
A SUBMISSION ON

THE NATIONAL SCHEME FOR ASSESSMENT, REGISTRATION AND CONTROL OF USE OF AGRICULTURAL AND VETERINARY CHEMICALS DISCUSSION PAPER

in relation to

UNNECESSARY, AND POSSIBLY HARMFUL, USE OF COMPANION ANIMAL VACCINES

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10 February 2010

Submitted to:

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Summary

The Australian Pesticides and Veterinary Medicines Authority's (APVMA) current regulation of companion animal vaccines is a failure, and is resulting in unnecessary and possibly harmful revaccination of pets.

There is no scientific evidence to support revaccination recommendations on modified live virus (MLV) vaccine product labels for diseases such as parvovirus, distemper virus or adenovirus. **Neither annual, nor triennial revaccination with these vaccines has been proven to be necessary.** The latest scientific evidence indicates these vaccines provide long duration of immunity, demonstrated to be at least seven years based on challenge and serological studies¹, and probably lifelong².

The APVMA's failure to provide "rigorous and independent evaluation of scientific information about the safety and efficacy"³ of companion animal vaccine products has been a significant factor in the prevalent and continuing problem of unnecessary revaccination of pets.

Due to the failure of the APVMA, the community cannot "be confident that (companion animal vaccine) products are safe and effective when used according to label instructions"⁴.

The continuing problem of unnecessary and possibly harmful revaccination of pets with **core vaccines for parvovirus, distemper virus and adenovirus, is an example of a systemic breakdown in the Federal and State regulatory process, and the veterinary profession's vaccination practice.** The APVMA, the Australian Veterinary Association, and State Veterinary Surgeons' Boards have ignored advances in scientific knowledge, and evidence-based companion animal vaccination 'best practice'.

These authorities failed to take the initiative to ensure Australian companion animal vaccination practice was brought into line with scientific advice contained in the scientific literature and international dog and cat vaccination guidelines, which have been available for many years.

It has been left to concerned pet owners to persistently bring this problem to the attention of the authorities. **These pet owners have faced enormous resistance to having their concerns addressed, particularly from the Australian veterinary profession.**

The continuing prevalent problem of unnecessary vaccination of pets must be addressed on an integrated national (and international) basis.

The failure of the veterinary profession to adopt vaccination 'best practice', and to continue to ignore and suppress the latest scientific evidence regarding long duration of immunity and the risk of adverse reactions and long term health problems with vaccination, must also be considered, **particularly as annual revaccination with core vaccines continues to be promoted in media articles in newspapers across Australia.**

(Note: I provided evidence of this unacceptable 'media promotion' of annual revaccination, with examples from newspapers in Western Australia, South Australia, Queensland and New South Wales, in my 'open letter' to the APVMA, AVA, Australian

Small Animal Veterinary Association, and the Competition and Consumer Policy Division, dated 24 January 2010. The letter is accessible via this link:)
http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_CCPD_24-01-10.pdf

Veterinary associations and government regulators must relay a simple and effective vaccination message to pet owners in line with current vaccination 'best practice'.

As the APVMA has acknowledged in its recently published Position Statement on Vaccination Protocols for Dogs and Cats (21 January 2010, revised 25 January 2010), **"the aim should be to ensure that all susceptible animals are vaccinated, rather than that already well-immunised animals are revaccinated"**.⁵

According to the scientific literature, dogs are likely to be protected from viral diseases such as parvovirus, distemper virus and adenovirus after the final puppy vaccination at 16 weeks⁶ – **no further revaccination is likely to be required for these diseases, although pet owners can seek serological testing if they wish to verify their dog's antibody status.**

Pet owners should be given this straightforward information, that a series of **core** vaccines for parvovirus, distemper virus and adenovirus is only required for puppies, **instead of confusing pet owners with ill-founded advice about ongoing 'annual' and 'triennial' revaccination of adult dogs with core vaccines.**

Pet owners should be advised that ongoing vaccination with **non-core** vaccines only needs to be considered in individual cases for less serious diseases and less prevalent diseases (e.g. 'kennel cough' and leptospirosis). They should also be advised of the limited efficacy and the risks of these vaccines, so they can weigh up the risks and benefits of repeated vaccination with these vaccines for their individual pet.

It is essential that dog and cat vaccination guidelines be regularly updated to take account of scientific developments in this area, and that veterinarians maintain 'best practice'.

While the focus of the Discussion Paper for the Product Safety and Integrity Committee appears to be "the growing positive contribution of chemicals...to the productivity of Australian agriculture".⁷ the Discussion Paper also states:

Where people have concerns that they believe are related to agvet chemicals they should feel free to raise those concerns in responding to this discussion paper.⁸

Specifically, I request that the Product Safety and Integrity Committee take urgent steps to ensure companion animal vaccine product regulation, labelling and vaccine product use be rapidly improved so that pets across Australia are effectively protected from unnecessary and possibly harmful revaccination, and pet owners protected from exploitation by veterinarians.

12 million Australians are associated with pets, so this issue is relevant to many Australians.⁹

Background to my submission

I, and other concerned pet owners, Bea Mies in Sydney and Pat Styles in Perth, started lobbying the APVMA and the Australian Veterinary Association (AVA), and other authorities, regarding the problem of unnecessary vaccination of pets after our own dogs became very ill (two dogs died) after unnecessary revaccination. We strongly suspect our pets were adversely affected by unnecessary vaccination.

During our research we have discovered that information on long duration of immunity, and adverse reactions and long term health problems associated with vaccines, has been withheld from pet owners for many years.

We have also discovered 'the system' is heavily weighted against recognising, acknowledging and reporting possible adverse reactions to vaccination. My colleagues and 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 unnecessary vaccination could be harming their pets' health.

In April 2009, the APVMA convened a meeting of its senior scientific staff to discuss our concerns, and subsequently promised that a Position Statement would be prepared to address the issue. I prepared a report to be tabled at the APVMA meeting in April 2009, titled "***Is over-vaccination harming our pets? Are vets making our pets sick?***" My report is accessible via this internet link: http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf

My 'over-vaccination' report, and my subsequent paper "***Over-vaccination of pets – an unethical practice***" dated 16 June 2009 and accessible via this internet link: http://users.on.net/~peter.hart/Over-vaccination_of_pets_-_an_unethical_practice.pdf were also circulated to the AVA, State Veterinary Surgeons' Boards, Heads of veterinary schools, the World Small Animal Veterinary Association, and other key members of the veterinary profession in Australia and overseas.

