

# AGRICULTURE AND ENVIRONMENT COMMITTEE

# Members present:

Mr GJ Butcher MP (Chair) Mr AJ Perrett MP Mr JE Madden MP Mr J Pearce MP

# Staff present:

Mr R Hansen (Research Director) Mr P Douglas (Principal Research Officer)

# PUBLIC HEARING—INQUIRY INTO THE HENDRA VIRUS EQUIVACC<sup>®</sup> VACCINE AND ITS USE BY VETERINARY SURGEONS IN QUEENSLAND

TRANSCRIPT OF PROCEEDINGS

THURSDAY, 7 JULY 2016 Nambour

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#### Committee met at 8.30 am

**CHAIR:** Good morning everyone and welcome. I start by acknowledging the traditional owners of the land on which we meet today for this hearing. I declare open the Agriculture and Environment Committee's public hearing in relation to its inquiry into the Hendra virus EquiVacc vaccine and its use by veterinary surgeons here in Queensland. My name is Glenn Butcher. I am the committee chair and the member for Gladstone. On my left is Mr Tony Perrett, the member for Gympie and the deputy chair of the committee; to my right is Mr Jim Madden, the member for Ipswich West; and to my far right is Mr Jim Pearce, the member for Mirani. I also welcome the Hon. Peter Wellington, the Speaker of the parliament and the member for Nicklin. I will invite Peter to make a statement after my brief introduction. I have apologies from Mr Robbie Katter, the member for Mount Isa, and Mr Ted Sorensen, the member for Hervey Bay, who cannot be with us today.

The inquiry was referred to this committee on 25 February 2016. The committee is required to report to parliament by 22 August 2016. Submissions accepted by the committee are published on the committee's inquiry web page. Witnesses are not required to give evidence under oath today, but I do remind witnesses that intentionally misleading the committee is a very serious offence. I remind those present that these proceedings are similar to parliament and are subject to the Legislative Assembly's standing rules and orders. In this regard, I remind members of the public that under the standing orders the public may be admitted to or excluded from the hearings of this committee. Mobile phones or other electronic devices should be switched to silent or turned off. Hansard is making a transcript of today's proceedings, which we intend to make available on our website as soon as it is ready. Those here today should note that the media may be present, so it is possible that you could be filmed or photographed. I ask witnesses who come forward to please identify themselves when they first speak and to speak clearly into the microphones provided.

Finally, I remind all witnesses of the importance of being relevant. Our inquiry has specific terms of reference and they dictate what the committee can and cannot report on. They include the incidence and economic impacts of adverse reactions by horses following vaccination and the reporting of those adverse reactions and economic impacts. We do not have scope to hear personal complaints, disputes or other grievances against vets, horse owners and others over the treatment of horses. If you wish to raise in your evidence such matters that you believe to be relevant to this inquiry, I ask that you do so without naming any individuals involved. I now welcome Mr Peter Wellington to make a statement.

**Mr WELLINGTON:** Mr Chairman, I welcome you and your committee members to Nambour, the heart of the Sunshine Coast. The Sunshine Coast community was instrumental in drawing this matter to the attention of the parliament and the government. I thank Mr Jim Pearce for his support in those early days when we were lobbying for this inquiry to happen. I acknowledge not just the horse owners but also our veterinary representatives who have made significant submissions, which were instrumental in the final terms of reference that the parliament adopted.

We are aware that you are on a tight time frame, as when you leave here you head off to Rockhampton for the next series of presentations. We are aware that you are due to report towards the end of August. We look forward to your written report and we wish you well in your deliberations. Thank you very much for coming.

# DENNIS, Dr Steve, Veterinarian, Private capacity

# DOHERTY, Dr Tony, Veterinarian, Private capacity

# POOLE, Dr Ben, Veterinarian, Private capacity

**CHAIR:** I will ask Dr Ben Poole, Dr Tony Doherty and Dr Steve Dennis to make brief opening statements.

Dr Dennis: My name is Steve Dennis. We are going to present individually, as we have made submissions individually. First, I thank you for the opportunity to contribute to this inquiry. I have been a veterinarian for 31 years and have worked predominantly in equine and mixed practice in rural Nambour -1- 7 Jul 2016

areas of Victoria, the United Kingdom, Western Australia, New South Wales and, for the past 12 years, in Queensland. I have extra qualifications in equine medicine. I have serviced the thoroughbred and standard breeding and racing industry and have been involved in attending race meetings in a professional capacity in Victoria at Ballarat and Kyneton, and in Western Australia in Bunbury. I have also vetted endurance rides in Victoria and Queensland, including the 2013 Tom Quilty Gold Cup at Kilkivan.

While working in the United Kingdom in 1988, I was involved in a mandatory vaccination of performance horses for equine influenza. Horse owners incurred the costs of the process and only vets could administer the vaccine, as the signed vaccination certificate became the horse's passport to allow it to compete. This policy has been in place for 40 years for performance horses and racehorses. Its implementation has not caused racing or FEI rides to face economic ruin or to be discontinued.

In late 2007, while working at Gympie, I was involved in the vaccination of horses during the equine influenza epidemic. The vaccine was a genetically modified live canarypox virus. It was flown in from France under the national AUSVETPLAN and we were advised to handle it very carefully. I spent many days vaccinating horses as part of the buffer zone, and also racehorses. The vaccine and the veterinary fees to microchip and vaccinate were covered by the federal government and hence cost owners nothing. Racehorse trainers from queuing up to get access to the vaccine, because without it race meetings could not continue. There were never complaints of adverse reactions and no suggestions of possible performance-limiting side effects. The only complaints came from pleasure horse owners who were annoyed that the racing industry had access to the vaccine before them.

Since late 2012, I have administered several hundred doses of the Hendra vaccine to around about 240 horses. I have had three horses develop sore muscles at the site of the injection. I have ameliorated this by administering the vaccine in the pectoral muscles and injecting anti-inflammatories.

I will now draw your attention to the Queensland Work Health and Safety Act, specifically section 19, the primary duty of care, and section 29, the duties of other persons at the workplace. Section 19(2) states clearly—

A person conducting a business or undertaking must ensure, so far as is reasonably practicable, that the health and safety of other persons is not put at risk from work carried out as part of the conduct of the business or undertaking.

That is, 'so far as is reasonably practicable'. Does this imply that any business involved in horses in a Hendra endemic area is breaking the law if they do not vaccinate their horses? Do you consider vaccination of horses not to be reasonably practicable? I guess the important thing we look at is that the health and safety of other persons is not put at risk from work carried out.

The other section, section 29, would apply to horse owners that do not conduct a business. Section 29 states—

A person at a workplace (whether or not the person has another duty under this Part) must

(c) comply, so far as the person is reasonably able, with any reasonable instruction that is given by the person conducting the business or undertaking to allow the person conducting the business or undertaking to comply with this Act.

In other words, as a veterinarian we attend a horse owner's property, which then becomes our workplace and we are responsible for their health and safety and our own health and safety. To comply with the act, we advise them that the best way to prevent problems would be to vaccinate their horses. If they then choose not to, are they breaking the law under this act?

Currently, as you well know, we have three veterinarians who are facing prosecution under the Work Health and Safety Act. The way I see it is that a lot of businesses and a lot of horse owners have obligations under the Work Health and Safety Act which, if you take it to the nth degree and look at this, especially since on many government websites it states clearly that the vaccination of horses is the single best way to prevent infection from Hendra in horses, if the business or horse owners have to comply with the act as we do and if we advise them that the best thing to do is to vaccinate their horses, then I believe that by not vaccinating their horses they are potentially transgressing the Work Health and Safety Act. I do not like the idea that we have to look into the Work Health and Safety Act and hold this up in front of horse owners and businesses, but we are forced almost to do this because of what is happening with our veterinarians being prosecuted by Workplace Health and Safety. That is as far as I will go. I think I have said enough as an introduction. Thank you for listening.

**Dr Poole:** My name is Ben Poole. I am a veterinary surgeon with 25 years experience. I am based in Cooroy, just up the road. I employ seven vets and 11 nurses. In 2010, my practice investigated a positive case of Hendra virus, so I know well and firsthand the stress that a positive Hendra horse creates to the horse, to the horse's owners and to my staff. Incidentally, that outbreak resulted in two people receiving the monoclonal antibody post-exposure therapy, which was very experimental at the time. They were the horse owners. Vets and veterinary assistants have proved by history to be at most risk of contracting Hendra virus, but recently it is horse owners or handlers who have been the recipients of the post-exposure therapy. This demonstrates that horse owners are at high risk and, of course, do not forget the poor old horse.

There is unfortunately deliberate deceit by some individuals and some equestrian organisations that are trying to confuse probability with risk. As you know, risk is a combination of probability and outcome. The outcome of death is always going to make the risk high to extreme. That is regardless of the probability. A horse owner might see the probability of exposure to Hendra virus as unlikely, whereas our profession sees it as likely. We are constantly hearing the ill-conceived argument that because it has never happened before, then that means there is zero risk. My house has never burnt down, but I still pay a very high premium to insure against that eventuality. Why? Because the outcome is catastrophic, but the probability is low.

I think that is how we need to look at the Hendra vaccine. It is an insurance policy. Your horse is extremely unlikely to die from Hendra virus. It is all but a guarantee. It is an insurance policy that you as a horse owner will not contract Hendra virus from your vaccinated horse. It is an insurance policy to ensure, if your horse gets sick, your vet will gladly attend and do their job, just as every vet wants to do. Vets understand risk and so do many horse owners. Our profession is grappling with practice policy. We are trying to balance our desire to provide care to horses with our obligations to protect ourselves, our staff and others under the workplace law.

As a horse owner, I cannot understand taking the risk. I vaccinated all of our horses the day that the vaccine became available. Why? Because I had followed the science of the disease and I had followed the science of the vaccine development. Yesterday, our colleague Dr Peter Reid eloquently summarised the history of the vaccine development and it should be beyond question. The development and approval process really should be beyond question.

We are trying to balance our desire to provide care to horses with our obligation to protect ourselves, our staff and others under the workplace law. As a horse owner I cannot understand taking the risk. I vaccinated all of our horses the day the vaccine became available. Why? Because I followed the science of the disease and I followed the science of the vaccine development. Our colleague, Dr Peter Reid, eloquently summarised the history of the vaccine's development yesterday and it should be beyond question. The development and approval process really should be beyond question. I knew the risk this disease poses and I wanted to protect my horses from the possibility of a horrible death. I also wanted to protect my family and anyone else who deals with our horses. Our horses have all had many Hendra vaccinations. None of them have shown any adverse event: no change in behaviour, no change in coat colour, no deaths, no laminitis, no mysterious illness, no lack of performance or any other Facebook-conceived condition. My practice has administered approximately 5,000 doses of the vaccine with the only adverse event being reported to us being mild muscle soreness at the site of injection. That occurred in about two in 1,000 doses.

