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FIFTIES RULES, NINETIES TESTING: THE NEED FOR THRESHOLDS FOR THERAPEUTIC MEDICATIONS

The development of ELISA tests for drugs and medications used in horse racing has led to dramatic increases in the sensitivity and efficacy of equine drug testing. While this increased sensitivity is essential for the detection of highly-potent, illegal medications, it creates significant problems for the industry when these techniques result in the detection of trace residues of legitimate therapeutic medications. For example, ELISA tests for Banamine and Isoxsuprine can detect minute traces of these agents in post-race urine samples from two to four weeks after administration of the last dose. Beyond this, these identifications have, occasionally, given rise to administrative actions based on these detections that have no reasonable basis in science or veterinary medicine.

These administrative actions have no reasonable basis in science or veterinary medicine because the beneficial and therapeutic effects of most therapeutic agents rarely lasts for more than one day after administration of the last dose. On this basis, the detection of minute traces of therapeutic medications for very long periods after the therapeutic effects of these agents have dissipated serves no useful regulatory purpose and adversely impacts the proper veterinary care of racehorses. Additionally, the publicity generated by these trace residue identifications does little for the industry, because the racing public or the press very rarely distinguishes between races of therapeutic medications and residues of agents that have no place in racing horses.

As well as being unaware of the specific nature of the medications involved, the racing public also has no awareness of how minute the concentrations of the agents involved often really are. For example, some of these identifications referred to above have been in the very low part per billion (or nanogram/ml) range. The easiest way to convey the reality of one part per billion to a layman is to tell him that one part per billion is one second in his life if he is about 32 years old. When viewed in these terms, the reality of a low

part per billion identification assumes a clearer reality, and they begin to realize the true non-significance of many of these findings.

The absolute non-significance of many of these findings has necessitated re-thinking of regulatory philosophies. In the old days, the chemist simply reported to his authority everything he detected, which automatically initiated an administrative action. However, the chemist who attempts this today can, if he wishes, stop racing dead in its tracks. In the words of Mr. Clinton Pitts, the Jockey Club Steward, "we have fifties' rules and nineties' testing technolgy" and because of this a signicant problem on our hands.

The problem is sufficiently serious that an International Workshop on this subject was convened at the Maxwell H. Gluck Equine Research Center at the University of Kentucky on August 18th and 19th, 1994. This workshop was called by the University of Kentucky, the University of Kentucky Research Foundation, the Kentucky Racing Commission, the Horsemen's Benevolent and Protective Association and the Jockey Club. The workshop had widespread support in the racing industry, including support from regulators, racetracks, horsemen's organizations and numberous individuals prominent in the industry.

The goal of the workshop was to analyze and resovle: to bring together for two days the world's authorities in the area of "Testing for Therapeutic Medications, Environmental and Dietary Substances in Racing Horses", the working title of the workshop. The workshop was attended by about 15 analysts, 15 regulatory veterinarians and thirty administrators and industry leaders from around the world. Additionally, analysts from human Olympic and human Drugs of Abuse (DOA) testing also attended to bring the workshop perspectives from these sister fields.

The analytical portion of the workshop examined the mechanisms by which racing authorities around the world approach the problems resulting from the greatly increased sensitivity of analytical testing. No fewer than seven distinct approaches to this problem were identified and the scientific basis and regulatory efficacy of each of these approaches were set forth by the individuals who developed and applied these approaches.

Having reviewed these differing approaches used worldwide, the workshop then held a round table discussion to review and resolve these approaches. In this concluding discussion, the workshop virtually unanimously supported the principle that there should be "limitations" on the sensitivity of testing for therapeutic medications, environmental and dietary substances in racing horses. The workshop also endorsed the limited sensitivity approach developed by our Canadian colleagues as a workable solution to these problems.

The Canadian approach is defined as "the deliberate non-selection of unncessarily sensitive analytical methods for specific substances." By limiting the sensitivity of their detection methods, the Canadians have effective thresholds for 71 therapeutic medications. The Canadians also have a strict policy of informing the racing community concerning the introduction of new tests for therapeutic medications, to allow the racing community to adapt to changes in the sensitivity of testing procedures.

The Canadian program also involves outreach. The chief veterinarian, Dr. Weber, visits racetracks and educates horsemen on how to read medication package inserts and how to read the medication booklet. Using this approach, the Canadians have reduced the number of therapeutic medication violations, while at the same time have increased their efforts against illegal medication.

