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Mr Ken McLeod PO Box 51 MORUYA NSW 2537

#### PRIVATE AND CONFIDENTIAL

Dear Mr McLeod

#### Re: Complaint concerning the Australian Vaccination Network

I am writing to advise you of the outcome of the Office of the Health Care Complaints Commission investigation into your complaint concerning the Australian Vaccination Network and its president, Ms Meryl Dorey.

The Commission has determined that the health education service provided by the Australian Vaccination Network on its website provides misleading and inaccurate information on the subject of vaccination. In view of this, the Commission has made the following recommendation to the Australian Vaccination Network, pursuant to section 42(1)(b) of the Health Care Complaints Act, 1993 (the Act):

#### Recommendation:

The Australian Vaccination Network should include an appropriate statement in a prominent position on its website which states:

- the Australian Vaccination Network's purpose is to provide information against vaccination in order to balance what it believes is the substantial amount of pro-vaccination information available elsewhere;
- 2. the information provided should not be read as medical advice; and
- 3. the decision about whether or not to vaccinate should be made in consultation with a health care provider.

Please find enclosed further information about the Commission's investigation and the reasons for its decision set out in the Investigation Report.

The Australian Vaccination Network has 14 days to comply with this recommendation.

Under section 44 of the Act, the Commission will follow up the implementation of the recommendation and in the event that the Australian Vaccination Network fails to comply with the recommendation the Commission will make a public statement.

If you have any enquiries regarding the contents of this letter please contact Leanne Evans, Investigation Officer, on 9219 7416 or by email to <a href="mailto:levans@hccc.nsw.gov.au">levans@hccc.nsw.gov.au</a>.

Yours sincerely

Kieran Pehm Commissioner

0 7 JUL 2010

#### Private and Confidential

### INVESTIGATION REPORT

Respondent: Australian Vaccination Network / Ms Meryl Dorey
Complainants: Mr Ken McLeod, Mrs Toni & Mr David McCaffery

File number: 09/01695 & 10/00002

Investigator: Leanne Evans

#### Background

The Australian Vaccination Network (AVN) is an Australian non-profit organisation registered in New South Wales, founded in 1994.

The AVN provides information about vaccination on its website <u>www.avn.org.au</u>. On the home page of the website is a welcome message stating 'The AVN urges you to investigate **before** you vaccinate' which goes on to say:

'We believe it is a parent's right to choose what's best for their child...some would say that this is one of the most basic rules of any civilised society. Yet governments all over the world have abridged or denied the right to free choice when it comes to vaccinations, vaccines and immunisations. The Australian Vaccination Network is working to help parents take back that right to free and informed choice by allowing them to see the less publicised side of this important issue before making a decision.'

Ms Meryl Dorey is the president of the organisation. Ms Dorey speaks on the subject of vaccination on local radio and at a number of different forums including the Bachelor of Naturopathy course conducted by Southern Cross University, pregnancy discussion groups, and the Woodford Folk Festival. Ms Dorey is also editor of 'Living Wisdom' magazine which is distributed through the AVN website.

#### The complaints

#### Mr Ken McLeod

On 22 July 2009, Mr Ken McLeod made a complaint about the AVN and Ms Dorey to the Health Care Complaints Commission (the Commission), alleging that the AVN engages in misleading and deceptive conduct in order to persuade people not to vaccinate themselves or their children.

In his complaint, Mr McLeod claimed that the AVN is a health organisation and Ms Dorey a health care provider under the *Health Care Complaints Act 1993* (the Act) and alleged that both the AVN and Ms Dorey engage in misleading and deceptive conduct to dissuade parents from vaccinating their children by:

ˈwww.avn.org.au

- 1. Claiming the AVN supports informed choice when it is only providing information directed at dissuading people from vaccination.
- 2. Stating on its website that Japan ceased using the measles, mumps and rubella (MMR) vaccine because of 'increased risk'.
- 3. Stating on its website that research has suggested there is a connection between vaccination and autism, Crohn's Disease and Irritable Bowel Syndrome (IBS) and published an AVN newsletter that the United States 'vaccine court' ruled vaccination caused autism in a child.
- 4. Stating on its website that measles, mumps and rubella are 'non-threatening illnesses in early childhood'.

#### 5. Ms Dorey:

- a. stating on Channel Seven's 'Sunday Night' programme that pertussis (whooping cough) did not kill 30 years ago and does not kill today; and
- b. writing in a magazine article that the majority of pertussis cases occur in vaccinated individuals.
- 6. Stating on its website the incidence of diphtheria decreased well before the use of mass vaccination.
- 7. Ms Dorey stating that bacterial meningitis has increased since meningococcal vaccines were introduced.
- 8. Ms Dorey selectively quoting from articles in order to link the vaccine, Gardasil, with deaths of vaccinated women.
- Conducting a seminar at which a number of statements were made including:
  - a. meningococcal disease is harmless and hardly kills anybody;
  - b. vaccination is useless as children gain immunity from picking up objects on the street and sucking on them;
  - c. vaccination is being used to spread AIDS in third world countries;
  - d. measles, mumps and rubella are less dangerous diseases than vaccination;
  - e. autism is caused by mercury in vaccines which do not contain mercury; and
  - f. vaccination is unnecessary as homoeopathy can treat and protect against disease.
- 10. Selling t-shirts imprinted with the slogan: 'Love them. Protect them. Never Inject them.'
- 11. Misrepresenting the facts of the death of Dana McCaffery.

Mr McLeod requested that the Commission make a prohibition order in relation to the AVN and Ms Dorey under section 41A of the Act on the basis that their activities are endangering public health and safety.

The AVN and Ms Dorey were provided with a copy of Mr McLeod's complaint on 31 July 2009.

#### Mr and Mrs McCaffery

On 16 December 2009, the Commission also received a complaint from Mrs Toni and Mr David McCaffery, whose four week old daughter, Dana, had died from complications of pertussis infection (whooping cough) in March 2009.

Mr and Mrs McCaffery alleged the AVN and Ms Dorey quote misleading statistics, spread misinformation through seminars and the internet, and give poor telephone advice. They also alleged that the AVN and Ms Dorey engaged in harassment and invasion of privacy following the death of their daughter.

Mr and Mrs McCaffery's complaint raises similar issues to those raised by Mr McLeod in that they also allege the AVN and Ms Dorey provide a health service that endangers public health. Mr and Mrs McCaffery allege the AVN and Ms Dorey:

- use misleading statistics to argue against vaccination for pertussis;
- actively target parents through seminars and provide misinformation about vaccination;
- have a website and Facebook group that give the impression of presenting information about vaccination but does not include information that is provaccination:
- give anti-vaccination telephone advice to people who contact the AVN for information on vaccination.

Mr and Mrs McCaffery also alleged that following the death of their daughter, Dana McCaffery, Ms Dorey:

- engaged in harassment and invasion of their privacy regarding the death of Dana;
- published inaccurate and misleading information in magazines, newspapers and AVN publications on the subject of Dana's death.

This complaint was assessed for investigation on 18 January 2010 and a decision was made to incorporate this complaint into Mr McLeod's complaint as the issues were essentially the same. The AVN and Ms Dorey were notified of this via a draft Investigation Report sent on 1 February 2010. The AVN and Ms Dorey were not provided with a copy of the complaint by Mr and Mrs McCaffery, as they expressed concern regarding risk of further harassment from AVN members.

Under section 16 of the HCCA, the Commission may give a copy of the complaint to the person against whom the complaint is made. However, if it appears that providing a copy of the complaint is likely to "place the complainant or another person at risk of intimidation or harassment" then the Commission is not obliged to do so.

### The Commission's handling of the complaints

To assist its initial assessment of the complaint, the Commission sought a response from the AVN. Ms Dorey responded on behalf of herself and the AVN by letter dated 7 September 2009, in which she submitted that the Commission did not have jurisdiction to investigate herself or the AVN<sup>3</sup>.

