



Beate Mies <beatemies@gmail.com>

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## Re: Canvac vaccine study and label update

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From: **Beate Mies** <beatemies@gmail.com>

Date: Mon, Jan 14, 2013 at 7:00 AM

Subject: Canvac vaccine study and label update

To: M.J.Day@bristol, sarah.mitchell@pfizer, raphael.zwijenberg@pfizer, australia.animalhealth@pfizer

Cc: editor@ava.com, "BRYCE, Allen" <Allen.Bryce@apvma>, schultze@svm.vetmed, Jolle Kirpensteijn

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Professor Day,  
The Pfizer Team,

With regard to my email to Professor Day on 12 May 2012 (please see copy in email thread below), the *Australian Veterinary Journal* (AVJ), it seems, has delivered the latest instalment of wilfully misleading and "**ethically dubious**"<sup>[1]</sup> veterinary education on canine vaccination, courtesy of Pfizer Australia and the Chairperson of the Vaccination Guidelines Group/Scientific Advisory Committee/One Health Committee, of the World Small Animal Veterinary Association (WSAVA).

Your report on a serological study in Australia, published in the December 2012 issue of the AVJ<sup>[2]</sup>, hardly reveals "new scientific data". Rather, it confirms that you ignored your own "**evidence for a minimum DOI** [duration of immunity] **of 9 years for CDV and CPV**"<sup>[3]</sup>, and subjected 235 client-owned "study" dogs to revaccination without applying "**the principles of 'evidence-based veterinary medicine'** [which] **would dictate that testing for antibody status (for either pups or adult dogs) is better practice than simply administering a vaccine booster...**"<sup>[4]</sup>

I suggest that the owners who consented to entering their dogs in your 'study' were not given pertinent BASIC information on current scientific evidence, and that, despite your better knowledge, you indiscriminately put 235 dogs at risk of an adverse reaction by administering what was undoubtedly an unnecessary intervention for the great majority of these dogs. Your conduct as well as that of the participating veterinarians in this 'study' is ethically questionable.

In the article, you credit "**Annual booster protocols for the vaccination of dogs and cats** [which] **have successfully prevented disease...resulting in a falling prevalence of once-common life-threatening diseases**", when, a mere 3 years earlier, your advertisement in, for instance, the *Australian Veterinary Journal*, painted a different picture:

**"One of the world's largest pet populations sadly under vaccinated...research reveals that the total (Australian) dog and cat population regularly vaccinated is as low as 50%"**<sup>[5]</sup>

The above underlines the enduring preposterousness of the marketing ploy called *canine vaccination* and its attendant protocols.

And IF, as you say, the road to approval by the regulatory bodies is long and arduous, why did Pfizer Australia not apply for the 'scientifically proven' (?) minimum 9-year "duration of immunity", rather than "beyond 3 years", when seeking variation of the Canvac vaccine label? Furthermore, how can you possibly justify a NIL SIDE EFFECT statement for an immunobiological product, in light of scientific evidence for immune-mediated disease in dogs triggered or caused by repeat vaccination; the latter, in fact, prompted the 're-evaluation' of the TRADITIONAL revaccination interval, e.g.

*"A series of events have however caused us to re-examine this practice [annual booster vaccination] and develop new vaccination recommendations for small companion animals... This re-evaluation was largely triggered by the first reports of feline injection site sarcoma (FISS) in the early 1990s coupled with reports that vaccination might be a trigger for canine immune-mediated haemolytic anaemia (IMHA) from the mid 1990s... These events were the 'driver' for the changes in companion animal vaccination that have been introduced over the past 10 years. (Day, 2010)[\[6\]](#)*

I call upon Pfizer Animal Health, and all other vaccine manufacturers/importers, to put an end to the enduring "debate" about the commercial vaccine DOI and apply the principle of MLV vaccination.

I further call upon Pfizer Animal Health, and all other manufacturers/importers, to make a monovalent CPV-2 vaccine available for use in Australia so that the infectious disease of greatest concern can be effectively tackled.

