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Medication — Walking the Tightrope

Moderator/Speaker:

Dr. Rick Arthur, Equine Medical Director, California Horse Racing Board

Speakers:

Rob McKinney, Deputy Director, Ontario Racing Commission

MS. WENDY DAVIS: Everyone in this room, thank you. My gosh, you guys are, you are the two-turn horses out here. You can keep going and going and going, I appreciate it. I know it's tough; it's the second to the last panel on the last day. It's great to see you in here and thanks for being so prompt, a little more prompt than we were here this morning or this afternoon.

This afternoon's topic is, "Medication – Walking the Tightrope." Certainly we've got, we may be few in number but we have a lot of information to get to you for this panel session. Your moderator as well as a presenter is Dr. Rick Arthur, certainly no stranger to any of you out there. Let me just remind you that Dr. Arthur has not only been a regulatory veterinarian in his current position, which is equine medical director for the California Horse Racing Board, but for many years was a practicing veterinarian on the backstretch. So when you put those things together, you get someone who really understands the issues from both sides, which I'm sure is very easy to see it from your shoes and never having stood in the other guys shoes.

So, Rick, thank you so very much for agreeing to do this, and I know it's been kind of a whirlwind, we're always on top of AAEP and Rick was there, probably only a few days ago. We could probably count it in hours rather than days, so again, thank you so much for taking the time to come and see us.

DR. RICK ARTHUR: Thank you, Wendy. Thank all of you for being here after lunch. How many trainers are there in the audience; any practicing veterinarians? A couple, good.

Well, "Medication — Walking the Tightrope," you should really have a trainer or a practicing veterinarian up here, because they are the ones that are really walking the tightrope.

But regulators also have the same problem. I just came back from the International Federation of Horse Racing Association scientific advisory meeting in France and they're bewildered as to why we have such odd rules in the States. Because most of the other jurisdictions are operated by NGOs, you have one small little oligarchy that makes all the decisions and that's the way it's going to be. In this country, we have 38 different racing jurisdictions we have to convince to do anything. And there is no unified organization that can tell anybody what to do. And that is why walking the tightrope is so difficult. I am actually going to have Bob McKinney start this lecture. Bob is a deputy director of the Ontario Racing Commission. He has a long history in law enforcement and he is going to be talking about out of competition testing in Ontario.

I would like to say that Canada does have a very interesting drug testing system, it's done federally, it's all under the direction of, there are three different laboratories, I believe, and it is all under the direction of one individual. All the tests across Canada are done in a very similar fashion, which is something we certainly don't have in this country and we'll talk about that a little bit later.

Bob?

MR. ROB MCKINNEY: First of all I would like to say thanks to the University for inviting me here to speak today. What I would like to do is give you an overview of Ontario's experience with our out of competition testing program.

A good way to begin, for those who don't know is kind of give you a sense of who we are and what Ontario is as a jurisdiction. As you can see from our statistics, there's over a billion dollars bet every year. There are 18 racetracks, that's 15 standardbred, two thoroughbred, and a quarter horse. We have over 30,000 licensees and we issue a number of rulings ever year.

The Ontario experience, kind of a starting point when we discuss anything about integrity and as we face challenges is we focus on a key message, and in Ontario, our key message is that by far, the majority of the 30,000 licensees play by the rules and care compassionately about the horse. Sadly, there are a few within the community who are willing to break the rules.

Basically, the Ontario experience is, what we were seeing was a decline in wagering and the bettors were turned away for a variety of reasons. And why? What we were seeing was abnormal changes in performance in regards to horses, unpredictable results, and there was what we believed or what there was perceived

to be a wide use of illegal medications in our industry. And at the time, the racing community felt powerless and with good reason. And what we've uncovered through our investigations is an international drug connection. This equine drug connection, as I said, is international and it is far reaching. And as you can see, it is two ways, there's drugs going out of Ontario and going into other countries and there's drugs coming into Ontario from other countries.

What also we learned from our investigation is a substance abuse cycle. This substance abuse cycle consists of substances such as EPO, cobra venom. Distributors, these are the individuals that are in our industry distributing equine drugs, and we found that some of these individuals have ties to organized crime, and then there is the consumers. The consumers are basically licensees or individuals who are using these illegal medications and abusing these drugs.

And what we need to do as an international community is break that substance abuse cycle. And how do we go about breaking it? What we need to do is identify and reduce substances, prosecute the criminals, regulate the industry and more importantly, be preventative and proactive in our enforcement.

These were all necessary and vital approaches, but what we recognized was something of more value to the process we needed to focus on. Faced with these challenges we determined that we needed to return to the passion of care and welfare for the horse. We needed to look at things through the eyes of the horse. Every program, every regulatory tool, every test for illegal medications should be through the eyes of the horse. Out of competition testing is one of these tools.

