

Uniform Medication Rules and Federal Oversight:

Past, Present and Future

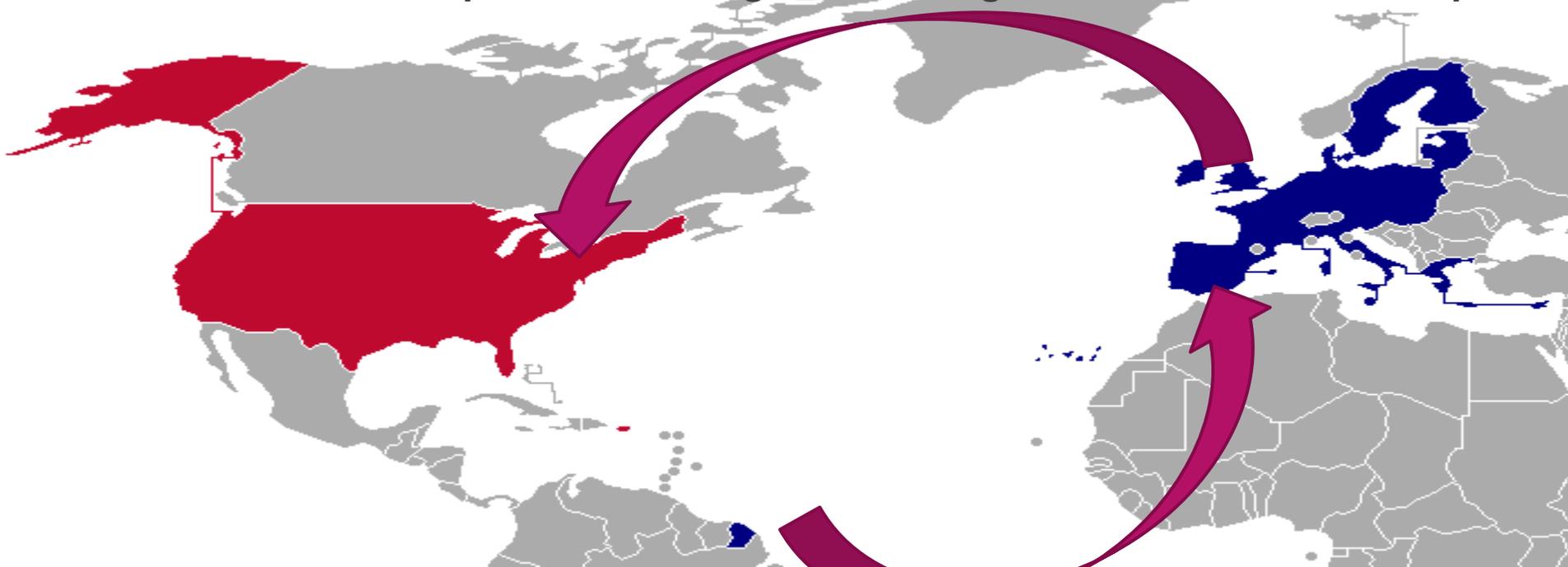
CLARA FENGER, DVM, PHD, DACVIM

SECRETARY, NORTH AMERICAN ASSOCIATION OF RACETRACK VETERINARIANS

Regulation of Horse Racing:

- ▶ **History of Drug Abuse in Horse Racing:**

- ▶ 1750: The leaves of the cocoa plant were brought to England from Peru for use in racehorses (cocaine and caffeine):
- ▶ 1895: “Speed Sustaining Elixir” brought to America from Europe



Regulation of Horse Racing:

- ▶ **History of Drug Abuse in Horse Racing:**

- ▶ **1892: Trainer Rankin was suspended for administering an injection to *Indian Rubber* prior to a race in New Orleans:**

“After the race it was announced that the injection given the horse was not the usual one of cocaine, morphine, or whatever the stuff they used – brandy, perhaps – but was a harmless dose of water, and that it hurt instead of helped the horse.”