The Commission subsequently decided to investigate this matter on 23 September 2009, as the complaint raised significant issues of public health and safety.

<sup>&</sup>lt;sup>2</sup> Health Care Complaints Act, 1993

<sup>&</sup>lt;sup>3</sup> Letter to Commission from the AVN dated 7 September 2009

#### Application of the Act

The Commission examined the AVN website in detail and noted that the provision of 'health education' was evident in the following pages on the website:

- a 'news' page, that summarises and provides links to a number of recent media stories and articles about the risks of vaccination;
- a 'weblog' page, containing a series of discussions about articles and publications on the risks of vaccination:
- a page containing a program of 'webinar' health talks online seminars regarding vaccination issues and other health issues.

Ms Dorey's participation in pregnancy discussion groups and in lecturing at university also suggests that the AVN operates as a 'health education service'.

The AVN includes a copy of its constitution on its website. In this document, it lists the purposes of the association as:

- '(a) the advancement and promotion of education and learning amongst the public about all matters concerning human health and human physical and social wellbeing;
- (b) the propagation, publication, dissemination and diffusion of knowledge and information to the public about all matters concerning human health and human physical and social well-being;
- (c) the encouragement and promotion of the widest possible dissemination to the public of all information concerning human health and human physical and social well-being. 3

According to its own constitution and through its activities the AVN is a health education service. Consequently it is a health service under section 4 of the Act.

#### The Commission's investigation

The Commission has predominantly investigated issues raised by Mr McLeod in the context of how they are presented on the AVN website, because the website provides the main source of information to members of the public who may be seeking information about vaccination.

Studies have shown that the internet has become the primary source of information for the general public, with health related websites among the most widely used.4 It is noted that in performing an internet search in Australia on 'vaccination' via search engine 'Google', the AVN website will often appear either first or second on the list of websites.

It is therefore appropriate to consider the AVN website as a common internet starting point for the general public in researching vaccination information.

<sup>&</sup>lt;sup>3</sup> Model Rules, AVN Inc

Kummervold PE, Chronaki CE, Lausen B, Prokosch HU, Rasmussen J, Santana S, et al. eHealth trends in Europe 2005-2007: a population-based survey. J Med Internet Res. 2008;10(4):e42.

Issue One: The AVN claims that it supports informed choice when it is only providing information directed at dissuading parents from vaccinations.

Mr McLeod alleged the AVN claims to issue balanced information and advice; but instead provides advice that is wrong, misleading, deceptive and biased.

In her response to this allegation, Ms Dorey stated that the information provided by the AVN is not anti-vaccination but is provided 'in support of parental choice when it comes to vaccination and health and provide(s) referenced information on the benefits and risks of vaccination. <sup>5</sup>

In investigating this part of the complaint, the Commission began with the 'General Vaccine Info' section of the AVN website that is accessed through the heading 'Vaccine Info' in a sidebar on the home page, as it seems reasonable that a person researching vaccination information for the purpose of making a decision about vaccination would begin by looking at the general information on vaccination and reasons for and against vaccination. This section contains the following:

#### '10 reasons why parents question vaccination'.6

#### Reason 1 - Vaccines have never been tested

The gold standard of medical science is the double blind crossover placebo study. This test has never been performed on any vaccine currently licensed in Australia. In an astounding leap of logic, contrary to all rules of science, vaccines are assumed to be safe and effective, and therefore, it is considered to be unethical to withhold vaccinations for the purpose of testing them.<sup>7</sup>

The statement that 'Vaccines have never been tested' is incorrect. In Australia, all vaccines currently available must pass safety testing before being approved by the Therapeutic Goods Administration (TGA) – the body that makes the final decision about the safety of new treatments, medicine and devices $^9$ . In Australia, clinical trials are regulated by:

- The National Statement on Ethical Conduct in Research Involving Humans, Good Clinical Practice.
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).
- The Australian Code for the Responsible Conduct of Research<sup>10</sup>.

Reported vaccine reactions are monitored by the TGA<sup>11</sup>. Other organisations are involved in the monitoring of vaccine safety, including the manufacturers of the vaccines.

Vaccines are not tested by means of double blind crossover placebo studies, where the researchers and subjects of the study do not know which treatment is being given to the subjects. 12

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<sup>&</sup>lt;sup>5</sup> Letter to Commission from the AVN dated 7 September 2009

<sup>&</sup>lt;sup>6</sup>At the commencement of this investigation, this information was accessible from the homepage, however with the restructure of the website in December 2009 it is now under this section.

www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination bid

<sup>&</sup>lt;sup>9</sup> www.mmri.mater.org.au

<sup>10</sup> www.clinicaltrials.org.au

<sup>&</sup>lt;sup>11</sup> Currently reactions are monitored through a TGA scheme. The Advisory Committee on the Safety of Medicine (ACSOM) is being established in 2010, and will monitor and manage the safety of medicines once they have been registered.

<sup>12</sup> www.wikipedia.com

To perform this kind of study for a vaccine, half the subjects would be given the vaccine and the other half a placebo - meaning that those who received the placebo would be at risk from exposure to the disease. Additionally, if the 'crossover' element of the study were to occur halfway through the study, the entire group would have been exposed to the vaccine. negating the capacity of the study to accurately measure the long-term safety of the vaccine.

The AVN does not explain the reasons why double blind crossover placebo studies are not generally conducted for vaccines. The AVN's information on vaccine testing thus gives the general impression that vaccines are not adequately tested and are simply 'assumed to be safe and effective 13. If the AVN were providing a complete picture with regard to vaccine testing, it should say that vaccines are tested in thousands of people in clinical trials; that the information from these trials is used in combination with longitudinal studies of vaccinated and non-vaccinated groups; and that all vaccines are monitored for safety.

#### Reason 2 - Vaccines contain toxic additives and heavy metals

The list of vaccine ingredients includes toxins such as formaldehyde, a substance which the Queensland Poisons Control Centre has said was "unsafe at any level if injected into the human body".14 ....

Thiomersal, a mercury based preservative which is a known neurotoxin ... It was also withdrawn from the American Hepatitis B vaccines, Engerix and HB Vax 11, though their Australian counterparts which are still being injected into children here today, are only just being made mercury free or mercury reduced (though the old, mercury-laced products will be used up rather than being withdrawn from us).15

The Commission was unable to locate the reference given by the AVN, nor the organisation named on the website as the Queensland Poisons Control Centre.

In her submission to the Commission<sup>16</sup>, Ms Dorey referenced this quote from a conversation between a member of the Vaccination and Information Network with an organisation called the Queensland Poisons Information Centre.

Formaldehyde is naturally produced in small amounts in the human body<sup>17</sup> and is normally present at low levels in the air. 18 Formaldehyde is included in many vaccines as an 'antimicrobial toxin inactivator, stabiliser" and is used during the manufacturing process. If any formaldehyde remains after filtering, its presence is no greater than that which can be found present in air and breaks down very quickly.20 The AVN has not included this additional contextual information about formaldehyde or the process for the manufacture of vaccines.

In her submission to the Commission, 21 Ms Dorey gave the example of Infanrix as a vaccine which contains formaldehyde. Clinical pharmacology for Infanrix is stated as: 'Each 0.5 mL dose also contains ... </=100 mcg of residual formaldehyde. 22

<sup>13</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination <sup>14</sup> Ibid

<sup>&</sup>lt;sup>16</sup> Submission to Commission from the AVN, received 25 June 2010

<sup>17</sup> www.atsdr.cdc.gov

<sup>18</sup> www.cpsc.gov

<sup>19</sup> Centres for Disease Control and Prevention (CDC) Vaccine Excipient and Media Summary

Public Statement, Agency for Toxic Substances & Diseases Registry

<sup>&</sup>lt;sup>21</sup> Letter to Commission from the AVN, received 5 March 2010

<sup>22</sup> www.us.gsk.com

The current standard for Australian vaccines is a maximum of 0.02% w/v of free formaldehyde. During testing of Australian vaccines by the TGA, including Infanrix, the maximum concentration of formaldehyde detected was 0.0004% w/v.<sup>23</sup>

Mr McLeod noted in his complaint that the AVN site refers in its information under diphtheria vaccination to the use of thiomersal as an additive.