After years of inexcusable delay, during which time annual vaccination was considered "accepted practice" by the Australian veterinary profession¹⁰, the AVA's Board ratified its new policy on Vaccination of Dogs and Cats on 26 June 2009.¹¹ (This new vaccination policy was substantially different to the draft policy circulated to members for comment by 13 March 2009. For instance, the draft policy¹² did not include a reference to the World Small Animal Veterinary Association's Guidelines for the Vaccination of Dogs and Cats¹³.)

The AVA's new dog and cat vaccination policy ambiguously notes:

...core vaccines need not be administered any more frequently than triennially and... ***even less frequent vaccination may be considered appropriate if an individual animal's circumstances warrant it. However, local factors may dictate more frequent vaccination scheduling.***¹⁴ (My emphasis.)

The new policy was finally announced publicly in August 2009¹⁵, after negative press in the *Sydney Morning Herald* and on the ABC regarding unnecessary vaccination of pets. The *Sydney Morning Herald* ran two stories on this topic, i.e. "Vets dogged by criticism over vaccinations"¹⁶ and "Annual vaccinations could be harmful: vets told".¹⁷ The *ABC News* also picked up on the story, i.e. "Pet owners dogged by 'unnecessary' vaccinations".¹⁸ Specialist dog breeder magazine *National Dog* also printed my article "Over-vaccination: Are vets making our pets sick?" in July 2009¹⁹. (*National Dog* published my follow-up article "The over-vaccination controversy continues..." in December 2009²⁰).

Bea Mies and I were invited to meet with the APVMA in September 2009. We requested that the AVA also be invited to attend this meeting, and the President of the AVA, Mark Lawrie; Deputy Veterinary Director, Bruce Twentyman; and President of the Australian Small Animal Veterinary Association (ASAVA), Graham Swinney, also attended the meeting at the APVMA's office in Canberra. This meeting gave us an opportunity to air our concerns. The APVMA also invited Bea Mies and me to comment on the APVMA's draft Position Statement on Vaccination Protocols for Dogs and Cats, and we appreciated this opportunity. We provided detailed written comments on the draft Position Statement to the APVMA.

After persistent follow-up by Bea Mies and me, including a number of 'open letters'²¹ to the APVMA, AVA and ASAVA, the APVMA finally published (*but, as far as I am aware, did not actively publicise*) its Position Statement on Vaccination Protocols for Dogs and Cats on 21 January 2010, nine months after the meeting on unnecessary vaccination of pets held in April 2009.

The Position Statement was subsequently revised, after my urgent criticism of a key statement, on 25 January 2010.²²

Recent publicity for the problem of unnecessary revaccination of pets

On Friday 5 February 2010, the *Courier Mail* publicised the APVMA's Position Statement when it published a story headlined "*Too many needles for pets*" which reported that "hundreds of thousands of cats and dogs are being over-medicated with unnecessary annual vaccinations".²³

In response, the APVMA issued a statement on its website on 8 February 2010 under the section: "Our View" titled "Over-vaccination Comments Over-stated". Despite the title of the APVMA's response, the APVMA admitted the media article "**was broadly correct...**"²⁴.

(Note: Another Queensland newspaper picked up the story on 9 February 2010 – "Annual pet shots not necessary" in The Morning Bulletin.²⁵)

The APVMA's response also advised that the APVMA and AVA had issued a **joint** media statement on the issue of Vaccination of Dogs and Cats²⁶. This joint media statement appears to be a cynical exercise in damage control, as both these organisations have obstinately resisted acknowledging long duration of immunity of modified live virus (MLV) vaccines, for diseases such as parvovirus, for many years.

As the professional body representing veterinarians, the AVA should have ensured that vaccination 'best practice' was adopted in Australia years ago, but it failed in its professional duty to work in the best interests of pet owners and, as a result, **numerous pets have been subjected to unnecessary vaccinations, and been needlessly put at risk of adverse reactions and long term health problems.**

Veterinarians have a conflict of interest in that they gain a financial benefit by urging pet owners to (unnecessarily) revaccinate their pets against viral diseases such as parvovirus. The results of a survey of veterinarians, published in a vaccine industry newsletter in 2005, note 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**".²⁷ The newsletter concluded: "Annual vaccination appears to be an important source of income for many veterinarians".²⁸

Veterinarians who continue to urge their clients to have unnecessary and possibly harmful interventions for their pets are failing in their professional duty to act in the best interests of their

clients and their pets. Unnecessary vaccination is an example of over-servicing in the veterinary profession.

The AVA should be brought to account for this serious lapse in professional responsibility.

As a *government* agency (albeit industry funded...) the APVMA is accountable to the Australian public, and its actions should be wholly transparent and above reproach. **It is a matter for serious concern that the APVMA is aligning itself so closely with a 'self-regulated' association of veterinarians which has ignored the existence of international dog and cat vaccination guidelines for many years, and has allowed unnecessary vaccination of pets to continue unabated.**

The joint media statement from the AVA and APVMA also illustrates that **the APVMA is endorsing unnecessary triennial revaccination of pets, when the APVMA knows very well that triennial revaccination has not been proven to be necessary. There is evidence that MLV core vaccines provide long duration of immunity, demonstrated to be at least seven years after challenge and serological studies²⁹, and probably lifelong.³⁰**

Information regarding long duration of immunity and possible adverse reactions and long term health problems continues to be withheld from pet owners

Pet owners are not being clearly informed that canine MLV vaccines have been demonstrated to provide long duration of immunity regardless of the manufacturers' 'annual' or 'triennial' revaccination recommendations. The 2006 American Animal Hospital Association (AAHA) canine vaccine guidelines advise that vaccines produced by the major biologics manufacturers against parvovirus, distemper virus and adenovirus **all** produce excellent immune responses and can be soundly and reliably administered at the discretion of the clinician in extended duration of immunity protocols.³¹ It is not necessary to use a designated 'three year vaccine' and it has not been proven necessary to revaccinate 'every three years'.³²

The public must be warned about the problem of unnecessary revaccination of pets, **particularly as there is evidence veterinarians are continuing to urge their clients to have their pets revaccinated annually with MLV core vaccines, despite the AVA's new reduced vaccination policy.**

Recent articles in local newspapers around Australia provide proof that **annual** revaccination of pets with MLV core vaccines is still common practice. **Information on long duration of immunity and possible adverse reactions continues to be suppressed from pet owners' consideration.**

(Note: I provided evidence of this unacceptable 'media promotion' of annual revaccination, with examples from newspapers in Western Australia, South Australia, Queensland and New South Wales, in my 'open letter' to the APVMA, AVA, Australian Small Animal Veterinary Association, and the Competition and Consumer Policy Division, dated 24 January 2010. The letter is accessible via this link:)

http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_CCPD_24-01-10.pdf

It is interesting that the APVMA and AVA felt no need to issue a joint media statement to warn pet owners of misleading media articles promoting unnecessary annual revaccination of pets, but reacted swiftly to defend themselves against a media report which warned pet owners that "hundreds of thousands of cats and dogs are being over-medicated with unnecessary annual vaccinations"³³ ...