What really gets my goat is that we as a profession are being accused of selling a vaccine for the purpose of making money. To have that accusation levelled at us is very disheartening. Our profession has done everything possible to deliver this vaccine as affordably as possible. It is delivered at very close to the cost of delivering the service, if not below in some cases. Ironically those making the allegations against us are the big end of town—the money men with hundreds of horses who want to bury their heads in their dollars and pretend there is no risk. Why? Because their money is more important to them than their horses' lives and the lives of the people who work with them. Thank you.

**Dr Doherty:** Good morning. I would like to thank you for the opportunity to speak here this morning. I am the owner of North Coast Equine, which is probably the largest equine practice on the Sunshine Coast. I also have the only surgical facility here on the coast. Just to set the record straight from the outset, I want to declare that I have no vested interest in this vaccine and I have no vested interest or association with Zoetis.

My main reason for appearing here today with my colleagues is because we have watched and seen the development of this disease since the early 1990s, and it has changed its manifestations in many presentations in that time. As a veterinarian of 26 years' experience, having studied hard and spent a lot of time in this profession, the bottom line for somebody like myself is horse welfare. It is Nambour -3 - 7 Jul 2016

paramount. We have a duty of care to provide that service. We also have a duty of care to our employees, to those who are working with us, to the horse handlers and horse owners, and I myself have a duty of care to my wife and three children whom I wish to go home and see every evening.

There are a couple of key factors regarding this that need to be set straight. This disease is endemic in Queensland and it is a very serious zoonosis usually ending in fatality, especially for equine veterinarians, one of whom succumbed to the disease and whom I knew personally. Based on those two assumptions, it seems incredulous that we have got to the stage of having a public inquiry as to adverse reactions and this general public hostility towards the vaccine. The vaccine itself has come to market a lot sooner than we had anticipated and that, as I have alluded to in my submissions, may have left some areas of doubt in people's minds.

There are a couple of key factors that must be borne in mind regarding this vaccine (1) it stops the infection of horses; (2) it stops the transfer from horse to horse; (3), most importantly, it stops the spread of it to humans. That is a key factor. If you looked at a vaccine people would say this is ideal. In fact, it is such a good vaccine that, in the event of a horse that is fully vaccinated being at an event where there is an outbreak, the DPI—an independent government organisation—will allow those horses to leave the facility. I cannot bring to mind any other vaccine in any other species where, in the face of an outbreak and a serious challenge, you would be allowed to leave the site and not be quarantined. It is very clearly an effective vaccine which has been assessed by people in another non-biased organisation, being a government department.

With regard to adverse reactions, we in our practice have done thousands of vaccinations and I can personally say that we have had none. In our submission we have alluded to our protocol for that. When I have spoken to people and asked about it, I find it incredulous that people can spend hours on social media disseminating this information, yet in the majority of cases did not think to call back either the veterinarian who administered the vaccine or another vet to investigate. Most of these go unrecorded and just seem to be more hearsay. This is a scientific matter and it needs to be looked at with a scientific approach. There has been a lot of very good scientific data and a lot of money invested in the research and development of this vaccine, and to see a very good product just being binned on the basis of scurrilous accusations seems incredulous. I think going forward from this inquiry the situation should improve with the now approved increased inter-vaccine interval to one year.

With regard to adverse reactions I think all stakeholders have an obligation, be they vets, horse owners, Zoetis or the APVMA, to set up some sort of formalised recording system. These adverse reactions have never been categorised as to whether they are true anaphylactic, whether they are bacterial contamination or whether it is to the antigen or to the vehicle carrying it, so there needs to be some systematic approach to record and categorise and grade these things. Maybe Zoetis, as a spinoff of them getting this product early to market and since they have a virtual monopoly, should be required or asked to make some sort of contribution. Obviously there needs to be some sort of independent analysis of this, and these have to be recorded and statistically analysed. This is a scientific matter and it must be dealt with in a scientific way.

The other bottom line pertinent to this is due to the serious zoonosis there must be recorded vaccinations, and I feel that the product should remain as a vet-only product ongoing. It cannot be allowed to be disseminated as an over-the-counter product because of the serious potential outcomes of this. Based on the fact that we have a good product with all of this adverse publicity, something needs to be done to address that and put this matter to rest before—because of financial constraints on Zoetis—we lose this. No-one else will enter this market because of the small size of the potential market and the fact that it has had such adverse publicity. Going forward I think vaccination is the only option. Thank you.

**CHAIR:** Thank you very much. We will now have questions from the panel. My first question is to Dr Dennis. I hear your concerns about Workplace Health and Safety. One of the comments yesterday was that out of the thousands and thousands of vets in Queensland, the three vets who have been charged were close together and reported by one individual from Workplace Health and Safety. Yesterday in Brisbane Workplace Health and Safety said that they would rather work with vets than prosecute. Is it such a concern to vets that Workplace Health and Safety is out to get them?

**Dr Dennis:** My take on the way this has come about would be that what happens is that when you get a positive Hendra case, Biosecurity come in to deal with the quarantine aspect and Queensland Health come in to try and determine if humans have been exposed. If anybody is at enough risk to require monoclonal antibody therapy, as Ben will testify—and I think he should answer

this as well—then Workplace Health and Safety come in and look at who might have been responsible or who might have responsibility for causing this event. One issue about that is—and I know we cannot talk too much about cases that are before the courts, but I think I can say this—one of the vets is being prosecuted for putting himself at risk. I think for us as veterinarians that is a really important issue. Not only is he being prosecuted for the fact that he may have put owners at risk but he is also prosecuted for putting himself at risk, and he is an employed veterinarian. I think that has been a big issue with the way in which practices have developed their policies regarding their employed veterinarians.

Getting back to the reason why Workplace Health and Safety have come in, I speculate: was there some round table discussion at Workplace Health and Safety saying, 'Who can we hit here? Who can we get?' As you will read in my submission, I think they are going after soft targets, and that is veterinarians. I have had two instances in my career where I dealt with a horse with colic and the horse fell on top of the owner and broke the owner's leg. One was in Victoria and one here near Gympie. At no stage did I think that Workplace Health and Safety were going to say, 'How were you managing that horse and why did that horse fall on that person and break their leg?' In our workplace it had never occurred to me until this issue that I have to be on the lookout for what might happen to owners and what might happen to people around me because this is my workplace and Workplace Health and Safety are going to scrutinise the outcomes of this event. It is only since the emergence of Hendra that we have seen this issue start to occur. Does that answer the question?

**Mr PERRETT:** My question to you, Dr Dennis, is with regard to the horse from Tin Can Bay that was referred to in your submission. Do you think any action should be taken to produce factual information for horse owners to effectively combat what you describe in your submission as the resistance on social media fuelled by reports of severe reactions that do not match the recorded data on reactions? Can you outline the events regarding the horse in Tin Can Bay referenced in your submission?

Dr Dennis: I do not know whether Gemma Antrobus is here, but I feel this is really a sad case. I have read her submission and I think a lot of things were handled badly in the whole process there. To answer your question regarding social media, what happened in that instance was that when the horse appeared to be unwell subsequent to being vaccinated, and possibly because of anti-vaccination sentiment, there was a massive response. She had a whole lot of people coming to help her, and you would think that is a great community thing. The press got involved in a big way and there was what appeared to be a protracted time when the horse may not have been getting the attention or the care that we would like to think. I cannot speak for the veterinary practice involved. I used to work there, but I cannot speak about what happened on that occasion. It does not read well in Gemma's submission. At the end of the day, what was highlighted in the press-and may still be in people's minds-was that there was an adverse reaction to the vaccine. It is my belief if you were the jury and this were a court case about somebody accused of a crime, the vaccine is guilty until proven innocent in the minds of the public at the moment and it should be the other way around. It became a big media issue, but once the post-mortem revealed that the horse actually did not have anything related to the vaccine as far as we understand now, that was a tiny little news event. I guess this is our culture. This is what we see with the news, the sensationalism. It sells news. It fills up their little airwaves. Unfortunately, when the truth came out we did not hear enough about it.

**Mr MADDEN:** Following on from what you said there, Dr Dennis, what positive action could be taken by the government, industry and professional groups to address this wave of misinformation on social media and the regular media?

**Dr Dennis:** Ben and I met with Peter after this was called in February, and I remember Peter saying what we want now is an opportunity for everybody with problems to come forward and tell their story, and this is what this inquiry is all about. You guys have heard the stories and you will be able to assess at the end of this whether there is overwhelming information to suggest that there is a problem with the vaccine. I have thought this through several times. Alluding to what Tony said, should there be money put aside from the government to set up a process, which stakeholders are involved in setting up the terms of reference, to investigate any unusual adverse reaction. So forget about the horse with a sore neck, et cetera. So the sequence of events is the owner feels that there is a relationship between the vaccine and a reaction occurring and then a process which is subsidised by the government, and it does not have to be forever, it could be just a moratorium of a 12-month period, so, rightio, we have all agreed that these are the terms of reference we use to determine if this is truly something that is the fault of the vaccine.

Having said that, we are potentially undermining the work of the APVMA. As veterinarians we use pharmaceuticals and vaccines that are registered by the APVMA every day of the week and certainly in my experience all these medications do what they are supposed to do with minimal side effects. Everything comes with a compromise, there are potential side effects, but you follow the dosage regime as it is registered to do. Our industry functions using pharmaceuticals because of the work of APVMA in registering that drug. So as far as I am concerned I have total faith that the APVMA are doing their job. If we are then saying, well, we need to do a bigger process to look at adverse reactions, are we in fact undermining or suggesting the APVMA are not doing their job or are we complementing the work that they are doing? That is a diplomatic thing. That is what you guys are good at, I suspect.

**Mr MADDEN:** Just to follow up on what you just said there, it has been suggested that arrangements could be put in place that the Queensland government either oversee or undertake at its own expense autopsies of any horses that pass away within, say, a two-week period of a vaccination. What do you think about that idea?

**Dr Dennis:** Certainly in light of what happened with Gemma's horse, I mean that was conclusive. At the end of the day we want conclusive evidence one way or another. I think I wouldn't limit it just to a post-mortem. Obviously there would have to be other diagnostic tests to deal with it. Unfortunately there does not appear to be, and you can look at this in human medicine as well, one set test that says yes, this is a vaccine reaction or this isn't. At the end of the day it is often a process of elimination. This isn't this, it isn't that and these are the sorts of things that we expect, looking at the symptoms, that this could be caused by. So it will be a process of eliminating as many things as possible. You may be looking at toxicology, and I can tell you that toxicology can be a very expensive business if you are trying to look at samples and then look at a whole range of possible toxins. Sometimes with toxicology by the time you get to do the post-mortem the actual toxin may be out of the system so you may have an inconclusive result.

In answer to your question, I think post-mortems, if it is a fatal outcome, would be great, but I think it has to be first of all worked out by all stakeholders that the process that we are using is going to fit the criteria and a post-mortem would be potentially part of that as well.

**Mr PEARCE:** A question to the three of you; you can answer individually: how many of your clients mentioned that they thought that their horse had been adversely affected by the vaccine but you decided it was not a reaction and did not facilitate an APVMA report?

