

---

# Is over-vaccination harming our pets?

## Are vets making our pets sick?

Elizabeth Hart

*Disclaimer: This report is a layperson's perspective of the problem of over-vaccination of dogs and cats. In this report, I review a broad range of veterinary literature, and make copious use of original quotes to illustrate my argument. The purpose of this report is to provoke discussion to aid in effecting change to current dog and cat annual and triennial vaccination protocols. Concerned pet owners are encouraged to do their own research on this topic to support any decisions regarding vaccinating their pets.*

### Summary

Annual revaccination of dogs and cats appears to be an entrenched practice in Australia.<sup>1</sup> This goes against the World Small Animal Veterinary Association's (WSAVA) Dog and Cat Vaccination Guidelines<sup>2</sup> which recommend that "vaccines should not be given needlessly. **Core vaccines should not be given any more frequently than every three years** after the 12 month booster injection following the puppy/kitten series".<sup>3</sup>

The WSAVA guidelines recommend: "We should aim to vaccinate every animal, and to vaccinate each individual less frequently."<sup>4</sup> These international guidelines also recommend that "we should aim to reduce the 'vaccine load' on individual animals in order to minimise the potential for adverse reactions to vaccine products".<sup>5</sup>

Despite the fact the recommendations in the WSAVA guidelines have been known for many years (e.g. the AAHA Canine Vaccine Guidelines, (on which the WSAVA guidelines are based), were first published in 2003)<sup>6</sup>, it has been my experience that the information contained in these guidelines has been withheld from pet owners in Australia. **Most importantly, information regarding long duration of immunity for the MLV core vaccines is not being passed onto pet owners for their consideration. Veterinarians are not obtaining "informed consent" from their clients before revaccinating their pets.**

After an inexplicably long delay, there is now a suggestion that a triennial vaccination protocol is being considered in Australia.<sup>7</sup> If a triennial protocol was adopted, this would bring Australia into line with the US where it appears veterinary schools have already adopted a triennial vaccination protocol.<sup>8</sup> **But would this be simply replacing one arbitrary vaccination protocol with another?**

---

<sup>1</sup> Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" (recently accessible on the internet) refers to "Responsible use of veterinary vaccines for dogs and cats". This draft policy admits that "annual vaccination is the currently accepted practice in Australia".

<sup>2</sup> Day, M.J., Horzinek, M.C., Schultz, R.D. 2007. Guidelines for the Vaccination of Dogs and Cats, compiled by the Vaccination Guidelines Group (VGG) of the World Small Animal Veterinary Association (WSAVA). Journal of Small Animal Practice 48 (9), 528-541: [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf)

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

<sup>5</sup> *Ibid.*

<sup>6</sup> The WSAVA Guidelines are built on the 2006 American Animal Hospital Association (AAHA) Canine Vaccine Guidelines, Revised and the American Association of Feline Practitioners (AAFP) Feline Vaccine Advisory Panel. The AAHA Canine Vaccine Guidelines were originally published in 2003.

<sup>7</sup> Email correspondence from Mark Lawrie, President of the Australian Veterinary Association, 2 March 2009.

<sup>8</sup> I understand that veterinary schools in the US have adopted a triennial vaccination protocol. I am currently undertaking a survey of all the US veterinary schools to verify this.

This report examines the history of canine vaccination and challenges the scientific credibility and ethical legitimacy of both annual and triennial revaccination with MLV core vaccines for canine parvovirus (CPV), canine distemper virus (CDV) and canine adenovirus (CAV). It argues that pet owners must be given the latest scientific evidence about vaccination so they can make an informed decision about vaccinating their pets.

To ensure that pets do not continue to be put needlessly at risk of suffering an adverse reaction to unnecessary revaccination, the veterinary profession, academia, government regulators and industry must cooperate and **take immediate action** to ensure that pet owners are informed of the long duration of immunity, probably lifelong for dogs, of MLV core vaccines.

***In response to my concerns about the over-vaccination of pets in Australia (see copy of correspondence attached at Appendix 1), the Australian Pesticides and Veterinary Medicines Authority is convening a special meeting of senior scientific staff on Wednesday 15 April 2009. I await the outcome of this meeting with interest.***

### **Background to my concerns**

My interest in the problem of over-vaccination of pets was initiated after my own dog, Sasha, an eight year old female Maltese x Silky terrier, became very ill after her last booster revaccination in September 2008. Research undertaken after her death leads me to suspect her illness and subsequent death was influenced or caused by her recent revaccination.

I have spent the past six months researching this topic to support my contention that my dog could have suffered a delayed adverse reaction to revaccination. During my research I have become increasingly concerned that this could be a widespread and hidden problem, affecting many pets whose owners may not be aware that ongoing over-vaccination could be harming their pets' health.

There is enormous resistance to acknowledging and acting on this problem in Australia. It is shocking that laypeople like myself are in the difficult position of trying to bring the veterinary profession to account. I am particularly aware of the possibility that if the problem of over-vaccination had been acknowledged and addressed years ago, my dog Sasha might still be alive. Who knows how many other people's pets may have been adversely affected over the years of inaction? As I have discovered, the system is heavily weighted against recognising, acknowledging and reporting possible delayed reactions to vaccination.

I am extremely alarmed about the lack of regulation, transparency and accountability in the veterinary profession that I have discovered during my investigations into the problem of over-vaccination of pets over the past six months. I have hit many "brick walls" with people ignoring my requests for information, and even demanding that I stop sending them emails which outline my legitimate concerns about the health and safety of pets in Australia. It is certainly frightening that people in positions of authority are refusing to listen or act upon pet owners' concerns.

I believe there are serious conflict of interest and ethical issues that must be acknowledged and addressed by the veterinary profession **immediately**. Action has been delayed for far too long.

***Who knows how many other people's pets might be needlessly adversely affected right now, while the practice of unnecessary annual (and triennial) revaccination with MLV core vaccines is allowed to continue?***

### What are the latest international dog vaccination guidelines?

The most recent guidelines for the vaccination of dogs (and cats) were compiled by the Vaccination Guidelines Group of the World Small Animal Veterinary Association (WSAVA) and published in 2007.<sup>9</sup>

These guidelines are built on those developed by the American Animal Hospital Association (AAHA) Canine Vaccine Task Force and the American Association of Feline Practitioners (AAFP) Feline Vaccine Advisory Panel.

The WSAVA guidelines were developed for **global** application.

These guidelines “have been drafted with the objective of educating and informing the profession and to recommend rational vaccine use for individual pets and dog/cat populations”. The guidelines are “based upon a consensus among experts” and “reflect a combination of opinion, experience, and scientific data, published and unpublished”.<sup>10</sup> The guidelines note that it is “necessary to continually re-evaluate vaccination practice.”<sup>11</sup>

The WSAVA guidelines strongly recommend “that wherever possible ALL dogs and cats receive the benefit of vaccination. This not only protects the individual animal, but provides optimum ‘herd immunity’ that minimises the likelihood of outbreak of infectious diseases.”<sup>12</sup> Even in developed countries it is estimated that only 30-50% of the pet animal population is vaccinated, and probably much less in developing countries.<sup>13</sup>

While the WSAVA guidelines aim for herd immunity they also stress the need to:

reduce the ‘vaccine load’ on individual animals in order to minimise the potential for adverse reactions to vaccine products. For that reason we have seen the development of vaccination guidelines based on a rational analysis of the vaccine requirements for each pet, and the proposal that vaccines be considered ‘core’ and ‘non-core’ in nature.<sup>14</sup>

The message that the WSAVA guidelines are most keen to impress is:

***We should aim to vaccinate every animal and to vaccinate each individual less frequently.***<sup>15</sup>

The WSAVA guidelines define **core** vaccines which ALL dogs and cats, regardless of circumstances, should receive.

Core vaccines for dogs are those that protect from **canine distemper virus (CDV), canine adenovirus (CAV) and canine parvovirus (CPV)**.<sup>16</sup> (Note: Rabies is also defined as a core vaccine where required by statute or in areas where the disease is endemic. Rabies vaccination is not required in Australia.)

The WSAVA guidelines recommend initial MLV core vaccination of puppies at 8 to 9 weeks of age followed by a second vaccination 3 to 4 weeks later, and a third vaccination given between 14 to 16 weeks of age. The WSAVA guidelines also recommend that all dogs should receive a

<sup>9</sup> Day, M.J., Horzinek, M.C., Schultz, R.D. 2007.

<sup>10</sup> *Ibid.*

<sup>11</sup> *Ibid.*

<sup>12</sup> *Ibid.*

<sup>13</sup> *Ibid.*

<sup>14</sup> *Ibid.*

<sup>15</sup> *Ibid.*

<sup>16</sup> *Ibid.*

booster 12 months after completion of the primary vaccination course. The 12 month booster will ensure immunity for dogs that may not have adequately responded to the puppy vaccination course.<sup>17</sup> The WSAVA guidelines note that "...in cultural or financial situations where a pet animal may only be permitted the benefit of a single vaccination, that vaccination should be with core vaccines at 16 weeks of age or above."<sup>18</sup>

The WSAVA guidelines advise that dogs properly vaccinated with MLV core CDV, CPV-2 and CAV-2 vaccines "would have  $\geq 98\%$  protection from disease. Similarly we would expect a very high protection from infection".<sup>19</sup>

The WSAVA guidelines also define **non-core** vaccines, which are "those that are required by only those animals whose geographical location, local environment or lifestyle places them at risk of contracting specific infections."<sup>20</sup> For example, dogs boarded at kennels may need additional vaccination for 'kennel cough'. However, given the possibility of adverse reaction to vaccination, pet owners should consult with their veterinarian to assess risk-benefit ratios, and consider very carefully if their pet actually needs any non-core vaccines.<sup>21</sup>

To allow veterinarians and pet owners to make risk/benefit assessments in the interests of individual animals it has been noted that access to single component vaccine products will be necessary.<sup>22</sup>

***Refer to the WSAVA guidelines for further information and recommendations about core and non-core vaccines.***

It is interesting to note that the WSAVA guidelines recommend that boosters for MLV core vaccines for dogs ***should not be given more often than every three years***. This is actually quite an ambiguous statement and is notably different from the recommendations of earlier guidelines.

For example, the 2003 AAHA Canine Vaccine Guidelines recommend that, "after a booster at 1 yr, revaccination ***every 3 yrs*** is considered protective" with CDV, CPV-2 and CAV-2 vaccines".<sup>23</sup> (My emphasis).

In the 2006 AAHA Canine Vaccine Guidelines, Revised, this recommendation changes slightly to "...revaccination is recommended at intervals of every 3 years ***or longer***."<sup>24</sup> (My emphasis.)

The recommendations of the more recent 2006 AAHA and WSAVA guidelines do ***not*** actually recommend revaccination with MLV core vaccines ***every*** three years.

The WSAVA guidelines note that:

<sup>17</sup> *Ibid.*

<sup>18</sup> *Ibid.*

<sup>19</sup> *Ibid.* (see Frequently Asked Questions: No. 35).

<sup>20</sup> *Ibid.*

<sup>21</sup> For more information about non-core vaccines refer to: Schultz, R.D. 2007. What everyone needs to know about canine vaccines and vaccination programs. 2007 National Parent Club Canine Health Conference:

<http://www.spinoneus.org/forum/uploaded/Admin/Vaccinations2007.pdf>

<sup>22</sup> Day, M.J. 2006. Vaccine side effects: Fact and fiction. Veterinary Microbiology. 117, 51-58.

<sup>23</sup> Paul, M.A., Appel, M.J., Barrett, R., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Keil, D., Lappin, M., Schultz, R.D., Thacker, E., Trumpeter, E., Welborn, L. 2003. Report of the American Animal Hospital Association (AAHA) Canine Vaccine Task Force: 2003 Canine Vaccine Guidelines, Recommendations, and Supporting Literature: [http://www.britfield.com/health/canine\\_vaccine\\_guidelines.pdf](http://www.britfield.com/health/canine_vaccine_guidelines.pdf)

<sup>24</sup> Paul, M.A., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Hurley, K.F., Roth, J.A., Schultz, R.D., Thacker, E., Welborn, L. 2006 AAHA Canine Vaccine Guidelines, Revised: [http://www.ufsheltermedicine.com/news/2006\\_AAHA\\_Canine\\_Vax\\_GL.pdf](http://www.ufsheltermedicine.com/news/2006_AAHA_Canine_Vax_GL.pdf)

Dogs that have responded to vaccination with MLV core vaccines maintain a solid immunity (immunological memory) for many years in the absence of repeat vaccination.<sup>25</sup>

*So why do the WSAVA guidelines include any mention of “three years” in their revaccination recommendations?*

This report will challenge the need for either annual **or triennial** revaccination with MLV core vaccines

### What is the duration of immunity for MLV core vaccines?

It appears ongoing revaccination of adult dogs with MLV core vaccines is **unnecessary** because these products have long duration of immunity.

According to my close reading of the 2003 and 2006 AAHA and WSAVA guidelines, **neither annual nor triennial revaccination is actually necessary.**

According to the Fact Sheets of the WSAVA Dog and Cat Vaccination Guidelines (which are built on the AAHA canine guidelines and the AAFP feline guidelines), duration of immunity after vaccination with MLV core vaccines is **7 years or longer**, based on challenge and serological studies, for Canine Parvovirus Type 2 (CPV-2), Canine Adenovirus (CAV-2) and Canine Distemper Virus (CDV) vaccines.<sup>26</sup>

The WSAVA guidelines also note:

Most vaccinated dogs will have a persistence of serum antibody (against core vaccine antigens) for many years. Immunologically, this antibody reflects the function of a distinct population of long-lived plasma cells (memory effector B cells). Induction of immunological memory is the primary objective of vaccination. For core vaccines there is excellent correlation between the presence of antibody and protective immunity and **there is long DOI for these products.**<sup>27</sup> (My emphasis).

The 2003 AAHA guidelines explain further:

#### *The Immune Response to Vaccination or Infection*

When an animal is vaccinated or infected, the immune response includes differentiation and expansion of clones of antigen-specific T and B cells that serve as effector cells for immediate protection and memory cells that provide long-term immunity. The effector cells themselves are usually short lived, dying in days or weeks after stimulation. Memory cells, on the other hand, survive for years, **often for the life of an animal** for some vaccines and infections. Memory T and B cells and the antibodies produced by long-lived memory effector B cells cooperate to provide protection from challenge at a later time in life for the vaccinated animals that come in contact with the pathogen. Available information suggests that vaccinal protection from infection and/or disease in the dog is regulated primarily by humoral immunity and secondarily by cell-mediated immunity. **This finding is particularly true when vaccination is known to prevent reinfection (sterilizing immunity). This is the ultimate form of immunity because disease cannot develop when infection is blocked or infection is significantly limited. Sterilizing immunity occurs after effective vaccination (protection) against**

<sup>25</sup> Day, M.J., Horzinek, M.C., Schultz, R.D. 2007.

<sup>26</sup> *Ibid.*

<sup>27</sup> *Ibid.*

**certain pathogens such as CDV, infectious canine hepatitis, and CPV.**<sup>28</sup> (My emphasis).

The 2003 AAHA guidelines confirm:

When MLV vaccines are used to immunize a dog, **memory cells develop and likely persist for the life of the animal.** Resident memory cells respond rapidly providing an anamnestic immune response at the time of challenge (infection) with the pathogen.<sup>29</sup>

In a more recent paper, Marian Horzinek, a member of the WSAVA Vaccination Guidelines Group, provides more explanation:

The scientific arguments in favour of less frequent revaccinations are traditionally based on antibody titers. Protection against most viral diseases is indeed antibody-mediated, and antibodies are easily measured. In dogs these have been found to persist for more than 7 years, the study did not look later. The high prevalence of adequate antibody response (CPV, 95.1%; CDV, 97.6%) in a large population (>1500 animals) “suggests that annual revaccinations against CPV and CDV may not be necessary” was the authors’ conclusion (Twark and Dodds, 2000)<sup>30</sup> **...The question whether the titers found are protective or not against a field virus challenge is irrelevant for this discussion. It is not the residual serum antibody that determines survival to challenge but the population of memory cells that can quickly expand.** The question about the longevity of memory cells has now been answered experimentally; the question was not, if lifelong immunity exists (which is common knowledge), but whether its mechanism relies on a lifelong presence of the antigen in the animal’s organism or of the cells’ longevity. The latter was not found to be the case. “Memory B-cell persistence is independent of persisting immunising antigen”; (Maruyama et al., 2000)<sup>31</sup> However, it is not an individual memory B-cell, rather a population of slowly dividing clones that persists during the life of the organism. Like in neurobiology, a paradigm has been shattered: neurons and memory cells can indeed divide.<sup>32</sup> (My emphasis.)

The 2003 AAHA guidelines go on to ask a very pertinent question, with a stunning answer:

So why revaccinate animals with these products annually when the minimum DOI (memory cells and antibody) is many years, if not a lifetime, for some of the vaccines?