It is likely that many veterinarians will continue to urge their clients to have unnecessary revaccination for their pets **because the APVMA's Position Statement provides them with a loophole to do so.**

The original APVMA statement, published on Thursday 21 January 2010, contained the following sentence:

"the APVMA...acknowledges that in some circumstances, such as communities with high prevalence of infection, **annual revaccination may be advisable**".³⁴ (My emphasis.)

In an email dated Friday 22 January 2010, I asked for urgent clarification of this statement, asking the following questions:

Can you please clarify, is the APVMA statement referring to core annual revaccination "in some circumstances"?

If you are indeed referring to core annual revaccination "in some circumstances", please provide the scientific basis for this statement, including references in the current evidence and literature.

I received the following email response from Allen Bryce, Program Manager, Veterinary Medicines on Sunday 24 January 2010:

The APVMA's draft Position Statement was published on our website on 21 January 2010. I note your question regarding our statement that "in some circumstances, such as communities with high prevalence of infection, annual revaccination may be advisable". As an example, there are situations, such as occur in remote Aboriginal communities, where distemper and parvovirus are present and dog control is poor; dog 'ownership' is a loose concept and records are difficult to keep. In these circumstances it is better to vaccinate dogs regularly, as it is not certain which dogs have been effectively vaccinated and which have not. This is admittedly not a situation that most Australian dogs or dog owners are familiar with, but it is very real, and in those cases the benefits of vaccination far exceed any risk created by unnecessarily vaccinating some dogs. The statement will be amended in response to your criticism.³⁵

I responded to Allen Bryce in an 'open letter' to representatives of the APVMA, AVA, Australian Small Animal Association, and the Competition and Consumer Policy Division, on Sunday 24 January 2010³⁶, saying that I was:

astonished by your specious argument about annual revaccination of dogs in remote Aboriginal communities. As you admit, this is "not a situation that most Australian dogs or dog owners are familiar with".³⁷

The APVMA's Position Statement was revised in response to my criticism, with this amended statement being published on Monday 25 January 2010:

The APVMA...acknowledges that **in some unusual circumstances, such as communities with high prevalence of infection and incomplete vaccination records, annual revaccinations may be advisable** - however, the aim should be to ensure that all susceptible animals are vaccinated, rather than that already well-immunised animals are re-vaccinated.³⁸ (My emphasis.)

Despite the rider that, "**the aim should be to ensure that all susceptible animals are vaccinated, rather than that already well-immunised animals are re-vaccinated**", it is likely many veterinarians will use the excuse that they practice in "communities with high prevalence of

infection and incomplete vaccination records” to continue to unacceptably justify annual revaccination with MLV core vaccines.

This likelihood was confirmed for me in correspondence with the President of the South Australian Division of the AVA, Warren Foreman, dated 28 January 2010.³⁹ I had contacted Warren Foreman in his capacity as a senior representative of the AVA about an article published in an Adelaide newspaper on 15 December 2009, titled “Canine deaths mystery”.⁴⁰ This article reported on a “mystery disease” killing dogs in the northern suburbs of Adelaide, which subsequently turned out to be parvovirus. I expect the eye-catching title of this story was sufficient to attract readers to the main thrust of this article, which was to urge pet owners to “immunise their dogs, at a cost of \$60-\$90, even if the animal was vaccinated last year”⁴¹.

I asked Warren Foreman “can you please advise me the scientific rationale for this revaccination recommendation?” He replied in his letter with a tortuous response that sought to justify annual revaccination for parvovirus, which I am still struggling to interpret. The gist of it seems to be that people in “Struggletown” (i.e. a low socioeconomic area) are unlikely to be able to remember when their pet was last vaccinated, so the message needs to be kept simple, i.e. “a yearly ‘vaccination’ visit”.⁴²

A similar attitude was displayed in a story reported on 3 February 2010 titled “Parvovirus cases detected in Ipswich” on *ABC Brisbane*, with **annual** boosters being recommended for dogs in this “increased risk”, “lower socio-economic” area⁴³.

This paternalistic attitude is unacceptable and conflicts with advice in the APVMA’s Position Statement e.g.:

- ...veterinarians should provide pet owners with pertinent, up-to-date information on vaccination best practice to assist in a joint decision as to whether and when to re-vaccinate their pet.
- It is important that veterinarians tailor vaccination regimens to suit the needs of each animal under their care, and discuss alternatives with their client.
- ...the aim should be to ensure that all susceptible animals are vaccinated, ***rather than that already well-immunised animals are re-vaccinated.*** (My emphasis.)

It is unacceptable that information regarding companion animal vaccination ‘best practice’, including information on long duration of immunity and possible adverse reactions and long-term health problems, be withheld from people on the basis of their socio-economic status, or their race (e.g. people living in remote Aboriginal communities.)

Veterinarians do not have a mandate to dictate vaccination practice to their clients. In its recent Position Statement, the APVMA has confirmed that “veterinarians and pet owners are under no obligation to follow revaccination intervals recommended on vaccine labels”.⁴⁴ **The self-appointed authority of veterinarians who dictate that pet owners have interventions for their pets without scientific foundation must be challenged.**

In my critique of the APVMA’s Position Statement, I will request that the offending statement regarding ‘annual revaccination’ in ‘unusual circumstances’ be reworded along the following evidence-based lines:

When an animal's **core** vaccination status is unknown, concerned pet owners can choose to have serological testing to verify their pet's antibody status, or a vaccination. The World Small Animal Veterinary Association's (WSAVA) Guidelines for the Vaccination of Dogs and Cats advise that "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'".⁴⁵ (My emphasis.)

Veterinarians have ignored evidence-based medicine and international dog and cat vaccination guidelines

The Australian Veterinary Association's Code of Professional Conduct notes:

Veterinary procedures and recommendations should be based on **sound evidence-based science and practice**.⁴⁶ (My emphasis.)

The *British Medical Journal* provides this definition of evidence based medicine:

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research....⁴⁷

The *Journal of the American Medical Association* provides additional definition:

Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.⁴⁸

In *Seminars in Perinatology*, David Sackett notes that:

Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients. The practice of evidence-based medicine is a process of life-long, self-directed learning in which caring for our own patients creates the need for clinically important information about diagnosis, prognosis, therapy, and other clinical and health care issues...⁴⁹ (My emphasis.)