**Dr Dennis:** I will answer that briefly. As I mentioned earlier, I have had three cases where horses had developed muscle soreness. I think I have reported one of those. Muscle soreness for a couple of days is a pretty well recognised adverse reaction. I am not sure, are we defining adverse reactions as something beyond muscle pain and a little bit of lethargy? I will admit that I didn't report one or two of those, but I know I have reported at least one of them.

**Dr Doherty:** I make it quite clear to my clients at the time of vaccination. Certainly when the vaccine was under permit in the early days where there was a legal obligation to report all of those, I made it quite clear to my clients, and I still do, that if there is an adverse reaction we want to know about it. I also make it clear to them that I will return and the cost matter I would probably try to take up with Zoetis. To date, and I have stated in my submission, we have had no serious adverse reactions, nothing more than a swelling of the size of a 20-cent piece around the vaccination area which is to be expected and to me is an indicator of a good immune response. But I do make it quite clear to all my clients at the time and tell them of their legal obligation while the product was under permit.

**Mr Poole:** I certainly concur with those statements. Certainly in the early days, yes, we were obliged to report all reactions whether they were expected or adverse. I must say now we tend not to report just the expected vaccine muscle soreness. It happens so rarely that it is not really a big issue. It is not something that we are seeing much of anyway.

**Dr Doherty:** Under the reporting of adverse reactions obviously they are supposed to be reported to the APVMA. We can also report them through Zoetis and Zoetis have an obligation to report that or pass that information on to the APVMA.

**CHAIR:** Thank you very much gentlemen. Your time is much appreciated.

# WILLIAMS, Dr Margaret, Private capacity

**CHAIR:** If you could just make a brief opening statement of approximately three to five minutes.

Dr Williams: It is going to be a little bit longer. I will try to talk fast.

CHAIR: Try and keep it brief if you can.

**Dr Williams:** My name is Margaret Williams. I am a general practitioner with some science background and also a horse owner. I went to several of the Hendra virus seminars early on prior to the vaccine release. I was eager to vaccinate initially, but after looking into the research and being shocked to find that there had been very minimal efficacy testing with this vaccine, and could find even less on safety, decided to adopt a wait-and-see approach. The basis for approval, use and public policy for the Hendra virus vaccine, like any medicine, should lay on a firm foundation of reliable and transparent evidence that the vaccine works and should rely on a well-documented and investigated safety data profile indicating a very low adverse reaction rate. I think it important to consider both the negative as well as the positive findings from the vaccine efficacy trials. There should be a responsibility to have fair balance to assess benefits and risks. With this in mind I would like to make a couple of points about the efficacy trials.

There has been minimal data from horse trials alone, so for this subunit vaccine other mammalian trials are also used for this assessment, in both Hendra viruses and closely related Nipah viruses. Prevention of the risk of asymptomatic viral shedding has been given as a reason for vaccination of animals. However, there have been several examples of evidence of viral shedding in HeV vaccinated animals as well. Here are two: in a cat study with Nipah virus challenge, all of the vaccinated cats had evidence of viral genome in oral swabs and in most of the vaccinated cats' urine. This likely viral shedding persisted in many cats to day 21 at the completion of the study. The highest levels of this viral genome in samples were from vaccinated cats which were higher than those of the unvaccinated controls. The cats showed good protective antibody levels prior to viral challenge. If you were worried about viral shedding, you would have been at more risk from vaccinated cats than the control cats in this study. Incidentally, you cannot find this information in the abstract of the manuscript and many manuscripts are in closed access repositories that require a payment to view, so most people won't look further. One needs to look at the results and discussion sections to find this information.

In the six-month horse study, one of the three vaccinated horses that was virus challenged had viral material in its nasal swabs over four days. Unfortunately, it was euthanased in the middle of the possible incubation period for a horse. The range is generally given to be 5-16 days and this horse was put down on day 8. It was euthanased a day prior to another vaccinated horse that did not have evidence of virus in its swabs. This horse did not have evidence of viral infection in its post-mortem samples, but it would be unlikely to prior to onset of fever, which seems to precede viral dissemination throughout the body. In discussions of this finding, it is commonly remarked 'but virus was not isolated', but this is potentially misleading as virus was also not isolated in any pre-euthanasia samples of any of the unvaccinated so-called control horses either, not even in the sick horses.

Evidence for Hendra virus can be made by PCR estimation and by viral isolation. Viral PCR technique is much more sensitive, so a negative viral isolation does not mean the virus is not there. There are other examples of viral infection in vaccinated animals. In the cat study, four of the six vaccinated cats had significant levels of viral genome in their brains at post euthanasia sampling, much higher than the control cats, and viable virus was identified at day 21 at post viral challenge. Vaccination did not protect these animals from significant levels of viral genome in the brain, although it did protect from multisystem organ disease. The highest levels of viral genome in the brains of these cats were found in the highest vaccine dosed cats. This finding, amongst other examples, sparked the discussion of the possibility of the risk of persistent infection in vaccinated animals in two of the manuscripts.

There are other examples of infection, including evidence for viral shedding, that did settle in two ferret studies and presence of viral genome in a bronchial lymph node of a vaccinated ferret. Protective antibody titre levels in the field are likely to be generally lower than those seen in most of the studies. In the studies, most have been performed at the time of maximal antibody response. Also, comparatively higher doses of the HeV antigen are given to the non-equine lab animals than are given to a horse. Zoetis presented two tables of titre levels prior to their intention to do 12-month duration of immunity testing. Over half of the before the six-month booster horses had protective antibody titres just at the limit of detection—that is, eight—and in group 2 horses with a different proposed protocol that did not involve a six-month booster at 12 months, over half of these vaccinated horses had HeV antibody levels at or below the limit of detection: eight. Under eight is the level of an

unvaccinated horse. There will be a big range of antibody titres in the field and not all horses will have good levels all the time. Horses or animals to my knowledge have not been tested to see if they can withstand Hendra viral challenge with such low levels of HeV antibodies. From a safety perspective then, how could you say that all vaccinated horses cannot have Hendra virus and apply two different treatment programs dependant on vaccination status, for example not using PPE in a vaccinated horse.

In saying all this, on the plus side, the vaccine is protective for Hendra virus infection in many cases and for signs and symptoms of disease, but there are many variables to consider. As the efficacy trials were small in number, very minimal in horses, the precautionary principle should be built into the formulation of policy. Overemphasising just positive findings while completely omitting or minimising negative findings may present risks for policy makers and could put lives of people and horses at risk. I don't believe you can say that Hendra vaccination of horses eliminates the risk, as some vets maintain, for horses to contract Hendra virus or people to contract Hendra virus from a horse. For example, for safety I believe people should still use the same level of PPE especially with very sick horses, whether it is vaccinated or not, and on all invasive procedures and always with autopsies. Another help in the way forward would be the stall-side HeV PCR test.

It is my firm belief that adverse reactions have been significantly under-reported, and it is highly likely that the current risk benefit analysis will be incorrect. I shall explain. Adverse events to a medicine or vaccine are handled as adverse events or experiences until, at the regulatory authority in this case the APVMA—causality is attached and then the events are labelled 'possible', 'probable' or 'unlikely' and so on. This process is essentially the same for the TGA, the Therapeutic Goods Administration of Australia, the FDA and the APVMA. In other words, an event can be anything with some association to the product. From the FDA pharmacovigilance guidelines for veterinary medicines, an adverse event is any observation, whether or not considered to be product related, that is unfavourable and unintended after use of the veterinary product.

The point of data collection is to establish incidence of known events, identify rare or unexpected events that may not simply be easily mechanistically explained but may present statistically and determine such things as exacerbation of pre-existing conditions. The idea of reporting is to collect a large data pool for analysis so nothing is missed. The regulatory authority, APVMA, is responsible for establishing likely causality. For example, someone I know of had a horse that was off colour after its vaccination and it died two months afterwards with colic. Her vet said it was too long after vaccination to be a reaction and did not report. Different vets will have varying opinions as to whether this was an adverse reaction or not, but there is just one correct answer from the point of view of reporting.

Once an observation has been noted and communicated to the vet or the registrant, Zoetis, it must be submitted to the regulatory authority, the APVMA, as an adverse event. Judgement made at the point of collecting data will reduce this valuable pool and goes against regulatory requirement. The vets do not have the oversight of the whole picture, Zoetis has a conflict of interest and inconsistencies that would emerge are obvious. I do not believe that it was made clear to the vets to report anything, as they were told simply to report adverse reactions.

Then there is the risk of bias and noncompliance in reporting for other reasons. Another friend had a horse which experienced severe local reaction with malaise and fever. The vet did not report and, after she spoke with Zoetis, no report has been lodged since either. Owners' voices, I believe, are critical in this process. They are the ones who live with their animal and are the ones most likely to pick up on any changes in their behaviour or their health. The vet gives an injection and goes away and may not even hear about a possible adverse event. Owners should have been made aware to report directly to APVMA early on in the permit process.

Finally, there have been several concerns voiced that that the horse industry is being adversely impacted in Queensland due to this current situation. I know of several people getting out of horses as the pleasure is taken out of this recreational activity. I know a breeding stud who say they are winding down and looking at exit strategies, as the Hendra issue is getting too hard, getting vets and so on. There are many issues at many levels. The horse industry has been estimated to contribute over \$6.2 billion annually to the Australian economy—from a rural industries research and development document—and is clearly one of our biggest industries. This inquiry, I hope, will present a way forward to take everybody's concerns into account and protect this industry.

CHAIR: Thank you very much. You gave a very thorough report.

**Mr PEARCE:** Prior to the release of the vaccine, are you aware of any risk assessment, risk management structures or anything to do with the whole risk management of the process? If not, could you give a qualified view of there being none of those things taking place?

**Dr Williams:** I am not privy to all of the information for a start. When I started looking into this, I was interested whether to vaccinate my own horses. All I could find before the vaccine came out was that there were two horses that had been vaccinated and challenged with Hendra virus and six ferrets—that is, with Hendra virus. When the permit came out, there was a mention of guinea pigs. No numbers were mentioned. There was very little that I could find on safety. I decided for me personally I would just adopt a wait-and-see approach. What else did you ask?

**Mr PEARCE:** Can you provide a qualified opinion if that was the right way to go about the whole introduction of the vaccine in such a short period of time and not having taken at least a risk assessment at that time?

**Dr Williams:** That will not ever happen in human medicine. Who would vaccinate their child after it has been tested on a couple of horses and six dogs? There were a couple more after that but, as far as safety assessments are concerned, if that is where the bar is it has to be raised because our industry is at stake. Vaccinating the whole horse population was proposed. There surely should have been more done. I think that is a big issue. Also, there is the issue of does it work and the limitations of the vaccine to take into account.

CHAIR: Thank you. I now call Dr Joanne Macdonald from the University of the Sunshine Coast.

# MACDONALD, Dr Joanne, Senior Lecturer in Molecular Engineering, Inflammation and Healing Research Cluster and Genecology Research Centre, University of the Sunshine Coast

CHAIR: If you could make a short opening statement, that would be much appreciated.