All vaccines on the current National Immunisation Program (NIP) for infants and children under the age of five years are either free of thiomersal, or contain a trace amount to maintain the sterility of the vaccine.<sup>24</sup>

In her submission to the Commission<sup>25</sup>, Ms Dorey states that the only diphtheria-tetanus (dT) vaccines currently used in Australia contain thiomersal: "the only DT vaccines licensed for use in Australia are produced by CSL Pty Ltd and both of these shots contain thiomersal". She uses the Australian Immunisation Handbook as her reference.

The Australian Immunisation Handbook states that ADT Booster can be given for a booster dose of dT in people aged ≥8 years or, if necessary, for the primary dT course<sup>26</sup>. Statens Serum Institut/CSL Biotherapies produce and distribute ADT Booster, which is free of thiomersal.27

Diphtheria-tetanus vaccines that contain thiomersal are the vaccine for children (CDT) and the adult vaccine (ADT). Currently, both ADT and CDT are registered in Australia - but they are not available for use. 28 The current designated diphtheria-tetanus vaccines are Boostrix, Adacel, Infanrix, Quadracel and Pediacel. 29 None of these contain thiomersal.

It is incorrect therefore for the AVN to indicate that thiomersal is present in any diphtheria vaccine currently used in Australia.

#### Reason 3 - Vaccines are contaminated with human and animal viruses and bacteria

All childhood vaccines, apart from the Hepatitis B (which is genetically engineered and carries with it a different set of problems) are cultured on either animal tissue, a broth of animal and/or human blood and blood products or the cell lines from aborted human foetuses.30

None of these culturing methods is able to guarantee an uncontaminated vaccine ... many foreign viruses and bacteria can and do contaminate vaccines ... SV40 (simian or monkey virus 40 - just one of the 60 monkey viruses known to contaminate the polio vaccines) has been linked with cancer in humans.31

<sup>&</sup>lt;sup>23</sup> National Health and Medical Research Council (NHMRC) The Australian Immunisation Handbook. 9<sup>th</sup> ed. Canberra: AGPS: 2008 – Appendix 5

NHMRC The Australian Immunisation Handbook. 9th ed. Canberra: AGPS: 2008 - Appendix 5

Submission to Commission from the AVN, received 25 June 2010

NHMRC The Australian Immunisation Handbook. 9th ed. Canberra: AGPS: 2008 – Section 3.14 Pertussis &

ADT™ Booster Consumer Medicine Information Leaflet

NHMRC *The Australian Immunisation Handbook.* 9<sup>th</sup> ed. Canberra: AGPS: 2008 – Appendix 3 <sup>29</sup> National Health (Immunisation Program – Designated Vaccines) Determination, 2009

www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination 31 Tbid

It is preferable to produce vaccines in human foetal cell lines because human immune systems prefer similar proteins and foetal cell lines divide more quickly. 32 The AVN does not give any explanation as to why vaccines are primarily cultured in this way.

The claim by AVN that SV40 simian virus has been known to contaminate polio viruses and has also been linked with cancer in humans, has been the subject of studies reviewing the SV40 contamination in polio vaccines between 1957 and 1963. These studies have produced conflicting evidence regarding the link with cancer.

The AVN provides references to two studies that show such a link - but not to other studies that fail to show a link, including a review commissioned by the TGA which concluded:

'Studies of the prevalence of SV40 antibody in the community and the presence of SV40 in human tumours do not absolutely exclude the possibility of rare involvement of the virus in individual cases of cancer, but fail to provide evidence of statistically greater risk for people immunised during the period when SV40 was likely to have been present in polio vaccine. 33

In providing the above information in Reason 3, there is evidence that the AVN selectively relies on references in order to support an anti-vaccination stance.

#### Reason 4 & 5 - Vaccines can cause serious immediate and long-term side effects

As long as there have been vaccines, there have been reports of serious side effects following their administration. These side effects include (but are not limited to) convulsions and epilepsy, permanent brain damage, anaphylactic (life threatening allergic) reactions, sudden infant death syndrome (SIDS), retinal and brain haemorrhages (now being confused with shaken baby syndrome) and death....Vaccines have been associated with conditions such as autism and inflammatory bowel syndrome... and a raft of other chronic and autoimmune conditions which are experiencing dramatic rises in incidence. 34

In Australia, if a medical condition arises or a reaction occurs after vaccination, it must be reported to the TGA. It is acknowledged that all reactions may not be reported. In the United States, post-vaccination reactions are monitored by the Vaccine Adverse Event Reporting System (VAERS). However, it should be noted that a reaction following vaccination need not necessarily be a side effect of vaccination. Significantly, the VAERS website states:

'When evaluating data from VAERS, it is important to note that for any reported event, no cause-and-effect relationship has been established. Reports of all possible associations between vaccines and adverse events (possible side effects) are filed in VAERS.

Therefore, VAERS collects data on any adverse effect following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event. 35

In relation to the issue of whether SIDS is a side effect of vaccination - there can be no demonstrated cause-and-effect relationship unless it can be shown that there is a higher incidence of SIDS in the vaccinated population than the non-vaccinated population.

35 www.vaers.hhs.gov

<sup>&</sup>lt;sup>32</sup> Department of Health and Ageing: Immunisation Myths and Realities: 4<sup>th</sup> ed. 2008

Review of the health consequences of SV40 contamination of poliomyelitis vaccines and in particular a possible association with cancers - Professor Yvonne Cossart, 14 December 2004

www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

There are studies showing that the incidence of SIDS reported after vaccination is below the rate of incidence in the general population.<sup>36</sup>

In relation to the issue of brain haemorrhages following vaccination being attributed to shaken baby syndrome (SBS) - there are large-scale studies indicating that the features of brain haemorrhage arising following vaccination never reproduce the findings present in SBS.<sup>37</sup>

There is a study which suggests that there is an increased risk of convulsion after DTP vaccination but little evidence that this produces brain injury or is a forerunner to epilepsy.<sup>38</sup>

The AVN claims that vaccination is linked with a range of long-term side effects. However, the AVN has provided no references to support their claim.

The Commission will address the issue of links between vaccination and autism and irritable bowel syndrome as alleged examples of longer term effects in more detail below under Issue Three.

In a submission to the Commission, Ms Dorey pointed out that the AVN website states that there have been reports of serious side effects following vaccination - not that these side effects are caused by vaccination.<sup>39</sup>

However, the use of the term 'side effects' suggests a causal relationship between the vaccine and the illness. The heading of Reasons 4 and 5 - "Vaccines can cause serious immediate and long-term side effects" also promotes a causal link.

It is noted that current events include the suspected link of influenza vaccination to a two year old girl's death in Queensland. Although the Queensland Coroner found no evidence to support a link between the vaccination and death, there continues to be a nationwide suspension on the use of this vaccine whilst investigations continue into the cause of adverse reactions among young children under the age of five.

The issue of vaccine-related side effects is an extremely important one and one where the AVN needs to be providing information that is factual and not misleading.

#### Reason 6 - Vaccines do not necessarily protect against infectious diseases

... parents are asked to allow their children to be given vaccines that at best, will provide a temporary sensitisation to illnesses and at worst, can make their children more susceptible to both opportunistic and infectious illness.<sup>40</sup>

The statement that vaccinations may make children more susceptible to illness suggests that vaccines are immuno-suppressive.

On the 'Sunday Night' programme on 26 April 2009, Ms Dorey also stated: 'vaccine by its very nature can suppress the immune system.'