Evidence based medicine has been described as a "paradigm shift":

When defects in an existing paradigm accumulate to the extent that the paradigm is no longer tenable, the paradigm is challenged and replaced by a new way of looking at the world. Medical practice is changing, and the change, which involves using the medical literature more effectively in guiding medical practice, is profound enough that it can appropriately be called a paradigm shift.⁵⁰

This paradigm shift to "using the medical literature more effectively in guiding medical practice", has led to the development of guidelines for medical practice. An article titled "Guidelines for Guidelines" in the medical journal, *Chest*, notes:

The increasing premium placed on making health-care decisions and assessing quality of care using the best available evidence highlights the importance of transparent, thoughtful, and rigorous guideline development.⁵¹

Another article on evidence-based guideline development in *Chest* notes:

Evidence based clinical practice guidelines (EBGs) can provide an invaluable distillation of knowledge regarding the best practices based on the available evidence.⁵²

Many veterinarians in Australia, and other countries such as the United States and Britain, have ignored evidence of long duration of immunity of MLV core vaccines, contained in the scientific literature and international dog and cat vaccination guidelines, for many years.^{53 54 55}

The most recent vaccination guidelines, the World Small Animal Veterinary Association's (WSAVA) Guidelines for the Vaccination of Dogs and Cats, recommend that:

We should aim to vaccinate every animal, **and to vaccinate each individual less frequently.**⁵⁶ (My emphasis.)

The WSAVA Guidelines warn 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.⁵⁷ (My emphasis.)

* Core vaccines are those MLV vaccines for parvovirus, distemper virus and adenovirus.

The WSAVA dog and cat vaccination guidelines warn:

We should aim to reduce the 'vaccine load' on individual animals in order to minimise the potential for adverse reactions to vaccine products.⁵⁸

It is important to note that the WSAVA guidelines do not actually recommend revaccination "every three years".

*Note: It must be acknowledged that there are ambiguities and inconsistencies in the WSAVA guidelines. For instance, why is there any reference to 'three years' in these guidelines given that the guidelines admit that there is long duration of immunity with MLV core vaccines, demonstrated to be at least seven years with challenge and serological studies? **This information should be passed onto pet owners for their consideration.** The reference to 'three years' must be clarified in the next edition of the WSAVA guidelines, expected later this year. (The WSAVA guidelines state they have been formulated "without consultation with industry". Nevertheless, it is interesting to note the WSAVA guidelines are sponsored by Intervet, the manufacturer of so-called 'three year' vaccine Nobivac DHPPi.)*

The WSAVA guidelines note that dogs properly vaccinated with MLV core vaccines (i.e. with the final puppy vaccination at 16 weeks) have very high protection from infection and ≥98% protection from disease.⁵⁹

The WSAVA guidelines note that:

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.⁶⁰

The WSAVA guidelines Fact Sheets advise that duration of immunity after vaccination with these vaccines is seven years or longer, based on challenge and serological studies.⁶¹

Earlier guidelines, issued by the American Animal Hospital Association (AAHA) Canine Vaccine Task Force in 2003, stated that MLV vaccines are likely to provide lifelong immunity, stating:

when MLV vaccines are used to immunise a dog, memory cells develop and likely persist for the life of the animal.⁶²

Ronald Schultz, a member of the WSAVA Vaccination Guidelines Group, 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. (My emphasis.)

The WSAVA guidelines currently recommend a 12 month booster injection with **core** vaccines (not to be confused with ongoing 'annual' revaccination which the WSAVA guidelines do **not** recommend) following the puppy/kitten series. The guidelines also acknowledge that "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'. (My emphasis.) (***Hopefully this apparent contradiction will be clarified in the next edition of the WSAVA guidelines later this year.***)

The WSAVA guidelines define vaccines for less serious or less prevalent diseases as **non-core** vaccines (e.g. 'kennel cough' and leptospirosis). These are required by "**only those animals whose geographical location, local environment or lifestyle places them at risk of contracting specific infections**".⁶³

In many instances **non-core** vaccines may not be necessary at all. The risks and benefits of these vaccines must be carefully weighed up in each individual case, particularly as the consequences of long term repeated vaccination are unknown.

It would be most useful if dog and cat vaccination guidelines (and the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats) presented a simple message to pet owners regarding 'best practice' vaccination for their pets.

As the APVMA has acknowledged "**the aim should be to ensure that all susceptible animals are vaccinated, rather than that already well-immunised animals are revaccinated**".⁶⁴

Pet owners should be simply advised that most dogs are likely to be protected from serious viral diseases such as parvovirus, distemper virus and adenovirus after the final puppy vaccination at 16 weeks – **no further revaccination is likely to be required for these diseases, although pet owners can seek serological testing if they wish to verify their dog's antibody status.**

(Note: Ronald Schultz compares vaccination of puppies with human vaccination⁶⁵, i.e. it is similar to children having measles shots – nobody expects to continue having measles shots as adults every year.)

Pet owners should be given this straightforward information, that a series of **core** vaccines for parvovirus, distemper virus and adenovirus is only required for puppies, **instead of confusing pet owners with ill-founded advice about ongoing 'annual' and 'triennial' revaccination with core vaccines.**

Pet owners should be advised that ongoing vaccination with **non-core** vaccines only needs to be considered in individual cases for less serious diseases and less prevalent diseases (e.g. 'kennel cough' and leptospirosis). They should also be advised of the limited efficacy and the risks of these vaccines, so they can weigh up the risks and benefits of repeated vaccination with these vaccines for their individual pet.

Marian Horzinek, a member of the WSAVA Vaccination Guidelines Group, makes the point that "the profession should issue regular updates of the 'code of vaccination practice'"⁶⁶.

It is essential that dog and cat vaccination guidelines be regularly updated to take account of scientific developments in this area, and maintain vaccination 'best practice'.

The risk of adverse reaction to vaccination

The only reference to adverse reactions in the APVMA's Position Statement is the following statement:

The incidence of adverse experiences associated with dog and cat vaccines reported to the APVMA's Adverse Experience Reporting Program (AERP) is low: less than 1 in 10,000 doses. The incidence of more serious reactions such as anaphylaxis is very low, and appears to be similar for initial vaccinations and revaccination, which is also true for human vaccines.⁶⁷

As I have already pointed out to the APVMA, this scant information is misleading.

The **voluntary** Adverse Experience Reporting Program run by the Australian Pesticides and Veterinary Medicines Authority appears to be just 'window dressing'. In my opinion, it has not been designed to be a truly effective post-marketing surveillance system.