**Dr Macdonald:** I am Joanne Macdonald. I am a researcher at the University of the Sunshine Coast. I was funded by the Queensland government to build rapid diagnostic devices over the past four years. It was a Queensland government Smart Futures Fellowship. As part of that process, we built a rapid assay for the detection of Hendra virus that we think could be implemented in a veterinary clinic. It is not a stall-side test. It could not be done by a horse owner. It requires a few pieces of equipment such as a centrifuge and a heating block, but it is a fairly simple process and we think that it could be implemented by vets.

Currently when a horse gets sick and a vet thinks that it might be Hendra, they have to take samples. These get shipped to Brisbane. They have to arrive by two o'clock. If they do not arrive by two o'clock, they have to wait until the next day at two o'clock when the tests are run, and the vets usually receive the results at 6 pm the next day. That is a long time for a sick horse to wait and several horses have died while waiting for that result to come back.

Currently the vaccination rates are about 30 to 40 per cent, I believe, which means that there are 60 to 70 per cent unvaccinated horses. The process of suggesting that vets could choose not to treat horses that are unvaccinated could lead to an extreme biosecurity risk where a Hendra virus horse could not be detected because it was not seen by a vet. I think that places a lot of risk in Queensland for a much larger outbreak than we have seen so far where a lot more horse-to-horse transmission could occur and more people could get infected. Currently a horse having to wait 24 to 36 hours to get a Hendra result is very inhumane. These horses have died in quite a bit of agony. It seems to me like it is not a good practice to have happened.

As far as I know, we are the only group that was funded to develop a rapid Hendra test. There was funding in 2011 for Hendra virus research. As far as I believe, no-one was funded at that point to create a rapid Hendra test. All of the funding was put to other uses—all very important uses—but there is a big gap in having the tools that vets need to know whether their horses have Hendra or not in a much faster way. We think that our test could help this process.

**CHAIR:** Thank you very much. I have a quick question about this test. I personally have brought this up during the hearing. One of the concerns that we have heard from some veterinarians and other people is the potential of a negative positive—the stall-side result coming back as a negative and vets treating that horse as a negative and then it turning out to be a positive Hendra test. They had some serious concerns about the potential for a negative result when it is actually positive. Can you talk about where you are at with your stall-side tests and the potential for that?

**Dr Macdonald:** Sure. For starters, all tests have diagnostic limits including the current test. It detects up to a certain level of Hendra. It has never actually been tested how much Hendra virus is detected by that test. The current assay in use has never been quantified, so nobody knows how many copies of the virus might be detected using that test. It is believed to be very low, based on the technique that is used which for other assays has been shown to detect as little as a single copy. The Hendra test has never been quantified, so it could be that already negative tests are positive but there is just such little virus that nobody is detecting it.

**CHAIR:** How far off is your research? We have heard of a funding shortfall of about half a million dollars bandied around by several people as well. Can you give us the facts on where you are at with the research and how quickly this test could potentially come?

**Dr Macdonald:** We went to Biosecurity Queensland and we tested our test on stored samples. Twenty tests were taken from samples known to be positive and all 20 came up positive in our assay. We also took one of those samples and diluted it down and tested it—our assay compared to the current assay—and both assays turned negative at the same time. We believe that our test is as sensitive as the current test but can be performed in a much faster manner in a location much closer to the horse than in a central location in Brisbane. We also tested about 20 negative samples known to be negative and all of those samples came up negative in our assay. That indicates that right now with the 40 samples that we tested the statistics look very promising. We think it could be something that—obviously we need to do more tests.

We have unfortunately run out of funding, so we need some funding to continue the testing and show that it has a good promise. To fully develop a test for commercial use takes a lot of resources, a lot of field trials and there are a lot of regulatory systems to get through. It is not entirely clear which

regulatory body would want to regulate this assay and whether Biosecurity Queensland would be willing to accept its results. There is a lot of work that needs to be done, a lot of both scientific and political work that needs to be done, to look at all aspects of this. But only with more funding can these answers come to light.

**Mr PERRETT:** The work that you have done is basically completed at the moment. You cannot progress it any further without some additional funding for that program. With your interaction with Biosecurity Queensland, what have they been saying back to you in respect of the way forward? Have they been providing any advice?

**Dr Macdonald:** I have not really spoken directly to them about the issue of whether they would accept the test results or not. We are yet to present the results to Biosecurity Queensland. We have not yet published those results. We are in the middle of finishing off the details of the paper. Once we have those results published then we will obviously be looking to talk to them some more.

**Mr MADDEN:** Thanks very much for coming in today. You need to be applauded for the work you are doing. It could be vital in dealing with this important disease. I just want to pick up some technical detail. You said that the essential equipment was a centrifuge. What was the other item?

**Dr Macdonald:** A heating block. The test requires an incubation for five minutes, or six minutes at 39 degrees.

Mr MADDEN: And this is relatively inexpensive equipment?

**Dr Macdonald:** Yes. You could get them for several thousand dollars. Again, a vet clinic would already have most of these items present, or they could source them fairly cheaply.

**Mr MADDEN:** We are told that the way the test would be done is that biopsies would be taken, or samples would be taken from the beast and then the vet would have to go back to their clinic.

Dr Macdonald: Yes, that is correct.

Mr MADDEN: And then the test would be positive.

**Dr Macdonald:** In its current format. Obviously, there is a lot of science out there that could be implemented to create a true stall-side test. Again, that is something that needs funding, which has not been funded to my group or any group. Sorry, I have forgotten the question now.

**Mr MADDEN:** I was just asking you about the technical process of getting the test done. The vet would have to go back, you would get the test—

**Dr Macdonald:** Yes, go back to their clinic. It would take about 15 minutes to run and then they would have the result, which would be a lot faster than shipping samples to Brisbane and waiting 36 hours.

Mr MADDEN: You mentioned that to date you have been funded by the state government.

**Dr Macdonald:** Yes. We had funding to develop assays that could detect not just Hendra but also lyssavirus, Japanese encephalitis, and Murray Valley encephalitis, all of which are also very important in horses. The funding was to develop some novel technology, which just happened to include Hendra. The agency was looking for things that were of high importance to Queensland and I think having Hendra in there really helped push it towards getting funded. But it was not funded through the 2011 Hendra funding round; it was a completely different agency.

**Mr MADDEN:** I understand from your answer to the question that the chair asked you that you cannot estimate how much is money is required to fund your work to the completion of the process. Can you give me some indication of how much it would cost to do an individual test?

**Dr Macdonald:** The cost of the test would be determined by the number of times that it would be used in the market and how much money people are trying to make when they are selling the test, but the actual reagents cost about \$10 underneath. Somebody will have to work out a price point once it gets closer to market.

**Mr MADDEN:** I have just one final question. With a test, does it determine the presence of Hendra, or the nonpresence of Hendra?

**Dr Macdonald:** It is looking for whether the Hendra virus RNA is present, which would only be present if the horse had an active infection. It will not tell you if the horse has had an infection in the past; it will just tell you whether it is currently infected to the limits of detection that are currently available for any test.

Mr MADDEN: Thanks very much

CHAIR: Thank you

Nambour

# HORNE, Ms Madeline, Private capacity

CHAIR: Would you like to give us a brief opening statement?

**Ms Horne:** Good morning, thank you for allowing me to speak today. I spoke to Peter Wellington, who is our local member, and asked that the public be allowed to speak on this matter. From my point of view, I would like to put forward three years of watching what is going on and show the inquiry some of the things that we have discovered and ask some questions that we have not been able to find answers for.

I completed the Marcus Oldham equine management course when I left school and went on to vet nurse for about six years. I am now a self-funded retiree whose passion is dressage and a sport in which I train my horses every day. I have a lesson at least once a week and compete most weekends. I have worked hard all my life, invested well, and I am now in a position to be able to follow my sporting dreams. When people ask me, 'What do horses cost?' I say, 'Everything—all of it. Every last cent.' Horses are a very large part of our economy. I represent the local dressage group, the Northcoast Active Riders Group—NAGS—and I am also a member of a prochoice social media group, which has nearly 7,000 members. Over the past week I have watched, listened and read all the transcripts and I am saddened about how few of the public were given a chance to speak as this is a public inquiry. Like it or hate it, social media is the public voice and I have here a pile of sad stories about what happened to their horses in relation to the Hendra situation.

I am very prochoice. I was happy to vaccinate my horses when this vaccine became available. In fact, we were only five years out from the EI vaccination. As part of the dealings with the Northcoast Active Riders, I went to Peter Wellington then and wanted to vaccinate our horses. We had been in lockdown for six months. The difference in this vaccine, as one of the vets was talking about earlier, is that the EI vaccine was brought in from overseas and had been tested on tens of thousands of horses for a long time. This was a brand-new vaccine. We were not told when we lined up for our vaccines—and we did line-up, because we wanted to protect our horses; no-one wants to lose a horse to Hendra, no-one wants to infect anyone. As part of my administration with the Northcoast riders, I knew Gill Rodgers, Ben Cunneen's widow. My own sister is married to a vet. So when the vaccine was available, we put up our hands and said, 'Yes, please.'

As my horses were given two shots in the first 21 days, I was very happy. I felt that I had protected them. I felt that I had protected the people who handled them—my vet, people around me, even my farrier, whose own horse, he says, has suffered a reaction to this vaccine. What I am not happy to do is overvaccinate my horse and I have here 16 titres. My friends and I have put our money where our mouth is and sent our horses' blood to CSIRO, used the same testing that Zoetis used when they released their duration of immunity—or DOI—in December 2013 and said to the team of Dr Middleton's, 'Tell us about our horses.' My personal horses had missed five boosters. They are still positively covered. Some of the horses have massive titres.

I would like to talk to you about one of them, which belongs to a lady called Jo Moore. Jo Moore's horse reacted so badly to his vaccine that she was frightened to vaccinate the horse againa valuable show horse. She then decided that she would titre and she was one of the first of us to do this. The vet came out. The horse was verging on the 12 months, which vets were allowing horses to get out to, and she then said, 'Well, we'll take the blood and we'll send it to CSIRO, but by the time we get the results back he'll be outside of the 12 months and the Health4Horses website says that if we miss that we have to start again.' That is a query that I would like to make about who decided that, because that is the only place it appears. After taking the titre for testing, they then gave the horse analgesics and antihistamines as well as the vaccine. A week later when the report came back-and I have included it in here—the horse had a level of 2048. There was no need to vaccinate that horse. I would ask any vet, 'Did that horse receive world's best practice in its looking after.' Presenting those, I think, makes this the largest testing shown to anybody, because Zoetis certainly has not published any of that. I have spoken to my vet and he accepts my horse's titre, as does Nathan Anthony's practice, WestVets. I have an email here to confirm that. I do not blame the vets for any of this. They have to be able to trust their regulatory body, the APVMA, and their association, the AVA. I do not believe-and I will go through some questions in a minute that we need to ask-that they were adequately informed of the trial minor permit use that they were about to encounter.