**Ironically, there is no scientific basis for the recommendation to revaccinate dogs annually with many of the current vaccines that provide years of immunity (e.g. CDV, CPV-2, rabies)...**<sup>33</sup> (My emphasis.)

Indeed, I would argue not only is there no scientific basis to revaccinate dogs annually with MLV core vaccines, **there is also no scientific basis to revaccinate dogs triennially...**

However, there are many in the veterinary profession who are unwilling to accept that ongoing revaccination is unnecessary. The 2003 AAHA guidelines note:

<sup>28</sup> Paul, M.A., Appel, M.J. 2003.

<sup>29</sup> *Ibid.*

<sup>30</sup> Twark, L., Dodds, W.J., 2000. Clinical use of serum parvovirus and distemper virus antibody titers for determining revaccination strategies in healthy dogs. J. Am. Vet. Med. Assoc, 217, 1021-1024.

<sup>31</sup> Maruyama, M., Lam, K.P., Rajewsky, K., 2000. Memory B-cell persistence is independent of persisting immunising antigen. Nature 407, 636-642.

<sup>32</sup> Horzinek, M.C. 2006(a). Vaccine use and disease prevalence in dogs and cats. Veterinary Microbiology. 117, 2-8.

<sup>33</sup> Paul, M.A., Appel, M.J. 2003.

Some researchers suggest that the only true way to determine DOI is by way of a prospective study that would be comprised of two (one group vaccinated; one group nonvaccinated) relatively large groups of dogs (representing common breeds) housed within a pathogen-free environment; therefore, at the end of the study, the non-vaccinated group would then be challenged with virulent isolates of each of the pathogens for which the vaccines were designed to provide protective immunity. Few minimum DOI studies using this study design have been done, and few, or none, will be done due to the high cost and difficulty of maintaining control (i.e. negative) animals. **More important, based on current knowledge of immunity resulting from vaccination, studies of this type need not be done.**<sup>34</sup> (My emphasis.)

Ronald Schultz, an expert in immunology and a member of the AAHA Canine Vaccine Task Force and WSAVA Vaccination Guidelines Group, has been arguing since the late 1970s that annual revaccination is unnecessary.<sup>35 36</sup>

In a paper published over 10 years ago, Schultz provided the following analogy:

An important question to ask yourself is: "What do we do to ensure that children who are vaccinated at an early age, usually less than 6 years of age, still have immunity at 20, 40, 60, or 90 years of age?" Nothing! We don't measure titers in people, and we don't routinely vaccinate adults. We rely on the memory cells of the immune system. Since vaccines for people are similar in many ways to canine or feline vaccines, since the immune system of a person is similar to that of an animal, and since immunity persists for the life of a person (average 70+ years), then why wouldn't immunity from canine or feline vaccines persist for 10 to 15 years? **The answer is that many canine and feline vaccines do provide the same lifelong immunity.**<sup>37</sup> (My emphasis.)

Schultz believes:

that dogs and cats vaccinated as puppies and kittens should be revaccinated at 1 year of age with the vaccines used earlier. **After that I do not believe there is an immunologic need to revaccinate annually with CDV, CPV-2, CAV-2...** My own pets are vaccinated once or twice as pups and kittens, then never again except for rabies... I have used this program since 1974 without incident of an infectious disease in my pets or the pets of my children and grandchildren.<sup>38</sup> (My emphasis.)

In his presentations to dog clubs, Schultz states that: "If a puppy is immunized with the three MLV vaccines used to prevent these diseases, there is every reason to believe the vaccinated animal will have up to life-long immunity!"<sup>39</sup>

I believe the argument that ongoing revaccination of dogs with MLV core vaccines is unnecessary is very persuasive and conclusive. So why does the majority of the veterinary profession persist in pushing annual or triennial revaccination? Why do they keep making unrealistic demands for challenge studies to prove annual or triennial revaccination is unnecessary? Challenge based duration of immunity studies are out of the question for the human population, so how can they be justified for the pet population? Humans aren't revaccinated every year. How can the ongoing revaccination of dogs with MLV core vaccines be justified?

<sup>34</sup> *Ibid.*

<sup>35</sup> Schultz, R.D. 1998. Current and future canine and feline vaccination programs. *Veterinary Medicine*. March 1998, 233-254.

<sup>36</sup> Schultz, R.D. 2006. Duration of immunity for canine and feline vaccines: A review. 2006. *Veterinary Microbiology*. 117, 75-79.

<sup>37</sup> Schultz, R.D. 1998.

<sup>38</sup> *Ibid.*

<sup>39</sup> Schultz, R.D. 2007.

The latest scientific research by immunology experts has demonstrated the principle that animals vaccinated with MLV core vaccines are likely to have “life-long immunity”.

Wouldn't it be more effective to expend greater effort to vaccinate more dogs in the interests of herd immunity, rather than revaccinate some dogs repeatedly? How can repeated revaccination of dogs with MLV core vaccines be justified, particularly as it puts adult dogs needlessly at risk of an adverse reaction?

*Why do so many veterinarians continue to recommend revaccinating dogs with MLV core vaccines annually or triennially?*

*How can they justify this apparently unnecessary and unethical practice?*

### **The vaccine product label revaccination recommendation – what is the scientific evidence?**

It appears veterinarians use the vaccine product label to justify continued annual (and triennial) revaccination.

For example, one vaccine product I believe is widely used in Australia recommends annual revaccination “to ensure continuity of protection”.<sup>40</sup> Since January 2009, I have made repeated enquiries to the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ascertain the scientific basis for this annual recommendation. So far they have not provided an answer.

I also contacted a vaccine company in Australia to enquire about the basis of the recommendation to revaccinate annually “to ensure continuity of protection”. I received a surprising verbal explanation, but my request for this explanation to be provided in writing was refused.

In the absence of formal advice from the Australian authorities, I am relying on the veterinary literature. From my reading of the literature, cited previously in this report, it seems there is **no** scientific justification for the vaccine label recommendation to revaccinate annually (**or triennially**) with MLV core vaccines “to ensure continuity of protection”.

An article titled “Are we vaccinating too much?”<sup>41</sup> published in 1995 (*i.e. 14 years ago...*) highlighted concerns about vaccine reactions and acknowledged that there was little scientific documentation to back up label claims for annual revaccination, noting that many vaccines would “last for years”. This article appears to have been the catalyst for challenging outdated annual revaccination protocols and instigating action for new guidelines to be defined.

In 2002 the AVMA Council on Biologic and Therapeutic Agents' report on cat and dog vaccines was published. This report noted:

Revaccination recommendations should be designed to create and maintain clinically relevant immunity while minimizing adverse event potential. The practice of revaccinating animals annually is largely based on historic precedent supported by minimal scientific data. There is increasing evidence that some vaccines provide

<sup>40</sup> Check PUBCRIS on the the Australian Pesticides and Veterinary Medicines Authority's website for vaccine label details: <http://services.apvma.gov.au/PubcrisWebClient/welcome.do;sessionId=vskyFtjLZKvxGrbpnfpZXLRLqj9Z390Z9Gk5JWF2nQBccpBXFFw!546591743>

<sup>41</sup> Smith, C.A. 1995. Are we vaccinating too much? JAVMA. Vol 207, No. 4 August 15, 421-425.



immunity beyond 1 year. Unnecessary stimulation of the immune system does not result in enhanced disease resistance and may expose animals to unnecessary risks.<sup>42</sup>

The 2003 AAHA guidelines provide some historical perspective on how annual revaccination became entrenched. Apparently, the annual revaccination recommendation originated in the late 1950s as a matter of convenience, but given more recent scientific evidence it can no longer be supported today.<sup>43</sup> (See page 17 of the 2003 AAHA guidelines for more information).

Ronald Schultz provides more background:

All vaccines, with the exception of rabies vaccines, were licensed by the United States Department of Agriculture (USDA) based on challenge studies performed from only a few weeks to a few months after vaccination. ***All the vaccine labels included the statement “Annual Revaccination Recommended” without the knowledge of whether the true DOI was a year or a life time.***<sup>44</sup> (My emphasis.)

Schultz notes:

The one year recommendation was not determined by any scientifically validated studies ***nor will one find in the literature publications that demonstrate a need for annual vaccination with many of the products in use.***<sup>45</sup> (My emphasis.)

As already noted in this paper, in more recent times it has been recognised that canine MLV core vaccines provide long duration of immunity. This is regardless of the manufacturer or product name. In 2003 the AAHA Canine Guidelines Task Force advised:

...that vaccines against canine distemper (CDV), canine parvovirus (CPV), and canine adenovirus-2 (CAV-2) produced by major biologics manufacturers *all* produce excellent immune responses and can be soundly and reliably administered at the discretion of the clinician in extended duration of immunity protocols. Discretionary administration indicates that all of these vaccines can be used in extended interval vaccination programs.<sup>46</sup>

In a review published in 2006, Schultz notes:

Recently, all major companies that make canine vaccines for the U.S. market have completed their own studies; published data show a 3 years or longer minimum DOI for the canine core products, canine distemper virus (CDV), canine parvovirus type 2 (CPV-2), and canine adenovirus-2 (CAV-2).<sup>47</sup>

I raised the issue of annual revaccination with Bruce Twentyman, Deputy Veterinary Director of the Australian Veterinary Association earlier this year and received the following response:

As to the frequency of vaccination, our members our *[sic]* advised to follow the manufacturer's recommendations as it is they that have done the scientific work and experimentation to enable the product to be registered in the first place. To go outside these recommendations would be to use the product in an “off-label” situation. There are

<sup>42</sup> Klingbord, D.J., Hustead, D.R., Curry-Galvin, E.A., Gumley, N.R., Henry, S.C., Fairfield, T.B., Paul, M.A., Boothe, D.M., Blood, K.S., Huxsoll, D.L., Reynolds, D.L., Riddell, G.Jr., Reid, J.S., Short, C.R. 2002. AVMA Council on Biologic and Therapeutic Agents' report on cat and dog vaccines. JAVMA. Vol. 221, No. 10, 1401-1407.

<sup>43</sup> Paul, M.A., Appel, M.J. 2003.

<sup>44</sup> Schultz, R.D., 2006.

<sup>45</sup> Schultz, R.D. 1998.

<sup>46</sup> Paul, M.A., Appel, M.J. 2003.

<sup>47</sup> Schultz, R.D., 2006.

now vaccines available that are registered to last 3 years and these are the ones that should be used in that manner.<sup>48</sup>

The obvious question is, if there are “vaccines available that are registered to last 3 years” why haven’t the vaccines with an “annual” recommendation been deemed obsolete and taken off the market, particularly when the risk of adverse reaction to vaccination is well known, and therefore unnecessary revaccination should be avoided? (*Of course, in reality, there is probably little difference between the annual and 3 year vaccines...they both provide long duration of immunity, probably life-long...*)

However, let us tackle the statement from the Australian Veterinary Association that the manufacturer has “done the scientific work and experimentation to enable the product to be registered in the first place”. As yet, the Australian Pesticides and Veterinary Medicines Authority has not advised me of the “scientific work and experimentation” that enabled “the product to be registered in the first place”, so I am still unaware of what is happening in an Australian context.

In the absence of this information, I will work on Ronald Schultz’s advice that annual revaccination was recommended without the knowledge of whether the true DOI of the vaccine was a year or a life time.<sup>49</sup> If this is indeed the case, it does not appear there was much done in the way of “scientific work and experimentation” to justify the annual revaccination recommendation.

It appears obvious that the more recent science based recommendations in the AAHA and WSAVA guidelines supersede the unfounded annual revaccination recommendation on the labels of MLV core vaccines.

David Hustead, who at the time of writing his paper “What you can and cannot learn from reading a vaccine label” was International Technical Director of Fort Dodge Animal Health, admits that the biologic necessity to revaccinate annually has not been demonstrated.<sup>50</sup> Hustead also notes that:

...the text found on a vaccine label is almost always behind the profession’s current expectations and, rarely, if ever, leads vaccine users toward better product understanding. Any reading of a current vaccine label must be viewed within the context of the rules that existed when it was licensed.<sup>51</sup>

Schultz notes that veterinarians are not constrained by label recommendations when administering vaccines, in effect it appears they are able to use vaccines ‘off-label’:

USDA approval is not required for the recommendation of extended DOI vaccination programs for any other vaccine. Thus a veterinarian or animal owner can administer any vaccines other than rabies as often or as infrequently as needed or desired regardless of whether minimum DOI studies have been performed or recognised by the USDA. Therefore, all USDA licensed canine and feline vaccines can legally be used to meet the extended interval guidelines recommended by AAHA, AAFP, or suggested in any other reports.<sup>52</sup> (Also see footnote <sup>53</sup> for a European perspective on regulatory issues).

<sup>48</sup> Email correspondence from Bruce Twentyman, Deputy Veterinary Director of the Australian Veterinary Association, 6 January 2009.

<sup>49</sup> Schultz, R.D. 2006.

<sup>50</sup> Hustead, D.R. 2001. What you can and cannot learn from reading a vaccine label. *Veterinary Clinics of North America: Small Animal Practice*. Vol 31, No.3, May, 539- 556.

<sup>51</sup> *Ibid.*

<sup>52</sup> Schultz, R.D. 2006.

<sup>53</sup> Michael Day provides a European perspective on regulatory issues: “The current attitude to vaccination guidelines in Europe is more conservative than in the USA. Veterinarians are encouraged to adhere to data sheet recommendations

In a paper titled "Vaccination guidelines: a bridge between official requirements and the daily use of vaccines", Etienne Thiry and Marian Horzinek also support 'off-label' use of vaccines in light of "new scientific data":

...although the vaccination schedule that appears in the package insert has been reviewed and approved by the licensing authorities, the practical use of the vaccine in the field can deviate from this official schedule. Furthermore, new scientific data can modify the vaccination approach, but the respective changes in the regulations can take several years before coming into force. In such cases, guidelines can serve as a bridge between official and unofficial recommendations for vaccine use.<sup>54</sup>

In particular, Thiry and Horzinek note:

It is of primary importance that the vaccination schedules followed by the veterinary practitioners are the most efficacious ones **even if this means that they do not strictly follow the recommendations of the package inserts.**<sup>55</sup> (i.e. "the label"). (My emphasis.)

Thiry and Horzinek make the important point that veterinary practitioners must follow the most "efficacious" vaccination schedules.

In the US, the government regulator, the US Department of Agriculture (USDA), and the American Veterinary Medical Association (AVMA) appear to have become more proactive on this issue.

The United States Department of Agriculture (USDA) issued Center for Veterinary Biologics Notice Draft No. 327 on the subject of "Studies to Support Label Claims of Duration of Immunity"<sup>56</sup> for comment by 27 October 2008. This document noted:

Studies conducted to support DOI label claims should be designed to **ensure claims which are not false and misleading**, as per Title 9, Code of Federal Regulations, Part 112.11(b).<sup>57</sup> (My emphasis.)

The American Veterinary Medical Association responded, saying it:

...supports science-based labels that provide pivotal safety and efficacy data summaries (including documented DOI) as a much improved means of providing product use guidance. As veterinarians recommend and administer biologics to millions of animals, the AVMA has repeatedly articulated the need for biologic labels to communicate an appropriate expectation of product performance to users of the products. We believe these data derived from USDA-reviewed data are greatly needed; therefore, the AVMA urges for provision of pivotal efficacy information on product labels.<sup>58</sup>

---

for vaccine administration, although it is recognised that any veterinarian with the informed consent of an owner may use a modified protocol in any individual animal." Day, M.J. 2006. For background on regulatory issues in the UK, refer to: Gaskell, R.M. 2006. Duration of immunity (DOI) – The regulatory issues. *Veterinary Microbiology*. 117, 80-85.

<sup>54</sup> Thiry, E., Horzinek, M.C. 2007. Vaccination guidelines: a bridge between official requirements and the daily use of vaccines. *Veterinary Sciences Tomorrow* – 29 June 2007: <http://www.vetscite.org/publish/articles/000065/index.html>

<sup>55</sup> Thiry, E., Horzinek, M.C. 2007.

<sup>56</sup> United States Department of Agriculture (USDA), Center for Veterinary Biologics Notice Draft No. 327 on the subject of "Studies to Support Label Claims of Duration of Immunity":

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/Noticedraft327.pdf](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/Noticedraft327.pdf)

<sup>57</sup> *Ibid.*

<sup>58</sup> American Veterinary Medical Association letter, re Center for Veterinary Biologics Notice Draft No. 327: Studies to Support Label Claims of Duration of Immunity dated October 27 2008:

[http://www.avma.org/advocacy/federal/regulatory/practice\\_issues/vaccines/duration\\_of\\_immunity\\_ltr.pdf](http://www.avma.org/advocacy/federal/regulatory/practice_issues/vaccines/duration_of_immunity_ltr.pdf)

In regards to Duration of Immunity Recommendations, the letter from the American Veterinary Medical Association goes onto say:

The AVMA urges that science-based labels should provide a summary of data to explain what is known about the DOI for that product. The data summary should identify the measured time interval, what outcomes were monitored, and how the outcome was determined (e.g., challenge, serology). Specifically, biologic labels should state what is known with respect to the interval at which immunity was demonstrated, i.e., animals were challenged x number of weeks post-vaccination.<sup>59</sup>

The AVMA believes it is preferable to use the label phrase “Immunity was demonstrated at...” rather than “duration of immunity” because the latter fails to distinguish between maximum and minimum duration of immunity; a distinction of great clinical relevance. The phrase “Immunity was demonstrated at...” is consistent with the science-based provision of licensure information and offers the opportunity to demonstrate the onset of immunity when available.<sup>60</sup>

The American Veterinary Medical Association’s letter also notes Additional Recommendations:

***The AVMA urges that the annual revaccination recommendation should be removed from all biologic labels where the statement lacks a scientific basis.*** We support statements indicating that a specific revaccination schedule has not been established for a product and consultation with a veterinarian is recommended.<sup>61</sup> (My emphasis.)