Who really knows how many adverse reactions, including delayed adverse reactions or long-term health problems, resulting from unnecessary vaccination, go unrecognised and unacknowledged? The failure in regulation and surveillance means veterinarians who unnecessarily vaccinate and over-service continue to get away with this unethical practice, **particularly as it has been recognised that 'some' veterinarians are reluctant to acknowledge and report adverse reactions**^{68 69 70}. The status quo is being protected from scrutiny.

The WSAVA guidelines warn that:

We should aim to reduce the 'vaccine load' on individual animals in order to minimise the potential for adverse reactions to vaccine products.⁷¹

The WSAVA guidelines also admit that

there is gross under-reporting of adverse events which impedes knowledge of the ongoing safety of these products.⁷²

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.⁷³

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.⁷⁴

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...

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 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.⁷⁵

David Husted, 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.⁷⁶ Husted also 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.” According to Husted “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”.⁷⁷

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.

In an article discussing adverse reactions to vaccination, Jean Dodds 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.**”⁷⁸ (My emphasis.)

Veterinary expert Richard Ford notes that “...delayed-onset (days-weeks-months) adverse events are much less likely to be recognized, reported, and studied”.⁷⁹

In the case of older animals, David Husted 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.⁸⁰

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.⁸¹

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.*⁸²

In his 1998 paper “Current and future canine and feline vaccination programs”, Ronald 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.**⁸³ (My emphasis.)

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. More recently, it has been shown experimentally that dogs develop an autoimmune response after vaccination, something that was known to occur in other species.^{84 85}

In his paper “Vaccine side effects: Fact and fiction”, Michael Day, a member of the WSAVA Vaccination Guidelines Group, 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”.⁸⁶

In a paper in preprint, Day also acknowledges the cumulative effects and consequences of repeated vaccination are unknown saying that **few “investigations have studied the phenomenon of ‘inflammageing’ (the effect of cumulative antigenic exposure and onset of late life inflammatory disease)”** in dogs and cats.⁸⁷

Bioethicist Bernard Rollin warns there is increasing evidence that over-vaccination can actually be conducive to disease development, not only as a consequence of immunological stress, but also more directly. For example, frequent vaccination has been implicated in the development of

autoimmune haemolytic anemia in dogs and injection site sarcomas in cats, both of which can be fatal.⁸⁸

Michael Day suggests vaccines containing alum may be implicated in cases of vaccine-associated autoimmunity. **Aluminium is also associated with cancer in dogs.** A study by Vascellari et al identified distinct similarities between canine fibrosarcomas from presumed injection sites and feline post-vaccinal fibrosarcomas, **suggesting the possibility of the development of post-injection sarcomas not only in cats but also in dogs.** In this study "aluminium deposits were detected in eight canine fibrosarcomas from presumed injection sites".⁸⁹

Cancer is reported as being the single biggest cause of death in dogs over two years old.⁹⁰ According to information from Texas A&M University, dogs and cats have a higher incidence of many tumors than do humans. Dogs have 35 times as much skin cancer, 4 times as many breast tumors, 8 times as much bone cancer, and twice as high an incidence of leukemia as do humans.⁹¹ A paper published in 2001 suggests long-term over-activation of the immune system may be a major cause of cancer.⁹² This research refers to cancer in humans, but given we are all mammals with similar genes,⁹³ perhaps this possibility is also relevant to dogs? **Could unnecessary vaccination, and the constant assault on the immune system, be causing a variety of cancers in dogs and cats over the long term?** It is certainly something to ponder. This possibility is also another important reason to cease unnecessary revaccination of animals.

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 five 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, death⁹⁴

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.⁹⁵

Novak's study⁹⁶ and another by George Moore et al titled "Adverse events diagnosed within three days of vaccine administration in dogs"⁹⁷ 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.⁹⁸

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"**.⁹⁹ (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.¹⁰⁰

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.¹⁰¹

Despite the mounting evidence about vaccine adverse reactions and possible long term health problems, many veterinarians continue to deny a link with vaccination.

Jean Dodds, an expert in adverse reactions, notes:

Some veterinarians today still tell their clients there is no scientific evidence linking vaccinations with adverse effects and serious illness. This is ignorance, and confuses an impressionable client.¹⁰²

Dodds says:

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.**¹⁰³ (My emphasis.)

Ronald Schultz also says “there is a reluctance to report reactions, even those that lead to the death of an animal”.¹⁰⁴

Members of the vaccine industry are also unwilling to acknowledge the possibility of adverse reaction to revaccination. In an 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.**”¹⁰⁵

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.¹⁰⁶

Lenz cites no evidence to support his statements. Vaccinating per label suggestion has **not been proven to be harm/less...**

In an article published in 1995, 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.**¹⁰⁷ (My emphasis.)

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.¹⁰⁸ (My emphasis.)

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**¹⁰⁹ (My emphasis.)

Despite ongoing warnings, in 2010, 15 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.

It appears there have been no longitudinal trials, or effective post-marketing surveillance of dogs in the community, to test the effects of repeated 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 are also unlikely to provide much detail about the range of possible immediate and delayed side effects, particularly if veterinarians and veterinary associations 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, and post-marketing surveillance is ineffective. 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.

Compounding the problem of under-reporting of adverse events by veterinarians, many pet owners may not associate adverse events or longer term health problems after vaccination with the vaccination. **Many pet owners would follow their veterinarian’s advice, and if the veterinarian does not acknowledge the possibility of an adverse reaction or health problem with vaccination, a pet owner may never recognise the possibility.**

Also, most pet owners would be unaware that they can make their own adverse experience reports to the Australian Pesticides and Veterinary Medicines Authority – are veterinarians telling their clients about the APVMA’s Adverse Experience Reporting Program? 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.¹¹⁰

And the stunning fact is, adult dogs simply don't need to be regularly revaccinated with MLV core vaccines, as they are likely to be protected after the final puppy vaccination at 16 weeks. When adult dogs are revaccinated with MLV core 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.¹¹¹

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 considered an unacceptable medical procedure,*** thus use only those vaccines that are needed and use them only as often as needed.¹¹²

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

Yet veterinarians unaccountably continue to use unproven revaccination recommendations on vaccine products in an attempt to justify the prevalent practice of annual (*and triennial*) revaccination of pets with MLV vaccines.

Unproven vaccine label revaccination recommendations - the APVMA's role in unnecessary vaccination

As mentioned previously, there is no scientific evidence to support revaccination recommendations on MLV vaccine product labels for diseases such as parvovirus, distemper virus or adenovirus.