***"...a dog that is appropriately immunized as a pup probably never requires another core vaccine during its lifetime."*** (Day, 2010)[\[7\]](#)

(Emphasis added to direct quotes above)

Regards  
Beate Mies  
Independent advocate for the judicious use of vaccines

P.S. I would point out that, contrary to your repeated statements in the December 2012 AVJ, the AVA policy for the vaccination of dogs and cats was down-graded to a position statement as ***"the AVA membership has conflicting views on the topic which is particularly the case with duration of immunity"***[\[8\]](#), thanks to authors such as yourselves; by the same token, the ethics of University graduates calling themselves veterinarians acting in the best interest of animal health and welfare obviously leave a lot to be desired...

AND, for Raphael: With regard to your letter dated 2 March 2006 (Fort Dodge Duramune Adult/Protech Duramune), it looks like the approval of extended inter-vaccination intervals does not require compliance "with higher viral titres" of the vaccines after all; but we both knew that, didn't we!

P.P.S. It is 'interesting' that there has been no move whatsoever on the feline vaccination schedules in Australia, despite AAFP spear-heading the Guidelines concept in 1998, and the EU-ABCD releasing its first set of guidelines in 2006. Could it be that, unless there is pressure from the public, it's all business as usual?

Copy to:

Anne Jackson, Editor In Chief/Scientific Editor, Australian Veterinary Journal  
Dr Allen Bryce, Acting CEO, Australian Pesticides and Veterinary Medicines Authority  
WSAVA Vaccination Guidelines Group/Committee members

Prof Ronald Schultz

Prof Jolle Kirpensteijn

Dr Hajime Tsujimoto

Dr Richard Squires

Dr Anna-Maria Brady, Head of Biologicals and Administration,  
Veterinary Medicines Directorate U.K.

Dr W. Jean Dodds, Hemopet U.S.A.

Elizabeth Hart, Co-advocate for the judicious use of vaccines, Adelaide/SA

Monika Peichl, Germany

Wendye Slatyer, National Dog/Ringleader magazine

The Members, Parramatta International Canine Sports Inc

Elizabeth Ivory, Sydney

With reference to Complaint lodged on 7<sup>th</sup> January 2013, copy to:  
The University of Sydney

Dr Michael Spence, Vice-Chancellor and Principal  
Professor David Emery, Pro-Dean  
Professor Paul McGreevy, Sub-Dean Animal Welfare  
Professor Rosanne Taylor, Dean Veterinary Science  
Dr Jacqueline Norris, Sub-Dean Teaching & Learning Vet Science  
Professor Vanessa Barrs, Head of Small Animal Medicine  
Dr Kim Ticehurst, Director University Teaching Hospital Sydney

Dr John Baguley, Registrar, Veterinary Practitioners Board of NSW  
The Hon Katrina Hodgkinson, Minister for Primary Industries, NSW Parliament --- *Your ref. MF 13/75*  
Dr Ben Gardiner, National President, Australian Veterinary Association  
Dr David Neck, President, Australian Small Animal Veterinary Association  
Dr Megan Parker, CEO, Australian & New Zealand College of Veterinary Scientists  
Dr Kersti Seksel, President, Australian Companion Animal Council

*Further dissemination and publication on the internet*

[1] M. Horzinek – Presentation at INTERVET SYMPOSIUM – STOCKHOLM 2005-12-06 OCH GÖTEBORG 2005-12-07

<http://kliniken.msd-animal-health.se/files/sv/symposium/files/F%C3%B6rel%C3%A4sn%20mtrl%20TOT.pdf>  
accessed 07-09-2011

[2] SA Mitchell, RJ Zwijnenberg, J. Huang, A. Hodge and MJ Day “Duration of serological response to canine parvovirus-type 2, canine distemper virus, canine adenovirus type 1 and canine parainfluenza virus in client-owned dogs in Australia”, *AVJ Vol 90, No. 12, December 2012*

[3] Michael J. Day “How I Vaccinate an Animal with Previous History of Adverse Reaction”,  
Proceedings of  
2010 WSAVA Congress,  
Geneva <http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2010&Category=&PID=56260&O=Generic>  
accessed 02-08-2010

[4] Mitchell et al AVJ Dec-2012 + WSAVA 2007 Guidelines for the vaccination of dogs and cats

[5] Pfizer Animal Health full page advertisement, *Australian Veterinary Journal*

[6] Michael J. Day “Vaccination in 2010: The Hot Topic of the Millennium”, Proceedings ASAVA Conference, Hobart/TAS, Australia, August 2010