Another advantage of the Canadian approach is that because the sensitivity of their testing methods is fixed, their scientists have been able to develop well defined "withdrawal times" for about 71 therapeutic medications used in racing horses. These are very useful guidelines for horsemen and veterinary practitioners, and have apparently reduced the incidence of detection of inadvertent traces of therapeutic medications, and have allowed the Canadian authorities to focus on the detection of illegal medications.

Soon after the workshop, Louisiana formally outlined its approach to the question of thresholds, which approach has been in place for several years. In Louisiana, ELISA tests are not used for ARCI class 4 and 5 medications, which effectively eliminates the use of high-sensitivity testing for these agents. Additionally, Louisiana has a graded penalty system for class 4 and 5 agents. under this system, a first offense for an ARCI Class 4 or 5 agent merits only a small fine. A second offense draws a larger fine, and it is only after the third offense within twelve months that the trainer faces suspension or loss of the purse. After each twelve month period the penalty slate wipes clean, and the whole process starts again.

The Louisiana scientists report that these changes cost almost nothing to implement, reduce the number of identifications of ARCI Class 4 and 5 agents (therapeutic agents) and free up resources to pursue the detection of ARCI Class 1 and 2 agents.

This approach is similar to the strategy that has long been used in Kentucky and has more recently been introduced in Florida. The plan has also been endorsed by the American Association of Equine Practitioners, and more recently, by the ARCI Quality Assurance Program veterinary chemists advisory committee.

This "rolling back" of the sensitivity of testing is, however, at best only an interim solution. A more sophisticated and equitable solution is to determine "threshold" or "cutoff" concentrations in plasma or urine for important therapeutic agents. These thresholds would be analogous to the 5 ug/ml threshold for phenylbutazone used by the ARCI and most United States racing commissions. If the concentration of drug in the plasma or urine test sample falls below the threshold, then the finding is of no forensic interst, and no administrative action is warranted.

The number of thresholds that would have to be developed would, initially at least, be small. This is because the number of therapeutic medications routinely used by equine veterinarians is relatively small, and nine of these agents generate 50% of the chemical identifications. Based on this small number of important therapeutic agents, it is quite practical and cost-effective to develop individual thresholds for the important therapeutic agents used in equine medicine.

In this regard, the recent introduction of thresholds for eight different therapeutic agents used in equine medicine by the California Horse Racing Board must be seen as a very significant step forward. These agents include acepromazine and promazine(25 ppb), albuterol(1 ppb), procaine, atropine and mepivacaine (10 ppb), benzocaine(50 ppb) and salicylate(750 ppm). These thresholds are at this time interim thresholds, and it must be expected that this list will be both modified and added to as the research base in this area develops.

In many ways the defining of thresholds in terms of specific concentrations in a biological fluid is, in forensic and regulatory terms, the most satisfactory approach to the problem of limitations on sensitivity of testing. This is because specific concentration thresholds are easily defined, easily written into the rules and, above all, easily transferred from laboratory to laboratory and jurisdiction to jurisdiction.

A final factor in this new regulatory approach is the enhanced role of the chief Commission Veterinarian. In the past, the Commission Veterinarian's role in the regulatory process was largely limited to expert testimony as to the likely performance effects of the agent in question. In the future, it appears as though the role of the Commission Veterinarian will be expanded to include much needed formal veterinary review of all analytical data.

In summary, therefore, the science of chemical (analytical) testing has improved to the point that we are now compelled to tell the analyst when he needs to stop testing for certain agents. The approach to this solution is two fold. In the first place, limitations on the sensitivity of testing either in the form of specified methodologies or specific thresholds being set in place. Beyond this, the role of the regulatory veterinarian in review of all analytical results is being established.

To this end a short course specifically designed for Commission Veterinarians is being developed to assemble and disseminate the rapidly growing body of information required to effectively regulate this are of racing.

--Thomas Tobin, Department of Veterinary Science, University of Kentucky--

EDITOR'S SIDEBAR (in honor of California courtroom behavior): The New York State Racing and Wagering Board has announced its approval of the use of furosemide, the diuretic commonbly known as Lasix, effective September 1. Jerry Bilinski, new Board chairman, who is also a veterinarian, assumed this job in May. We hope Dr. Tobin was pleased to see this as he was an early supporter of the use of therapeutic medication.