<sup>39</sup> Letter to Commission from the AVN, received 5 March 2010

Wennemann MM, Butterfass-Bahloul T, Jorch G, Brinkmann B, Findeisen M, Sauerland C, Bajanowski T, Mitchell EA; 'Sudden infant death syndrome: no increased risk after immunisation', Vaccine 2007;25(2):336–340.
<sup>37</sup> eMJA: National Australian conference on shaken baby syndrome, 21 January 2002

<sup>38</sup> Golden GS. Pertussis vaccine and injury to the brain. J Pediatr 1990; 116: 854-861

<sup>40</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

In her response to the Commission, Ms Dorey repeated the assertion that vaccinations are immuno-suppressive and provided a list of studies demonstrating that vaccines are immuno-suppressive.

The Commission has examined Ms Dorey's references and found that while some studies have been conducted which support this hypothesis, others discredit it.<sup>41</sup> <sup>42</sup> Two of the references provided by Ms Dorey support that vaccination can be immuno-suppressive, although one article concluded that the suppression period was temporary,<sup>43</sup> and the other concluded that booster vaccination would ensure long-lasting immunity<sup>44</sup>.

The AVN has also made specific assertions on the efficacy of vaccination, in the human papillomavirus (HPV) section of the section on specific vaccines where it has stated:

'There are more than 100 strains of HPV. The current vaccine, Gardasil, is quadrivalent or contains only 4 of these strains and states in the manufacturer's information that it cannot treat or prevent HPV from other strains. Therefore, even if HPV were the single or most prevalent cause of cervical cancer, use of this vaccine would literally be a shot in the dark. 45

Gardasil protects against two types of HPV that cause about 75% of cervical cancer cases. 46 Accordingly, the information provided by the AVN about Gardasil has the effect of misleading the reader.

Information about Gardasil also appears on the AVN website under the heading 'AVN News'. A link provides a summary of an article published by 'Natural News', titled 'Two more girls die after getting Gardasil 'cervical cancer' vaccine', 47 and quotes the following from the article:

'The European Medicines Agency (EMEA) has reported that two young women died shortly after receiving Merck's Gardasil, a vaccine against several varieties of human papillomavirus (HPV). The EMEA did not release the names or ages of the women who died, and said the cause of death was still unknown. It described their deaths as 'sudden and unexpected. 48

The AVN website then provides a link to the full 'Natural News' article. Examination of the full article reveals that the second paragraph is omitted on the AVN website page. This second paragraph states:

'Gardasil and Glaxo SmithKline's Cervarix protect against the two strains of HPV that are responsible for 70 percent of cervical cancer cases. Gardasil also protects against two HPV strains that cause 90 percent of genital warts. 49

The second paragraph contradicts the claim by the AVN that Gardasil is not effective in preventing most forms of cervical cancer. Its omission from the summary of the article is therefore significant.

<sup>42</sup> Bacterial infections, immune overload, and MMR vaccine E Miller, N Andrews, P Waight, B Taylor, Arch Dis

47 www.naturalnews.com

49 www.naturalnews.com

<sup>&</sup>lt;sup>41</sup> Gerber JS, Offit PA (2009). <u>'Vaccines and autism: a tale of shifting hypotheses'</u>. Clin Infect Dis 48 (4): 456–61. doi:10.1086/596476. PMID 19128068. http://www.journals.uchicago.edu/doi/full/10.1086/596476.

Child 2003;88:222–223

<sup>43</sup> Munyer Thomas P. et al, Depressed Lymphocyte Function after Measles-Mumps-Rubella Vaccination *The Journal of Infectious Diseases, Vol 132, No. 1 Jul (1975).*<sup>44</sup> Manfred S. et al Depression of Immune Personne to an Incelligated Hamalitie A Vaccina Administration.

<sup>&</sup>lt;sup>44</sup> Manfred S. et al Depression of Immune Response to an Inactivated Hepatitis A Vaccine Administered Concomitantly with Immune Globulin, *The Journal of Infectious Diseases, Vol 168, No.3 (Sept., 1993)* 

<sup>45</sup> www.avn.org.au - Vaccination Information - HPV

<sup>46</sup> www.gardasil.com

<sup>48</sup> www.avn.org.au - News-and-Events - Two more girls die after getting Gardasil cervical cancer vaccine

Ms Dorey submitted that it is not necessary to include the complete information from articles that are linked to the AVN website, because a reader can access the full publication and read it for themselves. <sup>50</sup> While this may be true, the AVN website does not clarify this and its selective reproduction of only some paragraphs of the article has the effect of misrepresenting the thrust of the article.

In her submission to the Commission<sup>51</sup>, Ms Dorey states: "We are not representing the article – the article is misrepresenting the protection conveyed by Gardasil and Cervarix vaccines and I refuse to include information on the AVN website that I do not believe is based in fact."

She further asserted that this is not selective reporting of information but that she "simply quoted the sections that I felt were important."

# Reason 7 - Doctors, as paid salesmen for vaccine products, are no longer considered to be trustworthy arbiters of their safety and effectiveness

Doctors are currently receiving several payments from the government to push vaccines. These include \$6 for reporting vaccinations to the Australian Childhood Immunisation Register (ACIR) ... As a result of this grossly unethical situation, doctors can no longer be thought of as objective when it comes to this issue. Parents no longer trust that their doctors will recommend that they vaccinate simply because it is the best thing for their child rather than the best thing for the doctor's bottom line.<sup>52</sup>

The Commonwealth General Practice Immunisation Incentive (GPII) scheme provides financial incentive to general practices that monitor, promote and provide immunisation services to children under the age of seven. The aim of this scheme is to encourage 90% of practices to achieve 90% proportions of full immunisation, which is consistent with current Government immunisation policy.<sup>53</sup>

The Medicare payment of \$6 is made to immunisation providers that make notifications of a vaccination to the ACIR. Additionally, a payment of \$3.50 per child under seven years of age per quarter is paid to practices (rather than the GPs themselves) that achieve a target of at least 90% immunisation coverage. 54

On the AVN website and in the submission to the Commission<sup>55</sup>, reference is made to a further \$18.50 for GPs on top of their Medicare rebate for vaccinating a child on time. This Service Incentive Payment of \$18.50 ceased to be available from 1 October 2008.<sup>56</sup>

It is not clear how these payments for an administrative service may compromise a medical practitioner's objectivity. It is current government public health policy to keep immunisation rates against certain diseases at the levels quoted above and it is not clear how it could be described as 'grossly unethical' for doctors to comply with government policy. Doctors have a choice whether or not to participate in this scheme and to suggest that those that do participate may be untrustworthy is not appropriate.

...

 $<sup>^{\</sup>rm 50}$  Letter to Commission from the AVN, received 5 March 2010

<sup>&</sup>lt;sup>51</sup> Submission to Commission from the AVN, received 25 June 2010

<sup>&</sup>lt;sup>52</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

<sup>53</sup> www.medicareaustralia.gov.au

<sup>&</sup>lt;sup>54</sup> GPII Guidelines, Medicare Australia April 2010

 $<sup>^{55}</sup>$  Submission to Commission from the AVN, received 25 June 2010  $\,$ 

<sup>&</sup>lt;sup>56</sup> Medicare Australia

In alleging that doctors are not trustworthy on the subject of vaccination, the AVN appears to be suggesting that it may not be appropriate to discuss the issue of whether or not to vaccinate with a medical practitioner.

In her submission to the Commission,<sup>57</sup> Ms Dorey states the AVN always advises people who contact it to visit their doctor or council clinic as well as accessing AVN information.

However, this information is not reflected on the AVN's website. In particular, information presented under this section of the website appears contrary to Ms Dorey's statement.

## Reason 8 – Pharmaceutical companies have paid for almost all vaccine research to date

Just as the tobacco companies paid for corrupt and incorrect research which purported to show that tobacco and tobacco products were safe for human consumption, so too the pharmaceutical companies have paid for and produced almost all of the research into vaccines.<sup>58</sup>

The majority of research and testing of new pharmaceuticals is conducted by the manufacturers as a part of the research and development process of vaccines for large-scale markets<sup>59</sup>. Manufacturers share an interest with the community in drugs and vaccines being safe and effective. Although manufacturers may carry out much of the testing of new pharmaceuticals, vaccines are further independently tested<sup>60</sup> and researched thoroughly in Australia before being made available for human use.