Regulation of Horse Racing:

▶ History of Drug Abuse

- ▶ 1901: “Doc” Ring has an “injection,” likely containing cocaine, which makes the round in New Jersey

“As used by Ring the new agent was a hypodermic injection, the component parts of which were known to Ring alone. He refused to accept pay for his services in the use of the syringe, and stipulated always that his only recompense should be a bet...”

Regulation of Horse Racing:

- ▶ **History of Drug Abuse in Horse Racing**
 - ▶ 1930's: Nitroglycerine, heroin, cocaine, strychnine, ephedrine
 - ▶ 1940's/1950's: Amphetamines
 - ▶ 1960's: Bute, Lasix
 - ▶ 1970's: Talwin, Fentanyl
 - ▶ 1980's: Etorphine (Elephant juice)
 - ▶ 1990's: Erythropoietin
 - ▶ 2000's: Cobra venom, Dermorphin

Regulation of Horse Racing:

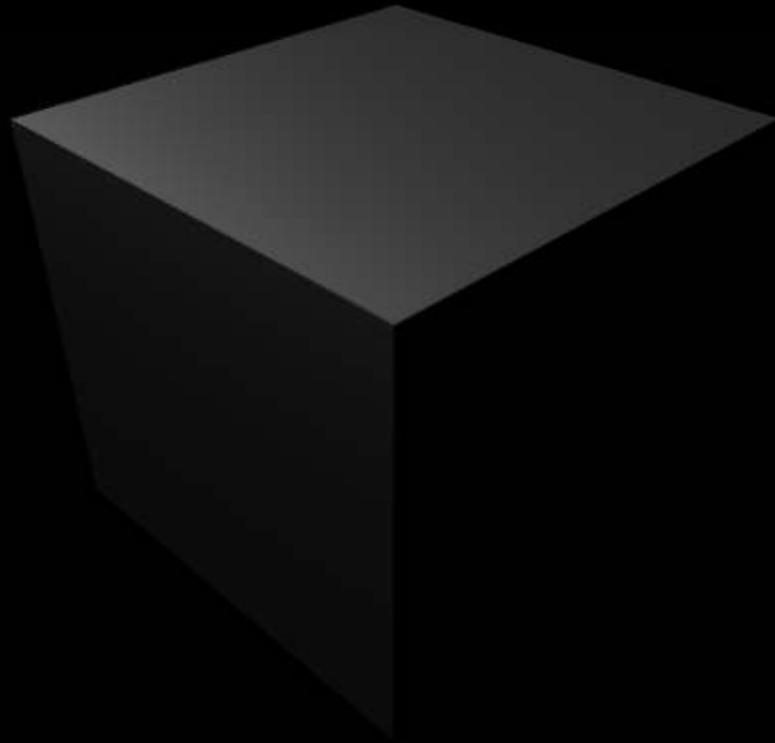
▶ History of Drug Testing

- ▶ Early 1900's: Horse saliva administered to frogs in Russia
- ▶ Early 1900's: France begins testing using analytical chemistry methods
- ▶ 1935: First US labs set up in Florida, then New York
- ▶ 1947: The Association of Official Racing Chemists (AORC) formed
- ▶ 1980's: Thin Layer Chromatography used to screen samples
- ▶ 1988: Introduction of ELISA testing
- ▶ 2000's: Instrumental Mass Spectrometer screening