Pet owners are not being clearly informed that canine MLV vaccines have been demonstrated to provide long duration of immunity regardless of the manufacturers' 'annual' or 'triennial' revaccination recommendations. The 2006 American Animal Hospital Association (AAHA) canine vaccine guidelines advise that vaccines produced by the major biologics manufacturers against parvovirus, distemper virus and adenovirus ***all*** produce excellent immune responses and can be soundly and reliably administered at the discretion of the clinician in extended duration of immunity protocols.¹¹³ It is not necessary to use a designated 'three year vaccine' and it has not been proven necessary to revaccinate 'every three years'.¹¹⁴

Despite the lack of scientific evidence to support repeated vaccination, the APVMA has allowed on the market MLV vaccine products with 'annual' and 'triennial' revaccination recommendations which have not been proven to be necessary, and with inadequate warnings about possible side effects and long term health consequences.

Manufacturers' revaccination recommendations on canine MLV vaccine product labels conflict with duration of immunity information contained in international dog and cat vaccination guidelines which have been available since 2003.

The APVMA Annual Report 2008-09, notes that registration of products:

is based on a rigorous and independent evaluation of scientific information about the safety and efficacy of a product. This careful evaluation ensures that the community and users of pesticides and veterinary medicines can be confident that the products are safe and effective when used according to label instructions.¹¹⁵

The APVMA's failure to provide "rigorous and independent evaluation of scientific information about the safety and efficacy"¹¹⁶ of companion animal vaccine products has been a significant factor in the prevalent and continuing problem of unnecessary revaccination of pets.

Due to the failure of the APVMA, the community cannot "be confident that (companion animal vaccine) products are safe and effective when used according to label instructions"¹¹⁷.

Importantly, the APVMA's recently published Position Statement now acknowledges the problem of *non-evidence based* vaccine product label revaccination recommendations:

The APVMA does not support the retention of label statements that direct or imply a universal need for life-long annual revaccinations with core vaccines. The APVMA supports the AVA's vaccination policy and is of the view that product labels should be amended to align with that policy. The APVMA is working with vaccine registrants with a view to updating labels.¹¹⁸

As part of my critique of the APVMA's Position Statement, I will be querying the APVMA re their support for the AVA's vaccination policy. I will also request clarification as to how vaccine product labels will be amended. **It is important that MLV canine vaccine product labels note that no endpoint to duration of immunity has been demonstrated.**

Despite scientific evidence regarding long duration of immunity with MLV core vaccines, many veterinarians have used, **and continue to use**, the unproven revaccination recommendations on vaccine product labels to unacceptably justify ongoing unnecessary revaccination of pets.

These veterinarians have ignored the call of veterinary immunology experts to use the most efficacious vaccination schedules **even if this means that they do not strictly follow the recommendations of the package inserts.**¹¹⁹ (i.e. 'the label'). (My emphasis.)

Importantly, the APVMA's recently published Position Statement now publicly acknowledges:

State and Territory legislation that controls use of veterinary medicines allows registered veterinarians to use veterinary medicines "off-label" in dogs and cats. **Veterinarians may therefore use vaccines at whatever interval they (and the client) determine is best for each particular animal.**¹²⁰

Veterinarians and pet owners are under no obligation to follow revaccination intervals recommended on vaccine labels.¹²¹

It appears that veterinarians who tell their clients they are bound to follow vaccine product label revaccination recommendations (either 'annual' or 'triennial') are misleading their clients.

I suggest one could question the ethics of a practitioner who continues to urge his/her clients to have their pets revaccinated if this possibly harmful intervention has not been proven to be necessary, and without passing on crucial information about long duration of immunity or possible immediate and delayed adverse reactions for their clients' consideration.

I suggest that veterinarians who continue to insist their clients have their dogs vaccinated with MLV core vaccines, and who do not obtain informed consent from their clients, i.e. do not inform them of vaccination guidelines and information on long duration of immunity, or the possibility of adverse reactions or longer term health problems, **are misleading their clients and breaking the law**. Taking the *Veterinary Practice Act 2003 South Australia* as an example, I suggest such veterinarians are contravening 'Part 7 – Miscellaneous, 68 – False or misleading statement'.¹²²

Also referring to the *Veterinary Practice Act 2003*, I suggest that veterinarians who mislead their clients about vaccination are guilty of unprofessional conduct, i.e. "improper or unethical conduct in relation to professional practice" and "incompetence or negligence in relation to the provision of veterinary treatment".¹²³

One would expect the appropriate course of action of a pet owner who believes their pet has been unnecessarily vaccinated would be to make a complaint to the relevant State Veterinary Surgeons' Board. Information on the Veterinary Surgeons' Board of South Australia website notes:

An important role of the Board is to maintain the public's confidence in the veterinary profession in South Australia. The main way the Board fulfills this role is by ensuring the profession maintains high standards.¹²⁴

The website also notes: "The Board will investigate complaints made by members of the public."¹²⁵

Under the provisions of the *Veterinary Practice Act 2003 South Australia*, it is the Veterinary Surgeons' Board's responsibility to protect "animal health, safety and welfare and the public interest by achieving and maintaining high professional standards both of competence and conduct in the provision of veterinary treatment..."¹²⁶ **The functions of the Board include preparing or endorsing codes of conduct and professional standards for veterinary surgeons; and preparing or endorsing guidelines on continuing education for veterinary surgeons.**¹²⁷ (My emphasis)

In this regard in April 2009, I forwarded a copy of my detailed and fully referenced report "**Is over-vaccination harming our pets? Are vets making our pets sick?**"¹²⁸ to the Veterinary Surgeons' Board of South Australia for comment. I received this response:

The SA Board noted your correspondence at its recent meeting and agreed that it is not the role of the Board to comment on this issue. It may be best for you to approach the Australian Veterinary Association with your report.¹²⁹

I also forwarded my report to other State Veterinary Surgeons'/Practitioners' Boards in Australia.¹³⁰ Only two bothered to respond, also declining to comment.¹³¹

The Veterinary Surgeons' Board of South Australia is failing in its responsibility to protect "animal health, safety and welfare and the public interest by achieving and maintaining high professional standards both of competence and conduct in the provision of veterinary treatment..."¹³²

Indeed, the Veterinary Surgeons' Board of South Australia is complicit in maintaining unnecessary and possibly harmful vaccination practice. Five months after the publication of the AVA's new dog and cat vaccination policy, the Veterinary Surgeons' Board of South Australia continues to recommend that boarding kennels require proof of vaccination of dogs against distemper, hepatitis and parvovirus **within the preceding 12 months** of admission.¹³³ (This

recommendation remains in place as at 10 February 2010, five months after the announcement of the AVA's new dog and cat vaccination policy).