There is no evidence that vaccines have been the subject of corrupt or incorrect research by manufacturers or independent bodies, although AVN's paralleling of the pharmaceutical industry to tobacco companies suggests that this is the case.

# Reason 9 – Doctors and health professionals rarely if ever report vaccine reactions

In discussions with representatives of both ADRAC ... and the SAEFVSS (Serious Adverse Events Following Vaccination Surveillance Scheme), the two government bodies charged with keeping track of reactions to vaccines and other drugs, the AVN's representatives were informed that less than 10% of all adverse reactions are ever reported.<sup>61</sup>

As noted above, practitioners notify reactions that follow vaccinations to the TGA in Australia. Reactions can range in severity and may or may not be attributable to the vaccination itself. It is important to recognise this when considering the figures for notification of vaccine reactions. The AVN has not given a reference for the source of the statistic of 10% nor explained the context of the information about vaccination reactions.

The AVN states it has developed an adverse reactions database from information provided by the public through the website, with over 800 'serious adverse vaccine reactions' which it states were not reported to doctors.

 $<sup>^{\</sup>rm 57}$  Submission to Commission from the AVN, received 25 June 2010

<sup>58 &</sup>lt;u>www.avn.org.au</u> – General Vaccination Information – 10 Reasons why parents question vaccination

The Vaccine Industry – An Overview – vaccine ethics.

<sup>60</sup> www.tga.gov.au

<sup>&</sup>lt;sup>61</sup> Ibid

The AVN provides supporting information about the criteria used to define an 'adverse reaction'. This information is anecdotal only. As an organisation that is providing health education the AVN should make this clear in order not to mislead the reader.

### Reason 10 - Some childhood illnesses have beneficial aspects and therefore, prevention may not necessarily be in the best interests of the child.

Measles, for example, has been used in Scandinavian countries to successfully treat such autoimmune conditions as eczema and many studies have [been] performed which show that children who do not contract measles naturally as a child are more likely to suffer from certain cancers later in life. In addition, recent studies have shown that contracting the common childhood illnesses help to prime and strengthen the immune system in a way that vaccinations just cannot do.63

In the submission to the Commission<sup>64</sup>, the AVN provided three references to support the statement that some childhood illnesses have beneficial aspects, and that contracting measles affords protection from certain cancers later in life.

Of these, the first refers to measles virus vaccine strain derivatives and not necessarily the virus itself.65 The second reference appears to be an article written by a doctor of anthroposophic and homeopathic medicine 66 which does not appear to have been published in any peer-reviewed journal. The third hypothesises there is a relationship between natural infections and the suppression of cancer6

Taking into account these claims that immunity against a disease is stronger when acquired naturally rather than artificially, research by the Commission shows there are studies into immunity levels that agree that naturally acquired immunity through exposure to illnesses may give higher antibody titres than primary vaccination<sup>68</sup>. However, it should be noted that most studies showing this were not questioning the effectiveness of vaccination but rather emphasising the importance of having a program of booster vaccinations to ensure longlasting immunity.

The assertion that improved immunity may follow exposure to a childhood disease does not take into account the risks of exposure to and the adverse effects of childhood illnesses.

### Summary: Issue One

In relation to the general information provided by the AVN on its website in the sections titled 'Vaccine Information' and 'Ten reasons why parents should question vaccination', the AVN is clearly taking an anti-vaccination stance.

This is not consistent with the mission on its home page, at the time of the investigation, to provide all the information that you need when deciding whether or not to vaccinate.

<sup>63</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

<sup>&</sup>lt;sup>64</sup> Submission to Commission from the AVN, received 25 June 2010

<sup>&</sup>lt;sup>65</sup> Msaouel et al. Engineered measles virus as a novel oncolytic therapy against prostate cancer. The Prostate, 2009; 69 (1): 82 DOI: 10.1002/pros.20857

<sup>66</sup> Philip Incao, M.D Supporting Children's Health From Alternative Medicine Digest (September 1997)

<sup>67</sup> Post A Environmental exposure to bacteria and viruses may provide oncolytic protection against cancers, and declining exposure to infections may contribute to a rising incidence of cancer. Med Hypotheses. 007;68(3):558-61. Epub 2006 Oct 9.

<sup>68</sup> Manfred C., op cit.

In her submission to the Commission<sup>68</sup>, Ms Dorey stated the words "all the information you need" were added to the AVN's website without her knowledge or permission by the website designer. This sentence has now been removed from the home page of the website.

The Commission has found that there is evidence that the AVN misleads readers by using reliable and peer-reviewed research but quoting selectively from it, often in contradiction to the conclusions or findings of the studies themselves.

In her submission to the Commission<sup>69</sup>, Ms Dorey stated in response to this allegation that: "It is true that oftentimes, our information will contradict the conclusions or summaries of the studies. This is because, as opposed to most doctors and government officials, we actually read the studies and frequently, the summary and conclusion does not agree with the raw data itself. It is as if there were a disconnect between the findings of the study and the research itself. Many times, that disconnect can be explained by the financial links between the study's researchers and the companies whose products are being studied. So, whilst the AVN does frequently draw different conclusions to those printed at the end of these articles, it is because our analysis of the data shows that the printed conclusions do not correspond with the raw data. This is not selective reporting – it is accurate reporting."

The AVN also provides information for which there are no references quoted and refers to cases where there are no tests of the reliability of data. The AVN gives this material the same prominence and authority as fully reviewed scientific literature.

The Commission further found evidence that the AVN makes strong assertions such as in relation to the benefit of exposure to childhood illnesses, without supporting them with any research.

There is evidence that the AVN also casts medical practitioners in a negative light, asserting that the profession is unethical and untrustworthy on the issue of immunisation without providing any cogent reasons or evidence for making such an assertion.

#### Issue Two: The AVN states on its website that Japan ceased using the MMR vaccine because of 'increased risk'.

Under the section relating to the MMR vaccine, the AVN website states: 'Japan ceased the use of the combination triple vaccine due to an increased risk of aseptic meningitis in vaccine recipients. 70

It is true that Japan ceased the use of the MMR combination vaccine in 1993. The mumps vaccine used in Japan was the Urabe strain and a causal link between the Urabe strain of mumps vaccine and aseptic meningitis has been established.

The mumps vaccine currently used in Australia is the Jeryl-Lynn strain and not the Urabe strain.71 No link between the Jeryl-Lynn mumps vaccine and aseptic meningitis has been established<sup>72</sup>.

 $<sup>^{68}</sup>$  Submission to Commission from the AVN, received 25 June 2010

 <sup>70</sup> www.avn.org.au - Vaccine Information - MMR
 71 Sanjaya N Senanayake, Mumps: a resurgent disease with protean manifestations, MJA 2008; 189 (8): 456-

<sup>459
&</sup>lt;sup>72</sup> Afzal M a, Pickford A R, Forsey T, Heath A B, Minor P D The Jeryl Lynn vaccine strain of mumps virus is a mixture of two distinct isolates. Journal of General Virology (1993), 74, 917-920

Issue Three: AVN states on its website that research has suggested there is a connection between vaccination and autism, Crohn's Disease and inflammatory bowel syndrome (IBS) and published in an AVN newsletter that the United States 'vaccine court' ruled vaccination caused autism in a child.

Under the section relating to the MMR vaccine, the AVN website states: 'Research also suggests that there is a connection between MMR vaccination and the development of autism, Crohn's Disease and Irritable Bowel Disease. 73

The AVN does not provide references in support of this claim. Ms Dorey, in her original response to the Commission, referred to Dr Andrew Wakefield's 1998 study on the link between the MMR vaccine and autism. 74 On 2 February 2010, The Lancet 75 retracted Dr Wakefield's 1998 publication, noting elements of his report had been falsified. The Commission notes that The Lancet's retraction of the Wakefield article occurred very recently.

