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July 7, 2011

Dear Commissioners, Owners and Trainers,

On July 21, 2011 the CHRB will hear comments and vote on Proposed CHRB Rule 1844 (Reduction of allowable post-race levels of Phenylbutazone "Bute" and Flunixin "Banamine").

It has been stated that the levels of Bute currently present in our racing Thoroughbreds interfere with the regulatory veterinarians' pre-race examinations by masking pain, inflammation and lameness. This interference causes the regulatory veterinarians to miss pre-existing conditions during these examinations leading to racing injuries and catastrophic breakdowns. It has also been stated that the need to lower the allowable post-race Bute level from 5 ug/ml to 2 ug/ml is a safety issue for both jockeys and horses. It has even been suggested that the current levels of Bute were responsible for the 18 fatalities at the most recent Santa Anita meet as well as for the threefold higher racing fatality rate in the United States than in other nations. While much has been stated, very little scientific evidence has been presented to support any of these comments.

Please be aware that while the allowable post-race level of Bute in California is currently 5 ug/ml, very few horses even approach this level. In fact, 85% of California horses already race with less than 2 ug/ml and over 90% race with less than 3 ug/ml. Virtually all of the remaining horses (less than 10%) race with less than 5 ug/ml of Bute present. These figures lead to the fact that **California horses already race with an average post-race Bute level of less than 2.35 ug/ml**.

For the proposed rule change lowering the allowable post-race Bute level to be a "safety issue", Bute at the levels currently present in our horses MUST cause injuries and catastrophic breakdowns. No scientific study has ever demonstrated a link or causative association between these low levels of Bute and racing injuries or fatalities.

It is also a fact that **pre-race examinations by regulatory veterinarians have been** scientifically proven to be effective. In these studies, regulatory veterinarians identified far more horses with pre-existing conditions than were actually injured during the study period. These studies were conducted in Kentucky during a time when Bute and Banamine could be administered together up to four hours prior to racing. The levels of Bute present in these horses were two to three times higher than in our California horses and many horses had both Bute and Banamine present during the prerace exams. The level of Bute present during pre-race veterinary examinations in California has never been documented to interfere with these pre-race veterinary examinations or with the detection of pre-existing conditions.

While California's pre-race veterinary examinations are not standardized or quantified and are not regulated to occur at a specified time prior to racing, these examinations are generally conducted about six to eight hours prior to racing. This timeframe is essentially the same as one Bute half-life. This means that if the average California horse races with less than 2.35 ug/ml of Bute, the average horse will have a Bute level of less than 4.7 ug/ml during the pre-race exam. As I have mentioned, 85% of our horses already race with a Bute level of less than 2 ug/ml. Therefore 85% of our horses, the vast majority of California horses, will have less than 4 ug/ml of Bute in their system during the pre-race veterinary examinations. Once again, this low level of Bute has NEVER been documented to interfere with pre-race veterinary examinations or with the detection of pre-existing conditions and has NEVER been associated with the occurrence of injuries or catastrophic breakdowns.

Please consult the articles and accompanying discussion posted on the CTT website for more information. These items provide documented scientific facts demonstrating that:

- The average level of Bute in post-race samples from California horses is less than 2.35 ug/ml.
- > 85% of California horses have a post-race Bute level less than 2 ug/ml.
- Pre-race veterinary examinations are effective at identifying pre-existing conditions even when Bute and Banamine are both present in the plasma.
- The Effective Plasma Concentration (EPC) of Bute has been established and can be utilized to determine if the level of Bute present in a horse's system is capable of producing clinically visible therapeutic effects. The EPC is the level of Bute necessary to provide clinically therapeutic effects.
- The Effective Plasma Concentration (EPC) of Bute was originally published in 1979 by Dr. Jenny as 7 ug/ml.
- Dr. Toutain utilized calculations based upon the excretion rate and half-life of Bute (which vary widely between horses) to generate an EPC range of 4.44 – 11.23 ug/ml.
- Virtually every horse racing in California has a post-race Bute level below any published EPC for Bute.