For example, when a firm has demonstrated immunity at one year ***or another timeframe***, the label should NOT bear a revaccination interval driven by that data point. That data point likely represents a minimum duration of immunity. Instead, the label should factually state that immunity was demonstrated on challenge at a specific interval of time post-vaccination.<sup>62</sup> (My emphasis.)

The American Veterinary Medical Association’s letter notes that the label should ***not*** bear a revaccination interval driven by the firm’s demonstrated immunity at one year ***or another timeframe*** as “that data point likely represents a minimum duration of immunity”. This appears to support my argument that not only are recommendations to revaccinate annually unjustified, but also recommendations to revaccinate ***triennially*** are also without scientific basis.

***Why hasn’t action been taken in Australia to address the contradiction between the latest scientific evidence and the unfounded vaccine product label?*** Why aren’t Australian veterinarians taking notice of the latest scientific evidence and following the most efficacious vaccination schedules?

Why hasn’t the Australian Veterinary Association provided leadership on this issue over the past years, and recommended that veterinarians use MLV core vaccines “off-label” to ensure they take notice of the latest scientific advice? Apparently the government regulator, the Australian Pesticides and Veterinary Medicines Authority (APVMA) allows for off-label use: According to the APVMA Fact Sheet on Veterinarians and Veterinary Medicines:

<sup>59</sup> *Ibid.*

<sup>60</sup> *Ibid.*

<sup>61</sup> *Ibid.*

<sup>62</sup> *Ibid.*

Veterinarians may also make treatment recommendations which are inconsistent with the instructions on labels of registered veterinary chemical products. The Agvet Code provides for these actions, as long as they are undertaken for animals under a veterinarian's care\* and are allowed under State and Territory laws.<sup>63</sup>

The APVMA is the government regulator. The APVMA's purpose is to:

...independently evaluate the safety and performance of chemical products intended for sale, making sure that the health and safety of people, animals and the environment are protected. Only products that meet these high standards are allowed to be supplied.<sup>64</sup>

The APVMA's mission is to:

protect the health and safety of people, animals and crops, the environment, and trade, and support Australian primary industries **through evidence-based, effective and efficient regulation of pesticides and veterinary medicines**.<sup>65</sup> (My emphasis).

On the information available to me so far, it appears the recommendation to revaccinate annually (or triennially) with MLV core vaccines to "ensure continuity of protection" is **not** evidence-based.

Given the widespread use of pet vaccines in the community, why haven't the Australian Pesticides and Veterinary Medicines Authority, State and Territory government authorities, vaccine companies and the Australian Veterinary Association united to address the anomaly of the outdated annual revaccination recommendation on MLV core vaccines, particularly as there is a risk of adverse reaction to vaccination, a risk which is being taken unnecessarily with ongoing revaccination with MLV core vaccines?

*What are the repercussions if the latest scientific evidence continues to be ignored?*

*Who will be responsible if pets in Australia continue to be subjected to unnecessary revaccination and needlessly put at risk of an adverse reaction to revaccination?*

## The risk of adverse reaction to vaccination

In an article published 14 years ago, titled "Are we vaccinating too much", Carin Smith notes:

In the past, it was believed that annual vaccination would not hurt and probably would help most animals. However, concerns about side effects have begun to change this attitude. The incidence of anaphylaxis and other adverse reactions appears to be increasing.<sup>66</sup>

Commenting in the same article, Ronald Schultz says:

The client is paying for something with no effect or with the potential for an adverse reaction. I believe that adverse effects are increasing because we are putting more and more components into these animals.<sup>67</sup>

<sup>63</sup> Australian Pesticides and Veterinary Medicines Authority Fact Sheet: Veterinarians and Veterinary Medicines: [http://www.apvma.gov.au/about\\_us/pdf/Veterinarians.pdf](http://www.apvma.gov.au/about_us/pdf/Veterinarians.pdf)

<sup>64</sup> Australian Pesticides and Veterinary Medicines: Vision, mission and purpose: [http://www.apvma.gov.au/about\\_us/vision.shtml](http://www.apvma.gov.au/about_us/vision.shtml)

<sup>65</sup> *Ibid.*

<sup>66</sup> Smith, C.A. 1995

<sup>67</sup> *Ibid.*

In 2006, eleven years after the publication of “Are we vaccinating too much”, the veterinary journal *Veterinary Microbiology* published a special issue including papers from an international scientific symposium entitled “Canine & Feline Vaccination – A Scientific Reappraisal”. The Preface of this special issue indicated not much had changed in the intervening years since “Are we vaccinating too much?” had been published:

Nowadays, the main topic for discussion, both at owner and professional level, is no longer how effective the products are at preventing disease, but on the one hand whether we should be continuing to recommend revaccination in the same way as we have until now, and whether vaccination in fact causes significant side effects to the extent that ***we are now doing more harm than good***<sup>68</sup> (My emphasis.)

Despite ongoing warnings, in 2009, 14 years after the publication of “Are we vaccinating too much?”, it appears the veterinary profession is still persisting with a scientifically unjustifiable practice that could be doing “more harm than good”...

Despite scientific evidence that annual (and triennial) revaccination with MLV core vaccines is unnecessary, this practice persists and continues to put pet dogs needlessly at risk of an adverse reaction.

The WSAVA guidelines provide a definition for adverse reactions:

Adverse events are defined as any side effects or unintended consequences (including lack of protection) associated with the administration of a vaccine product. They include any injury, toxicity or hypersensitivity reaction associated with vaccination, *whether or not the event can be directly attributed to the vaccine.*<sup>69</sup>

The WSAVA guidelines acknowledge that “there is gross under-reporting of adverse events which impedes knowledge of the ongoing safety of these products”.<sup>70</sup>

I have personal experience of under-reporting of adverse events “associated with the administration of a vaccine product”. In September 2008, my own dog, Sasha, an eight year old female Maltese x Silky terrier, became very ill after her last booster revaccination. Eight days after her revaccination, signs of illness (vomiting and diarrhea) became apparent. She was diagnosed as having “haemorrhagic gastroenteritis”, a mysterious disease the cause of which appears to be unknown. One source suggests “the most likely cause seems to be an abnormal immune response.”<sup>71</sup>

Sasha spent four days locked in a cage in a suburban veterinary surgery. The veterinarian who had been appointed to Sasha’s care finally advised us she was “dying” and should be put to sleep to end her suffering. Neither of the surgery’s veterinarians were able to offer any explanation for her illness. Needless to say, this was a deep shock, as Sasha’s illness had come completely out of the blue.

After Sasha’s death, I decided to do some research to try and find out what could have caused this totally unexpected and dreadful turn of events. It was at this time I discovered the controversy surrounding annual revaccination and the possibility it could cause an adverse reaction.

<sup>68</sup> Rottier, P.J.M., Sutton, D., 2006. Preface. *Veterinary Microbiology*, 117, p. 1.

<sup>69</sup> Day, M.J., Horzinek, M.C., Schultz, R.D. 2007

<sup>70</sup> *Ibid.*

<sup>71</sup> Provet Healthcare Information. Haemorrhagic Gastroenteritis (HGE): <http://www.provet.co.uk/health/diseases/git-hge.htm>

I raised this issue with the veterinarian who had revaccinated Sasha, but he refused to consider my suggestion that Sasha's illness might have been caused or influenced by her recent revaccination. Despite the fact I had forwarded him the internet link to the WSAVA guidelines, he insisted he was going to continue to "inform owners of the need to update immunity levels annually".<sup>72</sup> I was concerned about what this obstinate attitude meant for the ongoing health and well-being of other people's pets.

I contacted the Veterinary Surgeons' Board of South Australia to discuss my concern that my dog's illness might have been an adverse reaction to revaccination but the Registrar discounted this possibility. I also contacted the Australian Veterinary Association with my concerns, but again I encountered apathy and a reluctance to acknowledge Sasha's illness could be related to her revaccination.

Finally, in early October 2008, when reading a memorial website for pets whose owners believed they had become ill or died due to the ill-effects of veterinary products, I discovered a reference to the Australian Pesticides and Veterinary Medicines Authority, and found that pet owners could submit their own "adverse experience" report to this authority.<sup>73</sup> I contacted the Adverse Experience Reporting Program (AERP) Coordinator at the Australian Pesticides and Veterinary Medicines Authority and she listened sympathetically to my concerns. She advised me to take my time to make a report, saying it would be most useful if it was complete and detailed.

I have taken her advice and spent the past six months researching this topic to support my contention that my dog could have suffered a delayed adverse reaction to revaccination. During my research I have become increasingly concerned that this could be a widespread and hidden problem, affecting many pets whose owners may not be aware that ongoing over-vaccination could be harming their pets' health.

There is enormous resistance to acknowledging and acting on this problem in Australia. I am shocked that laypeople like myself are in the difficult position of trying to bring the veterinary industry to account. I am particularly aware of the possibility that if the problem of over-vaccination had been acknowledged and acted upon years ago, my dog Sasha might still be alive... Who knows how many other people's pets may have been adversely affected over the past years of inaction?

As I have discovered, the system is heavily weighted against recognising, acknowledging and reporting possible **delayed** reactions to vaccination. The visible signs of my dog's illness became apparent eight days after her revaccination. Bruce Twentyman, Deputy Veterinary Director of the Australian Veterinary Association was reluctant to acknowledge my dog's illness could have been a reaction to her revaccination, saying:

It is difficult to link Sasha's reaction to the vaccine due to the time lag between the injection and Sasha developing the gastroenteritis but I am not an expert in this field.<sup>74</sup>

In an article discussing adverse reactions to vaccination, Jean Dodds, an acknowledged "expert in this field", states "beyond the immediate hypersensitivity reactions, other acute events tend to occur 24 to 72 hours afterward, or **7 to 45 days later in a delayed type immunological response**".<sup>75</sup> (My emphasis.)

---

<sup>72</sup> Email correspondence from veterinarian, 17 October 2008

<sup>73</sup> Link to memorial website: <http://www.dogsadversereactions.com/moxidectin/memorial24.html>

<sup>74</sup> Email correspondence from Bruce Twentyman, Deputy Veterinary Director, Australian Veterinary Association, 6 January 2009.

<sup>75</sup> Dodds, W.J. 2001. Vaccination Protocols for Dogs Predisposed to Vaccine Reactions. *Journal of the American Animal Hospital*. May/June 2001, Vol. 37, 211-214.

Dodds also notes:

The veterinary profession and vaccine industry have traditionally emphasized the importance of giving a series of vaccinations to young animals to prevent infectious diseases, to the extent that this practice is considered routine and is generally safe for the majority of animals. Few clinicians are prepared, therefore, for encountering an adverse event and may overlook **or even deny the possibility**.<sup>76</sup> (My emphasis.)

Ronald Schultz also notes that “there is a reluctance to report reactions, even those that lead to the death of an animal”.<sup>77</sup>

Members of the vaccine industry are also unwilling to acknowledge the possibility of adverse reaction to revaccination. In a recent article published in Veterinary Practice News, Tom Lenz, Vice President of Professional Services at Fort Dodge Animal Health says:

“It can be scientifically proven that not vaccinating can cause harm to an animal **but vaccinating per label suggestion has not been shown to be harmful**”.<sup>78</sup>

Lenz also says:

Vaccines are pretty accurate the way they’re labeled. These reactions have nothing to do with the frequency as to which the vaccines are given.<sup>79</sup>

I disagree with Lenz’s statements that “vaccinating per label suggestion has not been shown to be harmful” and that “vaccines are pretty accurate the way they’re labeled”. And **how does he know** that “reactions have nothing to do with the frequency as to which the vaccines are given”?

Lenz does not cite any evidence to support his statements. I would argue that “vaccinating per label suggestion” has **not been proven to be harmless**...

According to a paper by James Wood and Vicki Adams, “Epidemiological approaches to safety investigations”, it appears there was little pre-licensure safety testing done to test short-term and delayed effects of vaccination:

Most safety testing is undertaken prior to granting of a marketing authorisation and is generally on a small scale. Field trials are usually much larger, but still involve relatively low numbers of animals compared to the number to which authorized products are administered. Safety testing is generally aimed at detecting common events; the numbers of animals used in the tests are too small for detection of all but the most common reactions. The efficiency of the tests depends on the frequency and severity of the adverse reaction and the ability to associate the adverse event with the product. The latter is affected by the period of time between administration and the event, as well as by its underlying frequency.<sup>80</sup>

In a paper titled “Vaccine-associated adverse events”, Kathryn Meyer advises that the results of safety testing are not routinely required on product labelling. This means that “rare events, events that occur after repeated exposure, and events that occur in a subgroup (e.g. specific

<sup>76</sup> *Ibid.*

<sup>77</sup> Schultz, R.D. 1998

<sup>78</sup> Tremayne, J. 2009. Titers join debate on vaccine frequency. Veterinary Practice News:

<http://www.veterinarypracticenews.com/vet-dept/small-animal-dept/titers-join-debate-on-vaccine-frequency.aspx>

<sup>79</sup> *Ibid.*

<sup>80</sup> Wood, J.L.N., Adams, V.J. 2006. Epidemiological approaches to safety investigations. Veterinary Microbiology. 117, 66-70.



breed, age)” are not noted on product labels. Meyer also notes that adverse event information derived from postmarketing surveillance is also not routinely required on the product’s label.<sup>81</sup>

David Hustead notes that “the quality and quantity of safety information on an animal vaccine label is much less than that found on the labels of common human vaccines.” Hustead notes that “it is not unusual for an animal vaccine label to essentially ignore the safety concerns of vaccine administration with the exception of anaphylaxis”. Animal vaccine labels contain only “a few short safety statements, that in all probability do not accurately reflect the clinical safety of the product as observed by all users”.<sup>82</sup>

Due to limited testing, vaccine labels generally only include details of possible immediate side effects, they do not include details of possible **delayed** adverse reactions to vaccination.

Ronald Schultz states that:

The risks of adverse reactions from vaccines are not well studied, nor are the adverse reactions rates well documented. Even where documented, the information is not readily available.<sup>83</sup>

In his 1998 paper “Current and future canine and feline vaccination programs”, Schultz provides a brief overview of suspected adverse reactions to vaccination:

Postvaccination neurologic disorders, immunosuppression, dermatologic abnormalities, and other problems have been demonstrated to occur after administration of canine and feline vaccines. These adverse reactions can range from mild, self-limiting illness to chronic disease or death. A certain low percentage of these reactions are expected with biologicals (also with pharmaceuticals), and they occur in every species including people. Some vaccines, however, have a greater likelihood of causing adverse reactions, and some animals are at greater risk. So the risks vs. benefits of every vaccine must be determined for each patient.<sup>84</sup>

In a later paper Schultz lists a broader range of possible adverse reactions:

The immune mediated hypersensitivities caused by vaccines are well known and occur in every species. The most commonly observed hypersensitivity is a type I (immediate) reaction which is most often caused by IgE antibody resulting in a local or generalized anaphylaxis. The most common signs of local reactions are facial edema, hives, itching and rarely sneezing; signs of a systemic reaction include urination, vomiting, diarrhea, which is sometimes bloody, dyspnea and collapse. According to a recent survey we have conducted, the most common vaccination reactions observed in dogs include pain, soreness, stiffness and/or lethargy at variable times after vaccination. Swelling, a persistent lump, irritation, hair loss and/or color change of hair at site of injection were also observed as common reactions. A change of behavior was reported in a small percentage of dogs after vaccination. Post-vaccinal neurologic disease (e.g. encephalitis) was rare. All of the reactions noted above generally occur within minutes, hours or days after vaccination; they were, therefore, likely to have been associated with a vaccination.

<sup>81</sup> Meyer, E.K. 2001. Vaccine-associated adverse events. *Veterinary Clinics of North America: Small Animal Practice*. Vol. 31, No. 3 May 2001, 493-513.

<sup>82</sup> Hustead 2001.

<sup>83</sup> Schultz, R.D. 2000. Considerations in designing effective and safe vaccination programs for dogs. In : Carmichael, L.E. (Ed.), *Recent Advances in Canine Infectious Diseases*. International Veterinary Information Service: [http://www.ivis.org/advances/Infect\\_Dis\\_Carmichael/schultz/IVIS.pdf](http://www.ivis.org/advances/Infect_Dis_Carmichael/schultz/IVIS.pdf)

<sup>84</sup> Schultz, R.D. 1998.