In Ontario, we conduct out of competition testing. What we do is we base it on change in performance and probable cause. Change of performance is, our judges and stewards everyday are looking at the horses competing on the track and if there's an abnormal change in performance, they'll have the trainers in and ask specific questions on how this change in performance came about. If they are satisfied with the answer they will continue to monitor that horse, if they are not satisfied with the answer, then an investigation is conducted into that change of performance. This information is also put into a databank in the investigations unit and we use that as a tool to track the people that have change in performance.

We also use probable cause. That is when we get information based on our investigations and intelligence sources, through informants, etcetera, etcetera. When the out of competition testing program first came into Ontario, I made a commitment to the industry that I would only test trainers who fit into those two categories. Also what we did is we issued a directive requiring trainers to produce horses for testing on demand.

What this is here is, basically, you can see the language of our directive here. And probably the most important thing is something Ontario learned just through experiences, when we first started, our directives strictly spoke to blood samples, well, there was an occasion where we had information that a certain horse had a certain drug in it and urine was the best source to detect that drug. When we had

blood samples, we didn't have the authority to go and take urine from the horse, so what we had to do is go there and get consent from the trainer. So as a result of that we've learned that biological samples, which aren't just limited to blood, urine and hair samples, because as testing changes, maybe the way that we collect those samples will change with it, that's why we've gone that route.

Also in our directive, you can see that there's a provision in it for failure for an owner or trainer to make those horses available for those biological samples. Included in it, like I said, is a penalty section or a refusal section, so any trainer who refuses or an owner who refuses us to go in and take the samples has refused the right to enter their horses in future races in Ontario. To date, we've had no refusals.

Just some of our statistics in Ontario, in 2006 we tested 217 horses involving 18 trainers. As a result of those tests, we have four confirmed positives for EPO which we felt was a serious breach of conduct. Those four positives were in relation to two trainers. One trainer had three positives; the other trainer had one positive. As a result of that we've successfully prosecuted the one individual who had the three positives. His penalty was he received a 10-year suspension and a \$40,000 fine.

Also, we successfully prosecuted a trainer just based on acquisition and possession of EPO, and that individual received a 10-year suspension and a \$20,000 fine.

To date, in Ontario, for 2007, we've tested 262 horses involving 30 trainers and we have one confirmed positive for EPO. And just to note, our one racetrack in Windsor is basically, it's in southwestern Ontario which borders Michigan. Trainers from Michigan often bring their horses into Ontario; we've gone into Michigan with the cooperation of the Michigan State Racing Commission and tested trainers out of Michigan.

Something also that we are starting to do in Ontario is any trainer that's found guilty, as I would say, of a positive test, we put a condition on his license. In Ontario we're only allowed to search and seize at a racetrack but we are now putting conditions on trainers who have positive violations which allows us to go into their stable and search and seize illegal or non-therapeutic drugs. They're also subject to our out of competition testing program. One of these individuals was from Michigan, we've also extended that authority to Michigan, so Michigan can go onto his property and search for those things also.

The science behind our out of competition testing, and this is kind of what we learned, and believe me, sometimes it was the hard way. You can't test for everything, and you must make a choice between blood or urine. Blood is our preferable choice just because collecting urine from an entire stable is somewhat time consuming. And more importantly, you must choose a lab that can do the types of testing that you're looking to do. You have to be able to work with them.

Again, when it comes to Aranesp/EPO, working with your lab is so important. We found that the R&D Elisa kit has given us the greatest reliability when it comes to Aranesp or testing for the drug EPO. In Ontario, we do antibody testing for EPO and there is an antibody Elisa. That test hasn't proven effective for us when it comes to out of competition testing. But we are right now in the rule change process, what we're going to do is, our TCO2 horses, any horses that are claimed are presently antibody tested using antibody Elisa, we're switching to go to the R&D testing on those horses.

So what happens when we get a suspected sample in the R&D test, we send it to the Pennsylvania Equine Toxicology and Research Laboratory for confirmatory testing. In Ontario, we take no action until the confirmatory test results are received. To my knowledge, Pennsylvania is presently the only lab in the world that is capable of doing this type of testing. The confirmatory test is quite expensive, but according to our labs, the price is quite reasonable.

Once again, when it comes to your Aranesp, your EPO and your non-therapeutic drugs, timing and strategic planning is everything, to be quite honest. Especially for your EPOs, our information is that EPO is only detectable, it began as 72 hours, now it's down as little as two hours. So again, strategic testing is everything, you have to go on the information that you've received and make sure that you plan out how you're going to do it and get out there and test.

And that kind of concludes my overview of the Ontario experience. But I would like to finish with a question: what should the international community response be to the use of illegal medications? What challenges do we as an international community face? I would respectfully suggest that there are three areas where we can cooperate more and more.

First is international efforts in science and research. Secondly, and this is very important, international efforts in shared investigations and intelligence information. And last but not least, and finally, international standards when it comes to medication control and identifying animal welfare issues. Thank you.

DR. ARTHUR: I have one question; were the horse's thoroughbreds, standardbreds or both?

MR. MCKINNEY: We've tested standardbreds, thoroughbreds and quarter horses.