Ms Dorey contends that: 'Dr Wakefield's study was only the first of many to indicate a very strong and, in some cases clinically verifiable connection between vaccination and the development of [autism spectrum disorders]. The lists ten articles to support this. these, four were authored by Dr Wakefield and a further three do not relate vaccination to autism. The remaining three articles hypothesise a link between MMR vaccine and autism, but have not established any causal relationship between vaccination and autism.

In the submission to the Commission<sup>78</sup>, Ms Dorey includes a number of new references which discuss the link between the MMR vaccine and IBS, Crohn's Disease and autistic enterocolitis. These references also include one where the alleged link was inconclusive 79 and one linking autism and ileal / colonic inflammation. 80 Ms Dorey supports the use of these references in this submission by stating: "While it is true that several of the articles I presented to confirm Wakefield's original hypothesis did not specifically mention vaccination, they all described conditions in children which are identical to the novel autistic entercolitis first discovered in the gut tissue of autistic children by Dr Wakefield."

Mr McLeod referred in his complaint to the AVN's claim about a US 'vaccination court'. The AVN sends newsletters to subscribers via email. The March 2009 newsletter requested donations to run an advertisement highlighting the link between vaccines and autism. The planned advertisement was based on one released by the American organisation, 'Generation Rescue81', which included information regarding a 'US vaccine court' ruling, involving a boy receiving compensation from the US Government because of the link between his MMR vaccination and his autism.82

<sup>78</sup> Submission to Commission from the AVN, received 25 June 2010

<sup>73</sup> www.avn.org.au – Vaccine Information - MMR
74 Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. (1998). Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. . Lancet. 351: 637-641.

<sup>75</sup> A peer-reviewed general medical journal <sup>76</sup> Letter to Commission from the AVN dated 7 September 2009

<sup>&</sup>lt;sup>79</sup> Afzal MA and Minor PD Vaccines, Crohn's disease and autism, Molecular Psychiatry (2002) 7, S49–S50 <sup>80</sup> Krigsman A et. al Clinical presentation and Histologic Findings at Ileocolonoscopy in children with Autistic spectrum Disorder and chronic Gastrointestinal symptoms, Autism Insights 2010:2 1–11

The 'Generation Rescue' website (www.generationrescue.org) claims it is 'an international movement of scientists, parents, and physicians researching the causes and treatments for autism, ADHD, and chronic

<sup>82</sup> Living Wisdom E-newsletter, March 2009

The Commission found a US Court of Federal Claims case, Banks vs. Secretary of the Department of Health and Human Services (SDHHS), which ruled that a boy contracted Acute Disseminated Encephalomyelitis (ADEM) as a result of his MMR vaccination. It was further ruled that his ADEM caused lasting, residual damage and retarded his developmental progress, under the generalised heading of Pervasive Developmental Delay (PDD), not autistic spectrum disorder.84

### Issue Four: Stating that measles, mumps and rubella are 'non-threatening illnesses in early childhood'

On the AVN website, under Vaccination Information - MMR, it refers to the diseases measles, mumps and rubella as 'non-threatening illnesses in early childhood'.85

In her submission to the Commission<sup>86</sup>, Ms Dorey clarifies this by stating that "for healthy, well-nourished children, measles mumps and rubella generally do not kill and present few long-term sequelae".

The most recent mortality figures show that there were no deaths from measles in Australia between 2003 and 2006.87 Statistics do show that measles is one of the leading causes of death among young children globally.88 Similarly, both mumps and rubella are serious diseases. In Australia, between 1996 to 2005, mumps has been reported as the underlying cause of death in four adults.89 Although there have been no deaths attributed to rubella in Australia in recent years, between 2003 and 2005, there were 116 notifications of rubella.90 More importantly, there are various serious neurological conditions that have been proven sequelae from all three of these diseases, including convulsions, meningitis and pan encephalitis. The available evidence indicates that measles, mumps and rubella are all potentially serious illnesses. There is no evidence that these illnesses can be described, in all cases, as non-threatening.

#### Issue Five: Pertussis:

- Mrs Dorey stated on Channel Seven's 'Sunday Night' programme that pertussis did not kill 30 years ago and does not kill today;
- Mrs Dorey wrote that that the majority of incidence of pertussis occurs in vaccinated individuals.

During Ms Dorey's appearance on the Channel 7 television programme 'Sunday Night' on 26 April 2009, she stated in relation to pertussis: 'You didn't die from it 30 years ago and you're not going to die from it today'.91

<sup>&</sup>lt;sup>84</sup> United States Court of Federal Claims Office of Special Masters no. 02-0738V 20 July 2007 Banks vs. Secretary of the Department of Health and Human Services.

 <sup>85 &</sup>lt;u>www.avn.org.au</u> - MMR
 86 <u>Submission to Commission from the AVN, received 25 June 2010</u>

<sup>&</sup>lt;sup>87</sup>Department of Health and Ageing website: www.health.gov.au/internet/main/publishing.nsf/Content/cdacdi32suppl.htm~cda-cdi32suppl-results.htm~cda-cdi32suppl-results-measles.htm <sup>88</sup> World Health Organisation Fact Sheet, December 2009

<sup>89</sup> NHMRC *The Australian Immunisation Handbook.* 9<sup>th</sup> ed. Canberra: AGPS: 2008 – Part 3

<sup>&</sup>lt;sup>90</sup> Vaccine Preventable Diseases and Vaccination Coverage in Australia, 2003 to 2005 Communicable Diseases Intelligence Volume 31 - Supplement - June 2007

<sup>91</sup> Channel 7, Sunday Night, 26 April 2009

In her submission to the Commission<sup>91</sup>, Ms Dorey explained that this statement was just a small part of a three hour interview that was aired by Channel 7. The Commission accepts that it is unfair to take into account one statement made, when it is subject to editing by a third party.

In the May 2009 edition of the magazine 'Living Wisdom', 92 of which Ms Dorey is editor, Ms Dorey stated in an article titled 'Pertussis: The Fear Factor':

'What about deaths from this disease? Well, to quote the CDI Bulletin from 25 December 1997, 'In the 20 years from 1976 to 1995, there were 21 deaths from pertussis in Australia.'93

The Department of Health and Ageing states that the number of deaths from pertussis between 1976 and 1995 is 25. In the decade before introduction of pertussis vaccination more than 2800 people died of pertussis. This figure was reduced by 75% in the decade following introduction of the pertussis vaccination. <sup>94</sup>

The evidence indicates that pertussis may still kill a proportion of those who contract it.<sup>95</sup> Some of the complications of pertussis include pneumonia, fractured ribs, pneumothorax, inguinal hernia, aspiration, hearing loss, carotid artery dissection, urinary incontinence and prolapses; seizures, encephalopathy and inter-cranial bleeding in the elderly; and possible death in the very young.<sup>96</sup> It is inaccurate for Ms Dorey to state that pertussis does not kill.

In the same 'Living Wisdom' article, Ms Dorey also stated:

'... in the US, vaccination was mandated for school entry in 1978 and since 1979, there has been a steady increase in the incidence of pertussis. This picture is duplicated in Australia and every other developed country where we see the majority of pertussis cases are occurring in fully vaccinated individuals.<sup>97</sup>

Further, the AVN's website, under Reason 6 – 'Vaccines do not necessarily protect against infectious diseases', states:

'Australian government statistics have shown that the majority of outbreaks (of pertussis) in Australia occur in those who have been fully vaccinated or were too young to be fully vaccinated.<sup>98</sup>

Currently, the peak incidence of pertussis in Australia occurs in adolescents and adults, with more than 70% of pertussis notifications occurring in people older than fifteen years in 2004–05. The disease is generally mild in previously vaccinated adolescents and adults. Although the exact duration of immunity provided by the pertussis vaccine is unknown, research suggests that immunity, whether from immunisation or infection, wanes after approximately six to ten years, resulting in renewed susceptibility to infection. A booster dose of pertussis vaccination is thus recommended.