More recently, it has been shown experimentally that dogs develop an autoimmune response after vaccination, something that was known to occur in other species.<sup>85 86</sup>

In his paper “Vaccine side effects: Fact and fiction”, Michael Day notes that “vaccination-induced immunosuppression may on occasion be sufficient to permit the development of severe disease in animals that are carrying subclinical opportunist pathogens”.<sup>87</sup>

Summarising the incidence of post-vaccination adverse reactions in a paper titled “Predicting the “unpredictable” vaccine reactions” Will Novak suggests that post-vaccination reactions can be classified into the following degrees of severity:

- Class I                Not related to vaccine
- Class II              Lump/swelling at vaccination site
- Class III             Facial swelling, generalized urticaria
- Class IV             Systemic signs; fever, vomiting, diarrhea
- Class V             Anaphylaxis, shock, collapse, death<sup>88</sup>

In a paper titled “Vaccination protocols for dogs predisposed to vaccine reactions”, Jean Dodds reports that a wide variety of breeds of dogs, ranging from shih tzus to Great Danes, and a great many in between, may be more vulnerable to suspected adverse reaction to vaccination.<sup>89</sup>

Novak’s study<sup>90</sup> and another by George Moore et al titled “Adverse events diagnosed within three days of vaccine administration in dogs”<sup>91</sup> report that small-breed dogs are at greater risk of an adverse reaction after vaccination.

Moore et al report the risk of an adverse reaction was inversely related to a dog’s weight and that small breeds had significantly more adverse reactions than other dogs. Young adult small-breed neutered dogs that receive multiple vaccines per office visit were at greatest risk of an adverse reaction within 72 hours after vaccination.<sup>92</sup>

The risk of an adverse reaction significantly increased as the number of vaccines doses administered per office visit increased; “each additional vaccine significantly increased risk of an adverse event by 27% in dogs ≤ 10kg (22 lb) and 12% in dogs > 10 kg”. The risk for dogs that weighed ≤ 5 kg was more than 4 times the risk for dogs that weighed > 45 kg. It was noted that **“these factors should be considered in risk assessment and risk communication with clients regarding vaccination”**.<sup>93</sup> (My emphasis).

It was noted that vaccines, in contrast to virtually all veterinary pharmaceutical products, are prescribed on a 1-dose fits all basis, rather than by body weight. Moore et al suggested that the volume of vaccine doses may impact negatively on smaller dogs. It was also suggested that pre-licensing vaccine trials may under-estimate the rate of adverse reactions in smaller dogs.<sup>94</sup>

<sup>85</sup> Schultz, R.D. 2000.

<sup>86</sup> Refer also to Dodds, W.J. 2001 and Meyer, E.K. 2001 for more information on adverse reactions.

<sup>87</sup> Day, M.J. 2006.

<sup>88</sup> Novak, W. 2007. Predicting the “unpredictable” vaccine reactions. Proceeding of the NAVC North American Veterinary Conference. Jan. 13-27, 2007, Orlando, Florida.

<sup>89</sup> Dodds, W.J. 2001.

<sup>90</sup> Novak, W. 2007.

<sup>91</sup> Moore, G.E., Gupta, L.F., Ward, M.P., Glickman, N.W., Faunt, K.K., Lewis, H.B., Glickman, L.T. 2005. Adverse events diagnosed within three days of vaccine administration in dogs. JAVMA. Vol. 227, No. 7, October 1, 2005. 1102-1108.

<sup>92</sup> *Ibid.*

<sup>93</sup> *Ibid.*

<sup>94</sup> *Ibid.*

In his study, Novak reported that “data from our practice’s national database examining the incidence of post-vaccination adverse reactions in small breeds versus large breeds shows a clear increase in incidence in smaller breeds.” Data indicates there is a relationship between breed size/weight and incidence of adverse reactions.<sup>95</sup>

Novak suggests vaccines “specially developed for smaller breeds may be warranted”.<sup>96</sup>

In the case of older animals, David Hustead notes:

Rarely does a vaccine label address expected responses in older animals, because there is a dearth of information about the vaccine needs of older animals and the responses that vaccines are likely to induce.<sup>97</sup>

In a paper titled “Postmarketing surveillance for dog and cat vaccines: new resources in changing times”, Moore et al note:

Adverse events that are relatively uncommon or that occur in high-risk subgroups (eg. elderly animals or specific breeds) are usually only detected through postmarketing surveillance. The full safety profile for a given vaccine can only be determined after the vaccine has been licensed and administered to large numbers (often millions) of individuals.<sup>98</sup>

In other words, dogs in the community are the guinea pigs for these vaccines. They (and their owners) are unknowingly part of a huge unregulated trial, the results of which are not being reported...

It appears there have been no longitudinal trials to test the effects of annual revaccination over the life of an animal. So it is unknown if repeated vaccination over a dog’s lifetime can have deleterious consequences or what those consequences might be.

Due to inadequate vaccine product safety labelling, vaccine certificates provided by veterinarians (see example at Appendix 2) are also unlikely to provide much detail about the range of possible immediate and delayed side effects, particularly if veterinarians are not keeping up with the latest scientific information warning of a possible broad range of side effects across different breeds of dogs, including delayed reactions. This means that pet owners are not being warned of possible side effects of vaccination, and are denied the opportunity to weigh the risks and benefits prior to revaccination. Neither are they being advised of the long duration of immunity of MLV core vaccines. ***This means that veterinarians are not obtaining “informed consent” from their clients before revaccinating their pets.***

The whole system is flawed. We are in a Catch 22 situation. When the vaccines were first licensed, the government regulators did not ensure that the vaccine label revaccination recommendations were evidence-based. Neither was the safety testing process adequate. In particular, it is unknown what effect ongoing revaccination might have on dogs of different breeds and ages. Side effect warnings on vaccine labels are minimal and do not indicate the possibility of other reactions. If reactions occur after vaccination, pet owners may not be aware of the urgency to seek immediate veterinary attention to address any symptoms.

---

<sup>95</sup> Novak, W. 2007.

<sup>96</sup> *Ibid.*

<sup>97</sup> Hustead, D.R. 2001.

<sup>98</sup> Moore, G.E., Frana, T.S., Guptill, L.F., Ward, M.P., Lewis, H.B., Glickman, L.T. 2005. Postmarketing surveillance for dog and cat vaccines: new resources in changing times. JAVMA. Vol. 227, No. 7, October 1, 2005, pp. 1066-1069.

And yet veterinarians in Australia still insist on following the vaccine product label recommendations to revaccinate because they erroneously believe (or want to believe...) that vaccine manufacturers "have done the scientific work and experimentation to enable the product to be registered in the first place".<sup>99</sup> ***But this so-called "scientific work and experimentation" is a sham.***

Postmarketing surveillance is also failing because it appears veterinarians are reluctant to acknowledge and report possible adverse reactions to vaccination. Three months after my initial correspondence with the Australian Veterinary Association, Bruce Twentyman acknowledged my concerns about under-reporting of adverse reactions:

One thing that I feel you rightly highlighted is the under reporting of adverse reactions. This does occur in the veterinary as well human medicine fields.

I have had contact with the APVMA before Christmas on this issue and we have given a commitment to more vigorously publicise to our members the need to report adverse reactions. It is only then as you correctly point out that manufacturers can get an assessment of any unexpected side effects of their product. The APVMA is also investigating improved ways to report this information back to the veterinary profession.<sup>100</sup>

I responded to Dr Twentyman on Thursday 8 January 2009, requesting that he advise me in more detail exactly what steps had been taken on this issue, but I received no reply.

Compounding the problem of under-reporting of adverse events by veterinarians, many pet owners may not associate adverse events after vaccination with the vaccination. Many pet owners would follow their veterinarian's advice, and if the veterinarian doesn't acknowledge the possibility of an adverse reaction, a pet owner may never recognise the possibility. Also, many pet owners may not be aware they can make their own adverse experience reports to the Australian Pesticides and Veterinary Medicines Authority. Of course, as the situation stands, even if reports of different adverse reactions are submitted, Kathryn Meyer advises us that additional types of adverse reaction are not being included on the vaccine product label.<sup>101</sup>

***And the stunning fact is, adult dogs simply don't need to be regularly revaccinated with MLV core vaccines.*** Alternative trials<sup>102</sup> suggest that dogs are likely to have lifelong immunity after the initial puppy series and 12 month booster vaccination with MLV core vaccines for CPV-2, CAV-2 and CDV, ***so when adult dogs are revaccinated with these vaccines they are undergoing risk for no benefit. Similarly, dogs undergo unnecessary risk when they are given non-core vaccines that they do not need.***

Ronald Schultz notes:

In my opinion, vaccines are used that aren't needed and vaccines are given to animals that don't need them.<sup>103</sup>

Vaccines are medical products that should only be given if needed and only as often as is necessary to provide protection from diseases that are a risk to the health of the animal.  
***If a vaccine that is not necessary causes an adverse reaction that would be***

<sup>99</sup> Quote from email correspondence from Bruce Twentyman, Deputy Veterinary Director, Australian Veterinary Association, 6 January 2009.

<sup>100</sup> Email correspondence from Bruce Twentyman, Deputy Veterinary Director, Australian Veterinary Association, 6 January 2009.

<sup>101</sup> Meyer, E.K. 2001.

<sup>102</sup> For example see Twark, L. and Dodds, W.J. 2001; and Schultz 2006.

<sup>103</sup> Schultz, R.D. 1998.

**considered an unacceptable medical procedure**, thus use only those vaccines that are needed and use them only as often as needed.<sup>104</sup>

Unnecessary annual (and triennial) revaccination of adult dogs with MLV core vaccines is “an unacceptable medical procedure”.

*Why does the veterinary profession persist with this “unacceptable medical procedure”? Why is important information on vaccination risks and duration of immunity of vaccines withheld from pet owners?*

*If veterinarians simply stopped unnecessary revaccination, this would instantly reduce the risk of adverse reactions.*

*Why does the veterinary profession persist with the unethical practice of over-vaccination and continue to put people’s pets at unnecessary risk of an adverse reaction?*

### Professional, ethical and legal considerations

So why does unnecessary revaccination of pets continue? Perhaps the health and welfare of dogs and cats is **not** the main focus of veterinarians...? **Perhaps turnover and profit comes before the wellbeing of pets?**

An industry newsletter reports that:

**89% of veterinarians indicated that dog and cat vaccinations were indeed the number one contributor to practice turnover** and 91% of veterinarians felt that a change from annual vaccination would have an adverse effect on their practice turnover. 80% of veterinarians also indicated that it would be difficult to attract clients on a regular basis should there be a change from annual vaccination.<sup>105</sup> (My emphasis.)

The newsletter concluded:

*Annual vaccination appears to be an important source of income for many veterinarians and veterinarians believe that annual vaccination imposes the discipline on the pet owners. **The results indicate that veterinarians will continue to vaccinate annually.***<sup>106</sup> (My emphasis.)

It appears annual vaccination of pets is used as a practice management tool by veterinarians to lure clients into their surgeries. Anecdotally, Ronald Schultz reports:

I have also been told by many practitioners that: “I believe the duration of immunity for some vaccines like distemper, parvovirus and hepatitis is many years, but until I find another way to get the client into my office on a regular basis I’m going to keep recommending vaccines annually”.<sup>107</sup>

This is not acceptable or ethical practice. As Schultz notes

Vaccines are medical products that should only be given if needed and only as often as necessary to provide protection from diseases that are a risk to the health of the animal.

<sup>104</sup> Schultz, R.D. 2007.

<sup>105</sup> Virbac Newsletter “Facts on Vaccination”, August 2005.

<sup>106</sup> *Ibid.*

<sup>107</sup> Schultz, R.D. 2007.

***If a vaccine that is not necessary causes an adverse reaction that would be considered an unacceptable medical procedure***, thus use only those vaccines that are needed and use them only as often as needed....Vaccines are medical products that should not be used as practice management tools.<sup>108</sup> (My emphasis.)

While an annual check up to monitor an animal's overall health, and to consider non-core vaccination, may be useful, this must be sold on its own merits. Veterinarians must not use the threat of serious diseases such as canine parvovirus to lure clients into their surgeries to have their pets needlessly **revaccinated**. If dogs have already been properly vaccinated with the puppy series and 12 month booster, as recommended by the WSAVA guidelines, they have had sufficient MLV core vaccinations.

Veterinarians who send annual reminder letters, sometimes cutely personally addressed to pets, saying they need annual boosters against canine parvovirus, canine adenovirus and canine distemper virus to "stay healthy", are misleading pet owners. Dogs do **NOT** need annual boosters with MLV core vaccines to "stay healthy". Indeed, unnecessary revaccination puts the animal's health at risk. (An example of text from a veterinarian's annual vaccination reminder letter is attached at Appendix 3).

Ongoing unnecessary revaccination is supported by veterinary authorities recommending that boarding kennels require proof of annual vaccination of pets from their clients. For example, the Veterinary Surgeons' Board of South Australia's "Code of Practice for the Operation of Boarding Establishments" states:

3.12 For dogs, pre-vaccination against distemper, hepatitis, parvovirus and kennel cough including bordatella is strongly recommended. It is desirable that a current vaccination certificate be produced for each dog prior to admission (i.e. **certifying that vaccination was done within the preceding 12 months**, not less than 1 week prior to admission, except for kennel cough which can be applied intranasally one day before admission).<sup>109</sup> (My emphasis.)

The status quo of unnecessary revaccination with MLV core vaccines is maintained not only by veterinarians relying on unfounded revaccination recommendations on vaccine product labels, **but also by veterinary authorities recommending that boarding kennels demand proof of annual revaccination with MLV core vaccines.**

A certificate indicating a dog has had the puppy series and 12 month booster with MLV core vaccines should be sufficient for a boarding kennel. If the certificate has been mislaid, serological testing could be performed to determine duration of immunity. (The WSAVA guidelines include information about serological testing.<sup>110</sup> Serological testing is not common in Australia, but it is available (Vetpath Laboratory Services)<sup>111</sup> and can also be co-ordinated with service providers overseas, (e.g. Hemopet<sup>112</sup>). I understand from a recent article in Veterinary Practice News that more "user friendly in-house" serological tests will be available in the not too distant future.<sup>113</sup> Of course, if a vaccination for 'kennel cough' is thought necessary, this can be arranged as required, e.g. "intranasally one day before admission".<sup>114</sup>

<sup>108</sup> *Ibid.*

<sup>109</sup> Veterinary Surgeons' Board of South Australia. Code of practice for the operation of boarding establishments: <http://www.vbsa.org.au/boarding.pdf>

<sup>110</sup> Day, M.J., Horzinek, M.C., Schultz, R.D. 2007.

<sup>111</sup> Vetpath Laboratory Services: <http://www.vetpath.com.au/>

<sup>112</sup> Hemopet: <http://www.hemopet.org/services.html>

<sup>113</sup> Tremayne, J. 2009.

<sup>114</sup> Veterinary Surgeons' Board of South Australia. Code of practice for the operation of boarding establishments: <http://www.vbsa.org.au/boarding.pdf>

As already outlined in this report, ongoing revaccination of adult dogs with MLV core vaccines is unnecessary. The latest scientific evidence is that duration of immunity is likely to be lifelong. It is of no benefit to continually revaccinate an animal with MLV core vaccines and this practice puts pets needlessly at risk of an adverse reaction. This practice conflicts with the medical ideal of “do no harm”.

Some people warn that dogs are at risk of serious disease if they do not continue to be revaccinated. For example, Ulrike McCray, Marketing Director for Companion Animal Health at Schering-Plough Animal Health says:

People tend to forget that infectious diseases like distemper, parvovirus and others are deadly for those dogs that are not protected against them...While these infectious diseases are rare among dogs and cats, it's because they've been vaccinated...**If we reduce vaccinations in dogs and cats, the infectious diseases will return.**<sup>115</sup> (My emphasis.)

This is simply fear-mongering. This is the method that veterinarians use to mislead pet owners into over-vaccinating their pets. This attitude was evidenced recently in a newspaper article titled “Parvo outbreak”<sup>116</sup> in which vets urged “pet-owners to ensure their pet's vaccinations are **up to date**”. If a dog has already had the puppy series and 12 month booster with MLV core vaccines, it doesn't need to be kept “up to date”, it doesn't need ongoing revaccination.

As Rosalind Gaskell notes in her paper “Duration of immunity (DOI) - The regulatory issues”:

Ultimately we need to target vaccination to a greater proportion of the population, rather than repeat-vaccinating the same individual animals.<sup>117</sup>

In “Are we vaccinating too much?”, Dennis Macy notes:

There is a mistaken assumption that if we recommend annual vaccination, a greater percentage of animals will be vaccinated... But it doesn't do any good to overvaccinate one segment of the population and not vaccinate the rest. **Your good clients' pets will have a higher risk of adverse reactions.**<sup>118</sup> (My emphasis.)