It appears futile to complain about unnecessary vaccination of pets to the Veterinary Surgeons' Board of South Australia, when this organisation is responsible for maintaining this unacceptable practice.

Conclusion

While the APVMA's Position Statement on Vaccination Protocols for Dogs and Cat is a major step forward in acknowledging the problem of unnecessary vaccination of pets, **it is not as clear and informative as it should be.**

In an article titled "The public and effective risk communication", Lynn Frewer argues:

Risk communication must take account of the actual concerns of the public...When the public want information about a risk, **they prefer a clear message regarding risks and associated uncertainties, including the nature and extent of disagreements between different experts.** Furthermore, societal priorities for risk mitigation activities may not align with those identified by expert groups. **Dismissing the former as irrelevant may result in increased distrust in the motives of regulators and industry, with consequences for public confidence in regulatory activities linked to public protection.** Awareness and understanding of public concerns must be the basis of an effective risk management strategy.¹³⁴ (My emphasis.)

For many years, the public has received a biased and non-evidence based view on vaccination of pets with MLV core vaccines from most members of the veterinary profession. It is way past time that pet owners were provided with critical information on vaccination 'best practice'.

I do not believe that the veterinary profession can be trusted with this task, it is up to the Federal government regulator, the APVMA, to take leadership on this issue and ensure the public is properly informed.

However, it is alarming that the APVMA has closely aligned itself with the AVA, particularly as many members of the 'self-regulated' Australian veterinary profession are brazenly continuing to unnecessarily revaccinate pets **annually** not to mention **triennially**...

As it currently stands, **the APVMA's Position Statement remains ambiguous and misleading, and subject to misinterpretation by veterinarians and the public.** I am preparing a critique of the Position Statement which I will forward to the APVMA in due course. I will also forward a copy to the Product Safety and Integrity Committee for consideration with this submission, when it is finalised.

It is important to note that the continuing problem of unnecessary and possibly harmful revaccination of pets **is an example of a systemic breakdown in the Federal and State regulatory process, and the veterinary profession's vaccination practice.** The Australian Pesticides and Veterinary Medicines Authority, the Australian Veterinary Association, and State Veterinary Surgeons' Boards have ignored advances in scientific knowledge, and evidence-based companion animal vaccination 'best practice'.

These authorities failed to take the initiative to ensure Australian companion animal vaccination practice was brought into line with scientific advice contained in the scientific literature and in international dog and cat vaccination guidelines, which have been available for many years.

It has been left to concerned pet owners to persistently bring this problem to the attention of the authorities. **These pet owners have faced enormous resistance to having their concerns addressed, particularly from the Australian veterinary profession.**

The prevalent problem of unnecessary vaccination of pets must be addressed on an integrated national (and international) basis.

The failure of the Australian veterinary profession to adopt vaccination 'best practice', and to continue to ignore and suppress the latest scientific evidence regarding long duration of immunity, and the risk of adverse reactions and long term health problems, must also be considered.

In this regard, in July 2009, I made a submission to Craig Emerson, Minister for Competition Policy and Consumer Affairs, on the Consumer Voices Issues Paper, highlighting the problem of unnecessary vaccination of pets, and requesting consumer protection for consumers of veterinary services in Australia. My submission is accessible via this internet link: http://www.treasury.gov.au/documents/1593/PDF/Elizabeth_Hart.pdf

While my submission to the Minister was made in July 2009, as of January 2010, I have received no advice from the Minister's department on any action being taken to address this problem, which is relevant to the 12 million people in Australia who are associated with pets.¹³⁵

I am taking the opportunity to bring the problem of unnecessary vaccination of pets to the attention of the Product Safety and Integrity Committee by making this submission on the National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals Discussion Paper.

While the focus of this Discussion Paper appears to be "the growing positive contribution of chemicals...to the productivity of Australian agriculture".¹³⁶ the Discussion Paper also states:

Where people have concerns that they believe are related to agvet chemicals they should feel free to raise those concerns in responding to this discussion paper.¹³⁷

Specifically, I request that the Product Safety and Integrity Committee take urgent steps to ensure companion animal vaccine product regulation, labelling and vaccine product use be rapidly improved so that pets across Australia are effectively protected from unnecessary and possibly harmful revaccination, and pet owners protected from exploitation by veterinarians.

To support my submission on the National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals Discussion Paper, I present below my papers and correspondence which provide more background on unnecessary vaccination of pets:

- ***Is over-vaccination harming our pets? Are vets making our pets sick?*** (13 April 2009). This report was tabled at a special meeting convened by the APVMA on 15 April 2009 to discuss the problem of unnecessary vaccination of pets:
http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf
- ***Over-vaccination of pets – an unethical practice*** (16 June 2009):
http://users.on.net/~peter.hart/Over-vaccination_of_pets_-_an_unethical_practice.pdf
- ***Over-vaccination: Are vets making our pets sick?*** (June 2009, published in *National Dog* in July 2009):
http://users.on.net/~peter.hart/Over-vaccination_-_Are_vets_making_our_pets_sick.pdf
- ***Submission on the Consumer Voices Issues Paper: Request for consumer protection for consumers of veterinary services in Australia*** (17 July 2009):
http://www.treasury.gov.au/documents/1593/PDF/Elizabeth_Hart.pdf
- ***The over-vaccination controversy continues*** (published in *National Dog* in December 2009):
<http://users.on.net/~peter.hart/Over-vaccination%20Controversy%20Continues.pdf>
- ***Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association and Australian Small Animal Veterinary Association*** (22 December 2009):
<http://users.on.net/~peter.hart/Open%20Letter%20to%20APVMA%20AVA%20ASAVA.pdf>
- ***Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association and Australian Small Animal Veterinary Association*** (8 January 2010):
http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_8_Jan_2010.pdf
- ***Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association, Australian Small Animal Veterinary Association, and Competition and Consumer Policy Division, The Treasury*** (24 January 2010):
http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_CCPD_24-01-10.pdf

Elizabeth Hart
10 February 2010

Endnotes:

¹ WSAVA Guidelines for the Vaccination of Dogs and Cats: 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

² 2003 AAHA guidelines: 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.