The AVA has reported in its financial statements that it has millions in the bank—13, I believe, in the last statement. I do not know why they are not turning up for the \$500,000 that Joanne needs to protect their members. I would think that that would be a very good investment of their funds. It is these groups along with Zoetis that I feel have too many unanswered questions. I also believe that our government departments must also take responsibility and stop sitting on their hands. We had an

example incident here in my area where a healthy young performance horse had been sold subject to leg X-rays but, when the horse arrived at the vet clinic, they were told that they could not X-ray the horse as it was unvaccinated and they would be prosecuted by Workplace Health and Safety. I emailed Trish Coward from Workplace Health and Safety—it is in this pile—and asked if this scenario was correct. She insisted on phoning me even when I said, 'No, I want it in writing' but would not give me a yes or no answer. I kept repeating the question, 'If this vet had taken this horse off this float and had X-rayed its legs, would it have incurred prosecution from you?' I could not get an answer. She just kept repeating, 'We believe that the vaccine is the most '- so do I. I have been there. But I want to know what would have happened. This horse was a very valuable horse. It was going out of this area. It was going to Sydney. There would be very little reason to risk this horse's health with this unnecessary vaccine.

I can see why the vets are worried. I have some investigation reports from the Office of Fair Trading and Worksafe Queensland practices, and I had to pay \$683 to get that. It is heavily redacted, but you can follow it, because the dates make it fairly obvious. I do not think in any way, shape or form that the vets should be legally in charge of someone else's property. I would be happy to sign a disclaimer to that fact. I believe that I am more than able, having attended the government's biosecurity workshops, to protect my horses with good biosecurity. I would expect the vet to do the same, but I certainly would not see him as responsible—no more than I would the farrier if my horse kicked me with a pair of shoes that he had just put on. That is not his responsibility and I do not believe that it is the vet's.

Over the past few months vets have been saying that, as of 1 July 2016, the new biosecurity guidelines would not allow them to tend to unvaccinated horses. The new rules are now out and there is no mention of Hendra or vaccines at all. What concerns me greatly is the rise of the generic letter in this. I have a letter here from the local All Animal vets stating, 'No, vacc, no care.' When questioned, I was told, 'It's is just a generic letter. My door would never be closed to your business.' It also seems that many of the vets' submissions were also on generic template types of letters. In fact, it looks like they were all submitted together as they have sequential numbering. I would ask the inquiry who and on what motive is supplying these generic submissions.

I am also concerned about the control that a company like Zoetis can hold over our universities through sponsorship. In this pile is a letter from a senior lecturer in veterinary science, who obviously has serious concerns but is unable to speak out. I have given the inquiry a copy of that email. I am also concerned about the conflict of interest between EA, the body I compete under, which mandated this and then withdrew when we all started to say, 'Well, we just won't ride under you anymore' and the AVA, EVA and Zoetis. We now have people coming in to DAF, out of DAF and into AVA. It seems to be that there is half a dozen key people who seem to be controlling a lot of this.

One of the ladies who called me yesterday whose horse died four days after vaccination has also reported to the inquiry and to the APVMA. The horse was vaccinated Friday, lunch, dead by Tuesday. Yet UQ Gatton would not even entertain a discussion on the Monday of this being an AE and it had immune-mediated thrombocytopenia, a disease that we had never heard of in horses. Now, I know at least six horses that have died of this. Yet in her vet's submission it says, 'We have no adverse reactions.' That vet's submission was written five weeks after this horse died.

I have a friend in Texas, USA who showed me a photo of what she thought was caused by a rattlesnake bite on one of her mares. I said it looked like IMT. Had it been vaccinated recently? She bit my head, as most people do when you mention vaccine. She said that she had always had vaccines done and she had no problem vaccinating her horse or her kids and that, yes, it had had a West Nile vaccine a week ago, but before that it had had no problems. Ironically, the vet arrived an hour later and confirmed it as an adverse experience and hospitalised the horse. Blood transfusions and massive steroids saved this mare. Here, we would have avoided the subject and watched her die. We need to lift our game. AEs are rare, but they can happen with any drug.

I have compiled a list of questions that I would like the inquiry to ask the APVMA and also Zoetis and have the answers back by the end of July so they can report by the 22 August deadline. I would ask Zoetis's representative, Dr Richard L'Estrange. He has been the first line of reporting. He and I were interviewed by ABC Radio. I had been blocked by the APVMA under freedom of information from getting an updated list of adverse reactions. They asked him about that and he said, 'No, that's not us,' yet I have a letter here in this pile from the APVMA stating, 'Yes, Zoetis is the third party that is blocking your application.' So I would ask him: what is his qualification? Does he have the qualifications to be able to assess an adverse reaction and decide whether it should be forwarded to the APVMA? What did Zoetis include in its online training modules to adequately cover the minor use permits and how it must be used? What did it cover in regard to adverse reactions and their

reporting? What did it cover in the off-label use with animals for prior illnesses or conditions that left them unsuitable for vaccination? Can Dr L'Estrange inform the inquiry of his interpretation of an adverse reaction? I would encourage everybody to have a look at Wikipedia to see exactly what they report to be an adverse reaction. What testing has Zoetis done on the use of other drugs at the same time as the vaccine to attempt to prevent a reoccurrence of an adverse reaction? Can Dr L'Estrange explain the advice given to an anti-inflammatory like phenylbutazone and also anti-inflammatories at the same time as the vaccine? I quote the example that I mentioned earlier.

Can Dr L'Estrange inform the inquiry whether you must start again with two doses 21 days apart if you miss a booster? It was tested and sanctioned. This is only mentioned on the Horses4Health information, not on any labels or APVMA information that can be found. Can Dr L'Estrange explain what testing and on whose authority added the then six-month booster to the second version of minor use permit No. 13510? The testing evidence remained the same on all five versions of that permit showing Dr Middleton's team that for all horses that were given two shots 21 days apart zero converted and 42 days later were covered. What was the testing? I would like to see that produced that made us so early in the piece need these boosters, which we have now proved after five missed boosters were not necessary. Can Dr L'Estrange explain: horse owners have at their own expense sent their bloods to be titre tested by CSIRO and have received very strong titres after missing up to five boosters; why have they not done this testing?

I have spoken about the generic letters and I have spoken about the ABC. The question I would like to ask the APVMA: before the release of this vaccine, their protocol is that an independent expert review was to have been carried out. Who was that independent expert? What was their recommendation? Was it upheld and can they produce a copy for public scrutiny or your scrutiny? This vaccine was released, and I have gone through the testing and the fact that they added. I would like that asked to the APVMA: who added the testing, who added the extra boosters and on what testing?

To remain current, I have gone back to the start again. I would like the APVMA to be made to show the testing that makes it necessary to start again if you miss a dose. I would like them to talk about what is an actual adverse reaction and who should decide that. Is it the owner, is it the vet, is it Dr L'Estrange or is it the APVMA? You will see in all these letters I have highlighted—we spoke to Richard L'Estrange. I have personally rung him. We have people behind us who are still waiting to have them classified who have spoken at length to Dr L'Estrange and have not got passed reporting to him.

I would like to know how many reports the APVMA has in from horse owners that they are still yet to clarify and why have some of those now been waiting for two years? Is it acceptable that the APVMA is funded through drug registration? How does that enable them to make an independent unbiased decision? In their recent gazette in May, they talked of making \$137 million in the last year in injectable vaccines. To me, that is like letting an arms dealer set our gun laws. These people cannot be impartial if they have to fund themselves through drug registrations. I would ask the inquiry to look into that.

CHAIR: Are you happy to table all of those documents?

**Ms Horne:** You can keep the whole lot. It is all yours.

CHAIR: Is the committee happy to have those tabled? All in favour.

**Ms Horne:** There is one other thing that I did not ask. I believe the only way to get honest open true public reporting is for the inquiry to subpoena the Horses4Health database and send out a questionnaire to every person. Not all of them are on email; it will have to go out in the snail mail. I would like them to ask: in your opinion as an owner did your horse's health change in any way after vaccination with EquiVacc (HeV); yes or no? If the answer is no, no further questions. If the answer is yes, did you then report this; yes or no? To whom: your vet, Zoetis, APVMA and an ability to click 'all of the above'? If no, please complete the note section to explain why this was not reported. If yes, were you satisfied with the investigation that followed; yes or no? If yes, then no further questions. If no, please complete the note section to explain why.

I think that is the only way we are going to really understand with a new vaccine. Yesterday some people spoke about this being a precursor to being able to be used on other areas and other illnesses such as Nipah and similar viruses. We as the testers have had this. I would query why owners have had to pay to be part of this testing and now have to pay with our titres, which are very expensive, to be not included in this testing. I would ask that we are able to find out exactly what happened and that is the only way we are going to find that out.

# CHAIR: Thank you very much.

**Mr PEARCE:** You have answered a lot of my questions. I have had it said to me quite a number of times with regards to the APVMA that they only post what they want to post and all the information they have is confidential. That is not very helpful to anybody who is trying to get a good understanding of what is happening out there.

**Ms Horne:** In that pile, there are several letters. In fact, there are quite a few and I have a few more at home. I have become quite a serial pest, I am sorry to say, with Kareena Arthy, the CEO of the APVMA. She was also CEO of Biosecurity in the Redlands outbreak. I am sure you have read the ombudsman's report on that. It is scathing.

I have seen myself as a bit of facilitator of information. I have plenty of time. I talk to people. People ring me. I was in the supermarket yesterday when a horse owner rang me to tell me about what had happened to her horse. I am also aware of a case in Sydney where a horse was forced to start again. It is a very VIP person. I believe you have a submission from them. I will not mention any names. Zoetis ran an ad that said, 'Zero deaths'. It was a full-page ad. It was put up on all websites and in all sorts of magazines, saying, 'Zero deaths from this vaccine'. I ran inside to my computer and sent an email to Kareena Arthy titled, 'Liar, liar, pants on fire. Here is a list of six horses that I know that have died where you cannot rule out the vaccine'. I have the email in that pile where she wrote back to me and said, 'We have told Zoetis to remove that advertising'.

There is so much you cannot get out of them. I think they should be open and honest and transparent and be answerable. At the end, they are all we have. They are our regulatory body. I think it is very unfair that the vets are placed in this position, if they cannot trust their regulatory body.

**CHAIR:** Thank you very much, Ms Horne. That was very informative. I now call on Dr Robert Mason.

# MASON, Dr Robert, Private capacity

**CHAIR:** Thank you, Doctor. Can you also be mindful that we need to keep moving, as we have a plane to catch. If you can be short and sharp, that would be lovely.

**Dr Mason:** I will be very brief. Thank you for the opportunity to speak to the committee. For the record, I would like to note—and this must be a recording issue—my written submission to the committee appears twice, No. 106 and No. 181. I think they are identical submissions. I do not know how that occurred.

I have spent quite a bit of time perusing and reading the background material. I have looked at material that has been presented already to this committee. The background and briefing material provided has been very detailed and quite scientific. I think it covers most things. There have also been formal presentations that you have received. You have also published written submissions. We must keep in mind your specific terms of reference for this inquiry. I will run down some of my very casual observations and comments on what I have found from what you have received so far. I think most of them, or some of them, have been covered this morning.