<sup>&</sup>lt;sup>91</sup> Submission to Commission from the AVN, received 25 June 2010

<sup>92 &#</sup>x27;Living Wisdom' magazine is on sale through the AVN website

<sup>93</sup> Living Wisdom magazine, Volume 3, published May 2009

www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi31suppl.htm~cda-cdi31suppl-1.htm
 www.health.nsw.gov.au - National Notifiable Diseases Surveillance System: Number of notifications of Pertussis, Australia in 2009

<sup>&</sup>lt;sup>96</sup> Ibid

<sup>97</sup> Living Wisdom magazine, Volume 3, published May 2009

<sup>98</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

<sup>99</sup> www.australianprescriber.com

<sup>100</sup> www.hps.scot.nhs.uk

<sup>&</sup>lt;sup>101</sup> Ibid

<sup>102</sup> www.ncirs.usyd.edu.au

In her article Ms Dorey does not refer to the issue of waning immunity over time and the need for booster vaccinations.

In her response to the Commission 104 Ms Dorey supported her assertion that vaccination for pertussis does not offer protection from infection by presenting two 'Australian Government' tables. One of these tables relates to 'Immunised children aged 0 to 6 yrs from 1989 to 2001'. The other relates to 'Percentage of children immunised at 2 yrs of age, for the birth cohort 1 January to 31 March 2006; assessment date 30 June 2008'. Ms Dorey compared the data from the two tables and stated they indicate that Australia has had an increase of over 23% in the rate of pertussis vaccination, while there has been a concurrent increase in the incidence of pertussis of almost 40 times, hence routine mass vaccination can lead to an increase in the incidence of pertussis.

The Commission expressed concern that these tables appear be two unrelated sets of statistical data, relating to different cohorts of children.

Ms Dorey further submitted 105 that the two statistics sets were appropriately compared and provided correspondence from Dr Gary Goldman 106 supporting this.

The Commission accepts that Dr Goldman has reviewed these data sets and has given an opinion that the comparison is appropriate. To an uninformed person, these clearly appear to be two unrelated sets of statistical data, relating to different cohorts of children and should not be compared without clear explanation. A detailed statistical analysis is not apparent to the general public and Ms Dorey has made no reference to the methodology of the calculations and, more importantly, no methodology nor calculations for her resulting statement that vaccination for pertussis does not offer protection from infection.

Significantly, these tables do not include the ages up to and beyond 15 years when immunity begins to decline, therefore to draw this conclusion is irresponsible.

These tables are also referenced from information provided by the Australian Bureau of Statistics<sup>107</sup> and Department of Health and Aging, 108 both of which are unambiguous in their support of vaccination regimes in Australia. Whilst these papers display the same tabulated data that Ms Dorey refers to, there is no associated mention specific to pertussis vaccination and notifiable disease made that supports Ms Dorey's claim that vaccination for pertussis does not offer protection from infection.

### Issue Six: Stating that the incidence of diphtheria decreased well before the use of mass vaccination

Under the 'Vaccine Info- Diphtheria' section, the AVN website states:

'Whilst there was a time in Australia when many children and adults died every year from this illness, better hygiene and nutrition in the early part of this century saw death rates drop substantially (well before mass use of the diphtheria vaccine). There has not been a case of diphtheria in Australia for many years. 109

<sup>104</sup> Letter to Commission from the AVN dated 7 September 2009

<sup>105</sup> Submission to Commission from the AVN, received 25 June 2010

President/Founder of Medical Veritas International Inc.- a non-profit, public charity that supports medical/scientific research and education (www.drgoldmanonline.com)

ABS Occasional Paper: Vaccination Coverage in Australian Children - ABS Statistics and the Australian Childhood Immunisation Register (ACIR), 2001

108 Department of Health and Aging, Communicable Diseases Intelligence Volume 32 No 3 - Sept 2008

<sup>109</sup> www.avn.org.au - General Vaccination Information - 10 Reasons why parents question vaccination

The information on the website does not provide any evidence to support the claim that substantial drops in death rates from diphtheria are attributable to improved hygiene and nutrition in Australia.

As a part of her initial response to the Commission, Ms Dorey provided Australian Bureau of Statistics (ABS) Yearbook statistics and stated:

'While there definitely was a very large decline in mortality from infectious diseases during the twentieth century, there is no evidence from government statistics to show that vaccination played any part in contributing to that decline. 110

The Commission has found that the ABS Yearbook 2001 states:

'Infectious diseases fell before widespread vaccination was implemented. However, since the 1950s, mass vaccination has been the single most effective public health measure to reduce the occurrence of infections, to reduce child deaths and to improve child health. <sup>111</sup>

# Issue Seven: Stating that bacterial meningitis has increased since meningococcal vaccines were introduced

Under the section 'Vaccine Information - 'Meningococcal' the AVN website states:

'The most sensible argument against this vaccine comes from the government's own bulletin which refers to the experience of the UK's 1999 campaign. 'A recent study has shown a 25% increase in serogroup B disease across all age groups in the United Kingdom since the vaccination campaign. This observation supports a hypothesis that serogroup replacement (i.e. B for C) may be an important factor in the epidemiology of meningococcal disease after the introduction of new vaccines. It therefore remains to be seen what the value of meningococcal vaccines will be in the future control of meningococcal disease.'

The available literature accepts that current meningococcal vaccines are not as effective in preventing meningococcal disease (which can cause bacterial meningitis) as other vaccines. Current vaccines provide protection against serogroups A, C, W135 and Y. There is currently no vaccine for meningococcal serogroup B. Serogroup B disease accounts for the highest incidence of invasive meningococcal disease (though serogroup C disease has been associated with a higher rate of septicaemia and mortality).

In 1999, the UK implemented a national immunisation program with the meningococcal C conjugate vaccine which resulted in an overall decrease in disease incidence of 81% from 1999 to 2001, at the same time the number of deaths decreased from 67 to 5. 115

The AVN has not stated which government bulletin it is referring to. The Commission asked Ms Dorey to provide further information regarding this source but, to date, she has not responded.

113 www.australianprescriber.com

<sup>110</sup> Letter to Commission from the AVN dated 7 September 2009

<sup>&</sup>lt;sup>111</sup> Australian Bureau of Statistics Yearbook Australia 2001, Child health since federation.

<sup>112</sup>www.health.gov.au

Www.australianprescriber.com

114 White Craig P, Scott Jeff, Meningococcal serogroup C conjugate vaccination in Canada: how far have we progressed? How far do we have to go? Canadian Journal of Public Health, 1 Jan 2010

115 Ibid

The Commission located an editorial on meningococcal disease<sup>115</sup> published on the Commonwealth Department of Health and Ageing website which refers to the UK campaign and the increase in serogroup B disease. This paper acknowledges that serogroup replacement is an important factor to consider. However, this paper also states: 'Ultimately the most effective public health strategy for controlling meningococcal disease may be routine vaccination of at-risk populations. 1116

The AVN has selectively quoted information to suggest that vaccination against meningococcal disease has been ineffective when there is no evidence of this. The evidence suggests that the most effective strategy for managing meningococcal disease is to widely vaccinate.