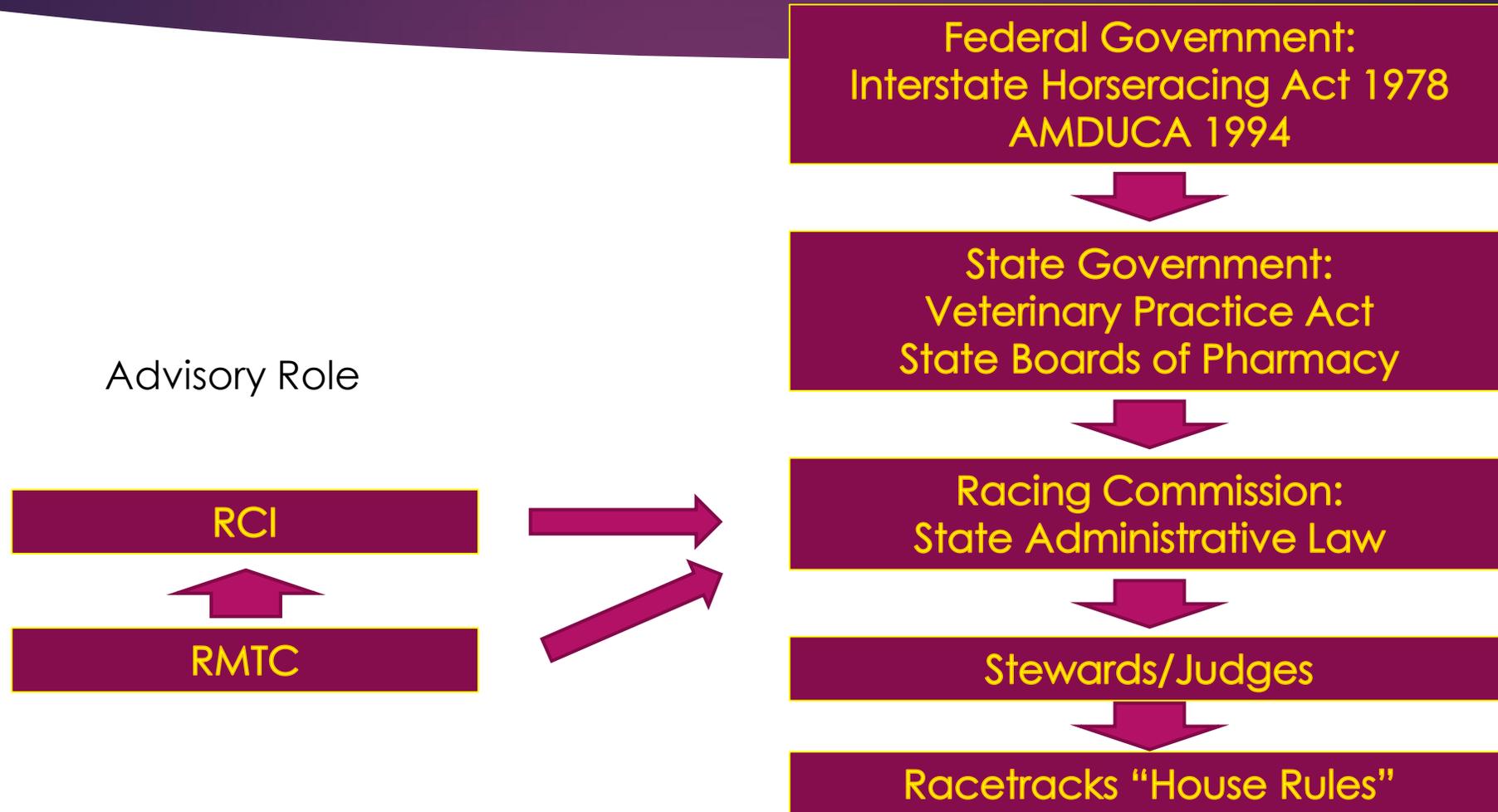


How are Rules
Promulgated Now?

Inside the black box:



Regulatory Oversight of Drugs in Racing



Regulatory Oversight of Drugs in Racing

Federal Government: Interstate Horseracing Act 1978

The IHA of 1978 permitted interstate wagering on simulcast signals and is responsible for over 90% of the money generated by the racing Industry

A key provision of the IHA is the absolute veto power by the horsemen to block the simulcast signal if an equitable agreement cannot be reached with the tracks

This veto power is the only arena in horse racing where the cash-strapped many have a voice in an industry dominated by large corporate and wealthy individuals

Regulatory Oversight of Drugs in Racing

Federal Government: AMDUCA 1994

The Animal Medicinal Drug Use Clarification Act of 1994 is the only Federal law regulating the use of drugs by veterinarians in animals, and has two primary provisions:

1. AMDUCA permits the use of any legal drug for use in a veterinary species on the recommendation of a veterinarian
2. AMDUCA requires a valid Veterinarian-Client-Patient Relationship for prescription drugs to be used in animals

Regulatory Oversight of Drugs in Racing

State Government: Veterinary Practice Act

Every state has a Veterinary Practice Act, which regulates the licensed veterinarians in the state.