The extensive use of social media is one aspect that has resulted in, I believe, churning of information between separate groups of people and interested parties. They are like-minded people and they just keep churning the information amongst themselves until they come to believe that this information is actually factual. In some instances it is demonstrably not based on 'evidence'. There is always a need to listen to people's concerns and recognise and respect their opinions as genuine. We should seek always to dissipate those fears and provide support. However, I think in this process there has been evidence of gossip and innuendo and blame sharing that has only served to circulate erroneous information and exacerbate the fear and anxiety in the horse-owning population and the veterinary profession.

There are a lot of submissions that, to me, indicate failures in communication between vets and clients, between vets and authorities, between the manufacturer and the vets. We just heard that the information system Health4Horses, the reporting and monitoring system, has not always been used correctly and may have been misunderstood in its use and purpose. Unfortunately, I think probably with the best will in the world the efforts of the manufacturer of the vaccine in providing assistance in marketing and promotion to implement a vaccination regime in an endemic flying fox area have been interpreted by some as a conflict of interest. It may or may not be.

There is also apparently amongst the submissions misunderstandings about the purpose and use of the vaccine. We have heard a fair bit about that. Remember, this is a veterinary product that is for use in animals, namely horses, but it has a secondary aim in that it also provides protection for humans who come in close contact with those horses. It is slightly different. It is not like vaccinating your cattle against three day sickness or something like that. It has a secondary purpose, as well.

Some submissions rather cynically accuse vets of money gouging. At the same time, some argue that vets should take all the risk to attend an unvaccinated horse or, indeed, possibly a vaccinated horse when the vet is the one who is in the front line. It is evident because of the deaths that have occurred that the vet is probably the person most at risk against this virus.

Probably this next point is the one that alarmed me, when I started picking up on it. I believe that in some submissions there are quite serious allegations being made about institutions such as the APVMA, the University of Queensland veterinary school, government departments such as Agriculture and Fisheries, Health, WorkSafe and even the racing industry itself. There has been criticism of the manufacturer and the Veterinary Surgeons Board. I even saw one that was critical of the actions of the ombudsman's office. To me, these allegations and accusations and innuendoes raise an apprehension of something that could include conduct that may include a contravention of law. It could be corrupt conduct. It might be conduct that could pervert the course of justice. It might be conduct that results in a wastage of public funds. It could be an abuse of public trust or position, or it could be maladministration or conduct that is unjust, oppressive or negligent. It might be conduct that unreasonably endangers health or safety, endangers the environment or is misconduct relating to scientific research, analysis and advice. Having said that, the fear with throwing around willy-nilly allegations and accusations without some way of forensically examining whether they in fact have a base is very dangerous ground, in my opinion.

We have heard about reporting adverse reactions. I think that the submissions clearly show that there have been some gaps in the processes there, in terms of follow-up investigations, diagnoses and explanations which, of course, bring worry and anxiety to people. The cost has been mentioned. Of course, there are the fears and worries of veterinarians, particularly in regard to the workplace and health issues.

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In summary, those impressions of mine are simply impressions gleaned from information that has been provided to this committee. I think it would be a great shame if something constructive did not eventuate from this process. Queensland is in a unique position geographically, environmentally and scientifically to take advantage in the field of global research of emerging and re-emerging pathogens. I respectfully make the following suggestions, very quickly: because it has cost the taxpayer quite a bit of money to date and we hear still further calls for further funding for research work, there should be some sort of actuarial examination of cost/benefit to the public and the taxpayer and the parties involved. There is obviously a need to review the adverse reaction reporting system and the APVMA should be front and centre in consultation on that process. The veterinary profession could well re-examine its communication strategies and methods with its clients and, of course, that should involve the Veterinary Association and horse associations.

With respect to workplace health and safety issues and obligations, I note that the new Biosecurity Act came into force at the beginning of July so shared responsibility is a big G note in that. Perhaps insurers could be involved, because insurance is a very difficult problem here, and the Health department. Because if something spills over, it involves expenditure on public health.

This one is a pet one of mine: to review the efficiency and effectiveness of the biosecurity legislation applying to the owning, breeding and keeping of horses. We know that if you keep horses on a property you should have a property identification. That is now mandatory. I think the equine influenza outbreak was a good demonstration. The problem with Hendra virus, notwithstanding some other integrity issues in relation to registered racing, is that it is a very, very important part of the process to have identification of the animals. It would help no end. I remember in the EI outbreak, which I came out of retirement to lend some assistance with, one of the most difficult things was to control the movement and to track the movement of animals. I think that one of the things that we probably should give serious consideration to is having permanent identification of animals so we know where they are, who owns them and who is responsible for them. I think it would assist animal legislation as well because it would sheet home responsibility to the owner.

I think—and I would push this one—that there should be as much support for research as possible into factors affecting emerging and re-emerging pathogens. I think it is a phenomenon that we are seeing on a global basis. Just on a quick calculation I found that there are probably 1,500 recognised human pathogens—that is viruses, bacteria and all the rest of them—and 58 per cent of those are zoonotic; in other words, they affect the animal and human beings. We all know about Ebola and HIV-AIDS et cetera. With the smallest mutation of one of these viruses we could end up with another Hendra virus, so there is a big need for monitoring research and primary research being done on a lot of these factors. It should be supported as best we can. We are blessed in Queensland with two good universities—James Cook University in Townsville and the University of Queensland at Gatton—plus other scientific faculties in various other universities in Queensland so we are admirably safe. We are in the right place in the right time with the right expertise available. If it is cultivated it could be very, very useful to the state of Queensland.

Lastly, and I agonised over this, but I think your committee should give serious consideration to referring some of the accusations and allegations to appropriate authorities at least for preliminary evaluation. I am thinking of bodies such as the CCC, the police, ASIC, ACCC, fair trading, the Auditor-General and there are probably others. Some of those allegations and accusations and innuendo could be referred to appropriate authorities for at least an initial scanning to see whether or not there is anything of substance that could form the basis of a more specific inquiry. I think that if that were done, this committee would be able to inform people who have concerns and made those types of 'allegations' that their submission to your inquiry has been taken seriously and that you have taken action to have it looked at further. You could notify the submission maker to that effect. That is about all I have to say. Thank you, gentlemen.

CHAIR: Thank you very much, Dr Mason.

# BONE, Ms Heather, Private capacity

# CLIFFORD, Ms Amanda, Private capacity

# KENNEDY, Mr Brian, Private capacity

CHAIR: Would you like to make a brief opening statement?

**Mr Kennedy:** I would like to thank you very much for allowing us to appear before the committee. I would like to start out by cutting to the chase. If you relate to the details of in-government documents and other investigation situations that took place after each infection, the seven people who were infected with HeV were all non-wearers of PPE. On the other side of that coin, no person who has worn appropriate PPE has ever been infected with Hendra, but we get from the vets the fact that it is too cumbersome and it is this and it is that. At the end of the day there is nothing more cumbersome than death or infection. It is not just for Hendra either. I believe they should be looking at it to cover themselves for such things as lyssavirus, Q fever and leptospirosis et cetera. As the man said before, there are about 1,500 different pathogens. As far as I see it, the only people ever infected with HeV—and it is documented in evidence—are people who have dealt internally with a horse without PPE. There are at least 100 plus people who have dealt with the same horses not internally—so casually or however you want to describe that—and none of those people have been infected. Zero.

Then you have to look at the other side of the coin as far as infections, in that you have probably I think 1.2 or 1.3 million horses in the country. You have people dealing with those horses on a daily basis. On the basis of that detail, I would like you to think about it. Our horses, for instance, would be handled by somebody up to 10 times a day. If they are not handled at all that is fair enough, but then you relate to 1.2 million horses being handled 10 times a day over a period of a week, over a period of a year. Over the period of 22 years that we are talking now there has not been one casual infection from those contacts. Zero. I do not doubt there is a risk, but the way I see it on the basis of the figures and the evidence available the risk is minuscule at best. If you wear PPE, then the way I relate to that is as there has been no infection, there should be no infection. I will leave that where it is.

The other thing I would like to relate to is the scurrilous situation that the previous vet happened to mention. The reason people are on Facebook and other social media situations is because there is no good or what I would call proper communications via the vets and consumers. I have gone to a vet with my adverse reactions and they were dismissed. Ask anybody you like who has had an adverse reaction and spoken to a vet: they are dismissed. They just fob it off. They are not interested. 'There is no such thing.' Are they trying to tell us they are all coincidences? Fifteen hundred to 2000 reported cases of adverse reaction have gone into the APVMA. They have publicly put those out there, so it is not a myth. It is happening. The problem we have—and you have seen it today—there were three vets sitting there and every single one of them dismissed it ad hoc. 'No such thing. A little lump on the neck.'

I had two horses that ended up with lesions which never had a problem prior to vaccination, and now they are both dead. I have three other horses that have had laminitis problems, which is separation of the hoof, and other hoof issues and leg issues and skin issues that have now gone away two to three years since I vaccinated the horses. If that is the only thing I did differently, if it was your horse wouldn't you believe that there had to be something relating that problem with the horse to the vaccine? Up until the point I vaccinated them, those five horses never had a problem in any way, shape or form. We manage our horses because they are competition horses, so we know on a daily basis what is going on with them. Part of the process is good management. On the basis of that, what I see wrong is that the vets should not have dismissed adverse reactions. It should have been looked into in some depth, and as far as I am concerned as a consumer, APVMA should have requested that Zoetis look into and justify the validity of their vaccine. We are paying for it; we are entitled to a good product. If that product is not doing what we want it to do, we have every right to complain. Whether it be butter, eggs, milk or vaccine, the same rules should apply.

As far as I am concerned, the other thing you have to relate to is credibility. This vaccine was brought onto the market under permit supposedly only to be used in areas that were endemic. In that period of time while it was under permit—and the vets cannot deny it—they sold that vaccine in Perth. Do you realise there are no flying foxes in Perth? They vaccinated over 2,000 horses according to the records I have seen. They have vaccinated horses in Adelaide, Canberra, Hobart and Melbourne—all over Australia—where there has never been one infection of Hendra in history. Where

does credibility come from that? 'Show me the money!' That is what it is about. They can say what they like. They can bring up risk, but the risk is minuscule when you relate the number of people who have dealt with horses over the period of time.

In the last 22 years we have had seven people infected; four people have died. Every single one of those people were negligent to their own wellbeing. They were irresponsible in the way they dealt with an infectious disease, and every one of those horses were infected. That is the proof. It is there on the record. From that point of view, the way I see it is that five of them at least were either vets or involved with vets. If they had done what their education told them to do, and that was to use adequate and appropriate PPE, they would still be with us today. The only two that did not do that were Vic Rail and his helper, and they had ignorance as an excuse possibly. Even so, had they worn PPE there is every chance they would have survived.

