and the penalty provisions thereof.

The ARCI Model Rule subsection (1) to their out of competition testing rules state, "This rule does not apply to therapeutic medications approved by the United States Food & Drug Administration (FDA) for use in the horse." The only proposed change to '71 IAC 8-3-5 and 71

IAC 8.5-2-5 Out of competition testing' would, in fact, eliminate the therapeutic use of FDA-approved medications while horses are not racing by limiting concentration levels to that of "racing horses." Any therapeutic use of these FDA-approved medications would have concentration levels higher than that of a racing horse simply due to their prescribed treatment.

Both '**71 IAC 8-3-5 and 71 IAC 8.5-2-5'** are proposed to include the phrase "endogenous concentrations of the naturally occurring substances as defined in...." each rulebook's proposed anabolic steroids rules which are also under consideration as '**71 IAC 8-1-8 and 71 IAC 8.5-1-8.**' The proposed out of competition rules only refer to the concentration levels, yet both of these anabolic steroid rules include the following passage "(f) Any horse to which an anabolic steroid has been administered in order to assist in its 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 administrated AAS, the horse is eligible to be removed from the list."

With this subsection, clearly, the commission has recognized that androgenic-anabolic steroids can be used therapeutically during a race meeting and has a mechanism for monitoring horses treated in such a way. The point is to not allow a horse to race on elevated levels. With only allowable endogenous concentration levels, the proposed rules fail to allow for therapeutic use of FDA-approved androgenic-anabolic steroids out of competition thus making the owner and the trainer of a horse standing in a field during the off season treated in such a way subject to penalties. This incongruity needs to be rectified as part of these proposed rules.

Thank You,

Jim Hartman
IBOP Vice-President

Commissioners and Commission Staff:

Please consider the following comments from Indiana Breeder & Protection, Inc. (IBOP) regarding proposed emergency rules **'71 IAC 1-1-94.1 and 71 IAC 1.5-1-94.1 "Sample" defined'** as dated February 21, 2014. For reference purposes, we've copied the flat racing version of this proposed new rule.

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."

Given that these proposed emergency rules include certain aspects that go well beyond a simple definition and that are not based upon ARCI Model Rules, we believe that any promulgation of these two administrative rules should be completed using the regular rulemaking process, not the emergency rulemaking process. To date, there's not been an explanation as to how these proposed definitions fit into the commission's policy on rulemaking with emergency consideration.

The ARCI Model Rules begin with a "Terms" section applicable to both their flat racing rulebook and their standardbred rulebook. On page 6 from Version 5.6 of the ARCI Model Rules approved by the ARCI Board of Directors on December 13, 2013 'sample' reads as follows:

ARCI-001-010 Terms
(75) Sample is a portion of any bodily substance or fluid, including but not limited to, tissue, hair, blood or urine obtained from a horse or greyhound at the direction of the commission for the purposes of determining the presence and/or concentration of regulatory analytes.

While the first sentence in the proposed new rules is similar in nature to the ARCI Model Rules definition of sample, these 'definitions' claim a property right to cleared samples which can be used for "research and/or investigative purposes" that don't exist in any ARCI definition or rule. To date, there has been no explanation as to the necessity of these new definitions. In addition, a "Test Sample" definition already exists in Indiana statute, which reads as follows:

IC 4-31-2-23
"Test sample"
Sec. 23. "Test sample" means a body substance taken from a horse for the purpose of analysis, under the supervision of the commission or state veterinarian and in the manner prescribed by the commission.
As added by P.L.341-1989(ss), SEC.2.

With "Test Sample" already defined in Indiana statute, which has been the sole definition needed for 20 years, the inclusion of the property language seems to be the main goal of these so-called definitions. We are concerned with that claim as well as the concept of the need for further investigation of test samples after being cleared. The question that needs to be answered is why would there be a need for any "investigative purposes" from a cleared test sample? Without any further description of "investigative purposes," these definitions could be used to further prosecute horsemen beyond a cleared primary sample or even beyond a cleared split sample. We also see potential statutory authority issues with these definitions.

In creating these proposed new rules, **'IC 4-31-3-9 Powers'** is cited as giving the commission the authority to create these rules. Our review of **IC 4-31-3-9** finds no specific, or even implied, authority allowing for rulemaking that would grant the commission a property right in any sample or specimen for whatever reason. **IC 4-31-2-23 "Test sample"** is also cited as providing rulemaking authority. While this statue does provide indirect rulemaking authority by stating "in a manner prescribed by the commission," that indirect authority is limited to how a test sample is "taken from a horse," not the ability for that sample to become commission property.

