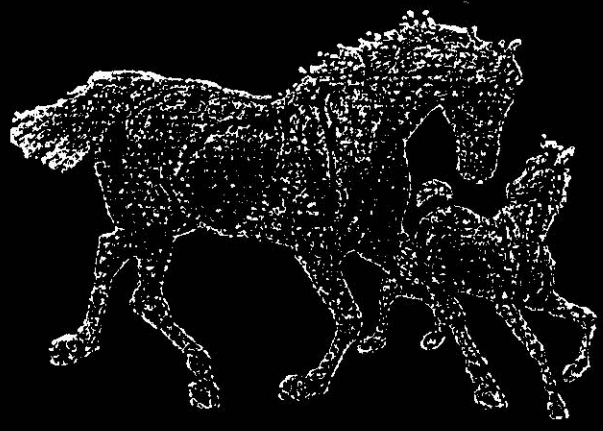

Testing for Therapeutic Medications, Environmental and Dietary Substances in Racing Horses

A workshop held at
The Maxwell H. Gluck Equine Research Center
University of Kentucky
Lexington, Kentucky

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Interim Report

The workshop commenced on the morning of August 18th, 1994 with a welcome to Kentucky from Commissioner C. Bruce Hundley and to the center from the Director, Professor Peter Timoney. The workshop brought together about seventy analysts, veterinarians and industry leaders in the auditorium of the Gluck Equine Research Center. These individuals represented a cross-section of thought in the medication area, from liberal to conservative viewpoints.

Overall, about fifteen analysts were present, including representatives from the US, the UK, Canada, Australia and Hong Kong. Additionally, the director of the ARCI quality assurance laboratory and the official consultant to ARCI attended. Beyond this, analysts from the human Olympic and forensic drug testing areas also attended.

The veterinary area was represented by regulatory veterinarians, an equine medical director, academic veterinarians, commission veterinarians and representatives of the American Association of Equine Practitioners. Countries represented by the veterinarians included the US, Canada, Australia and France and a broad spectrum of opinions was represented.

Other representatives included several commissioners, representatives from the HBPA and ARCI, several attorneys, three Jockey Club representatives, and representatives from the Kentucky Thoroughbred Association and the American Horse Shows Association. Regrets were received from a number of industry leaders including the Honorable Brereton C. Jones, Governor of the Commonwealth, who telephoned a message of greeting to the workshop participants.

As soon as the introductions were completed we set forth the goals of the workshop and established the definitions, guidelines and terms of reference to be used. This ensured that the workshop was focused on ONE SINGLE QUESTION, namely how to handle our increasing ability to detect "trace" or pharmacologically ineffective residues of therapeutic medications, environmental and dietary substances.

This focus was a critical factor in the success of the workshop, since medication discussions easily divert into philosophical exchanges and the participants lose sight of their areas of commonality. By narrowly focusing the workshop, an unusual measure of unanimity was achieved.

Mr. Edward S. Bonnie organized the first discussion panel, which reviewed veterinary and regulatory problems with enforcement of current medication rules and problems associated with the introduction of threshold levels. This panel, which consisted of a practicing veterinarian, a Jockey Club steward and two chemists, was chaired by Mr. Bonnie, a world authority on equine medication and the law. This panel came out strongly in support of the concept of limitations on the sensitivity of testing for therapeutic medications.

What ultimately became the clear sense of the workshop was succinctly expressed by the Jockey Club Steward, Mr. Clinton Pitts. Mr. Pitts pointed out that, "We have 1950's rules and 1990's technology," and, with caveats in the area of costs, this was the message of the introductory panel.

The workshop then presented the points of view of those who are regulated: the owners, trainers, and veterinarians. Next the views of the regulatory professionals, the chemists and commission veterinarians were detailed. Finally, the views of the commissioners were presented. By this time the individual players in the medication control scene had defined their positions and perceptions, and the stage was set for review of the eight identifiable approaches to modulating the sensitivity of the analysts' art.

It must be emphasized that virtually all presentations at the workshop were made by the specific individuals involved in developing and implementing the approaches, namely the ultimate authorities. The organizers of the workshop owe a debt of gratitude to the world leaders in this area for their willingness to travel to Lexington and participate in this workshop, in most cases at no cost to the workshop.

The workshop first reviewed the well-established international thresholds for salicylate, arsenic, DMSO, hydrocortisone and the previous threshold for theobromine, which are all endogenous or dietary substances. The workshop then reviewed the American practice of regulating certain medications, principally non-steroidal anti-inflammatories,

through the use of thresholds. Additionally, the workshop also reviewed the use of thresholds in show horses.

This brought the first day's proceedings to an end, and the group retired to Commissioner C. Bruce Hundley's Saxony Farm where the Commissioner entertained the workshop delegates in true Bluegrass style. The Summer Kitchen at Saxony farm presented a unique setting on a perfect summer night, and the event gave the workshop participants an opportunity to interact in a more relaxed setting.