And Marian Horzinek adds:

It is of course more arduous to solicit new clients than to summon old ones, but it needs to be done.<sup>119</sup>

Ten years ago, the Australian Veterinary Association published its then “draft policy” on vaccination in the Australian Veterinary Journal. Ten years ago the AVA acknowledged that “scientific information suggests that the duration of immunity delivered by some immunobiologicals and against some diseases may be variable”<sup>120</sup>. Why has this “scientific information” continued to be ignored? **Most importantly, why has this information been withheld from pet owners?**

<sup>115</sup> Tremayne, J. 2009.

<sup>116</sup> Foy, Sally. 2009. Parvo Outbreak. Bay Post: <http://moruya.yourguide.com.au/news/local/news/general/parvo-outbreak/1451569.aspx>

<sup>117</sup> Gaskell, R.M. 2006.

<sup>118</sup> Smith, C.A. 1995.

<sup>119</sup> Horzinek, M.C. 2006(a)

<sup>120</sup> AVA Draft policies. 1999. (Appendix X guidelines for responsible use of veterinary immunobiological in cats and dogs). Australian Veterinary Journal. Vol. 77, No. 7, July 1999.

There is currently no clearly defined national policy on dog and cat vaccination publicly available in Australia. The Australian Veterinary Association's current policy on dog and cat vaccination provides little detail on this issue:

The Australian Veterinary Association (AVA) believes that veterinarians must maintain a highly professional approach to all aspects of the use of immunobiologicals (vaccines). This includes ensuring that vaccines are not used unnecessarily, ensuring that the latest techniques are adopted (as appropriate) and appreciating that the profession will be held responsible for the correct use of immunobiologicals. Veterinarians should aim to maintain the profession as the source of informed knowledge on the use of these agents.<sup>121</sup>

Even this brief policy demonstrates there is conflict with the "real world" practice of annual vaccination, a practice which is admitted in the AVA's current draft vaccination policy.<sup>122</sup> The current practice of annual revaccination with MLV core vaccines goes against the AVA's existing policy that "vaccines are not used unnecessarily". As the veterinary profession in Australia appears to be ignoring the latest scientific advice, as summed up in the international WSAVA and AAHA guidelines, it also appears the "latest techniques are not being adopted" and veterinarians in Australia are not maintaining "the profession as the source of informed knowledge on the use of these agents".

14 years ago, in the article "Are we vaccinating too much?", Ronald Schultz made the following comment:

It is my understanding that one should provide the current practice or art of medicine...If I or one of my colleagues were asked, we would have to say that there is no scientific justification for annual vaccinations. However a veterinarian is in a tough situation ***if all the others in the community are vaccinating annually, despite the scientific evidence***. The medically correct approach is to understand which of those vaccines need to be used annually, and which last longer. We should examine what is needed at what ages, and give the appropriate vaccine at the appropriate time.<sup>123</sup> (My emphasis.)

***But why are "all the others in the community" continuing to vaccinate "annually, despite the scientific evidence"? Why are they not acknowledging the latest scientific evidence and following the most efficacious vaccination schedules?***

Why are veterinarians in Australia not providing "the current practice or art of medicine"?<sup>124</sup> Why are they continuing to revaccinate dogs annually with MLV core vaccines, despite the scientific evidence? Why are they ignoring international guidelines on vaccination of dogs and cats and, ***most importantly, withholding this information from their clients?*** This goes against the AVA's own Code of Professional Conduct, e.g. Item 3.b. "Veterinary procedures and recommendations should be based on sound evidence-based science and practice". It also goes against the AVA's goal to "strive to provide the best possible veterinary services and improve the quality of animal health and welfare at every opportunity"; and to "maintain and continue to enhance your professional knowledge and skills". ***Very importantly, veterinarians are ignoring***

<sup>121</sup> AVA Policies. Part 2 Use of veterinary medicines. 2.1 Responsible use of veterinary immunobiologicals in cats and dogs:

<http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Policies&Template=/CM/HTMLDisplay.cfm&ContentID=2156>

<sup>122</sup> Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" (recently accessible on the internet) refers to "Responsible use of veterinary vaccines for dogs and cats". This draft policy admits that "annual vaccination is the currently accepted practice in Australia".

<sup>123</sup> Smith, C.A. 1995

<sup>124</sup> Smith, C.A. 1995



**Item 4.c. when they fail to obtain the “informed consent” of their clients by withholding the latest scientific advice on vaccination of dogs and cats.**<sup>125</sup>

Veterinarians who fail to keep up with the latest scientific information relevant to their profession are also contravening Item 7.a. of the AVA Professional Code of Conduct:

Continuing veterinary education and the advancement of knowledge are fundamental to the role of the professional. **Failure to keep informed about relevant advances in veterinary science is a dereliction of this responsibility.** (My emphasis.)<sup>126</sup>

On the topic of education, I have been left wondering if even Australian University veterinary schools are up-to-date on this issue.

Marian Horzinek says “vaccinological knowledge must be acquired, entertained and kept current, which should start at the university and be perpetuated by continued education”.<sup>127</sup>

I wonder if veterinary school students are being taught “the basics of vaccine induced ‘immunologic memory’”?<sup>128</sup>

I recently conducted a survey of five Australian veterinary schools<sup>129</sup> (copy of correspondence attached at Appendix 4) to ascertain if they were teaching their students the latest international dog and cat vaccination guidelines. I also asked questions about what is being taught on the topic of “veterinary ethics”, for example on obtaining “informed consent” from clients for veterinary interventions concerning their pets (e.g. vaccination); and about veterinarians’ responsibility to report possible adverse reactions to veterinary products and interventions to the APVMA.

The response was most unsatisfactory. Some people simply ignored my enquiries, while others demanded I cease sending them emails. Some members of teaching staff were willing to engage in email discussions, but were unable to properly address my questions about vaccination protocols, the concept of “informed consent” and reporting of adverse reactions.

After repeated enquiries, only one school out of the five was able to provide me with a definitive dog and cat vaccination protocol (and that was after first telling me that the school’s vaccination policy was “for staff use only and not for public distribution”). This protocol recommended revaccination with MLV core vaccines “every 3 years for the animal’s life using a modified live vaccine”. I replied asking on what scientific basis this triennial recommendation was made. As yet I have received no response.

I am also currently conducting an email survey of US veterinary schools, enquiring about their dog and cat vaccination protocols. So far, it appears a policy of revaccinating dogs with MLV core vaccines “every three years” is in place. As part of my survey, I will be challenging the US veterinary schools about this policy, as it appears there is no scientific basis for annual **or triennial** revaccination of dogs with MLV core vaccines.

<sup>125</sup> Australian Veterinary Association’s Code of Professional Conduct:

[http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code\\_of\\_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741](http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code_of_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741)

<sup>126</sup> *Ibid.*

<sup>127</sup> Horzinek, M.C. 2006(a).

<sup>128</sup> Schultz, R.D. 2007.

<sup>129</sup> Initial correspondence was forwarded on 12 January 2009 to: Faculty of Veterinary Science, University of Sydney; Faculty of Natural Resources, Agriculture and Veterinary Sciences, The University of Queensland; Faculty of Veterinary Science, The University of Melbourne; School of Veterinary and Biomedical Sciences, Murdoch University; School of Veterinary Science, University of Adelaide. I subsequently discovered there were another two veterinary schools in Australia, and sent emails to the following on Friday 3 April 2009: School of Animal and Veterinary Sciences, Charles Sturt University and the School of Veterinary Biomedical Sciences, James Cook University.

Of course the situation in Australia remains much worse than the US. ***A culture of annual revaccination with MLV core vaccines remains entrenched.*** It is shocking to think of the lack of action over the past ten years and I am concerned how long this inertia is going to continue.

I have been writing to the Australian Veterinary Association (AVA) about my concerns since October 2008. In early February I sent two more detailed emails to the President of the AVA, Mark Lawrie, and other key AVA members. One of these emails contained eight detailed questions about the AVA's Professional Code of Conduct, vaccination policy, "off-label use", "sound evidence-based science and practice", veterinarians as a "source of informed knowledge", and the concept of "informed consent". These questions remain unanswered. (The text of these two emails is attached at Appendices 5 and 6).

In an email dated 2 March 2009, the President of the AVA, Mark Lawrie advised me:

The AVA has acknowledged that the previous policy on vaccination requires updating, and this process is underway. A draft policy is with our members for comment. ***Some experts have already provided input about the need to amend the draft policy to one which outlines the scientific basis for vaccination every three years for core vaccines.***<sup>130</sup> (My emphasis.)

On 4 March and 25 March I sent emails to Dr Lawrie enquiring "what is the scientific basis for vaccination ***every three years*** for core vaccines?"

This question remains unanswered.

In an email dated 26 March, Dr Lawrie advised me:

We are reviewing the AVA policy, and it may be that the new one will contain similar guidelines as those in the World Small Animal Veterinary Association Guidelines for the Vaccination of Dogs and Cats. Once the policy review is finalised, we will undertake a more extensive communications program to Australian veterinarians about the policy.<sup>131</sup>

At least Dr Lawrie now acknowledges the World Small Animal Veterinary Association (WSAVA) guidelines – there was no mention of them in the draft policy for the "Responsible use of veterinary vaccines for dogs and cats"<sup>132</sup>, that had been on the AVA's website for comment by members by 13 March 2009...

Dr Lawrie's email of 2 March also noted that:

The ASAVA executive has given its in-principle support for the WSAVA guidelines, while recognising that ***the ultimate decisions are made for each individual animal through consultation between the pet owner and veterinarian.***<sup>133</sup> (My emphasis.)

This means the pet owner is still reliant on the veterinarian relaying the latest scientific advice, something which has not been happening in the past. As the veterinary profession is largely unregulated, the pet owner remains vulnerable to being kept in the dark if the veterinarian chooses not to relay the latest scientific advice about vaccination.

<sup>130</sup> Email correspondence from Mark Lawrie, President, Australian Veterinary Association, 2 March 2009.

<sup>131</sup> Email correspondence from Mark Lawrie, President, Australian Veterinary Association, 26 March 2009.

<sup>132</sup> Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" (recently accessible on the internet) refers to "Responsible use of veterinary vaccines for dogs and cats".

<sup>133</sup> Email correspondence from Mark Lawrie, President, Australian Veterinary Association, 2 March 2009.

As well as undertaking “a more extensive communications program to Australian veterinarians” about its new policy, ***I suggest the Australian Veterinary Association should do more to ensure the public is alerted to the latest scientific information regarding vaccination, particularly that ongoing revaccination with MLV core vaccines is unnecessary, of no benefit, and needlessly puts dogs at risk of an adverse reaction. Pet owners need to be informed so they can make their own decision about revaccinating their pets.*** A more detailed policy on dog and cat vaccination, publicly available on the Australian Veterinary Association website, plus an information sheet in the “Community”<sup>134</sup> section, would be a good start, along with a media campaign.

As time goes by, pet owners are more likely to find out this information via other means. For example, the internet provides the opportunity for others to disseminate information. Some people disparage the internet as a source of gossip and rumour. However, the internet is a gateway to knowledge and offers a portal into the world’s libraries and access to scientific journals, where laypeople can find out the facts for themselves.

Marian Horzinek offers the veterinary profession some advice:

If the profession wants to play a leading role in the public discussion, if the vet (and not the internet) is to stay the animal health authority for pet owners – if microbiological, immunological and vaccinological knowledge is to be conveyed to (and rewarded by) the clientele, the profession must change its attitude.<sup>135</sup>

The veterinary profession also needs to consider the legal implications if it continues to willfully ignore more recent scientific advice on dog and cat vaccination, and continues to withhold this information from pet owners. Horzinek describes the situation in the US where:

future claims will increasingly be centered at the practitioner: malpractice, failure to adhere to the standard of care, wrong vaccine selection and administration and no informed consent by the client may all result in litigation.<sup>136</sup>

One wonders how much longer veterinarians in Australia can get away with “false and misleading statements”...<sup>137</sup> As the pet-owning public becomes more aware that veterinarians are over-servicing and over-vaccinating their pets, there will be a greater demand for consumer protection.

## Conclusion

There is no scientific basis for annual, or triennial, revaccination of dogs with MLV core vaccines. This practice is of no benefit to the animal and puts it needlessly at risk of an adverse reaction.

According to statistics, 12 million Australians are associated with pets. 63% of the 7.5 million households in Australia owns pets.<sup>138</sup>

The President of the Australian Veterinary Association, Mark Lawrie, acknowledges the significance of the loss of a pet:

<sup>134</sup> Australian Veterinary Association “Community” section:

<http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Community2>

<sup>135</sup> Horzinek, M.C. 2006(a)

<sup>136</sup> Horzinek, M.C. 2006(b). Concluding Remarks. *Veterinary Microbiology*. 117, 98-101.

<sup>137</sup> For example *Veterinary Practice Act 2003*. Part 7 – Miscellaneous. 68 – False or misleading statement:

<http://www.legislation.sa.gov.au/LZ/C/A/VETERINARY%20PRACTICE%20ACT%202003/CURRENT/2003.41.UN.PDF>

<sup>138</sup> Pet Statistics: <http://www.petnet.com.au/petstatistics.asp>

Eighty per cent of people consider their dog is part of the family, so for eight out of 10 people it's like losing a member of their family.<sup>139</sup>

Imagine what those people would feel if they discovered their veterinarian was putting their pet needlessly at risk with over-vaccination...

People bring their pets to the veterinarian because they care for their animals and want to protect their health. They don't expect that veterinarians will put their beloved pets at risk with unnecessary interventions like over-vaccination with MLV core vaccines.

It is devastating for people if their pet gets lost, or it's killed in an accident, or when it dies of old age. Pets are part of the family and you grieve their loss. But when you discover your pet may have become sick and died because a vet manipulated you into buying a revaccination that wasn't going to provide any benefit, and actually put your pet's life at risk, it is very hard to bear.

As more and more people discover that there are veterinarians who are actually putting their pets needlessly at risk, there is likely to be a significant backlash against the veterinary profession.

Those veterinarians who value the integrity of their profession need to address this untenable situation and work to ensure that the unethical practice of unnecessary over-vaccination is ceased immediately. This scandal has been going on for years and it must stop **now**.

*for Sasha...*

**Acknowledgements:**

*Many thanks to family and friends for their support over the past six months, particularly those people who generously provided information and references.*

---

<sup>139</sup> Foy, S. 2009. Parvo outbreak. Bay Post: <http://moruya.yourguide.com.au/news/local/news/general/parvo-outbreak/1451569.aspx>

## References:

- American Veterinary Medical Association letter, re Center for Veterinary Biologics Notice Draft No. 327: Studies to Support Label Claims of Duration of Immunity dated October 27 2008: [http://www.avma.org/advocacy/federal/regulatory/practice\\_issues/vaccines/duration\\_of\\_immunity\\_ltr.pdf](http://www.avma.org/advocacy/federal/regulatory/practice_issues/vaccines/duration_of_immunity_ltr.pdf)
- Australian Pesticides and Veterinary Medicines Authority Fact Sheet: Veterinarians and Veterinary Medicines: [http://www.apvma.gov.au/about\\_us/pdf/Veterinarians.pdf](http://www.apvma.gov.au/about_us/pdf/Veterinarians.pdf)
- Australian Pesticides and Veterinary Medicines: Vision, mission and purpose: [http://www.apvma.gov.au/about\\_us/vision.shtml](http://www.apvma.gov.au/about_us/vision.shtml)
- Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" (recently accessible on the internet) refers to "Responsible use of veterinary vaccines for dogs and cats".
- Australian Veterinary Association's Code of Professional Conduct: [http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code\\_of\\_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741](http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code_of_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741)
- AVA Draft policies. 1999. (Appendix X guidelines for responsible use of veterinary immunobiological in cats and dogs). Australian Veterinary Journal. Vol. 77, No. 7, July 1999.
- AVA Policies. Part 2 Use of veterinary medicines. 2.1 Responsible use of veterinary immunobiologicals in cats and dogs: <http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Policies&Template=/CM/HTMLDisplay.cfm&ContentID=2156>
- Day, M.J. 2006. Vaccine side effects: Fact and fiction. Veterinary Microbiology. 117, 51-58.
- Day, M.J., Horzinek, M.C., Schultz, R.D. 2007. Guidelines for the Vaccination of Dogs and Cats, compiled by the Vaccination Guidelines Group (VGG) of the World Small Animal Veterinary Association (WSAVA). Journal of Small Animal Practice 48 (9), 528-541: [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf)
- Dodds, W.J. 2001. Vaccination Protocols for Dogs Predisposed to Vaccine Reactions. Journal of the American Animal Hospital. May/June 2001, Vol. 37, 211-214.
- Foy, Sally. 2009. Parvo Outbreak. Bay Post: <http://moruya.yourguide.com.au/news/local/news/general/parvo-outbreak/1451569.aspx>
- Gaskell, R.M. 2006. Duration of immunity (DOI) – The regulatory issues. Veterinary Microbiology. 117, 80-85
- Horzinek, M.C. 2006(a). Vaccine use and disease prevalence in dogs and cats. Veterinary Microbiology. 117, 2-8.
- Horzinek, M.C. 2006(b). Concluding Remarks. Veterinary Microbiology. 117, 98-101.
- Hustead, D.R. 2001. What you can and cannot learn from reading a vaccine label. Veterinary Clinics of North America: Small Animal Practice. Vol 31, No.3, May, 539- 556.
- Klingbord, D.J., Hustead, D.R., Curry-Galvin, E.A., Gumley, N.R., Henry, S.C., Fairfield, T.B., Paul, M.A., Boothe, D.M., Blood, K.S., Huxsoll, D.L., Reynolds, D.L., Riddell, G.Jr., Reid, J.S., Short, C.R. 2002. AVMA Council on Biologic and Therapeutic Agents' report on cat and dog vaccines. JAVMA. Vol. 221, No. 10, 1401-1407.
- Maruyama, M., Lam, K.P., Rajewsky, K., 2000. Memory B-cell persistence is independent of persisting immunising antigen. Nature 407, 636-642.
- Meyer, E.K. 2001. Vaccine-associated adverse events. Veterinary Clinics of North America: Small Animal Practice. Vol. 31, No. 3 May 2001, 493-513.
- Moore, G.E., Frana, T.S., Guptill, L.F., Ward, M.P., Lewis, H.B., Glickman, L.T. 2005. Postmarketing surveillance for dog and cat vaccines: new resources in changing times. JAVMA. Vol. 227, No. 7, October 1, 2005, pp. 1066-1069.
- Moore, G.E., Guptill, L.F., Ward, M.P., Glickman, N.W., Faunt, K.K., Lewis, H.B., Glickman, L.T. 2005. Adverse events diagnosed within three days of vaccine administration in dogs. JAVMA. Vol. 227, No. 7, October 1, 2005. 1102-1108.
- Novak, W. 2007. Predicting the "unpredictable" vaccine reactions. Proceeding of the NAVC North American Veterinary Conference. Jan. 13-27, 2007, Orlando, Florida.