The other thing that I need to bring up is the Health department. I have documents here that tell you emphatically. It is in your own documentation in your own government bodies. The largest amount of PPE used by any of those people that were infected was seven per cent: a pair of gloves. If you read the other Health report, it states that people were infected via respiratory secretions. When you think about it, really a face mask, a pair of glasses and gloves would probably suffice in the majority of cases, because the people who were dealing with their own infected horses were kissing them goodbye when they were dying and they did not get infected. As far as I can see, reading all of the documentation that I have and doing all the investigation that I have on that documentation—because these are not my sentiments. These are sentiments that have been put down in black and white—the infection situation is such that, unless you are irresponsible or negligent, your chances of being infected are minuscule at best. Thank you very much.

**Ms Bone:** Good morning. I thank you for the opportunity to speak. Due to the fact us final three speakers have been given on average less than seven minutes to speak, my statements will be in order of importance and may seem random. Speakers in favour of vaccination have been allotted approximately 75 per cent of the time at these hearings, whilst speakers for choice have been given less than 25 per cent time.

Over the past six years our small horse related business has had expenditure of over a quarter of a million dollars. This will cease if a solution is not found to the current unacceptable situation. We have the science and we have the facts. Many thousands of horses cannot be vaccinated due to prior adverse reactions or pre-existing conditions. I have four of these horses. Horse owners love their horses and consider them family, just as much as dogs, cats and other domestic pets. We spend hours with them daily. We know our horses. We know when something is wrong or different with them. If they have been perfectly normal prior to vaccination and something is wrong or different after vaccination, we know. How can any vet who sees our horse only occasionally and briefly possibly say any reaction is not due to the vaccine? Having another more plausible explanation does not mean the reaction is not a result of the vaccination. It must be considered possible and should not be discounted. Owners know their horses.

Vets have attended my horses and agisted horses several times. I have seen horses intubated for colic, given IV and IM injections, have blood drawn, seen their vitals checked, injuries treated. Not once can I recall ever seeing any competent vet prick themselves or get any horse body fluids on themselves except when not wearing gloves while checking capillary refill time, inserting cream into an ulcerated eye or treating and suturing major injuries. I have administered hundreds of vaccinations and antibiotics and never once have I pricked myself. I rarely need a vet attendance as I can handle many things myself, yet daily I live in fear for my horses' lives because in the event of a serious event which I cannot treat I know most vets are now refusing to attend my horses, which cannot be vaccinated and my horses could die. I am afraid-very afraid-but I am also resourceful and resilient so I and very many owners like me are learning how we can try to save our horses. We don't want to do this, but we cannot stand back and do nothing. When vets refuse to attend we have no choice but to treat our horses ourselves so we research, we watch and we learn from YouTube, we buy the PPE, the equipment, the medications et cetera, we learn how to suture a wound, we watch, we talk and we learn from each other. We find a farmer with a gun or we get one so that when a vet refuses to come to end our horse's extreme suffering we can do so. We absolutely hate that we may have to do this, but when one has seen the prolonged and tortuous agony of a horse thrashing around violently with colic and knowing they will not recover we will find the fortitude to end that pain and suffering for them. Our horses which cannot be vaccinated deserve this. Vet euthanasia involves IV injection-a very brief, simple procedure with negligible risk of needle prick or contact with any horse body fluids so why will vets not come to do this? I can think of only one reason: because they are trying to force us into vaccination.

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Some of us have knowledge to keep us safe. Very many thousands don't. Vets not attending will mean cases of Hendra will go undiagnosed, meaning no confirmation, no isolation, no quarantine measures and a very much greater risk to human health. Vets not attending is putting human lives at risk. In 1994 Ray Unwin was infected. He did not die; he recovered. In '94 Mark Preston was infected and recovered. There is evidence his death 14 months later was not from Hendra. His autopsy showed evidence of past Hendra infection, not current infection. His death was more likely a result from a virus that killed most of the pigs at a piggery where he was working just two months prior to his death. His vet wife Margaret performed a necropsy on a Hendra infected horse and was not infected. In 2008, in the close confines of a vet hospital, Ben Cuneen died after he did not wear PPE while treating sick horses and performing an autopsy on a Hendra infected horse. A vet nurse was infected when she did not wear PPE while treating sick horses and was exposed to bodily fluids of Hendra infected horses. She did not die, she recovered. In 2009 vet Alister Rodgers died after he did not wear PPE and had significant exposure to horse body fluids while treating a seriously ill Hendra infected horse. It has been 22 years since Vic Rail and Mark Preston became infected back in 1994 before Hendra was identified and named. In those 22 years only two people-two-have died from Hendra-both vets who did not wear PPE and had very significant exposure to horse body fluids while performing extremely risky procedures on Hendra infected horses. Hendra is not easily transmitted or contracted. Hundreds of people have been exposed to Hendra, some with very significant exposure, and have not become infected. They have tested negative. Many thousands of horses have tested negative to Hendra. In 2004 a vet not wearing PPE was infected, became only mildly ill and remains well. In 2008 at Redlands a vet did not become infected when she pricked herself when euthanasing an infected horse. John Bowman had blood on his hands from a deceased Hendra horse, he did not become infected.

My extensive research has shown no rulings from any regulatory body which says a horse cannot be treated without Hendra exclusion. In fact, they all show the procedures to follow if treating a horse where Hendra may be suspected. There are bats in all states of Australia. Horses are being vaccinated in all states. There are an estimated 1.2 million horses in Australia. As at January 2016 AVA advises approximately 120,000 horses have been vaccinated throughout Australia. That is approximately 10 per cent of horses vaccinated, leaving 90 per cent—1.08 million horses— unvaccinated horses have died. I believe there is no substantiation to the so-often repeated statement 'the single most effective way of reducing the risk of Hendra virus infection in horses is vaccination.' It is an opinion only—no proof whatsoever.

Biosecurity advise very high concentrations of virus material is deposited under trees and this area is extremely high risk and almost no virus is deposited outside the perimeter of these trees. Horse owners know this and have acted accordingly. With over one million horses unvaccinated, the statistics say the single most effective way of reducing the risk of Hendra virus in horses is owner awareness and management practices. In addition to the thousands of horses which cannot be vaccinated, thousands of others will not be vaccinated due to cost or because owners have and will continue to refuse to be blackmailed, intimidated or forced into doing something against their will. We are Queenslanders. We are Australians. We will fight for our right for freedom of choice.

Mandating vaccination is not practicable. Policing compliance would be impossible. The vaccine label shows the vaccine is an aid in the prevention of clinical symptoms of Hendra. The effectiveness of the vaccine in the face of Hendra has not been studied. The potential for vaccinated horses to shed virus cannot be ruled out. PPE should be worn even with vaccinated horses as not all vaccines can provide guarantee. That is the vaccine's label. As previously mentioned, it is fact that a vaccinated horse has been found to have viral genome levels higher than in some unvaccinated horses. That horse was euthanased the next day and the significance of that finding was minimised. There is no proof that vaccinated horses cannot be infected with Hendra. Instead of mandating vaccination, mandate PPE. There are only approximately 7,000 vets, very significantly less than 1.2 million horses. Mandating PPE is logical. It is sensible. It is achievable. There is nothing to prevent it. Policing compliance would be easy and it will protect vets, not only from Hendra, but from any infection diseases. I cannot think of any other at-risk professions which do not wear PPE. Why should the vet profession be any different? There is absolutely no excuse for them not to do so. They say it spooks the horses. Many of us have already desensitised our horses to people wearing PPE and others can easily do the same. They say it is too hot. Most vet visits last less than an hour and the horse can be brought to a shady area. Vet PPE is lightweight. It is nowhere near as hot and heavy as PPE firefighters wear and they go out and fight fires in that heavy PPE which weighs up to 8kg.

Since the initial nine infections in 1994, over the next 18 years up to vaccine release in 2012 there were 50 confirmed horse deaths and two human deaths. Before the vaccine we were told the truth, the facts: Hendra is very rare and is not easily transmitted. It is very easily destroyed with disinfectant, soap and water and sunlight. It is very fragile and does not last long once excreted from the horse's body. People need substantial exposure to infected horse body fluids to become infected and the only human infection has been in people not wearing PPE. The proof: in the enclosed confines of the lab during trials CSIRO could not achieve natural infection of bats to horses or horses to horses.

To achieve infection, they had to manually inoculate the virus into animals. Their conclusions-

Horses can be infected by oronasal routes-

which is what they did manually—

and can excrete HeV in urine and saliva.

Transmission from bats to horses could not be proven. Neither could transmission from horses to horses—

Under the experimental conditions of the study-

in the lab-

the virus is not highly contagious.

**CHAIR:** Excuse me, Ms Bone, if you could get to wrapping up your presentation. We have to catch a plane to the next destination. Just come to your conclusion and that would be great.

**Ms Bone:** We have heard the Workplace Health and Safety rulings. Those directions are subject to interpretation. They have significantly changed since 1 July 2016. Social media: some information may not be factual, much of it is and is widely circulated. Government records show a total of 72 confirmed horse deaths and a further 20 suspected but unconfirmed. Dealing with the confirm facts: of the 72, nine were before Hendra was identified and named. In the 22 years since then, 63 confirmed horse deaths, 14 in the 15 years up to 2009, the date of the last human death, an average of less than one horse per year. Forty-nine horses have died in the six years from 2009 to 2015. That is an average of eight horses per year—eight times greater risk, yet no human infection. None of the owners, riders, handlers or family members who cared for those horses became infected. None of the vets who attended, diagnosed and tested became infected. No Biosecurity staff who attended became infected. Six years, 49 infected horses, eight times greater risk and not one person has been infected because we have all learned so much since Ben and Alister died.

Statistics say that the single most effective way of reducing the risk of Hendra virus in humans is owner awareness, management practices and the wearing of PPE. Unfortunately, there have been many horse deaths since the last confirmed case of Hendra, because vets have refused to attend. Very sadly, the greatest risk to our unvaccinated horses is not Hendra, but the vets who refuse to come to treat them. There are a few caring, responsible vets who will come to treat our horses. To those we say a heartfelt thankyou and we thank God there still are some.

To date, I personally have not needed a vet to attend my horses, which cannot be vaccinated, so I do not know if my vet will come if I call. I pray that he will. I live in fear that he will not. But I am prepared. Thank you for your attention.

**Ms Clifford:** I am going to read from this, because I am not familiar with public speaking. So bear with me, I will not be giving you a lot of eye contact, but I am very happy to answer questions. I am not a vet and I am not a professional in any capacity whatsoever. I am a complete nobody really. I am, however, a mother and whilst I was doing what I thought was best for my daughter's horses, I had the experience of adverse reactions to the Hendra vaccination and went on to further discover lots of information that was and still is of great concern to me. I imagined, though, that I am not the only one looking for answers, just some very simple questions about the vaccine and the virus.

I would like to go back to the basics of why this inquiry was asked for and granted. It was after hearing from owners just like me whose horses were having severe adverse reactions in excess of what could be considered reasonable. I would like to say here that I vaccinate everything in my household for everything. I just have issues with this product in particular and also, in my opinion, its inappropriate use.