DR. ARTHUR: What about the positives?

MR. MCKINNEY: The positives were all standardbreds.

DR. ARTHUR: Any other questions for Rob?

Rob's lecture underlies a very important point that I think that we all have to recognize, whether it's TCO2, whether it's EPO, whether a few other things that I'll give examples of. If there is a hole in your system, it is going to be exploited. You

have to expect that, you need to be looking at what your drug testing and security and regulatory system is and try to look at holes in it that people can exploit, because if there is a hole, horsemen are going to find it. That is just the way it is, we just have to face the reality. And to put it in perspective, at Santa Anita a few years ago there were 450 trainers that had started horses at that meet and I will tell you, out of 450 trainers, there was more than a handful of those people that are starving to death and desperate, and even the successful ones, possibly, their success can be based on figuring out ways to exploit the system.

Well, you know, this seems — this is from California rules, and I'm sure every state has the same sort of rules, it seems very simple. We make sure that there are no prohibited substances to protect the integrity of horse racing. And then we get into the exceptions, and this oftentimes is where we get into trouble and get into some confusion. And nothing is worse than phenylbutazone. Incidentally, they consider these to be very, very serious drugs, they have much longer withdrawal times on these drugs than drugs we would consider to be more serious. But if you look at the most common positives, and this is from the RCI and I can't remember what period this was, I cut and pasted this from a year or two ago. Look at the number of positives just from phenylbutazone and flunixin, it's an enormous number. Why do we continue to have these problems? Part of it is simply because we don't have a penalty system that convinces people that this is unacceptable. In fact, in California, high bute is just a \$300 fine, no redistribution at all, and that's why we have 150 of them a year.

For years, California had a 500-nanogram level in blood for flunixin. It was in place for a very long time before it became obvious about 20 years ago that people were exploiting this. Banamine was given on race day. The RMTC, one of the first things that they did was establish a 20-nanogram per ml plasma or serum level based on studies that were purported by one of the chemists. Well, when California went to the 20 nanogram level it became obvious there was something amiss because we were running about five percent of our horses on Banamine that were in fact over. We looked at these studies and it ended up that they were just three horses and that was all that was used to make this particular determination. Well, the question is, how did these other jurisdictions get away with this? Well, simply put, they were screening at 100 nanograms but not calling positives unless they were 20. If you screen at 100, for all intents and purposes your regulatory is 100, it's not 20, whether you publish it that way or not. In California and those states that use LCMS, we screen at a confirmatory level. If we screen it and it is above 20 nanograms it will confirm above 20 nanograms, that is just the way it's done.

What we did in California, we administered flunixin in a standard 500-milligram IV dose, analyzed the samples at Ohio State and UCD laboratory to eliminate a laboratory variation and we analyzed the data statistically. This is a subset of this, and this top level, you will actually see that there are normal horses, and these are horses that we controlled, and it wasn't a size factor, there were about five percent of the horses that tested over 20 nanograms. So what we did, what you have to remember, no matter what you do in a natural sample, they are

going to be subject to some form of a bell-shaped curve, that's just the way it is, so you really have to statistically analyze data to determine what withdrawal time or threshold levels are.

Just remember, just think of that issue as being which side of the fence, how you want to regulate that. We basically took a statistical method that is used in human or in food animal medicine to determine drug withdrawal times. This is actually a requirement before a drug can be used on food animals, the companies have to do this drug withdrawal research and it is something that we are going to be proposing and discussing at the RMTC at the next meeting, that we require a similar sort of process. Let them spend their money if they want to sell their product on our racetracks.

But essentially what it does is it takes the standard deviations, you convert it to a log form and you basically do the statistical analysis. The K factor, I don't want to get into it, it has to do with the confidence intervals and your sample size, so you end up with a, in the data that we used, a 40-nanogram per ml level, we can be confident that there is going to be nobody who properly treated a horse, go over that level. We just ended up setting it up at 50 because it seemed simple to do.

Well, the question is, can people get their head under this particular tent, and if you look at this, PK data is, basically tells you where the drug is, when it's eliminated and that sort of information. PD, which is pharmacodynamics, basically tells you what a drug does. Fortunately, on flunixin, we have that information; we don't on a lot of drugs, but we can look at this and essentially see that at a lower dose, this drug essentially has no effect. It is virtually impossible for somebody to treat a horse on race day, even with this 50-nanogram per ml limit, and get through our system, and we don't see that. We usually see someone who is below 20 or they are over 100, it is very seldom that they are in between. .”**Other terms, concepts and keywords contained in the balance of this transcript are:**

Clenbuterol, positive in Europe, Banamine, RMTC, Category B penalty, Category A penalty, total carbon dioxide milkshake testing, threshold, manipulation of performance, blood doping agents, California, Florida, Pennsylvania, EPO, Arenesp, Oxyglobin, Cone snail venom, anabolic steroid, vet accountability, Lasix..... If you desire a full transcript contact bpewitt@ag.arizona.edu