- Paul, M.A., Appel, M.J., Barrett, R., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Keil, D., Lappin, M., Schultz, R.D., Thacker, E., Trumpeter, E., Welborn, L. 2003. Report of the American Animal Hospital Association (AAHA) Canine Vaccine Task Force: 2003 Canine Vaccine Guidelines, Recommendations, and Supporting Literature: [http://www.britfeld.com/health/canine\\_vaccine\\_guidelines.pdf](http://www.britfeld.com/health/canine_vaccine_guidelines.pdf)
- Paul, M.A., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Hurley, K.F., Roth, J.A., Schultz, R.D., Thacker, E., Welborn, L. 2006 AAHA Canine Vaccine Guidelines, Revised: [http://www.ufsheltermedicine.com/news/2006\\_AAHA\\_Canine\\_Vax\\_GL.pdf](http://www.ufsheltermedicine.com/news/2006_AAHA_Canine_Vax_GL.pdf)
- Pet Statistics: <http://www.petnet.com.au/petstatistics.asp>
- Provet Healthcare Information. Haemorrhagic Gastroenteritis (HGE): <http://www.provet.co.uk/health/diseases/git-hge.htm>
- Rottier, P.J.M., Sutton, D., 2006. Preface. Veterinary Microbiology, 117, p. 1.
- Schultz, R.D. 1998. Current and future canine and feline vaccination programs. Veterinary Medicine. March 1998, 233-254.
- Schultz, R.D. 2000. Considerations in designing effective and safe vaccination programs for dogs. In : Carmichael, L.E. (Ed.), Recent Advances in Canine Infectious Diseases. International Veterinary Information Service: [http://www.ivis.org/advances/Infect\\_Dis\\_Carmichael/schultz/IVIS.pdf](http://www.ivis.org/advances/Infect_Dis_Carmichael/schultz/IVIS.pdf)
- Schultz, R.D. 2006. Duration of immunity for canine and feline vaccines: A review. 2006. Veterinary Microbiology. 117, 75-79.
- Schultz, R.D. 2007. What everyone needs to know about canine vaccines and vaccination programs. 2007 National Parent Club Canine Health Conference: <http://www.spinoneus.org/forum/uploaded/Admin/Vaccinations2007.pdf>
- Smith, C.A. 1995. Are we vaccinating too much? JAVMA. Vol 207, No. 4 August 15, 421-425.
- Thiry, E., Horzinek, M.C. 2007. Vaccination guidelines: a bridge between official requirements and the daily use of vaccines. Veterinary Sciences Tomorrow – 29 June 2007: <http://www.vetscite.org/publish/articles/000065/index.html>
- Tremayne, J. 2009. Titers join debate on vaccine frequency. Veterinary Practice News: <http://www.veterinarypracticenews.com/vet-dept/small-animal-dept/titers-join-debate-on-vaccine-frequency.aspx>
- Twark, L., Dodds, W.J., 2000. Clinical use of serum parvovirus and distemper virus antibody titers for determining revaccination strategies in healthy dogs. J. Am. Vet. Med. Assoc, 217, 1021-1024.
- United States Department of Agriculture (USDA), Center for Veterinary Biologics Notice Draft No. 327 on the subject of "Studies to Support Label Claims of Duration of Immunity: [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/Noticedraft327.pdf](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/Noticedraft327.pdf)
- Veterinary Surgeons' Board of South Australia. Code of practice for the operation of boarding establishments: <http://www.vsbbsa.org.au/boarding.pdf>
- Virbac Newsletter "Facts on Vaccination", August 2005.
- Wood, J.L.N., Adams, V.J. 2006. Epidemiological approaches to safety investigations. Veterinary Microbiology. 117, 66-70.

## APPENDICES

- Appendix 1: Email to Dr Simon Cubit, Manager, Public Affairs, Australian Pesticides and Veterinary Medicines Authority
- Appendix 2: Example of veterinarian's vaccination certificate
- Appendix 3: Example of veterinarian's annual vaccination reminder letter
- Appendix 4: Email to Heads of five veterinary schools in Australia
- Appendix 5: Email to Dr Mark Lawrie, President of the Australian Veterinary Association (AVA) and other key members of the AVA (originally emailed to Dr Bruce Twentyman, Deputy Veterinary Director of the AVA)
- Appendix 6: Email to Dr Mark Lawrie, President of the Australian Veterinary Association (AVA) and other key members of the AVA

## APPENDIX 1

***In response to my email (see below), Dr Simon Cubit, Manager, Public Affairs, Australian Pesticides and Veterinary Medicines Authority, advised:***

Monday 23 February 2009

*I would like to update you on our response to your question about overvaccination. We have sought advice from our Veterinary Medicines team. That advice will be reviewed by a specially convened meeting of Dr Phil Reeves, one of our Principal Scientists, and two of our Science Fellows Professors Mary Barton and Glen Browning. That meeting will take place on 15 April.*

*We are aware of the WSAVA VSG guidelines and the observations on multivalent core and non-core vaccines.*

*We will consider the information you have already provided. If there is any additional information you would like us to see please forward it to me.*

In response to the invitation to forward “additional information”, I am forwarding my report “Is over-vaccination harming our pets? Are vets making our pets sick?” to be circulated and tabled at the APVMA meeting on Wednesday 15 April 2009. I will also circulate this report to other parties.

See below the text of an email sent to Dr Simon Cubit, Manager Public Affairs, Australian Pesticides and Veterinary Medicines Authority (APVMA) on Monday 16 February. A copy for information was also forwarded to Dr Mark Lawrie, President of the AVA, and other key members of the AVA, on Friday 20 February 2009, and to the Heads of five veterinary schools in Australia, on Sunday 22 February 2009.

Dear Simon

Thank you for listening to my concerns last Friday.

***As indicated during our telephone call, I am concerned there is a problem with dogs and cats being over-vaccinated in Australia.***

According to international dog and cat vaccination guidelines published by the World Small Animal Veterinary Association in 2007:

Vaccines should not be given needlessly. ***Core vaccines should not be given any more frequently than every three years*** after the 12 month booster injection following the puppy/kitten series.” (My emphasis).

Ref: WSAVA VGG Guidelines [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf) A hard copy is also attached for your information.

The World Small Animal Veterinary Association (WSAVA) is an ‘association of associations’. Its membership is made up of veterinary organisations from all over the world, which are concerned with small companion animals such as cats, dogs, rabbits, guinea pigs etc. Currently there are 76 member and affiliate associations, representing over 70,000 individual veterinarians from around the globe.



The WSAVA VGG guidelines were published in the Journal of Small Animal Practice, 2007; 48(9):528-541) and are available on the WSAVA website: <http://www.wsava.org/SAC.htm>

The WSAVA guidelines were developed for **global** application. While these guidelines “do not represent a standard of care or set of legal parameters”...“they have been drafted with the objective of educating and informing the profession and to recommend rational vaccine use for individual pets and dog/cat populations”. I understand these guidelines are “based upon a consensus among experts” and “reflect a combination of opinion, experience, and scientific data, published and unpublished”. The WSAVA VGG Guidelines were published in 2007 and built on the 2006 AAHA Canine Vaccine Guidelines and the 2006 American Association of Feline Practitioners Feline Vaccine Advisory Panel Report.

***In my personal experience, these international guidelines are not being followed by some (many?) veterinarians in Australia.*** I am extremely concerned there is a widespread practice of veterinarians in Australia deliberately misleading their clients into believing their adult dogs and cats need to be revaccinated with core MLV vaccines every year with deceptive and unsolicited annual reminder letters. Most importantly, I am concerned the recommendations contained in the international guidelines may not be being relayed to veterinarians' clients. I am concerned that many veterinarians may not be obtaining “informed consent” from their clients before revaccinating their pets.

Recently, as a quick experiment, I randomly selected 10 veterinary surgeries out of the Adelaide telephone book, and rang to enquire about vaccination for my five year old dog and to ask how often vaccination was recommended. I spoke to each receptionist and it appeared clear to me they were relaying the vaccination protocol of the surgery. From their response, it was quite obvious to me that annual revaccination with core MLV vaccines was common practice. I specifically asked if annual revaccination, with core MLV vaccines (i.e. CPV2, CDV, and CAV) was necessary. They all advised it was. There was no mention of triennial vaccination. I conducted this exercise to check my suspicions, and my suspicions were confirmed... (Costs ranged from around \$A76-\$A105 dollars, which I understand generally included a consultation.) (Note: CPV2 is canine parvovirus type 2, CDV is canine distemper and CAV is canine adenovirus)

During a WSAVA conference in Sydney in August 2007, Australian veterinary expert Dr Steven Holloway, Head of Small Animal Medicine at the University of Melbourne, stated that “it is not possible to defend the practice of annual vaccination for CPV2, CDV, CAV given the volume of data available”.

Ref: Current Issues in Vaccination:

<http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2007&PID=18190&Print=1&O=Generic>

***And yet here in Australia in 2009, it appears the indefensible practice of annual vaccination for CPV2, CDV, CAV continues today...***

***This is a very important issue as over-vaccinating dogs and cats unnecessarily puts them at risk of an adverse reaction.*** Compounding this situation, I am concerned that many possible cases of adverse reactions may not be being reported in Australia. For example, the WSAVA Vaccination Guidelines Group (VGG) notes:

The VGG recognises that there is gross under-reporting of vaccine-associated adverse events which impedes knowledge of the ongoing safety of these products.

Ref: WSAVA guidelines: [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf)

I have personal experience of under-reporting of adverse events by veterinarians. My own dog, Sasha, an eight year old Maltese x Silky terrier became very ill with what was diagnosed as haemorrhagic gastroenteritis eight days after her last C5 booster. She became so ill that four days later, on 22 September 2008, the veterinarians at the veterinary surgery where she had recently been revaccinated stated there was no hope for her recovery and she should be put to sleep to end her suffering.

After Sasha's death I discovered the controversy about over-vaccination of dogs and cats. I suggested to the veterinarian concerned that Sasha's last revaccination with the C5 booster might have been a possible cause for her illness. He refused to consider this possibility. As the veterinarian would not accept the possibility of Sasha's illness being an adverse reaction to vaccination, I have been researching the issues to prepare my own adverse event report on Sasha's case for the APVMA. The veterinarian concerned also insisted: ***"I will not be changing my opinion on the need for annual Vaccination and consequently will continue to inform owners of the need to update immunity levels annually"***. [sic]. Ref: Email correspondence dated 17 October 2008.

During the course of my research into preparing an adverse event report on Sasha's case, ***I have become increasingly alarmed at the possibility that there may be many cases of adverse reaction to revaccination that simply never get reported***. For example, the label on (Product Name) MLV vaccine only lists the more immediate type of reaction that can occur after vaccination, there is no mention of the possibility of delayed reactions.

Yet, according to a paper by an expert in this area, Dr Jean Dodds, ***vaccination reactions can occur up to 45 days later, or even longer***.

Ref: See paper attached: "Adverse Vaccine Reactions". The contents of this paper were originally published in the Journal of the American Animal Hospital Association, May/June 2001, Vol 37, pp 211-214.

Who knows how many other people's pets have gotten sick or died a week, a month or even longer after a revaccination and they haven't made the connection that vaccination could have been at fault? In my experience, veterinarians aren't willing to make the connection. In such cases, veterinarians "bury their mistakes", and pet owners may never be any the wiser that the vaccination could have been at fault.

Regardless of what was responsible for Sasha's illness and subsequent death, I believe she underwent unnecessary risk when she had her last revaccination with core MLV vaccines. Sasha was eight years old. During her life she had seven annual vaccinations given by this veterinarian, one P+PI2+B Final and six C5 boosters. Most of these revaccinations were unnecessary and put her at unnecessary risk of an adverse reaction.

I have raised this issue with Dr Bruce Twentyman, Deputy Veterinary Director of the Australian Veterinary Association and he responded:

As to the frequency of vaccination, our members are advised to follow the manufacturer's recommendations as it is they that have done the scientific work and experimentation to enable the product to be registered in the first place. To go outside these recommendations would be to use the product in an "off-label" situation. [sic]  
There are now vaccines available that are registered to last 3 years and these are the ones that should be used in that manner.

Ref: Email correspondence dated 6 January 2009

In his first paragraph, Dr Twentyman appears to be justifying veterinarians following the manufacturers' recommendation because to do otherwise would be to go "off-label". So he

appears to indicate that veterinarians must follow a recommendation for **annual** vaccination if the manufacturer recommends it. He then goes on to say that “there are now vaccines available that are registered to last 3 years and these are the ones that should be used in that manner”.

It is my understanding that the vaccine recommendations in the WSAVA guidelines are for any of the core MLV vaccines, regardless of brand name or registered duration of immunity. According to the Fact Sheets attached to the WSAVA guidelines (see pp 15-17), in the case of dogs, MLV vaccines for parvovirus, distemper and adenovirus all provide duration of immunity for seven years or longer. This advice indicates the vaccine label recommendation to revaccinate annually “to ensure continuity of protection” is not valid.

The more recent science based recommendations in the WSAVA guidelines supersede the outdated annual recommendation on the labels of MLV vaccines such as (Product Name). On 20 January 2009, I submitted a request to the APVMA via John Owusu, asking on what scientific basis the (Product Name) recommendation for annual revaccination was made. I have not yet received a response to my request.

On Friday 13 February I rang (Vaccine Company) and spoke to (Company Representative) about this annual recommendation on the (Product) label. He told me there had been a 12 month trial of the vaccines. After 12 months the dogs were challenged with parvovirus, distemper and adenovirus and didn't catch the disease, so this proved they were still immune. From the results of this trial they recommended revaccination every 12 months. How can it be logical to recommend revaccination every 12 months because all the dogs were still immune after 12 months? This does not follow. It appears there is no scientific validity for the (Product Name) recommendation to revaccinate annually to “ensure continuity of protection”.

During my telephone call with (Company Representative) I challenged him as to why (Company Name) still sold a core MLV vaccine with a recommendation to revaccinate annually, such as (Product Name), when international guidelines specifically warned against revaccinating adult dogs (and cats) annually with core MLV vaccines. He was unable to give a satisfactory response to my question. The best he could do was blame veterinarians for not taking up the triennial vaccines. But why are annual core MLV vaccines still on the market?

In an academic paper titled: “Vaccination guidelines: a bridge between official requirements and the daily use of vaccines” by Etienne Thiry and Marian C Horzinek, they make the point that:

It is of primary importance that the vaccination schedules followed by the veterinary practitioners are the most efficacious ones even if this means that they do not strictly follow the recommendations of the package inserts.

Ref: <http://www.vetsci.org/publish/articles/000065/index.html>

Simon, as you suggested on the phone, perhaps this is a case where veterinarians should apply for “veterinary prescription rights”? Given that warnings that core MLV vaccines should not be given more than every three years have been made internationally since at least 2003 (and actually these warnings go back to the late 1970s), why haven't veterinarians in Australia applied to disregard the outdated annual recommendation on the labels of core MLV vaccines, such as those contained in (Product Name), before now? Why hasn't the APVMA moved to address this anomaly?

Indeed, Dr Twentyman notes that triennial vaccines are registered for use now, so to avoid any ambiguity, why haven't core MLV vaccines with an outdated annual recommendation simply been taken off the market?