³ Quote from the APVMA Annual Report 2008-09: http://www.apvma.gov.au/about/corporate/annual_reports/2008-09/annual_report_08-09_full.pdf

⁴ *Ibid.*

- ⁵ Australian Pesticides and Veterinary Medicines Authority's Position Statement on Vaccination Protocols for Dogs and Cats. Published 21 January 2010, revised 25 January 2010: http://www.apvma.gov.au/news_media/news/2010/2010-01-21_vaccination_position.php
- ⁶ WSAVA Guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ⁷ A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals: Discussion Paper. (Roger Rose and Nick Sheppard, December 2009).
- ⁸ *Ibid.*
- ⁹ Pet Statistics: <http://www.petnet.com.au/pet-statistic>
- ¹⁰ Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" 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".
- ¹¹ Australian Veterinary Association's Policy on Vaccination of Dogs and Cats, ratified by the Australian Veterinary Association's Board on 26 June 2009: <http://ava.informz.net/ava/data/images/documents/ava-vaccination-policy-final-june09.pdf>
- ¹² Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" 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".
- ¹³ WSAVA Guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ¹⁴ *Ibid.*
- ¹⁵ "Important to get vaccination message right", AVA Media Release, 12 August 2009: <http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTFILEID=4558>
- ¹⁶ "Vets dogged by criticism over vaccinations". The Sydney Morning Herald, 1-2 August, 2009: <http://www.smh.com.au/environment/vets-dogged-by-criticism-over-vaccinations-20090731-e4f7.html>
- ¹⁷ "Annual vaccinations could be harmful: vets told". Sydney Morning Herald, 11 August 2009: <http://www.smh.com.au/environment/annual-vaccinations-could-be-harmful-vets-told-20090810-efms.html>
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³⁹ Letter from Warren Foreman, President of the South Australian Division of the Australian Veterinary Profession, dated 28 January 2010.

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⁴⁹ Sackett, D.L. Evidence-based medicine. Seminars in Perinatology. Vol. 21, No.1 (February) 1997: pp 3-5.

⁵⁰ Evidence-based medicine: A new approach to teaching the practice of medicine. JAMA. November 4 1992. Vol 268, No. 17.

⁵¹ Guidelines for Guidelines: We’ve come a long way. Chest. 132/3 September 2007.

⁵² ACCP Evidence-based guideline development: A successful and transparent approach addressing conflict of interest, funding, and patient-centered recommendations. Chest. 132/3 September 2007.

⁵³ Australian Veterinary Association’s (AVA) “Draft Policies and Position Statements – For members’ comment by 13 March 2009” 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”.

⁵⁴ The 2006 AAHA canine vaccine guidelines recommend “every three years **or longer**” (My emphasis). 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.aahanet.org/PublicDocuments/VaccineGuidelines06Revised.pdf>

However, my correspondence with veterinary schools in the US indicates that an ‘every three years’ recommendation is taught there.

⁵⁵ In Britain, the British Veterinary Association fact sheet ‘Vaccination – The Facts’ states that: “Vets must use vaccines in accordance with the licence stipulations. It should be noted that **it would be negligent of a vet to deviate from the medicinal data available to them and/or use a vaccine not in accordance with the instructions on the label and the summary of the product characteristics or data sheet.**”: Vaccination – The Facts. Enc 7, Annex C. British Veterinary Association: http://www.bva.co.uk/public/documents/Vaccination_FAQs.pdf

If vets are using MLV vaccines “in accordance with the (current) licence stipulations” I suggest they are unnecessarily vaccinating pets. I am seeking clarification of the statement in the BVA Vaccination Sheet.

⁵⁶ WSAVA Guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf

⁵⁷ *Ibid.*

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² 2003 AAHA guidelines: 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.

⁶³ WSAVA Guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf

- ⁶⁴ Australian Pesticides and Veterinary Medicines Authority's Position Statement on Vaccination Protocols for Dogs and Cats. Published 21 January 2010, revised 25 January 2010: http://www.apvma.gov.au/news_media/news/2010/2010-01-21_vaccination_position.php
- ⁶⁵ "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.**" Schultz, R.D. 1998. Current and future canine and feline vaccination programs. Veterinary Medicine. March 1998, 233-254.
- ⁶⁶ Horzinek, M.C. Vaccine use and disease prevalence in dogs and cats. Veterinary Microbiology. 117 (2006) 2-8.
- ⁶⁷ Australian Pesticides and Veterinary Medicines Authority's Position Statement on Vaccination Protocols for Dogs and Cats. Published 21 January 2010, revised 25 January 2010: http://www.apvma.gov.au/news_media/news/2010/2010-01-21_vaccination_position.php
- ⁶⁸ Dodds, Jean, Hemopet, Santa Monica, CA. Abstract of presentation on: Compliance or resistance to current vaccine guidelines?. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
- ⁶⁹ 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.
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- ⁷¹ WSAVA Guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ⁷² *Ibid.*
- ⁷³ Wood, J.L.N., Adams, V.J. 2006. Epidemiological approaches to safety investigations. Veterinary Microbiology. 117, 66-70.
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- ⁷⁶ Husted, 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.
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- ⁷⁸ 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.
- ⁷⁹ Ford, Richard, College of Veterinary Medicine, North Carolina State University. Abstract of presentation on: Post-vaccinal ischemic vasculitis in dogs: Satellite skin lesions. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
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- ¹²¹ *Ibid.*
- ¹²² Veterinary Practice Act 2003 South Australia: <http://www.legislation.sa.gov.au/LZ/C/A/VETERINARY%20PRACTICE%20ACT%202003.aspx>
- ¹²³ *Ibid.*
- ¹²⁴ Refer to the “Public” section of the Veterinary Surgeons’ Board of South Australia website: http://www.vbsa.org.au/Public_side_link_34_Public.html
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- ¹²⁶ Veterinary Practice Act 2003 South Australia: <http://www.legislation.sa.gov.au/LZ/C/A/VETERINARY%20PRACTICE%20ACT%202003.aspx>
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- ¹²⁸ Hart, Elizabeth. Is over-vaccination harming our pets? Are vets making our pets sick? 13 April, 2009: http://users.on.net/~peter.hart/ls_%20over-vaccination_harming_our_pets.pdf
- ¹²⁹ Email correspondence received from Sue Millbank, Registrar of the Veterinary Surgeons Board of South Australia, 15 May 2009.
- ¹³⁰ A copy of my report “Is over-vaccination harming our pets? Are vets making our pets sick?” was forwarded to Veterinary Surgeons/Practitioners Boards in Queensland, New South Wales, South Australia, Western Australia, Australian Capital Territory and Victoria on 18 April 2009.
- ¹³¹ Apart from the response from the Veterinary Surgeons Board of South Australia, only two other responses were received to email about my over-vaccination report. These were from Glenn Lynch, Registrar of the Veterinary

Practitioners Board of NSW, and Sue Godkin, Registrar of the Veterinary Surgeons Board of WA. They also advised that their boards had declined to comment on my report.

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¹³³ Veterinary Surgeons Board of South Australia Code of Practice for the operation of Boarding Establishments:

<http://www.vsbsa.org.au/boarding.pdf>

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