[7] Michael J. Day “How I Vaccinate an Animal with Previous History of Adverse Reaction”,  
Proceedings of  
2010 WSAVA Congress,  
Geneva <http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2010&Category=&PID=56260&O=Generic>  
accessed 02-08-2010

[8] E-Ructations, AVA NSW Division Newsletter, Issue 26 May 2011

----- Forwarded message -----

From: **Beate Mies** <[beatemies@gmail.com](mailto:beatemies@gmail.com)>

Date: Sat, May 12, 2012 at 3:14 PM

Subject: 21st Century Vaccination: What we do know --- but choose to ignore

To: [M.J.Day@bristol](mailto:M.J.Day@bristol)

Cc: Elizabeth Hart <[eliz.hart25@gmail.com](mailto:eliz.hart25@gmail.com)>

Professor Day,

As you, and others, continue to ignore my letter to WSAVA dated 6<sup>th</sup> February 2012 ([http://users.on.net/~peter.hart/WSAVA\\_Critique\\_Owner\\_Breeder\\_Guidelines.pdf](http://users.on.net/~peter.hart/WSAVA_Critique_Owner_Breeder_Guidelines.pdf)) --- a great “show” of solidarity, or the proverbial honesty among thieves? ---, so will I continue to monitor industry renditions on “developments” and “progress” with canine vaccination, and challenge you, and others, on the wilfully misleading information on this medically unsound and contentious practice.

Overall, your presentations at recent vet forums in Australia, ie. Pfizer sponsored lecture series on “21<sup>st</sup> Century Vaccination”, and the BSAVA annual conference in the U.K. on “What we need to know about vaccination and titre testing”, reinforce the commercial rather than the scientific message on canine vaccination practice. To quote one Australian attendee who, it seems, took umbrage to your not-so-high-tech reasoning that “**...3 years [revaccination interval]...is what we thought we could sell to you**”, and vented his frustration on a professional forum:

***“Not that the scientific evidence at hand showed 3 yearly was the best interval, but that us as Veterinarians would be more likely to accept 3 years. Way to go! Some clients already believe that we are trying to deceive them with annual revaccination. The best way to combat that...more lies!”***

This certainly is not a vote of confidence in academia, or the profession for that matter.

While, in the Preface to *Veterinary Immunology: Principles and Practice* (Day & Schultz, Manson Publishing 2011), you criticise that

*“In many universities, immunology is taught to veterinary undergraduates at a superficial level...”*, YET

*“(O)ne of the main clinical applications of immunology is the practice of vaccination, and all graduating veterinarians must have a solid understanding of the principles of vaccinology”*

your apparently industry-sponsored lectures lack the key elements of the “principle of vaccinology” – so succinctly summarised in the above mentioned textbook:

*“The final component of adaptive immunity is the development of a regulatory response that will switch off the system when it is no longer required (ie when the pathogen has been eliminated) so as not to cause damage to normal body tissue. However, once this is achieved, the immune system retains the memory of that immune response. **Immunological memory is another key feature of the adaptive immune response. Memory allows the generation of a much more effective secondary immune response if that same antigen is ever reencountered, and this phenomenon underpins the application of vaccination in clinical medicine.**”* (emphasis added)

And with the apparent *inappropriate focus* on the commercial aspects of vaccination, the basic principles underlying the use of immunobiological products to protect both the individual and the herd are further obscured.

In your Australian address, buried amongst the painfully drawn-out and fundamentally incorrect representation of minimum licensure requirements for canine core antigens, you – FINALLY - admit that:

***“it is not that some wonderful new product has been developed that provides longer-lasting immunity”***

***BUT “MLV core vaccines have always been able to provide long-lived (and probably lifelong) immunity”***

The above supports your statement in the August 2010 interview with ABC Radio in Australia, i.e.

***“The vaccines that we use for dogs and cats - a lot of them are actually very old. They're 40 year old products. But they still work incredibly well.”***

Conversely, your portrayal of “vaccine technology” at the recent BSAVA conference in the U.K. more than suggests that different (re-developed) vaccines are in use today. When providing background to the “*fundamental changes in the last decade*”, you informed your audience that

*“...new vaccination schedules...have been accommodated by vaccine manufacturers **introducing products with extended duration of immunity**...”* (emphasis added)

I am curious as to how such diametrically opposed statements by the same research scientist and on the very same subject matter can possibly be explained, argued, or defended?