***I now pose two questions to the APVMA:***

**Question 1: Given that warnings that core MLV vaccines should not be given more often than every three years have been made since at least 2003 (and actually these warnings go back to the late 1970s), why haven't veterinarians in Australia applied to disregard the outdated annual recommendation on the labels of core MLV vaccines, such as those contained in (Product Name), before now? Why hasn't the APVMA acted to address the contradictory recommendations of the outdated core MLV vaccine labels and the more recent recommendations of international vaccination guidelines?**

**Question 2: Given that the WSAVA guidelines recommend that core MLV vaccines should be given no more often than three years after the puppy/kitten series and booster at 12 months of age, why are core MLV vaccines for parvovirus, distemper and adenovirus with a recommendation for annual revaccination of adult dogs (and the relevant core MLV vaccines for cats) still on the market? Since triennial vaccines are available, surely core MLV vaccines with a recommendation for annual revaccination should be deemed obsolete and removed from sale?**

I have spent the last four months researching this issue. I have written to the Australian Veterinary Association, the Heads of all the Veterinary Schools in Australia, the APVMA and WSAVA. I have been in contact with individual academic veterinary experts in some of the universities. I have also recently contacted (Vaccine Company) about this issue. I am also in contact with other people who believe their pets were adversely affected after over-vaccination.

***I have spent an extraordinary amount of my own time working on this issue during evenings and weekends, and including most of my Christmas and New Year leave. I have desperately tried to get attention for this issue, to try and raise the alarm that there might be a serious problem with over-vaccination of dogs and cats in Australia, and that this might be resulting in often unreported adverse reactions. I am disgusted at the lack of action by the relevant authorities. My calls for attention for this problem in Australia are being ignored. I have been shocked at the apathetic response I have received from the authorities in Australia, a response that borders on contempt.***

According to statistics, over 12 million people in Australia are associated with pets. 91% of pet owners report feeling "very close" to their pets, reinforcing that pets are an integral member of the family.

Ref: Pet Statistics: <http://www.petnet.com.au/petstatistics.asp>

Pets are a very important part of many people's lives. What do you think these people would think if they discovered veterinarians, vaccine manufacturers and the APVMA were all conspiring to maintain an unethical practice of revaccinating adult dogs and cats annually with core MLV vaccines, a practice that is of no benefit to the animal and which needlessly puts it at risk of an adverse reaction? When other pet owners discover what has been going on for the past years, that vaccination recommendations from international scientific experts have been ignored and not passed on to them for their consideration, and that the authorities have been warned about this, I think pet owners are going to question the ethical standards of the veterinarians, the vaccine manufacturers and the regulatory body, the APVMA.

As a pet owner, I am extremely concerned at the standard of veterinary practice in Australia, in particular that unethical veterinarians are misleading their clients into having their adult pet dogs and cats unnecessarily revaccinated with core MLV vaccines every year, an intervention that is of no benefit to the animal and which needlessly puts it at risk of an adverse reaction. Such vets are not advising their clients about the recommendations in the WSAVA guidelines. Such vets are not offering their clients the opportunity to revaccinate with triennial vaccines or the option to have serological testing. Such vets are, in my view, using the unacceptable "off-label" excuse to unethically justify the practice of revaccinating adult dogs and cats every year with core MLV

vaccines simply to lure people into their surgeries to pay for a useless and possibly harmful intervention.

I am concerned that every day thousands of adult dogs and cats may unnecessarily be being put at risk of an adverse reaction. ***Why is this being allowed to happen?***

***I request that the APVMA take urgent action on this issue, and put out a warning to ensure this unnecessary, unethical and possibly harmful practice is halted immediately.***

I am trying to find somebody in the APVMA who will take this issue seriously, who will take responsibility. So far I have been unsuccessful. You have indicated you will take up this problem for me. My next step will be to contact the CEO of the APVMA, Dr Eva Bennet-Jenkins and Tony Burke, the Minister for Agriculture, Fisheries and Forestry. As the regulatory body, I believe the APVMA should take responsibility for this important issue.

I would appreciate your acknowledgement of this email.

I look forward to your urgent response to the important issues raised.

Many thanks again for listening to my concerns.

Yours sincerely  
Elizabeth Hart

## APPENDIX 2

***Veterinarian's Certificate of Vaccination***

---

Certificate of Vaccination

---

This is to certify that ..... Veterinary Surgery has vaccinated the following animal with the vaccines shown:

Owner: Mrs E Hart

Phone:

Patient Sasha  
Sex: Female Spayed  
Details: Tri Colour Maltese X  
Age 8 years

**Vaccines Administered**

09/09/2008 C5 Booster

**Important Points to Remember**

Protection after vaccination may take up to 2 weeks. Isolate Sasha during this period. A booster vaccine will be necessary to maintain immunity. Vaccines are usually harmless, however, if Sasha shows signs of illness after vaccination, please contact us immediately.

\_\_\_\_\_ 0/09/08

.....  
For ..... Veterinary Surgery

**Details of Next Vaccination:**

09/09/2009 C5 vaccination

## APPENDIX 3

### *Text of Veterinarian's Vaccination Reminder Letter*

Dear Sasha

#### *It's time for your vaccination!*

Yes, it's been 12 months since your last one, and you need a booster against **Distemper, Hepatitis and Parvovirus**. If you haven't also been covered for **Canine Cough** you'll need to be updated for this as well.

You may not be aware of it, but if you are going to stay healthy, you need this vaccination. And if you are going to be boarded out, the people will need an up-to-date vaccination certificate.

When you come in, we'll also give you a general check up. If there is anything about your health you need to know, such as routine worming, flea, skin or dental problems, get your owner to ask!

Remember that **Heartworm disease** is in your area - so make sure that your owner is giving you the "once a month" tablets (or new once yearly injection) to prevent you from getting it.

So, get your owner to phone for an appointment as soon as possible, and I'll look forward to seeing you again.

Kind regards

## APPENDIX 4

***See below the text of an email sent to the Heads of five veterinary schools in Australia:***

This email was sent individually to all of the following on Monday 12 January 2009:

- Professor Leo Jeffcott, Dean, Faculty of Veterinary Science, University of Sydney;
- Professor Roger Swift, Executive Dean, Faculty of Natural Resources, Agriculture and Veterinary Sciences, The University of Queensland,
- Professor Ken Hinchcliff, Dean, Faculty of Veterinary Science, The University of Melbourne;
- Professor John Edwards, Dean and Head of School, School of Veterinary and Biomedical Sciences, Murdoch University;
- Professor Gail Anderson, Head of School of Veterinary Science, University of Adelaide

I subsequently discovered there were another two veterinary schools in Australia, and sent the email to the following on Friday 3 April 2009:

- Professor Kym Abbott, Head of School, School of Animal and Veterinary Sciences, Charles Sturt University
- Professor Lee Fitzpatrick, Head of School and Dean Vet Science, School of Veterinary Biomedical Sciences, James Cook University

Dear Professor \_\_\_\_\_

***I am preparing a report on vaccination of pets in Australia and I would be grateful if you would answer the following questions:***

- ***Can you please advise me what dog and cat vaccination guidelines are currently being taught to students in your veterinary school?***
- ***Does your veterinary school follow the Guidelines for the Vaccination of Dogs and Cats, compiled by the Vaccination Guidelines Group (VGG) of the World Small Animal Veterinary Association (WSAVA), published in 2007?***

(Link to WSAVA VGG Guidelines: [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf) )

- ***What is being taught on the topic of “veterinary ethics”, for example on obtaining “informed consent” from clients for veterinary interventions concerning their pets (e.g. vaccination)?***
- ***What is being taught about veterinarians’ responsibility to report possible adverse reactions to veterinary products and interventions to the APVMA?***

The following information provides background to my enquiry:

I understand the WSAVA Vaccination Guidelines Group was convened to develop guidelines for the vaccination of dogs and cats that have **global** application. The VGG guidelines are built on those developed by the American Animal Hospital Association (AAHA) Canine Vaccine Task Force and the American Association of Feline Practitioners (AAFP).

The VGG guidelines recommend that: ***“We should aim to vaccinate every animal, and to vaccinate each individual less frequently.”***



The VGG guidelines state:

***“Vaccines should not be given needlessly. Core vaccines should not be given any more frequently than every three years after the 12 month booster injection following the puppy / kitten series.”***

(Ref: VGG guidelines p. 2)

On the subject of revaccination of adult dogs, the VGG guidelines note:

***Dogs that have responded to vaccination with MLV core vaccines maintain a solid immunity (immunological memory) for many years in the absence of any repeat vaccination. Following the 12 month booster, subsequent revaccinations are given at intervals of three years or longer, unless special conditions apply.***

(Ref: VGG guidelines p. 4)

The VGG guidelines also note that:

***We should aim to reduce the ‘vaccine load’ on individual animals in order to minimise the potential for adverse reactions to vaccine products.***

(Ref: VGG guidelines p. 2)

***Adverse events are defined as any side effects or unintended consequences (including lack of protection) associated with the administration of a vaccine product. They include any injury, toxicity, or hypersensitivity reaction associated with vaccination, whether or not the event can be directly attributed to the vaccine. Adverse events should be reported, whether their association with vaccination is recognised or only suspected....The VGG recognises that there is gross under-reporting of vaccine-associated adverse events which impedes knowledge of the ongoing safety of these products.***

(Ref VGG guidelines p. 8)

It has been my experience that in Australia **annual** vaccination of dogs and cats is **still** being recommended by veterinarians. This has certainly been my experience. Every year I receive letters from our regular vet (addressed personally to our pets) warning us that “if you are going to stay healthy, you need this vaccination”.

***It appears manufacturers of vaccines also recommend annual vaccination.*** For example, the label on (Product Name) recommends “that dogs be revaccinated annually with (Product Names) vaccines to ensure continuity of protection.”

I am currently undertaking investigations to discover the scientific basis for the manufacturers’ recommendation for annual vaccination.

In the case of (Product Name), the manufacturer’s recommendation appears to contradict information contained in the VGG guidelines which recommends that revaccination of, in the case of dogs for example, the core MLV vaccines for parvovirus, distemper and adenovirus ***should not occur more often than every three years.*** (Ref: VGG guidelines p. 9)

The VGG guidelines also note that challenge and serological studies of these vaccines have shown duration of immunity is seven years or longer. (Ref: VGG guidelines pp 15-17).

***So, there appears to be a serious contradiction here, with the manufacturer recommending vaccination with core vaccines every year, and the VGG guidelines recommending vaccination with core vaccines every three years.***

The vet I regularly attended with my Maltese x terrier dogs, Sasha (now deceased) and Coco, told us to vaccinate annually, including core vaccines. In his annual reminder letter, personally addressed to our dogs, he insisted: “if you are going to stay healthy, you need this vaccination”. He has never provided any information about the AAHA and WSAVA VGG guidelines. At no time have I been offered the option to vaccinate three-yearly with the core vaccines. The vet has not given me the opportunity to consider and decide between the manufacturer’s recommendation and the recommendation of the AAHA / VGG guidelines.

When vaccinating my pets, the vet has not obtained my “informed consent”. He has certainly never informed me about the very persuasive arguments supporting three yearly vaccinations. I relied on the vet for his “expertise and professional guidance”, but I do not believe this was forthcoming. I believe the vet put the health of my pets at risk by insisting on unnecessary vaccinations, with the possibility of adverse reaction.

***Considering my experience, I believe the vet has contravened Australian Veterinary Association policy and professional conduct, in particular:***

## **PART 2 – USE OF VETERINARY MEDICINES**

### **2.1 – Responsible use of veterinary immunobiologicals in cats and dogs**

#### **Policy**

***The Australian Veterinary Association (AVA) believes that veterinarians must maintain a highly professional approach to all aspects of the use of immunobiologicals (vaccines). This includes ensuring that vaccines are not used unnecessarily, ensuring that the latest techniques are adopted (as appropriate) and appreciating that the profession will be held responsible for the correct use of immunobiologicals. Veterinarians should aim to maintain the profession as the source of informed knowledge on the use of these agents.***

Link to AVA policy 2.1:

<http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Policies&Template=/CM/HTMLDisplay.cfm&ContentID=2156>

## **AVA Code of Professional Conduct**

### **3. Strive to provide the best possible veterinary services, and to improve the quality of animal health and welfare.**

b. Veterinary procedures and recommendations should be based on sound evidence-based science and practice.

### **4. Foster and maintain good communications and relationships with your clients, earning their trust and respecting professional confidentiality\***

b. Clients should be informed about any available alternative procedures or treatments, in terms they are likely to understand.

c. Prior informed consent of the owner should be obtained for any procedure or treatment, if readily available.

**\* The veterinarian-client relationship is important as the basis for most professional interactions. A *bona fide* relationship exists where each of the following occurs:**

i. The veterinarian has assumed responsibility for making judgments regarding the health and welfare of the animal(s) and the need for treatment, with the owner’s (client’s agreement).

iii. The veterinarian is available, or has arranged for adequate emergency coverage, for follow-up evaluation in the event of an adverse reaction or failure of the treatment regimen.

Link to AVA Code of Professional Conduct:

[http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code\\_of\\_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741](http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Code_of_Conduct&Template=/CM/HTMLDisplay.cfm&ContentID=5741)

Vaccination of pets is not a mandatory requirement in Australia. However, in my experience, vets are pushing their clients to have their pets vaccinated **annually** with core vaccines, and sending their clients unsolicited vaccination reminder letters to enforce this practice.

***Vets who carry out this practice are using vaccines “unnecessarily”. It could also be argued they are not basing their recommendations on “sound-evidence based science and practice”.***

***Also, by not informing their clients of scientific information regarding duration of immunity and the international move towards three yearly vaccinations, such vets are not maintaining “the profession as the source of informed knowledge on the use of these agents”. They are also not obtaining “informed consent”.***

***It is a matter of concern to me that AVA policy on vaccination is rather vague. As far as I can tell, there is nothing on the AVA website to inform members of the public about the international move towards three yearly vaccination with core vaccines.***

***I am preparing a report on the problem of over-vaccination in Australia which I intend to forward to a wide range of individuals and organisations for comment.***

This report will include discussion on:

- frequency of vaccination and the controversy surrounding frequency of vaccination (including opinion of academic vets and recent guidelines);
- ***what vaccination guidelines are currently been taught in Australian veterinary schools;***
- unnecessary vaccination;
- manufacturers' product labelling and recommendations;
- AVA policy on vaccination;
- vets as “a source of informed knowledge”;
- ethical issues such as unsolicited annual vaccination reminder letters and informed consent;
- the range of adverse reactions to vaccines;
- under-reporting of adverse reactions – particularly reporting of adverse events that can lead to detection of ***previously unrecognised reactions***.

***As you will see above, I intend to include a compilation of the responses received to my enquiry to Australian veterinary schools about what vaccination guidelines are currently being taught to students in veterinary schools.***

***I would appreciate your acknowledgement of my enquiry, and your urgent consideration and response to the issues and questions raised.***

I look forward to your response.

Yours sincerely  
Elizabeth Hart

## APPENDIX 5

*See below part of an email containing questions for the Australian Veterinary Association (AVA), sent to Dr Bruce Twentyman, Deputy Veterinary Director of the AVA on Friday 6 February 2009. This email was also forwarded to Dr Mark Lawrie, President of the AVA, and other key members of the AVA, on Sunday 8 February 2009*

As of 13 April, these questions have not yet been answered.

**Re Unnecessary Vaccination:**

Regardless of what was responsible for Sasha's illness and subsequent death, I believe she underwent unnecessary risk when she had her last revaccination with core MLV vaccines. According to the WSAVA VGG Guidelines: "Vaccines should not be given needlessly. **Core vaccines should not be given any more frequently than every three years** after the 12 month booster injection following the puppy/kitten series."

Ref: WSAVA VGG Guidelines [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf)

Sasha was eight years old. During her life she had seven annual vaccinations given by the veterinarian, one P+PI2+B Final and six C5 boosters. Most of these revaccinations were unnecessary and put her at unnecessary risk of an adverse reaction.

AVA Policy 2.1 – "Responsible use of veterinary immunobiologicals in cats and dogs" notes that vaccines should not be used "unnecessarily".

**QUESTION 1:** *Can you please advise what, in the AVA's opinion, constitutes "unnecessary" use of vaccines? Does the AVA support annual revaccination with core MLV vaccines after the puppy/kitten series and 12 month booster?*

**Re "Source of Informed Knowledge" and "Informed Consent":**

AVA Policy 2.1 also notes that "Veterinarians should aim to maintain the profession as the source of informed knowledge on the use of these agents."

