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Testimony before the House of Representatives, Subcommittee on Commerce, Manufacturing, and Trade

Topic: Horseracing Integrity and Safety Act of 2013".

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1. Summary of Presentation

Progress in Racing Industry Laboratory Accreditation: Prior to 2008, only **5** of the 18 US Racing Laboratories were accredited to the ISO/IEC 17025 standard; as of June 2013, **10** of the 16 are accredited. Laboratories Accredited to ISO/IEC 17025 meet technical and quality management system requirements necessary to consistently deliver technically valid and legally defensible test results to the industry. These standards are globally recognized by Asian Pacific, European Union and Inter-American Accreditation Council; these Councils form the International Laboratory Accreditation Cooperation (ILAC). A committee appointed by the Racing Medication and Testing Consortium **(**RMTC) was charged with developing accreditation program for the Equine Racing Industry. This is in addition to, not a substitute for ISO/IEC 17025 international standards. The aim of the program was to further improve, upgrade and standardize the quality of analysis by equine laboratories and to assure that all laboratories have similar capabilities. This committee developed the "Laboratory Accreditation Requirements and Operating Standards". The requirements for this second level of accreditation are extensive and were guided by the requirements outlined by the U.S Anti-Doping Agency (USADA) laboratories. A major requirement is to successfully participate in External Quality Assurance Program and adhere to performance standards for a Drug and Medication Control Laboratory. To date, 8 racing laboratories are involved in some phase of the accreditation process and 2 laboratories have been accredited.

Progress has also been made on the drug control front. Anabolic steroids have been banned from use in North America and the intra-articular injection of the equine joint has been regulated the result is curtailment of injection close to race time. With the improvement in equipment, high through-put analytical methods have been developed allowing, for example, screening of 60 of anabolic and androgenic steroids in equine plasma. Similar methods have been developed for other drugs allowing for the screening of hundreds of drugs in each sample.

National guidelines were subsequently published by the RMTC which included the intra-articular injection of corticosteroids. Included in this list of drug were guidelines for withdrawal times for the use for 24 of commonly used therapeutic drugs. This allows for treatment of horses during training and if used properly should not be a violation on race day.

2. Accreditation of Racing Laboratories to ISO/IEC 17025:2005 Standards.

One of the first racing laboratories to become accredited by the American Association of Laboratory Accreditation (A2LA) was the Pennsylvania Equine Toxicology and Research Laboratory (PETRL) which is the official racing forensic laboratory for the Pennsylvania Horse and Harness Racing Commissions. The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service, accreditation organization. It provides requirements for the accreditation of all types of testing performed i.e.: chemical, mechanical, environmental, forensic and calibration laboratories, nationally and internationally. Chemical testing and calibration laboratories accredited by A2LA agree to adhere to the strict management system requirements of ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories* and A2LA's proficiency testing and record keeping requirements. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. Accreditation to ISO17025:2005 means a laboratory meets both the technical and quality management system requirements necessary to consistently deliver technically valid and legally defensible test results to clients. This standard is globally recognized by Asian Pacific, European Union and Inter-American Accreditation Council; these Councils form the International Laboratory Accreditation Cooperation (ILAC).

The standards require the laboratory to implement a quality assurance system aimed at demonstrating ability to consistently produce valid and defensible test results, starting from proper handling of incoming samples (maintaining verifiable chain of custody) to reproducibility and accuracy of analytical results. A2LA also requires internal audits by a designated quality assurance (QA) Officer of the laboratory. The QA Officer is expected to identify discrepancies from the laboratory's standard operating procedures (SOP), initiate corrective actions, and indicate opportunities to improve the reliability and reproducibility of testing. The laboratory is also expected to demonstrate on-going competency by regularly analyzing proficiency samples from an accredited or approved proficiency sample provider.

The Pennsylvania laboratory has been re-accredited yearly since 1997. Re-accreditation requires the submission of extensive records from the in-house systems that demonstrate proper quality control over all testing technologies. On-site re-assessments of the laboratory occur every other year. A 3-day inspection by A2LA assessor includes review of all the laboratory procedures and all documented quality control data. The assessor comments on deficiencies, issues a report and A2LA requires all deficiencies to be corrected by the laboratory and approved by a Re-Accreditation Council prior to re-accreditation of the laboratory.

Accreditation by A2LA is requested on a voluntary basis, there is no oversight organization that demands that the laboratory be accredited to conduct testing in the State of Pennsylvania. Fortunately, the PA Racing Commissions required and financially supports accreditation processes. More importantly, because of the size of the laboratory, number of forensic and research samples (> 40, 000) processed each year and the extensive research program a full time Quality Assurance Officer is on the staff as a full time employee.

