Proposed Phenylbutazone (PBZ) Rule Change





Dr. Keegan's study -- 2008

"...there is scant objective evidence that a combination treatment with phenylbutazone and flunixin meglumine allows horses with lameness to perform as if they were sound such that veterinary inspection is compromised..."

Discussing study horses with lameness grades of 1-3 that were treated with PBZ alone or with PBZ + Banamine and the level of PBZ ranged from .28-8.58 ug/ml (mean 3.6 ug/ml).

"...neither treatment regimen was successful at completely masking lameness." In fact, "Five horses had an increase in lameness after both NSAID treatment regimens."

Dr. Keegan Am J Vet Res (69) 2008

?? The Questions ??

- ➤ Minimum therapeutic dose of PBZ?
- ➤ Same effect for every pathologic condition or anatomic location (foot pain vs. bone/muscle/visceral/ or joint pain)?
- ➤ What level of PBZ is present during the pre-race exams?
- ➤ Does PBZ at 2, 5, 7, or 10 ug/ml interfere with the exams?
- ➤ Are pre-race exams effective at identifying at-risk horses?

Phenylbutazone: Minimum Therapeutic Level



- ➤ 7 ug/ml Dr. Eduardo Jenny 1979

 Journal of Veterinary Pharmacology and Therapeutics
- ➤ EffectivePC 4.44 11.25 ug/ml based on calculations by Dr. Toutain EVJ 34 (3) 2002
- ➤ 5 ug/ml Dr. Scott Stanley 2010
 Comment at CHRB Medication Committee Meeting
 (Discussing the level at which analgesia <u>begins</u>)
- ➤ CTDuration 14 16 hours
 Toutain et al J Vet Pharmacol Ther 1994

"The levels of the NSAID's permitted on race day are arguably well below a clinically active dosage.

In fact, in California where the 5 ug/ml in plasma level (for PBZ) has been in place for nearly 20 years, the vast majority of horses test below the 2 ug/ml level.

The 5 ug/ml level simply provides a safety margin to avoid inadvertent positives."

** Dr. Rick M. Arthur, California Equine Medical Director, in a letter to the Oregon Racing Commission (from the Oregon HBPA)

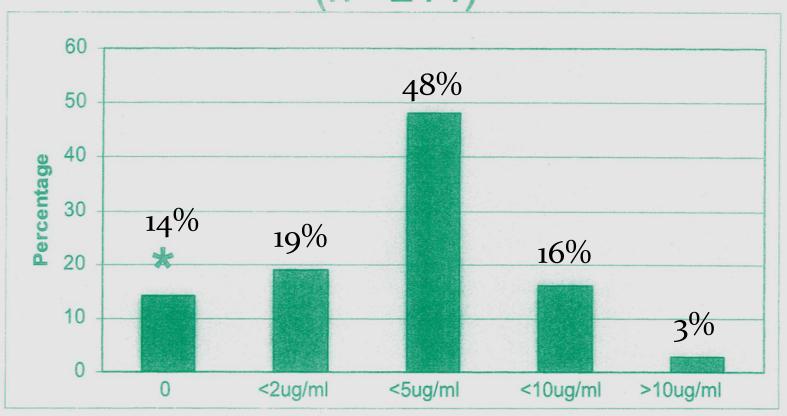
Are High PBZ Levels a Problem in California?

- ➤ More than 80% of California horses have < 2 ug/ml of PBZ in the post-race sample.
- More than 90% have < 3 ug/ml.</p>

The current 5 ug/ml PBZ rule established an allowable level that is below any stated analgesic threshold of PBZ so that horses are not racing on pain-killing dosages.

Note: Approximately 81% of the samples are <5 ug/ml 90% are <7 ug/ml (best guess)

CA & KY Exam Time Samples (n= 214)



Includes 10 samples with flunixin in excess of regulatory threshold

Actual percentages were not provided. The numbers depicted are based on this graph.

Numerous studies have estimated the incidence of racing injuries in various racing jurisdictions: Racing Injuries – Between 3.3 and 8.4/1000 starts (Avg. 5.9/1,000 starts) Catastrophic Breakdowns – Between 1.4 – 1.9/1,000 starts (Avg. 1.7/1,000 starts) California Starts - now average about 73/race day it takes 13.7 days of racing to have 1,000 starts. Pre-race exam PBZ level – 90% of horses are <7 ug/ml (the minimum therapeutic dosage) - 80% are <5 ug/ml

Statistical Analysis

On average 1 horse will be injured every 2.3 race days or 168 starts

- It will take 23 race days (1,680 race starts) before 1 injured horse would have had a PBZ level above 7 ug/ml during the pre-race exam the level at which PBZ might begin to affect certain conditions minimum therapeutic concentration.
- It will take 81 race days or 5,913 starts before 1 catastrophic breakdown would have had a PBZ level > 7 ug/ml during the pre-race exam.

- Dr. Cohen's studies in Kentucky demonstrated that pre-race exams are effective:
- ➤Only 3.5% of non-injured horses were identified to be at greater risk while 18.5% of injured horses were so identified.
- ➤ Regulatory veterinarians identified areas of concern on far more horses than were actually injured during the study period (834 identified, 36 injured 26 high-risk and 10 low-risk).
- >Exams demonstrate sensitivity, but not time specificity.
- > Horses in the high-risk group were injured at 4X the overall rate.
- Horses found to have fetlock, suspensory or tendon abnormalities were 2.4, 3.4 and 15 times more likely to be injured than normal horses.

Variable Effectiveness of PBZ

- Foot pain managed for 24 hours conditions studied rare in racehorses
- Carpal arthritis model pain managed for 14 hours arthritis is common
- ➤ Naturally occurring fore and hind limb osteoarthritis with lameness grades 1-3 not totally masked by PBZ or PBZ + Banamine at 12 hours
- ➤ Surgical pain managed for 8.4 hours
- ➤ Back pain managed better with massage and chiropractic treatment
- PBZ does not decrease pain from thermal stimuli
- > Other factors may have greater impact on exams:
 - -- Hydro-therapy, Ice, Massage, Pre-exam exercise??



In 2001, Dr. Mary Scollay commented on catastrophic musculoskeletal injury rates in California, Kentucky and Florida.

Kentucky had a four hour medication rule for phenylbutazone and flunixin, and these medications could also be used in combination.

California & Florida were 5 ug/ml.

Catastrophic Musculoskeletal Injury Rates:

Florida -- 1.2/1,000 starts (5 ug/ml Rule)

Kentucky -- 1.4/1, 000 starts (no regulatory limit)

California -- 1.7/ 1,000 starts (5 ug/ml Rule)

**Obviously many factors affect injury rates, not just PBZ levels.