With potential concerns related to rulemaking authority, as well as lack of specifics regarding necessity of these new definitions, the regular rulemaking process would allow for an appropriate legal review by the Attorney General's Office as part of the process. This is especially true given that, **IC 4-31-12-6(b)** states, "The cost of analyzing specimens shall be borne by the commission." Even if the commission can legally take a property right in cleared samples, Indiana statute seems to indicate that any research or investigative purpose using cleared samples would be at the expense of the commission even if test samples were given to a third party. That, of course, is assuming a third party would be involved since the who, what, how, when, and why of these definitions is not evident.

Thank You,

Jim Hartman
IBOP Vice-President

Commissioners and Commission Staff:

Please consider the following comments from Indiana Breeder & Protection, Inc. (IBOP) regarding proposed emergency rules **'71 IAC 8-1-7.1 and 71 IAC 8.5-1-7.1 Multiple Medication Violations'** as dated February 21, 2014. While these proposed rules are based upon ARCI Model Rules, there are significant deviations in them when compared to the ARCI Model Rules which change the meaning significantly. Those deviations will be noted below.

Pages 273 and 426 from Version 5.6 of the ARCI Model Rules approved by the ARCI Board of Directors on December 13, 2013 read as follows:

(13) 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

(IBOP Comment: While the ARCI Model Rules states in (13)(a) that a trainer, "shall be assigned points...," the proposed rules state that a trainer, "may be assigned points...." which changes the meaning of the ARCI Model Rules. Essentially, this change makes the MMV and the assignment of points an option in Indiana. Yet, there has been no communication under what circumstances points will be assigned, when points won't be assigned, and who will make those decisions. Perhaps the commission staff could provide such an explanation.)

(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.

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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. **(IBOP Comment: No such footnote exists in the proposed MMV rules.)**

(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.

(IBOP Comment: "A trainer's cumulative points for violations in all racing jurisdictions shall be maintained and certified by the Association of Racing Commissioners International" from (13)(c) in the ARCI Model Rules does not exist in the proposed rules. To date, there has been no explanation as to this deviation. Yet, (13)(e) of the ARCI Model Rules provides that "the official ARCI record shall constitute prima facie evidence of a trainer's past record....." as well as (13)(f) which also references "the trainer's official ARCI record.")

(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 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

MMP'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.

(IBOP Comment: On a technical basis, (13)(g)(i) and (13)(g)(ii) above are numbered as (3) and (4) in the proposed rules, yet there is no (1) or (2).)

(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.

(IBOP Comment: The proposed new rules from the packet at the March 5, 2014 commission meeting end with subsection (i). There is no inclusion of subsection (j) in the proposed MMV rules which include a trainer's ability to petition the ARCI to have points expunged and the timing for points being expunged from a record.)

(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

Please note: Per pages 280 & 433: Version 5.4 to 5.5 ARCI Board 7/31/13 included language adopting Multiple Medication Violations (MMV)

In a statement released on April 7, 2014, Alex Waldrop, President of the National Thoroughbred Racing Association said, "The MMV penalty system was not introduced until last fall. Eight states have committed to implementation of the program including Delaware, Indiana, Maryland, Massachusetts, New Jersey, New York, Virginia, and West Virginia." While IBOP is not opposed to a broader penalty system for repeat offenders, we are concerned that Indiana's administrative rules lack any significant notification requirements to immediately inform the owner of a horse of a positive test result from a primary test sample. We would appreciate the commission's commitment to a course of action to do so along with consideration of the MMV.

We are also concerned with a couple technical aspects of the proposed MMV rules that could lead to the invalidation of these rules as currently proposed. One of these technical issues is that administrative rules are prospective in nature. Mr. Waldrop went on to state, "The Association of Racing Commissioners International national database, the required central database into which the points are reported and monitored, was up and running as of Feb. 1, 2014, and all medication violations are being assigned points as of Jan. 1, 2014. In short, the industry has begun to keep score of multistate offenders while the individual states complete their rule-making and adoption process."

If the industry is already keeping score and assigning points to a trainer's official ARCI record, those points assigned prior to any administrative rule's effective date in Indiana become problematic. As currently written, the commission would be required ("shall") to incorporate those points into any MMV penalty. This is tantamount to issuing a current penalty for a transgression that had already occurred prior to the existence of the penalty. In the same way in which 'three strikes and you're out' laws are routinely overturned by appeals courts for application of a retroactive penalty, any use of assigned points prior to any MMV effective date in Indiana could lead to the same result.

The regular rulemaking process, in addition to establishing MMV rules as emergency rules, would allow for a much broader review of the technical issues involved with these proposed rules.

Thank You,

Jim Hartman
IBOP Vice-President

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.