In the last few years the stakeholders of the Racing Industry and the State Regulatory bodies have been pressing their respective laboratories to become accredited. Prior to 2008, only **5** of the 18 US Racing Laboratories serving racing jurisdictions were accredited to the ISO/IEC 17025 standard and as of June 2013, **10** of the 16 US Laboratories were accredited **(see Racing Medication and Testing Consortium (RMTC), website for updates (www.rmtcnet.com.).**

3. Additional Accreditation by the Equine Racing Industry: Laboratory Accreditation Requirements and Operating Standards

A committee appointed by the Racing Medication and Testing Consortium **(**RMTC) was charged with developing an accreditation program for the Equine Racing Industry. The aim of the program was to improve, upgrade and standardize the quality of analysis by equine laboratories and to assure that all laboratories have similar capabilities in the detection of drugs and a commitment to research. This committee developed the "Laboratory Accreditation Requirements and Operating Standards" **(see appendix 1)**. The requirements for this second level of accreditation are extensive and were guided by the requirements outlined by the U.S Anti-Doping Agency (USADA) laboratories.

To be accredited to the standards established by the RMTC, the laboratory shall maintain accreditation from the relevant accreditation body, to ISO/IEC 17025:2005. Additionally, the laboratories must successfully participate in the horse testing laboratory External Quality Assurance Program, which involves single-masked proficiency test samples. These are blood and urine samples, provided by an Accredited Proficiency Sample Provider, submitted to the laboratory for analysis. The laboratory must successfully identify, confirm, and/or quantify the drug in blood or urine sample. The laboratory knows that the samples are coming, but does not know the content of the blood or urine samples. Included in the set is a blank set containing no drugs. Participation in a double-masked program, is planned, but will not be required until such a program is provided by an accredited proficiency sample provider. The double-masked program differs from the single-masked in that the laboratory does not know that the sample has been shipped to the laboratory, as it is co-mingled with test samples from a race track. The PA Laboratory has had this double-masked program in place for the past 13 years and is administered by the QA officer.

The laboratory must meet all criteria of the (ISO/IEC 17025:2005) for accreditation as they apply to the analysis and reporting of results for equine racing blood and urine samples. The Laboratory shall also comply with the RMTC Code of Ethics, must screen a minimum number of samples per year, and maintain a research program committing at least 10% of the total annual budget to this area and document publication of results. An important part of this program is the sharing of information between laboratories and the laboratory must allow inspection by RMTC at any time.

The above requirements are but a few of the important aspects of the program that determine if laboratories have the capabilities, personnel and instrumentations required to detect substances of concern at the concentrations that are mandated by the racing industry. The stated goal of the RMTC accreditation and External Quality Assurance Program process is to ensure that all laboratories are operating at the same high standard of drug analysis. This consistency will foster uniformity and strengthen the integrity of racing and ensure the safety, health and welfare of all equine and participating human athletes.

4. Voluntary vs. Mandatory Programs

Accreditation of racing industry laboratories to the ISO/IEC 17025:2005 standard is voluntary; it is the responsibility of each State Racing Commission or Authority to insist on accreditation of the laboratory and provide the resources to initiate and maintain the accreditation. The accreditation to the RMTC developed standards is currently ongoing, is voluntary and at the request of each State Racing Commission or Authority. To date, 8 laboratories are involved in some phase of the accreditation process and 2 laboratories have been accredited by RMTC **(**www.RMTCnet.com.) Currently, the resources and personnel to provide proficiency samples, review the laboratory documentation, and conduct onsite inspection are being provided by the industry. Chemist analyzing the samples and personnel providing the proper documentation are resources provided by each laboratory. The process is not without a considerable amount of laboratory personnel time. If a laboratory fails, the consequences are; corrective action, root cause analysis and revocation of RMTC accreditation until RMTC determines that the laboratory can once again meet the accreditation standards.

5. Rules Regarding Medications.

At a hearing before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, held in June 2008, the topic of discussion was "Breeding, Drugs, and Breakdown: The State of Thoroughbred Horse Racing and the Welfare of Thoroughbred Racehorse". Medication issues were discussed in the session in the context of the welfare and safety of horses. The drugs in focus for the presentation were anabolic steroids, intra-articular (joint) injection of corticosteroids and administration of furosemide (Lasix™, Salix™). Progress has been made on the banning of the use of anabolic and androgenic steroids and curtailing the use of the intra-articular injection of corticosteroids into the equine joints. Analytical methods were developed for the detection, quantification and confirmation of anabolic and androgenic steroids in plasma, and the methods were published in 2005 and 2006 [1,2]. Studies were also conducted on the pharmacokinetics (elimination from the body) of 2 of the most commonly used anabolic steroids, boldenone and stanozolol [3]. High through-put multiple drug analytical methods have been developed, validated and published for use by other equine laboratories in their efforts to enforce the ban on anabolic and androgenic steroids in racehorses [4-8].