I will begin by saying that I understand many of the aspects some vets are speaking of and appreciate that some of them have done their homework beyond what the manufacturer and their associations have probably provided for them. This gives me hope that we will all eventually be seeking answers to the same questions. A quick sample of those kinds of questions include ones such as: is every horse at risk? Is every horse a candidate for this vaccine? Does every horse build

antibodies from this vaccine? How exactly do horses contract Hendra? Accurate, transparent and truthful information is what the clients-we consumers, the owners-expect and deserve. People are tired of trying to decipher what is factual and what is personal opinion or hypothesis from the vets, the drug company and the relevant government departments.

I am not going into a long spiel repeating my submissions. I trust that you have read them. If vou have not, please dig them out and read them word for word and I would be very grateful if you had a good look. I have far too much further evidence to present to you and I will simply draw your attention to my personal submission, which I trust you have read. It outlined among other things my two out of three horses' adverse reactions to this vaccine in November 2012-very soon after release—and my descriptions of their reactions are in the submission; the loss of my online reporting with the APVMA; months passing between requests for further details and finally one of the horse's reports coming months later and again being classified as a probable adverse reaction, that is, meaning probably caused by the vaccine. I am still waiting now two years later for the second horse's classification report, which had very similar symptoms.

Following the reactions, I spent time researching the vaccine and what I initially had known about the virus looking for information for many questions that I hoped to answer. I was not willing to risk another severe adverse reaction in my horse. I have not continued revaccinating. APVMA chose to record ataxia, which is a loss of control of body movement. How I would describe that in my horse was that he was frozen. Injection site reaction: lethargy, listlessness, oedema and pain were this horse's report. Nurse that for a week and tell me that you do not think that that is severe.

I paid for the titre testing that showed my confirmed probable horse more than three years and three months after receiving only two shots three weeks apart-a period of 1,191 days-had what was described as a very healthy reading of 512. We skipped seven boosters. This got me thinking of the vaccine requirements and the individuality of horses' responses as also seen in the 14-horse Zoetis duration of immunity challenge. Further I researched, starting with the label. I have included that in here as well so you can have a look. That, I know, has been spoken about before.

With the label, I have heard many opinions given by professionals over the last couple of years, months and, in particular, the last few days. Vets had to do an online education module to register to administer this drug. Did they read any information after that point, such as the label? Did they give the pamphlet to their clients to read? I cannot help think that sometimes we might be looking at two very different labels, because what I see and what it says on mine does not seem to be what is the reflected by some vets. I have heard vets say, statement No. 1, 'We can drop the PPE for vaccinated horses.' You have heard that at the inquiry so far? Let us have a look at the label. Under 'Additional user safety' it says-

Personal Protective Equipment ... should be worn whenever Hendra virus disease is suspected even in vaccinated horses as not all vaccines can provide a guaranteed protection.

That is clear. So where is the information that says, 'You may dismiss suspicion of Hendra on the basis of vaccination?' Where is that, because that is what we have been told time and time again? Do some vets have different information than this product produces and the regulatory body has written? I am just reading the instructions for use straight off the label. If this authorised use as a safety tip does not need to be followed, then can the committee please find that research that would allow people to so confidently disregard this vital information? This is the obvious and correct source of the similar clauses, which are included in the government departments of Biosecurity and Workplace Health and Safety guidelines for good reason.

I have included all the evidence here. It is numbered. It is ready to go. Take the whole folder when you go. Evidence No. 2: see permit No. 13510, an early permit. Under 'safety directions caution' it states that-

In the event of an outbreak of Hendra virus, appropriate personal safety precautions should be implemented and strictly enforced even around vaccinated horses.

It appears to direct users again to the fact that this vaccine should not replace or reduce PPE requirements.

Evidence No. 3: next permit, under the conditions of use-this is the third minor use permit and the first time that this condition of use is issued. The pamphlet reads that-

The persons using this product must follow all directions and precautions set out in the label particulars and attachment No. 1 to this permit.

They need to abide by that. It is written there-'Use this product. This is what it stands for. This is what you are required to do.' The vets are saying to you that they have complete trust in this vaccine. If you read the pamphlet, what information exactly-exactly-are those guarantees based 7 Jul 2016 Nambour

on? With all the talk of the desperate need for this vaccine as the epitome of best practice in keeping those professionals safe, then one would assume that this product and these conditions of use and this safety information and a full understanding of these would be intimately known by every person registered to use it.

Statement No. 2: 'We have never seen a reaction. We've vaccinated thousands.' Evidence No. 1 on the first permit, under 'Side effects'—just bear with me for this, it is a small process of a few pages—

Transient swelling may develop at the site of vaccination in some horses but should resolve within one week without treatment.

That is the sum total number of side effects and reactions listed on the first permit. Evidence No. 2, permit No. 14887 under 'Side effects', the above statements are there plus—

In some horses transient post-vaccination reactions including injection site reaction, pain, increase in body temperature, lethargy, inappetance, and muscle stiffness have also been observed.

Additional reported clinical signs have included urticaria, sweating, mild peripheral oedema and mild transient colic. Clinical signs may vary in severity and occasionally may require veterinary intervention. Systemic allergic reactions such as anaphylaxis may require parenteral with adrenalin, corticosteroids and antihistamines as appropriate supportive therapy.

Evidence No. 3—I am building the picture; stay with me. The current label, under 'Side effects', same two sentences begin the paragraph then the—

Additional reported clinical signs of urticaria, sweating, oedema and colic-

and the following two sentences remain the same after that. 'Mild peripheral oedema; is now just 'oedema'. 'Mild transient colic' is now just 'colic'. Okay, another couple of years we are dropping off some of those descriptions—a loss of both of 'mild' and 'transient' as the descriptions. Are these words carefully chosen? It would be expected so, because that is what consumers are looking for— 'What is likely to happen if I use this product on my horse? What is possible?'

Does this prove an increase in side effects and reactions officially noted about this vaccine? Absolutely. It seems that the reporting of adverse reactions has led to permit changes. They must have been occurring. So over the life of the vaccine so far the label details and the side effects sections have increased each permit edition and again at registration. Are we done yet with what is going to be added here? Do you think we are done yet? That is what owners would like to know. Is there more information to come yet? It is built year on, year on with information added to that list.

Evidence No. 4, APVMA email dated 23 July 2015, says that—

you can be assured that the team has looked at all the reports of adverse reactions from the Hendra vaccine. The majority of reactions were known or to be expected. We look at the unexpected reactions and work with the applicant—in this case Zoetis—to determine if there is a broader issue or whether instructions for use of the product need to be amended.

That should certainly read, I would say, that instructions for the use of this vaccine 'needs' to be amended. This occurred because of the reporting of adverse reactions of the unexpected kind.

Evidence No. 5, APVMA email dated 30 March 2016, says that—

the rate of one in 300 is about right for all reports over the lifetime of the permit and registration. Label changes were initiated at the time of registration to reflect some of the concerns that were expressed at the time. With regard to ongoing concerns and the reaction rate, I will not be able to determine what the reporting rate is under registration until the end of this year.

Does this seem like the mythical and tactical efforts of a couple of anti-vaxxers, as have been stated repeatedly by some professionals, with regard to these reported reactions? It is not myths: people are responding to the APVMA. People are reporting, and you just were handed a big bunch of them. I do not think that is even scratching the surface. I personally know probably a dozen more people who are not particularly confident enough to think that they should put in a report and they did not want to second-guess themselves or their VET about it.

Evidence No. 6 is a permit. Under the heading 'safety' it says—

That of the adult horses, 3.4 of the animals in the vaccine group had an injection site reaction following the first dose of the vaccine. 34.5 per cent of animals were recorded as having visible and/or palpable injection site reactions the date after the second dose of the vaccine was administered.

That is a massive increase, isn't it? That is undeniable. In the safety trials a 10 times increase in the reaction on the second dose was seen, and yet this type of still reportable reaction is not apparently being seen or noted by many professionals.

Statement 3 says that they give Bute at the same time to help stop reactions—

The compatibility of EquuVac HeV Hendra virus with other vaccines and veterinary chemical products has not been studied.

This raises the question: how do those professionals giving Bute to dampen reactions know they have not deactivated the vaccine, rendering it ineffective? What is their proof? I personally can see the attraction of giving an anti-inflammatory prior to vaccination and at the time, but doing it with no data or research seems extremely risky to the intention of building immunity with this vaccine.

All of the talk about reactions—some known by the regulatory body, some expected and some unexpected—gives a sense of confusion to owners as to how to know when to report what they consider to be a decline in health post vaccination. The fact remains that all reactions to the vaccine are still supposed to be reported, whether acknowledged already on the label or the emailed letters or not. It makes you wonder how many people have decided that they have the accepted known reactions and do not need to report them.

I have not mentioned the more severe reactions but these can be found on the APVMA website, as you would all be aware. The APVMA has said that typically only a small percentage of reactions are ever reported. It could be as low as 10 per cent. They have already said it is one in 300. The last update brought it up to 1,100 adverse reactions reported. If you multiply that by 10, that is the APVMA's prediction of the real story. This is not a myth: this is from the government regulatory body. The APVMA said yesterday that one in 10,000 adverse reactions was acceptable, that is, 0.1 per cent. Zoetis then followed by saying there has been on average between a .24 per cent and .28 adverse reaction rate with this product. Can someone please explain? If the reaction rate according to the APVMA is being exceeded by nearly three times the acceptable rate, why has this issue not yet been addressed? These figures would then give weight to the public's concerns with regard to excessive adverse reactions in their horses.

At this point I have to ask about horse welfare. What price is too high to pay in pain for a one in how many hundreds of thousands chance of the horse actually contracting Hendra virus compared to the chance and possible severity of an adverse reaction? Many owners ask this question. I understand the APVMA spoke of horse and animal welfare yesterday. I would like to leave you with an anecdotal conversation in an email between the APVMA and a friend of mine. APVMA, initials EC: 'The vaccine has ticked all boxes to gain full registration.' My friend is SM: 'How can it tick the animal welfare box?' APVMA: 'There isn't an animal welfare box.'

I trust this committee will find and read the independent—this is very important—scientific peer reviews that should have been done prior to and after the vaccine's release as well as the Ombudsman's—

CHAIR: Ms Clifford, do not chastise the committee. Get on with your story, please.

**Ms Clifford:** Sorry. History is recorded there also in the Ombudsman's Redlands report, not in the personal recounts years later. That is also worth a read, I would suggest. I wish I had time to ask many more questions such as: when some professionals describe their belief that this vaccine is safe, what aspect exactly are they referring to? When some professionals choose to exclude treating horses on the grounds of vaccination, how do they justify treating the vaccinated horses differently considering the label information? I am only looking for reports, data, research et cetera to answer these questions. Emotions, conjecture or disregard for product use, instructions et cetera will not do. Lastly, thank you for your efforts today. May your heads rest as easily as they deserve tonight.

**CHAIR:** Unfortunately, we do not have time for questions but you can table your story. I do thank everyone for coming today. There were some very good submissions and follow-up stories which we will include in our inquiry. You have tabled a lot of the evidence that is required today. I now declare this Agriculture and Environment Committee hearing closed.

# Committee adjourned at 10.52 am