**QUESTION 2:** *Can you please advise what, in the AVA's opinion, constitutes a "source of informed knowledge on the use of these agents"? For example, can a veterinarian who ignores the WSAVA VGG Guidelines, and who refuses to pass the recommendations of these guidelines on to his/her client be regarded as a "source of informed knowledge"? (Note: I understand the WSAVA VGG guidelines were published in the Journal of Small Animal Practice, 2007; 48(9):528-541) and are available on the WSAVA website. These guidelines were developed for **global** application. While these guidelines "do not represent a standard of care or set of legal parameters"... "they have been drafted with the objective of educating and informing the profession and to recommend rational vaccine use for individual pets and dog/cat populations". I understand these guidelines are "based upon a consensus among experts" and "reflect a combination of opinion, experience, and scientific data, published and unpublished". The WSAVA VGG Guidelines were published in 2007 and built on the 2006 AAHA Canine Vaccine Guidelines and the 2006 American Association of Feline Practitioners Feline Vaccine Advisory Panel Report.)*

I have found the AVA Code of Professional Conduct to be quite interesting reading... Take for example **Point 4. Foster and maintain good communications and relationships with your clients, earning their trust and respecting professional confidentiality, c. Prior informed consent of the owner should be obtained for any procedure or treatment, if readily available.**

In my experience, when my dogs were (over)vaccinated, I was never warned of the types of adverse reactions that could occur, either those noted on the label of (Product Name), or the possible delayed effects which could occur that have been noted in scientific literature (but not on the vaccine label). I was also given to believe that annual revaccination with the core MLV vaccines for **CPV2, CDV and CAV was essential to protect my dogs' health**. The veterinarian I regularly attended for the last seven years (at least annually...) always sent an annual reminder, personally addressed to my dogs, advising them the following:

"You may not be aware of it, **but if you are going to stay healthy, you need this vaccination**. And if you are going to be boarded out, the people will need an up-to-date vaccination certificate." (My emphasis) (See copy of text of vaccination letter attached).

This annual reminder letter was misleading, in fact it could more accurately be described as an outright lie.

Subsequent to Sasha's death, in email correspondence with the veterinarian who had over-vaccinated Sasha for nearly every year of her life, I challenged him about his practice of revaccinating every year. This was his response:

The debate with regards to +/- vaccinate, annual or triennial vaccinations, possible vaccination reactions still rages and will do so for some time to come.  
As Veterinarians our focus is on preventative health care. To cease vaccinations merely on anecdotal evidence or scare campaign tactics can in my opinion only harm all that has been achieved in the field of Veterinary Medicine over the last decades of research.

**Forewarning of 'possible' reactions can only have a negative effect for the same reason.**

So long as the debate still continues and until such time that real evidence is presented to the contrary **I will not be changing my opinion on the need for annual Vaccination and consequently will continue to inform owners of the need to update immunity [sic] levels annually.**

(My emphasis)

(Email correspondence dated 17 October 2008)

This veterinarian is obstinate in his intention to ignore the WSAVA VGG Guidelines (which I had brought to his attention in previous correspondence), and his flagrant intention to continue to ignore the recommendations is totally unacceptable. His negative attitude to "forewarning of 'possible' reactions" is also unacceptable. What would an Ethics Committee make of his intention to deliberately continue to inform owners of the need to update immunity levels annually, which infers that he will not be advising them of the WSAVA VGG Guidelines? What would an Ethics Committee make of his refusal to forewarn his clients about possible adverse reactions?

**QUESTION 3:** *I have personal experience of a vet sending his clients annual reminder letters to have their adult pet dogs (and cats) unnecessarily revaccinated with core MLV vaccines. This unnecessary revaccination is needlessly putting at risk those adult dogs and cats (which have already been vaccinated via the puppy/kitten series and 12 month booster) of adverse reaction to over-vaccination. Is the AVA concerned about this unprofessional and unethical practice?*

**QUESTION 4:** *I have personal experience of a vet not obtaining "informed consent" from his clients before carrying out revaccination. He is not informing his clients of the recommendations of the WSAVA VGG guidelines. He is not forewarning his clients of the possible adverse reactions that can occur. He is not giving his clients the opportunity to make an "informed decision" regarding revaccination. Is the AVA concerned about this unprofessional and unethical practice?*

**Re: “Off-label Use” and “Sound evidence-based science and practice”:**

In our previous correspondence you also made this point:

As to the frequency of vaccination, our members are advised to follow the manufacturer's recommendations as it is they that have done the scientific work and experimentation to enable the product to be registered in the first place. To go outside these recommendations would be to use the product in an “off-label” situation. [sic]

I assume you are referring to the labelling on products like (Product Name), which recommends annual revaccination to “ensure continuity of protection”?

I have submitted an enquiry to the APVMA, querying the scientific basis on which this recommendation for annual revaccination to “ensure continuity of protection” is made, and I am still awaiting an answer.

However, it is my understanding from the AAHA and WSAVA guidelines that the core MLV vaccines for CPV2, CDV and CAV provide duration of immunity for 7 years or longer, regardless of brand name etc. In a paper titled “Vaccination guidelines: a bridge between official requirements and the daily use of vaccines”, Etienne Thiry and Marian Horzinek note:

It is important to produce guidelines because the time between the initial development of a vaccine and its use in the field can be very long: several different players become involved and scientific knowledge develops, so the initial recommendations for use may no longer be the most appropriate.

***It is of primary importance that the vaccination schedules followed by the veterinary practitioners are the most efficacious ones even if this means that they do not strictly follow the recommendations of the package inserts.*** (My emphasis).

Ref: <http://www.vetscite.org/publish/articles/000065/index.html>

I see that the AVA's Code of Professional Conduct notes that veterinarians should **3. Strive to provide the best possible veterinary services, and to improve the quality of animal health and welfare, b. Veterinary procedures and recommendations should be based on sound evidence-based science and practice.**

***QUESTION 5: If there is more recent scientific evidence to suggest that vaccine manufacturers' recommendations for annual revaccination with core MLV vaccines are no longer appropriate, shouldn't veterinarians abandon the label recommendation and base their current vaccination protocol on the most recent revaccination guidelines which are the “most efficacious” and which are based on “sound evidence-based science and practice”? Shouldn't veterinarians, at the very least, give their clients the opportunity to weigh up the recommendations of the latest international revaccination guidelines, i.e. those contained in the WSAVA VGG Guidelines, and ensure that the client makes the final (informed) decision on whether to revaccinate his or her pet?***

**Re Triennial Vaccines:**

Re your comment that:

There are now vaccines available that are registered to last 3 years and these are the ones that should be used in that manner.

**QUESTION 6:** *The WSAVA VGG Guidelines recommend that revaccination with core MLV vaccines shouldn't happen more often than every three years. So why are veterinarians continuing to use core MLV vaccines that have a label recommendation to revaccinate annually? Such "annual" core MLV vaccines should be deemed obsolete. As you say, there are triennial vaccines available now, so annual core MLV vaccines should simply be taken off the market. I will be writing to the APVMA about this issue.*

Of course the concept of "triennial" vaccines is also a matter of concern to me. The WSAVA VGG Guidelines note that duration of immunity for the core MLV vaccines is seven years or longer. The Guidelines recommend that "core vaccines should not be given any more frequently than every three years after the 12 month booster injection following the puppy/kitten series". However, it seems to me the vaccine companies are seeing the writing on the wall that their recommendation for annual vaccination is under threat in the future, so they are now trying to protect their future vaccine market and ensure vaccines sales at least every three years by interpreting the WSAVA VGG's recommendation as "revaccinate every three years".

**QUESTION 7:** *If duration of immunity is seven years or longer, why should it be necessary to revaccinate every three years? If this triennial dictum becomes entrenched, I am particularly concerned about the impact this might have on older dogs, particularly as duration of immunity is seven years or longer and so therefore revaccination would be unnecessary for older dogs. In fact, Professor Ron Schultz, who is a member of the WSAVA Vaccination Guidelines Group, suggests the "maximum duration of immunity may be for the life of most (>80%) vaccinated animals". Ref: Considerations in Designing Effective and Safe Vaccination Programs for Dogs: [http://www.ivis.org/advances/Infect\\_Dis\\_Carmichael/schultz/IVIS.pdf](http://www.ivis.org/advances/Infect_Dis_Carmichael/schultz/IVIS.pdf) So revaccination after the initial puppy series and 12 month booster might not be necessary at all...*

#### **Re Serological Testing to Determine Duration of Immunity:**

The WSAVA VGG Guidelines note:

The VGG recognises that at present such serological testing has limited availability and might be relatively expensive. However, the principles of 'evidence-based veterinary medicine' would dictate that testing for antibody status (for either pups or adult dogs) is better practice than simply administering a vaccine booster on the basis that this should be 'safe and cost less'. In response to these needs, more rapid, cost-effective tests are being developed.

Ref: [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf)

**QUESTION 8:** *Is the AVA working to promote serological testing in Australia as a facility for those pet owners who want to accurately determine their dogs' immunity levels? Is the AVA encouraging the development of "more rapid, cost-effective tests"?*

Bruce, I would appreciate your urgent response to the eight questions I have raised in this email. So far, I have been less than impressed by the answers you have given to my previous questions and correspondence.

For your information, I will also be writing to the President of the AVA, Dr Mark Lawrie, (cc Dr Kevin Doyle, Veterinary Director) about the alarming problem of over-vaccination of dogs and cats in Australia, and the AVA's lack of acknowledgement and action on this serious problem.

***I look forward to your response to the urgent and important questions I have raised.***

Yours sincerely  
Elizabeth Hart



## APPENDIX 6

**See below the text of an email sent to Dr Mark Lawrie, President of the AVA, and other key members of the AVA, on Sunday 8 February 2009**

**RE: CONCERN ABOUT OVER-VACCINATION OF DOGS AND CATS IN AUSTRALIA**

Just over three months ago one of my dogs, Sasha, an eight year old Maltese Silky x terrier, became very ill eight days after her last C5 Booster vaccination. Four days later, on 22 September 2008, she was put to sleep.

I now suspect that Sasha's illness and subsequent death was caused or influenced by an adverse reaction to her last revaccination. The veterinarian who revaccinated Sasha refused to consider the possibility that her illness might have been caused or influenced by the revaccination. I am now in the process of preparing my own Adverse Event report for the APVMA, plus a report for the Veterinary Surgeons' Board of South Australia. I also intend to produce a general report on the problem of over-vaccination of dogs and cats in Australia.

I was shocked when Sasha died, and bewildered how this could happen so suddenly. Undertaking research after Sasha's death, I discovered the controversy surrounding over-vaccination of dogs and cats. I had no idea of this previously, I had simply trusted my veterinarian's advice to revaccinate my dogs every year. Now I know about the international guidelines that state the duration of immunity for the core MLV vaccines for dogs is seven years or longer, and that dogs and cats should not have core MLV vaccines more often than every three years. But it is absolutely no thanks to the veterinarian in whom I had misplaced my trust for the last seven years, and who I had, unknowingly, taken my dogs to for unnecessary revaccinations every year.

In his annual reminder letters, cutely personally addressed to my dogs he said ***"You may not be aware of it, but if you are going to stay healthy, you need this vaccination". That was a lie. My dogs did not need the revaccination, and far from keeping them healthy, it put them needlessly at risk of an adverse reaction. And now one of my dogs is dead.*** (Copy of annual reminder letter text attached).

I challenged the veterinarian about his revaccination policy after Sasha's death, but he insisted he was still going to "inform owners of the need to update immunity levels annually". (Ref: Email correspondence dated 17 October 2008).

I understand that published dog and cat vaccination guidelines have been available since at least 2003. For instance, the AAHA Canine Vaccine Guidelines were published in 2003, updated in 2006, revised in 2007, and published for global application by the World Small Animal Veterinary Association (WSAVA) in 2007. The WSAVA VGG Guidelines for the Vaccination of Dogs and Cats recommend that: "Vaccines should not be given needlessly. **Core vaccines should not be given any more frequently than every three years** after the 12 month booster injection following the puppy/kitten series." (My emphasis).

Ref: WSAVA VGG Guidelines [http://www.wsava.org/PDF/Misc/VGG\\_09\\_2007.pdf](http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf) )

Vaccination expert Professor Ron Schultz has been warning against annual revaccination with core MLV vaccines since the late 1970s. Professor Schultz, who is a member of the WSAVA Vaccination Guidelines Group, suggests the "maximum duration of immunity may be for the life of most (>80%) vaccinated animals".

Ref: Considerations in Designing Effective and Safe Vaccination Programs for Dogs:  
[http://www.ivis.org/advances/Infect\\_Dis\\_Carmichael/schultz/IVIS.pdf](http://www.ivis.org/advances/Infect_Dis_Carmichael/schultz/IVIS.pdf)



***So revaccination after the initial puppy series and 12 month booster might not be necessary at all...***

During a WSAVA conference in Sydney in August 2007, Australian veterinary expert Dr Steven Holloway, Head of Small Animal Medicine at the University of Melbourne, stated that "it is not possible to defend the practice of annual vaccination for CPV2, CDV, CAV given the volume of data available".

Ref: Current Issues in Vaccination:

<http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2007&PID=18190&Print=1&O=Generic>

***And yet here in Australia in 2009, it appears the indefensible practice of annual vaccination for CPV2, CDV, CAV continues today...***

Recently, as a quick experiment, I randomly selected 10 veterinary surgeries out of the Adelaide telephone book, and rang to enquire about vaccination for my five year old dog and to ask how often vaccination was recommended. I spoke to each receptionist and it appeared clear to me they were relaying the vaccination protocol of the surgery. From their response, it was quite obvious to me that annual revaccination with core MLV vaccines was common practice. I specifically asked if annual revaccination, with core MLV vaccines (i.e. CPV2, CDV, and CAV) was necessary. They all advised it was. There was no mention of triennial vaccination. I conducted this exercise to check my suspicions, and my suspicions were confirmed... (Costs ranged from around \$A76-\$A105 dollars, which I understand generally included a consultation.)

***I am extremely concerned there is a widespread practice of veterinarians in Australia deliberately misleading their clients into believing their adult dogs and cats need to be revaccinated with core MLV vaccines every year, simply to justify an annual health check and a visit to their surgeries.*** If veterinarians believe an annual health check is advisable for an animal, the pet owner should be allowed to consider this recommendation on its own merits. Veterinarians must no longer be allowed to deliberately mislead their clients into believing that their adult dogs and cats need to be revaccinated with core MLV vaccines to justify an annual visit to their surgeries, a revaccination that is of no benefit to the adult dog or cat and which can actually cause harm and even death.

What has happened to the ideal of "do no harm"? Why is there no adherence to the concept of "informed consent", i.e. fully informing the client of the recommendations of the latest international vaccination guidelines, and letting the client make the final decision on whether to revaccinate?

It is simply despicable that veterinarians continue to lure clients into their surgeries by sending them reminder letters telling them that annual revaccination with core MLV vaccines is essential if their pets are "going to stay healthy". This is immoral, unethical, unprofessional and I will soon be making enquiries to find out if it is actually illegal. Because if it isn't, it should be.

Can you appreciate just how angry and upset I am to discover that my pet dog Sasha's illness and subsequent death could have been caused by a totally unnecessary intervention? If the veterinarian had been following the WSAVA VGG Guidelines published in 2007 and, more importantly, if he had advised me of the Guidelines and allowed me to make my own informed decision, I simply would not have had my dogs revaccinated on 9 September 2008, because they did not need it. ***Sasha would not have been revaccinated, and perhaps her subsequent illness and death might not have happened.***

***The situation in Australia has been allowed to fester for far too long now. Too many people and organisations are conspiring to maintain the status quo. It is now time for Australian pet owners to be properly informed about the latest international recommendations on vaccination for their pet dogs and cats. The decision to revaccinate should be the***

***informed pet owner's, not the veterinarian's. The veterinarian's role is to provide the best and latest scientific advice for the continued good health of their clients' dogs and cats. They can no longer be allowed to get away with recommending over-vaccination with core MLV vaccines, an intervention that provides no benefit to the animal, and which actually puts it at needless risk of an adverse reaction, even death.***

I initiated correspondence on this issue with the Australian Veterinary Association's Deputy Veterinary Director, Dr Bruce Twentyman, back in early October 2008. I have to say I am most dissatisfied with the response I have received so far from Dr Twentyman. Recently, I sent him another email detailing my concerns, ***including eight specific questions that I want answered by the AVA.*** I will also forward a copy of my recent email to Dr Twentyman (dated 6 February 2009) to you for your consideration. ***I request the AVA's urgent attention to the questions raised.***

Also for your information, I will forward a copy of my correspondence with Dr Walt Ingwerson of WSAVA, where I outline my concerns about what is happening in Australia re over-vaccination of dogs and cats.

I will also forward to you a copy of my email letter to the Heads of Veterinary Schools in Australia, in which I ask what dog and cat vaccination guidelines are currently being taught to students in Australian veterinary schools, and also what is being taught about veterinary ethics, e.g. the concept of "informed consent". I also ask what is being taught about veterinarians' responsibility to report possible adverse reactions to veterinary products and interventions to the APVMA. So far, I have received no meaningful response from them to the important questions and issues raised.

***I would appreciate your urgent consideration of my concerns and questions raised in this email and my email to Dr Bruce Twentyman, and my correspondence with WSAVA and the Heads of Veterinary Schools in Australia.***

***I look forward to your prompt response.***

Yours sincerely  
Elizabeth Hart