These regulations vary state by state, but govern legal and ethical behavior among veterinarians.

Typical provisions are Veterinarian-Client-Patient Relationship for prescriptions, confidentiality of medical records, etc.

Regulatory Oversight of Drugs in Racing

State Government: State Boards of Pharmacy

Every state also has a State Board of Pharmacy, which regulates how medications can be dispensed in the state.

These regulations vary state by state, but govern prescription drugs, both manufactured and compounded.

Typical provisions are medical labeling, how compounded medications can be prescribed or dispensed, etc.

Regulatory Oversight of Drugs in Racing

Racing Commission: State Administrative Law

In those states with Racing Commissions, the Commission is charged with the oversight of the integrity of racing to ensure a level playing field

These administrative regulations typically include drug thresholds, restricted administration times, and penalty structures

ALL STATES HAVE ANABOLIC STEROID AND BLOOD DOPING BANS IN EFFECT, but have minor variations on the uses of therapeutic medications

Regulatory Oversight of Drugs in Racing

Stewards/Judges

Stewards/Judges have the role of the police force and first line of judicial oversight

Stewards/Judges notify the horsemen of any medication violations, and can adjust punishments with limitations by evaluating “mitigating circumstances”

Regulatory Oversight of Drugs in Racing

Racetracks "House Rules"

Racetracks can also exercise their Fifth Amendment private property rights, by which it is the owner's exclusive authority to determine how private property is used

Typically, these rules include safety or liability provisions, such "no glass by the pool" or "all dogs must be on a leash"

Recently, tracks have extended these to medication rules:

Los Alamitos: clenbuterol ban

Gural tracks: Cobalt thresholds

Stronach tracks: On track pharmacies

Regulatory Oversight of Drugs in Racing

RCI

Racing Commissioners International is the only umbrella organization of official rule making bodies for professional horse racing

RCI consists of representatives from commissions of most racing jurisdictions, and serves in an advisory capacity to racing commissions and legislatures

Draft rules are submitted to RCI, and reviewed and voted on

Model Rules which are approved in this manner are brought to racing commissions and legislatures for adoption

Regulatory Oversight of Drugs in Racing

RMTC

The Racing Medication and Testing Consortium evolved out of a 2001 AAEP Racing Medication Summit to craft a National Uniform Medication Policy (NUMP)

The RMTC consists of 23 members which include horsemen's groups, racetracks and other industry representatives (but not all industry representatives)

The RMTC has been the major advisory voice to the RCI on the topic of medication policy over the last 10 years.

How we got here: the RMTC

- ▶ **The assignment of the RMTC: Develop Uniform Medication Rules**
 - ▶ Permit the use of therapeutic medications for the treatment of a living breathing animal athlete using the most advanced Modern Medicine for the benefit of the horse
 - ▶ Prohibit the use of all performance enhancing drugs (PEDs) within proximity to racing for a level playing field
 - ▶ Impose penalties sufficiently harsh to discourage cheating

Uniform Therapeutic Medications

- ▶ The RMTC took on the Herculean task of crafting a Uniform Medication Policy with a Uniform Penalty Policy, and made the cornerstone of the program the **Controlled Therapeutic Medication Schedule (CTS)**.
 - ▶ The RMTC took 26 medications which are used in a therapeutic fashion in horses, set the threshold for some in the picogram quantities, and set the penalties at mandatory disqualification for these violations.
 - ▶ A multiple medication violation system was recommended, which would add escalating penalties for multiple **therapeutic** and other medication violations

RMTC's "Accomplishments"

- ▶ 4 "legs" to the RMTC's NUMPS"
 - ▶ Controlled Therapeutic Schedule
 - ▶ 3rd Party Lasix Administration
 - ▶ Multiple Medication Violation Penalties
 - ▶ RMTC Lab Accreditation