- Dr. Toutain calculated the clinical therapeutic duration of Bute to be between 14-16 hours.
- Clinical studies have demonstrated that the duration of action of Bute depends upon the condition being treated. The times below represent the duration of lameness improvement, not the total absence of lameness.

Ineffective on thermal pain 8.4 hours for surgical pain 14 hours for a carpal arthritis model 12-14 hours for naturally occurring arthritis 8-24 hours for various causes of foot pain

- Horse racing injuries and fatalities are multifactorial in nature and the incidence or rate of their occurrence has never been shown to be attributable to Bute usage at the low levels found in California race horses.
- In the paper by Dr. Dirikolu said to demonstrate a connection between higher levels of Bute and injury occurrence, the average Bute level in the injured group was 5.8 ug/ml (a violation under our current rules). The injured group also had Banamine present 71% of the time in addition to Bute (another violation) and the vast majority of horses with Banamine present had levels more than twice our current allowable limit for Banamine (a third violation).
- The average Bute level in Dr. Dirikolu's uninjured groups (Winners and Randomly selected horses) was 4.4 ug/ml. In other words, an average Bute level of 4.4 ug/ml was not associated with injury occurrence in this study. The average Bute level in California horses is already less than 2.35 ug/ml.
- No scientific study has ever demonstrated an association between Bute levels below 5 ug/ml and the occurrence of injuries or catastrophic breakdowns. This level has also never been documented to interfere with pre-race examinations and the detection of pre-existing conditions.
- In a recent RMTC study, one horse out of twenty treated with 2g of Bute administered IV possessed a Bute level of 2.1 ug/ml at twenty-four hours post-treatment. If this rate holds, we would see 500 overages in every 10,000 starts – 5% of all horses treated with 2g of Bute IV at 24 hours before racing will be over the 2 ug/ml level.
- Utilizing the data from the study above and the internationally adopted method used to establish regulatory thresholds, the standard 2g dose of Bute administered IV at 24 hours prior to racing would result in a regulatory threshold of about 3 ug/ml (2.5 – 3.3 ug/ml).

The standard 2g dose of Bute, even when administered IV 24 hours prior to racing, will result in inadvertent positives if the 2 ug/ml regulatory threshold is adopted. The standard 2g dose of <u>Bute must no longer be considered a 24</u> <u>hour medication.</u>

We as horsemen have a duty to consider what is in the best interest of the horse, the breed, the industry and the public. Public opinion does matter and will impact the viability of our industry moving forward. Our commissioners must weigh the effects their decision on this proposed rule change will have on each of these areas. I am certain that the horsemen will stand firmly behind rules that are clearly demonstrated to improve the health, safety and welfare of the horse.

In regards to the matter before us, we must remember that **the average California horse** already races with a level of Bute that is less than 2.35 ug/ml. When 85% of the population already races with less than 2 ug/ml, the proposed change will not be hard to meet, but it will also have very little beneficial effect. However by stating that Bute (the standard 2g dose IV) is still a twenty-four hour medication, the 2 ug/ml level will ensure 500 overages per 10,000 starts. This certainly represents a large and negative impact to our industry.

Executive Director Breed has recently announced a research program with UC Davis valued at nearly \$1,000,000. This program is intended to determine the cause of every catastrophic injury suffered by a horse while racing. I suggest that we utilize the newly announced research program to determine if the levels of Bute currently present in California racehorses are associated with injuries and fatalities. We need to determine if this truly is a safety issue or not.

We have been governed by the current 5 ug/ml rule for about twenty years. I propose that we take six to twelve months to study the questions at hand and determine exactly what is fact and what is fiction. Statements are easy to make but only become factual when they are supported by scientific data. We need to determine what the data truly tells us about Bute levels and injury occurrence. We need to objectively look at the data and state the facts rather than make unsubstantiated statements intended to be taken as fact.

Sincerely,

Don Shieldr, DVM

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