On Friday morning the workshop reviewed the use of defined but unpublished thresholds, a regulatory approach never hitherto openly presented. This led to what became the critical presentations of the workshop, those of Drs. Stevenson and Weber outlining the Canadian approach to medication control.

Since these were the pivotal presentations of the workshop, they will be described in some detail. The Canadians define their method as the "deliberate non-selection of unnecessarily sensitive analytical methods for specific substances." Simply put, once the Canadians have developed an adequate analytical method for a therapeutic medication, they "freeze" its sensitivity and generate dose and withdrawal time guidelines to assist horsemen in staying within the rules.

The Canadian program has developed withdrawal time information for no less than seventy-one therapeutic medications. These data are published by Agriculture Canada as an eighty page booklet, a copy of which was provided to each workshop participant.

The Canadians emphasize that their approach extends from the laboratory to the backside. Noting that "all drugs are not created equal" and that they are not in the business of prohibiting legitimate therapeutic medication, the Canadian program is proactive. It brings its message and literature directly to the horsemen, teaching them how to read medication labels and use the booklet to avoid inadvertent positives. These outreach programs are coordinated by the Canadian HBPA and have been highly successful.

Another Canadian policy that is also implemented in some US jurisdictions is that of announcing the impending deployment of new tests for legitimate therapeutic medications. This allows horsemen to readjust their medication practices to accommodate the new regulatory reality, and virtually eliminates the rash of positives that may otherwise accompany the introduction of a new test for a legitimate therapeutic agent.

Ms. Stevenson and Dr. Weber emphasized that the Canadian approach made testing for therapeutic medications less expensive and allowed them to focus resources on the detection of illegal medications.

Dr. Richard Sams noted that Ohio also had policies of announcing the introduction of new tests for legitimate therapeutic agents and of his going to racetracks to explain drug testing and violation avoidance to horsemen. Horsemen actively cooperate in these educational approaches and support the vigorous pursuit of illegal medication.

The next approach presented was that entitled "Panel Review/ Medical Director", where an administrative review step exists between chemical identification of a possible violation and regulatory action. Presentations in this area included those by Dr. Robert Jack, Equine Medical Director for the California Horse Racing Board, Dr. Larry Soma of the University of Pennsylvania and Dr. John Lengel of the American Horse Shows Association.

Other approaches presented were those of "Elective Testing" by Drs. George Mundy and Scott Stanley, "Time Rules", "Notification of Treatment" and, finally, the only approach available in the US to date, the compilation of "Withdrawal Time" estimates. At this time also, the workshop overviewed the methods available to quantify pharmacological effects in the horse and technical problems associated with development of urinary thresholds.

The workshop finished with a round table discussion and summary. By this time, it had become evident that limits on the sensitivity of testing for therapeutic medications were needed but that the analysts were uncomfortable with the concept of thresholds. In particular, the analysts were concerned that thresholds would absorb scarce resources and open up points of legal attack. Based on these concerns, the workshop clearly leaned towards the Canadian approach, which was the only comprehensive approach presented.

The summary round table panel consisted of Dr. Richard Sams, Director of the Analytical Toxicology Laboratory of the Ohio State University, Dr. Adrienne Stevenson, administrator of the Canadian

program, Dr. Rick Arthur, a veterinary practitioner from California, Dr. David Cowan of Kings College London, an IOC analyst and Dr. Roland Devolz, a veterinarian from the Societe D'Encouragement, France. The panel was chaired by Dr. Tobin.

The starting point of the final panel was expressed by Dr. Devolz, who said that "As soon as your technology leads you into nonsense, you must reverse direction. The veterinarian needs to be able to do his work. Keep it simple. There is always a solution among pragmatic people."

There was strong support among the panelists for the Canadian solution, defined as "the deliberate non-selection of unnecessarily sensitive analytical methods for specific substances." Once a satisfactory method is developed for a therapeutic agent, the sensitivity of the method is fixed and withdrawal times developed.

The Canadian approach also involves significant outreach. The chief veterinarian, Dr. Weber, visits racetracks and educates horsemen on how to read medication package inserts and how to use the medication booklet to avoid violations. The Canadians believe that their program has reduced the number of inadvertent therapeutic medication violations and allowed them to devote increased effort to detection of illegal medications.

These approaches were strongly endorsed by the workshop, which believed that they represented an economical and workable approach to the problems presented at the workshop.

Reviewing the possibility of adapting the Canadian model to the US, it was noted that nine agents give rise to more than half of the therapeutic medication violations in the US. These agents are isoxsuprine, methocarbamol, dexamethasone flunixin, prednisolone, acepromazine, promazine, pyrilamine and procaine. It was suggested that these agents represent a logical starting point for adaptation of the Canadian approach to other jurisdictions.

In summary, therefore, the workshop clearly supported the thesis that limits on the sensitivity of testing for therapeutic agents, dietary and environmental substances are required. From the approaches presented, the workshop pointed to the Canadian model as the most workable approach. As a potential starting point for adaptation of the Canadian system to the US, the workshop identified the nine therapeutic medications in the US that cause the majority of inadvertent therapeutic medication violations.

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