Current State of Uniformity in Racing

- ▶ NUMPS plagued with problems:
 - ▶ Lack of appropriate science to support thresholds and withdrawals...resulting in positives across the country:
 - ▶ Delaware-betamethasone
 - ▶ Virginia Steeplechasing-Depo-Medrol
 - ▶ Dexamethasone, Banamine, Xylazine...
 - ▶ Legality of the MMV system questioned

Incidental Environmental Exposure

- ▶ The RMTC refuses to evaluate or investigate setting thresholds for substances which may result from incidental exposure:
 - ▶ Common over the counter substances used in humans, such as Ibuprofen or Naproxen
 - ▶ Common prescription medications used in humans, such as Ritalin or Tramadol
 - ▶ Substances of human abuse, such as methamphetamine, cathinone (bath salts)
- ▶ The result is that positives for these substances are being called across the country in picogram concentrations

Exactly How Much is a Picogram?

- ▶ A picogram is a trillionth of a gram
- ▶ Exactly how many is one trillion?
- ▶ One trillion **seconds** ago, or 31,000 **years** ago, this cave drawing was created by our Paleolithic ancestors
- ▶ ***Under No circumstances does a picogram quantity of ANY substance have a physiologic effect***



Consequences of picogram detection

- ▶ Methamphetamine positives:
 - ▶ Meth positives across the Globe at sub-100 pg/mL levels
 - ▶ Kentucky, Ontario, Australia, Minnesota, Oklahoma
- ▶ Therapeutic Medications:
 - ▶ Xylazine in Washington State
 - ▶ Betamethasone in Princess of Sylmar in Delaware Handicap 2014
 - ▶ Depo-Medrol, Dexamethasone, triamcinolone, Levamisole, etc

And the end result was...

10/03/2014 1:26PM

O'Neill barred from entering horses in Breeders' Cup

By Jay Privman

Print

Recommend 21

Tweet 14

+1 0

Comments



Trainer Doug O'Neill

Trainer Doug O'Neill, recently by the New York State Gaming Commission for a medication violation, is not allowed to add horses to his stable over the next 12 months.

INDIANA GRAND REPORT: 47 DRUG POSITIVES

by Press Release | 12.17.2014

Facebook Twitter LinkedIn YouTube Tumblr + Email Print

RECOMMEND

The Indiana Horse Racing Commission has issued 47 drug test positive rulings for positive tests for various substances over the past 12 months.

Sheppard fined after two horses test positive for methocarbamol

Updated on 08/14/2014 3:30PM

By Matt Hegarty

Print

Recommend 17

Comments 10

Email

SARATOGA SPRINGS, N.Y. – Hall of Fame trainer Steve Asmussen and assigned one point under Delaware's new medication rules for positives for the muscle relaxant methocarbamol in two horses.

Two \$1,000 fines were levied at Delaware tested positive prior to a race in Delaware on Aug. 26, after tests of samples pulled from five of his horses indicated illegal concentrations of a painkiller that was indicative of the drug being administered according to a complaint prepared by the commission.

Indiana commission seeks 3-year ban for trainer Norris

By Matt Hegarty

Print

Recommend 8

Tweet 1

+1 0

Comments

The Indiana Horse Racing Commission is seeking to suspend a trainer for three years for failing to report a medication violation. The trainer named in the complaint, Mike Norris, was summarily suspended by the commission on Aug. 26, after tests of samples pulled from five of his horses indicated illegal concentrations of hydrocortisone succinate, the name for the medicinal form of the natural occurring steroid hormone cortisol, which is released in the body in response to pain and stress.

The post-race samples were pulled from horses who ran at Indiana on May 28 to June 20, according to the complaint. In a report accompanying the suspension, the commission cited "mitigating factors" that led to the positive, according to a report based on multiple samples. Rick Sams, the commission's executive director, said the commission is not aware of any other trainers who have been suspended for similar reasons.

THIRD TIME'S NOT A CHARM: RODRIGUEZ GETS THIRD DRUG POSITIVE

by Paulick Report Staff | 03.30.2013 | 8:07am

RECOMMEND

Trainer Rudy Rodriguez, who conditions undefeated Kentucky Derby hopeful Vyjack, has had a third horse test positive for Banamine, according to a report in the Daily Racing Form. Rodriguez is currently serving a 20-day suspension after two other horses in his barn tested positive for the same medication. Rodriguez's brother and assistant trainer, told the Daily Racing Form that Marquet tested positive for flunixin, the name Banamine, after winning a race at Aqueduct March 10.