Administration of anabolic steroids was banned by the State of Pennsylvania and throughout the country in April 2008.

In June, 2009, the Pennsylvania Racing Commissions regulated the intra-articular injections of glucocorticoids, to no less than 7 days prior to race-day. National guidelines were subsequently published by the RMTC which included the intra-articular injection of corticosteroids initiated by the State of Pennsylvania. Included in this list of drug were guidelines for withdrawal from use for 24 of commonly used therapeutic drugs **(see appendix 2).** This would allow for treatment of horses during training and if used properly should not be a violation on race day.

6. Use of Furosemide (Lasix™, Salix™) for the treatment of Exercised Induced Pulmonary Hemorrhage (EIPH)

Furosemide has been used empirically and has been approved for many years by the racing industry for the management of exercise-induced pulmonary hemorrhage (EIPH) or "bleeding" in racehorses. Its use in horses for this purpose has been controversial and has been criticized by organizations outside and inside of the racing industry. North America is the only continent that allows the use of Lasix on race day. Many in the racing industry acknowledge that the administration of furosemide to racehorses is harming the breed. There is no scientific data to substantiate this perception, but unfortunately, perception become reality in the minds of many.

Despite the use of furosemide, horses continue to present blood in the trachea after exercise. No studies have shown a complete absence of blood from the trachea, in horses diagnosed with EIPH post-race or exercise, as a result of furosemide administration [9-15]. The majority of published reports indicate that furosemide does not prevent EIPH in horses.

7. Furosemide and Performance.

Literature available on this subject suggests that furosemide increases performance in horses without significantly changing the bleeding status. In a race track study conducted on Thoroughbred horses, there was an improvement in racing times in many horses after the administration of furosemide with similar observation in Standardbred horses [16-18]. In a population study of 22,589 Thoroughbred horses competing in US and Canada

with and without the pre-race administration of furosemide (Lasix) concluded that horses administered furosemide raced faster, earned more money, and were more likely to win or finish in the top 3 positions than horses that were not administered furosemide [19].

Results from treadmill studies indicated that the increase in speed was due to weight loss produced by the administration of furosemide and not by any specific stimulatory or direct effects on the horse. Thus, the sudden weight loss due to water loss induced by furosemide (Lasix) allowed the horse to run faster. This effect was reversed by the addition of the weight lost [20,21]. Others have also concluded that the reason for the increase in speed of the horse was the loss of weight due to the loss of body fluids produced by the administration of furosemide (Lasix) [22]. Replacing this weight loss negates the effect of its administration.

8. Comments on the Health, Safety and Welfare of Horses

A very basic element in the health, safety and welfare of the horse is the living and training environment of race tracks. Well-ventilated barns are essential in reducing dust in the environment that horses are exposed to on a daily basis, and reducing the transfer of communicable diseases when outbreaks occur. Dusty and poorly ventilated barn conditions contribute to pharyngitis, bronchitis and other respiratory disorders that can sideline a horse from competition. Track surfaces on which the horse train and compete is an issue that that has been discussed in great detail.

Funding for research in horse health, safety and welfare is limited to non-existent and yet the horse carries the burden and the responsibility of keeping us in the business of racing. The total annual economic impact of the horses and horse racing in many states is huge, yet the research on the health issues of one player upon which the weight of the industry rests is generally neglected. Other viable industries have vigorous research and development programs.

There are many health issues that can be addressed, but the ones outlined below can have the greatest short-term and long term economic impact on the racing industry. An area of greatest concern for short-time economic loss in the competing horse, are muscle and skeletal injuries and respiratory and airway diseases. Many of these conditions impact the well-being and prevent the horse from competing on a short-time basis. Conditions

that result in catastrophic economic loss and death in the horse are laminitis, gastro-intestinal emergencies, and catastrophic track injuries. Other areas of concern for maintaining the health and well-being of the horse are lack of good pain management in injured horses and the growing concern of antibiotic-resistant infections, as well as equine nutrition, reproduction, growth, and nutrient management. Maintaining the strength of the gene pool requires investigations into improvement of the longevity of breeding female and male horses and research into foal losses and sustaining pregnancy to term. Others can add to this list of the many conditions were research funds would contribute to the health of the horse. Veterinarians are the primary advocates for the health, safety and welfare of the horse and it is essential that these concerns be actively and regularly addressed.

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