In the 21<sup>st</sup> Century, despite admitting that **“(I)t is not possible to predict for any one animal when the ‘window of susceptibility’ (where there is no longer sufficient MDA to provide adequate protection, but still sufficient MDA to block endogenous response to vaccination)..”**, you continue to subscribe to the industry driven approach to puppy vaccination, i.e. repeated jabs, which may or may not result in protection of the individual by 14-16 weeks, and playing Russian Roulette with the health of countless puppies which may be unresponsive and thus remain susceptible until the 12-month “booster” is given. Of course, some of these puppies may encounter shed vaccine virus or street virus and seroconvert without “re”-vaccination, while others may be infected with wild virus and become seriously sick or die --- such infection risk is likely ‘limited’ to CPV-2 exposure as CDV and CAV-1 have not been diagnosed in the general dog population for several decades.

Why, in the 21<sup>st</sup> Century, would you advocate to base medical care on ASSUMPTIONS, rather than scientific evidence or, in this case, the very principle of MLV vaccination?

Why is there no recommendation to test puppies for MDA to enhance the chances of a response to a properly timed vaccination, and why do you not suggest that the immune response post-vaccination is, indeed, verified, rather than waiting until the next instalment at 12 months?

Given that MDA, and not age, is the main denominator for susceptibility to infection, antibody titre testing would, undoubtedly, be the scientific approach, if animal health and welfare, including effective and long-term protection against infectious viral diseases, were indeed the main drivers for vaccination.

Then, there is your paradoxical caution about **“higher-titre vaccines [which] increase the concentration of MDA, which persists for a longer period”**. Not only does this contradict your earlier statement about the ‘state-of-the-art’ and inherent properties of the core canine vaccines, but the “40-year-old vaccines” were presumably concocted based on minimum immunising titres, which has been the recurring theme to justify as to why a tea-cup poodle needs the same vaccine dose as a Great Dane. Therefore, if those “40-year-old” products were effective in the first place, resulting in a robust immune response, why would higher titre vaccines – which would require regulator approval as minimum/maximum release titres for vaccines batches are part of the marketing authority – be necessary at all? A vaccine, administered to an immunocompetent puppy, is either immunogenic, or it isn’t --- the 1994/95 Finland distemper outbreak springs to mind here...

Why would you encourage practitioners to contribute to COMMERCIAL disease surveillance schemes, but not to actively report suspected adverse events --- *“a reality with biological products”* (Martinod, Pfizer U.S.A., 1999) ---, and obvious vaccine failures to the regulating authorities? CICADA and Disease WatchDog are both commercial projects which are undeniably aimed at maximising vaccination in existing vet patients.

Why does academia, including WSAVA and AAHA, continue to encourage veterinarians to ‘bridge the 3-year gap’ between core vaccines by using unnecessary non-core products of dubious safety and efficacy on a regular basis? **“In fact”**, you stated in Australia, **“in most situations, dogs and cats will still receive an annual vaccination...”**.

Why would you recommend titre-testing of adult dogs on a yearly basis, if not to replace one unnecessary practice: that of revaccination of already immune animals, with another: that of looking for residual antibody which, in the absence of environmental challenge, e.g. CDV and CAV-1, would - not unexpectedly! - be at low levels? Why would a low titre in a successfully vaccinated = immunised adult dog be synonymous with a requirement for revaccination if the quintessential scientific principle of immunisation was applied, i.e. the pre-emptive exposure of the immune system to attenuated viral antigens in order to program memory cells which do not appear to have a ‘use-by’ date, and thus rendering most healthy vaccine recipients capable of generating an anamnestic response upon re-exposure? This very principle is relied upon in human medicine, without check/re-check (titre testing), and “maintenance of immunity” is taken for granted as the basic function of the body’s adaptive immune system.

As for the Australian lecture series' sponsor, Pfizer, their Australian marketing strategy for canine MLV vaccines can only be described as dubious, if not cynical. We recall that Pfizer was the first company to publish data, in the U.S. in January 2004, on the "Duration of serologic response to five viral antigens in dogs" (*JAVMA Vol. 224, No. 1*); the study had been conducted using a commercial vaccine, Vanguard (Norden Laboratories), and involved over 300 client-owned dogs.