GULFSTREAM PARK

Ray? Grants

Ask Me



DARBY DAN FARM



Ask Ray? tips+questions+grants

Ask Me



Trainer Rudy Rodriguez

ROCKY TRANSITION FOR NEW DRUG RULES IN WEST VIRGINIA

by Ray Paulick | 07.29.2014 | 8:07am

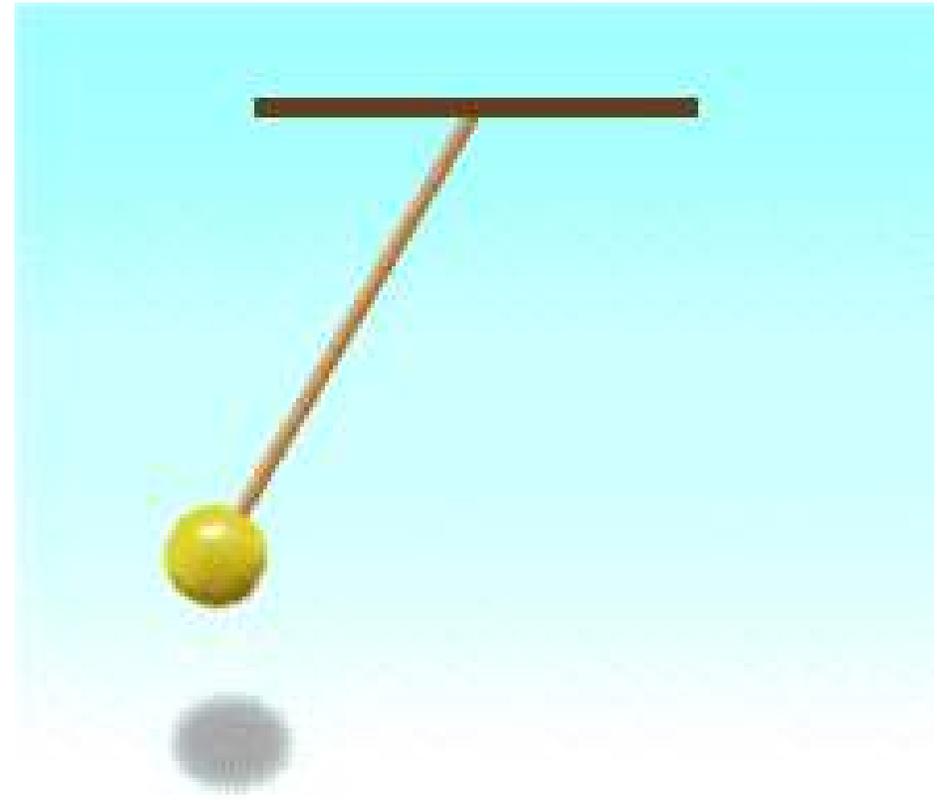
RECOMMEND

Facebook Twitter LinkedIn YouTube Tumblr + Email Print

West Virginia horseracing's transition to new medication rules has been a rocky one. Since the so-called Mid-Atlantic Uniform Medication Rules went into effect on July 9, dozens of trainers and owners have been fined or suspended for medication violations. The transition has been particularly challenging for trainers who have been used to the more lenient rules of the past.

Uniform Therapeutic Medications

- ▶ **The Result?:** Insufficient information is available to allow veterinarians to make recommendations to trainers on how to use therapeutic medications in racehorses.
- ▶ The pendulum has swung from the “olden days” of performance enhancing drugs to over-regulation of therapeutic medications





Widespread drug abuse dating back as long as horses have raced.

NUMPS is fraught with inaccuracies leading to persecution of honest horsemen, while cheaters go undetected

Is this Industry even worth saving?