When I asked Pfizer Australia, in July 2005, whether their (CSL) Canvac vaccine label claim will be updated for extended inter-vaccination intervals, their reply was "...not all vaccines are the same...You can rest assured that the Canvac range of vaccines has an excellent track record for safety and efficacy following annual vaccination...".

In 2007, the Australian Canvac 3 approved label still stated: "**Annual booster vaccinations are recommended to maintain adequate immunity**"

During 2009, Pfizer's full page advertisements in the Australian Veterinary Journal reiterated that "Pfizer Animal Health has a proven annual vaccination protocol..."

Then, in November 2010, the *Canvac 3* vaccine label was updated, and it now reads:

*Maintenance of immunity: With regard to canine distemper, infectious canine hepatitis and canine parvovirus, this product has been assessed as providing at least 12 months protection. **The APVMA has not assessed the duration of immunity of this product beyond 12 months.** However, revised policy of the Australian Veterinary Association (AVA), June 2009, proposes that in most cases, "core vaccine antigens" (distemper, hepatitis & parvovirus) need not be administered any more frequently than triennially, and that even less frequent vaccination may be considered appropriate if an individual animal's circumstances warrant it. Conversely, local factors may dictate more frequent vaccination scheduling. In formulating the vaccination regimen for the maintenance of immunity in any individual animal, the veterinarian, in consultation with the client, will consider the many factors involved to make best decision, including the history and health status of the animal, disease prevalence in the local area, the likely exposure of the animal to other animals, contemporary guidelines and published veterinary literature. (Emphasis added)*

The APVMA has not assessed the DOI beyond 12 months!!!!??

In late 2011, Pfizer's "Canvac Versatility Guarantee" surfaced: Pfizer now "**supports your vaccine protocol decisions by offering a 3-antigen, 4-year, \$ 5,000 guarantee**".

Now Canvac has a guaranteed minimum DOI of 4 years!!!!???

Speaking of Pfizer and the "rigorous testing of canine vaccines", to which you refer in your talks, does it not strike you as odd that the CDV strain in the Vanguard vaccine had not been correctly identified since at least 1993, although the monographs (USP + Ph EUR) do call for verification of strain identity? Then, the swift and quiet 'updating' of the label by regulators around the world following publication of the findings by Demeter *et al* (Hungary) in *Veterinary Microbiology* (2010)...

And, still on the subject of "rigorous testing of canine vaccines", what might be the likely long-term repercussions for canine health from feline retrovirus RD-114 contaminated vaccines (as published by Japanese researchers in 2011), and, what other exogenous (retro)viruses and other contaminations in the "40-year-old products" do go unnoticed simply because they aren't tested for?

The ag-vet legislation in the Western World does not concern itself with companion animals *per se*; companion dogs in particular have inspired and created a global multi-billion dollar industry, and the great majority of practicing veterinarians in Australia and elsewhere rely almost exclusively on companion animals, notably dogs, for their income. Coupled with self-regulation and the freedom from scrutiny by their licensing (government) bodies, veterinarians by and large have an unfair advantage in their dealings with the consumer. For whatever reasons, veterinarians appear to be incompetent in the fields of immunology and vaccinology (a deficit encouraged by vaccine manufacturers and supported by academia); as a profession, they have not deemed it necessary turn the tide on

traditional vaccination practices, despite the decade-long 'debate' and scientific 'revelations' – developments that have been intentionally withheld from the consumer of veterinary services. In the absence of "mandatory standards for the supply of veterinary medicines" (Australian Competition & Consumer Commission (ACCC) personal correspondence, 2005) and the profession's failure to adhere to legally prescribed ethical standards (informed consent), the veterinary industry as a whole exploits the unsuspecting consumer, who places his/her trust in the skilled professional to safeguard his/her animal's health and welfare. The industry's actions create an unconscionable degree of social injustice, consumer detriment, and disregard for animal welfare.

Professor Day, I will delay the broadcast of this email for a week or so, in the hope that you will engage in some meaningful dialogue on the appropriate vaccination of dogs, perhaps along the lines of

***"...a dog that is appropriately immunized as a pup probably never requires another core vaccine during its lifetime".***

Sincerely,

Beate Mies  
Advocate for the JUDICIOUS Use of Vaccines