WHOA

Drug Abuse in Horse Racing: Current

- ▶ **WADA (2012):**
- ▶ 1.19% positive tests out of 267,000 tests in athletes worldwide
- ▶ **Half of those tests were for illegal anabolic steroids**



Drug Abuse in Horse Racing: Current

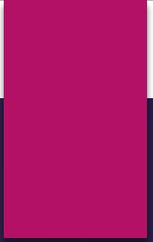
- ▶ In US horse racing, in 2013, out of 346,840 horses tested, only 0.34% were declared post-race positive tests.



- ▶ Of these, the majority were overages of therapeutic medications, with a very small number of positive tests for anabolic steroids.

Drug Abuse in Horse Racing: Current

- ▶ Human Sports overseen by WADA: 1.19% positive, likely “true” cheating
- ▶ US Horseracing: 0.34% positive, very few “true” attempts to cheat
- ▶ **Horseracing is doing a better job regulating itself than human sports overseen by a central regulatory body**



What is the Rule Making
process Now?

Where do Rules come from?

- ▶ Any Industry stakeholder can submit a draft rule for consideration
- ▶ The RCI Model Rules Committee meets twice a year to consider new rules
- ▶ Almost all medication rules in the last 10 years have been submitted by the RMTC

Where do Rules come from?

- ▶ Problems are identified
 - ▶ Public perception of widespread abuse
 - ▶ Regulatory “Intel”
 - ▶ Surveys? McKinsey Report
- ▶ Organizations react:
 - ▶ Every level of regulatory oversight

Where do Rules come from?

- ▶ Rules are reviewed and voted on at RCI Model Rules Committee Meetings
- ▶ Rules are debated at the local level and adopted (or not) at local commission levels
- ▶ This process reveals all of the warts and shortcomings, allowing revisions and adjustments to go back to RCI



Federal Regulation:

Why Not?

Uniformity and Therapeutic Medications

- ▶ This system works:
 - ▶ It is NOT fast...this is **GOOD**
 - ▶ A slow system of adopting Uniform rules allows the shortcomings to be identified before widespread adoption across the country
 - ▶ All concerned parties CAN show up at RCI Model Rules Meetings and express their concerns.

Uniformity and Therapeutic Medications

- ▶ We have Uniformity where it counts:
 - ▶ Anabolic Steroids BANNED in proximity of racing
 - ▶ All blood doping agents BANNED
 - ▶ RCI Rule Committee meetings twice a year for rapid review of emerging threats

Uniformity and Therapeutic Medications

▶ Federal Legislation:

- ▶ We cannot allow a third disinterested party a backdoor into the IHA: It is the only mechanism by which the horsemen have a vote
- ▶ The current proposed bill strictly endorses the flawed NUMPS system which is currently wreaking havoc on racing across the country
- ▶ There is a loophole by which funding of the THADA can be provided by wealthy private entities, endangering its “impartiality” further marginalizing the rank and file of horse racing: the horsemen



Uniformity of therapeutic
medication in Horse
Racing going forward:

A lost cause?

Uniformity and Therapeutic Medications

- ▶ Common sense thresholds:
 - ▶ The RMTC's work was a positive step in the right direction, but fell short of being able to cobble together a fair and workable NUMP
 - ▶ Picking up where the RMTC left off, the vets and horsemen can finish the job started by the RMTC, and the end result will be VALID thresholds and withdrawals which can serve as a basis for a Uniform Policy

Uniformity and Therapeutic Medications

▶ Common sense thresholds:

- ▶ A collaboration between HBPA affiliates, as well as Harness and Quarter Horse associations with the Equine Health and Welfare Alliance and the North American Association of Racetrack Veterinarians has started threshold research initiatives on:
 - ▶ Methylprednisolone (Depo-Medrol)
 - ▶ Betamethasone
 - ▶ Dexamethasone

Uniformity and Therapeutic Medications

- ▶ Common sense thresholds: Future Goals
 - ▶ Crafting of common sense thresholds for incidental environmental exposure positive tests
 - ▶ **PUBLISHED** research to support the use of therapeutic medications, and rational withdrawals and thresholds
 - ▶ The argument that rules must be implemented before the publication of the underlying science is fallacious:
 - ▶ It takes 3 to 6 months for most online journals to publish research: This is NOT an unreasonable expectation.