#### Issue Eight: Selectively quoting from articles relating the vaccine, Gardasil, to deaths of females

The June 2009 e-newsletter of AVN states: 'The total number of Gardasil-related deaths is 47 since the vaccine was approved in 2006 117

The reference given for this is a report from a US organisation, 'Judicial Watch' 118, which claims to have analysed US Food and Drug Administration reports regarding this issue. However, this information has been rebutted by US government and medical sites including 'CQ HealthBeat (10/4), 119 which raises suspicions about the data because the analysis included reports which come from several sources, some of which are unreliable. 120

As discussed earlier, further information about deaths and Gardasil also appears on the AVN website, under the heading 'AVN News', providing a link to an article from 'Natural News'. Apart from the omission discussed under Reason 6, the fourth paragraph of the original 'Natural News' article has not been reproduced by the AVN. This is important as it changes the context of the original article. The fourth paragraph states that the EMEA concluded:

'In both cases, the cause of death could not be identified. No causal relationship has been established between the deaths of the young women and the administration of Gardasil, the agency said. 121

In not including this paragraph, it has the effect of suggesting there have been deaths related to the administration of the Gardasil vaccine when the full reference states that there is no causal link between the vaccine and the deaths.

#### Issue Nine: Conducting a seminar in which a number of anti-vaccination statements were made.

Both Mr McLeod and Mr and Mrs McCaffery have made allegations that the AVN holds seminars at which incorrect and misleading information on the subject of vaccination is aired.

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<sup>115</sup> Department of Health and Aging, Communicable Diseases Intelligence, Volume 25, Issue number 3 - August 2001, Editorial: Meningococcal disease

Living Wisdom E-newsletter, June 2009

<sup>118</sup> The Judicial Watch website (www.judicialwatch.org) states it is a conservative, non-partisan educational

foundation, promotes transparency, accountability and integrity in government, politics and the law.

119 The CQ website (www.cq.com) states that CQ HealthBeat is a new federal health care policy website and email newsletter
120 www.medicalnewstoday.com/articles/84804.php

<sup>121</sup> www.naturalnews.com

While the statements reportedly made at AVN seminars would seem to be in some cases grossly inaccurate, it is open to an organisation such as the AVN to hold seminars where participants and guest speakers make statements that are anti-vaccination or that raise questions about vaccination.

# Issue Ten: The AVN sells t-shirts imprinted with the slogan: 'Love them. Protect them.'

It is open to the AVN to sell items that express anti-vaccination views. It is noted that selling these items may have the effect of disclosing honestly to members of the public the actual anti-vaccination stance of the AVN. Members of the public are free to make a choice to buy such items.

#### Issue Eleven: Misrepresenting the circumstances of the death of Dana McCaffery

Both Mr McLeod's and Mr and Mrs McCaffery's complaints alleged that the AVN and Ms Dorey had misrepresented the facts of Dana's death, harassed her family, and invaded their privacy. Since their daughter's death, Mr and Mrs McCaffery have made public statements advocating vaccination.

Ms Dorey contacted Mr Paul Corben, Director of Public Health, NSW Department of Health seeking further details on Dana's death, and contending he had misled the public in attributing her death to pertussis. 122

Mr and Mrs McCaffery stated in their complaint to the Commission that on 4 September 2009, Ms Dorey presented tables of data on the incidence of pertussis and the incidence of vaccination in two different cohorts of children (see discussion of these tables in Issue Five above) during an appearance on an Australian Broadcasting Corporation (ABC) North Coast radio programme. Mr and Mrs McCaffery subsequently complained to the ABC outlining their concerns about the accuracy of the information as well as some references to their daughter.

In its investigation of the complaint, the ABC conceded that the comparative manner in which these statistics were presented was misleading, stating "comparing the two statistics was inappropriate". 123

Ms Dorey also posted claims about Dana's death on her blog, the AVN Yahoo Discussion forum, letters to media outlets, radio interviews and various AVN publications – asserting that Dana did not die from pertussis.

Mr and Mrs McCaffery, as the parents of Dana, chose to speak with the media about the circumstances of her death and the evidence they have about the cause of Dana's death and any contributory factors.

While Ms Dorey joined the debate in the media, she was not in possession of all the information relating to the facts and circumstances of Dana's illness and death when she spoke with the media and posted information relating to Dana on her weblog. This was offensive and painful for Dana's parents and family, although it does not appear Ms Dorey was acting as a health service provider in this context.

Letter to Mr & Mrs McCaffery from Audience & Consumer Affairs, ABC, dated 26 October 2009

<sup>122</sup> Email from Mr Corben to Mrs McCaffery dated 19 May 2009

#### **Summary**

The AVN provides information through its website, a Facebook site, electronic magazines, seminars and webinars. Additionally Ms Dorey, through media appearances both locally and nationally, represents AVN and provides information in relation to vaccination.

The Commission has focussed chiefly on the issues raised by Mr McLeod and Mr and Mrs McCaffery in relation to the AVN website, examining most closely those elements of the website that would be commonly accessed by a person browsing the site for information.

The Commission has not examined the Facebook site run by AVN as this kind of social networking site may represent the views of AVN as well as subscribers and participants not associated with AVN and it is not reasonable in these circumstances to hold AVN wholly responsible for the content of such sites.

In Australia, vaccination is a key plank of public health strategy. It is thus extremely important for individuals, especially parents, to be able to make informed decisions about vaccination. The AVN provides information that is misleading for the average reader by inaccurately representing information, selectively reporting information, and giving non-peer reviewed and anecdotal material the same authority as peer-reviewed literature. In all cases of misrepresentation, selective and inaccurate reporting and indiscriminate use of research material, the AVN and Ms Dorey were doing so to maintain an anti-vaccination position.

In her response to the Commission, Ms Dorey conceded that the AVN provides antivaccination information. Ms Dorey stated there is a need to provide information about vaccination alternative to that disseminated by Government, pharmaceutical companies and the mainstream medical community which is one-sided and invariably pro-vaccination, submitting:

'The AVN's charter is to put a balance of information regarding health policy before its users/website users/subscribers. 125

'While the AVN has always stated that we support everyone's right to make free and informed choices and we have spent years providing referenced information on the risks and effectiveness of medical procedures – information sourced from peer-reviewed, mainstream medical journals – we have never stated that we would provide information which the government and the medical community makes freely available to all Australians.....it is not our role nor are we resourced to provide the government's information though we do have links on our websites..... where people can access this information. 126

While Ms Dorey has offered a justification for the AVN presenting anti-vaccination material, this is not a cogent reason for failing to clearly and frankly indicate its anti-vaccination position. If the AVN genuinely wants to empower people to make informed choices concerning vaccine use and education about risks, adverse reactions, and contraindications for vaccination, it should either present balanced and reliable information or clearly and openly articulate its stance against vaccination.

A similar organisation, *Vaccination Information South Australia* (VISA), has a section on its website headed, *'What to do if you decide to have your child vaccinated'* with steps such as discussing the risks and benefits with the immunisation provider; reading the manufacturer's leaflet in the vaccine package, and keeping notes of information provided.<sup>127</sup>

127 www.visainfo.org.au

<sup>125</sup> Letter to Commission from the AVN dated 7 September 2009

<sup>126</sup> Ibid

VISA is clearly not in favour of vaccination - but it makes it clear that the reader should consider other relevant information.

Essentially the general public needs to know that the information they are reading on the AVN's website is anti-vaccination and is not consistent with current Government policy and mainstream medical opinion. Providing this context for its information would still enable the public to make an informed choice about whether or not to vaccinate.

Any decision affecting a person's health should be taken seriously and researched thoroughly through whatever means available. The current health climate is such that the internet provides a wide source of information for the general public on a wide range of health issues and concerns. Internet users who are conducting research need to be cautious that, when seeking health care information online, there may be misleading, incomplete, and inaccurate information. 128 A study on the issue of internet health care information has found:

'substantial variation in both the completeness and accuracy of this [health care] information ... Internet users must still proceed with caution when seeking healthcare information online, as incomplete, inaccurate and even dangerous information still abounds in cyberspace'. 129

It is noted that just recently, on 23 April 2010, a nationwide ban on the influenza vaccinations for children under five was issued after more than twenty children suffered various reactions after receiving the vaccine in Western Australia.

Also, the Queensland Coroner has investigated the death of a two year old girl, on 9 April 2010, after receiving the influenza vaccine.

Whilst investigations have not established clear links between these vaccinations and the side effects, these recent events have illustrated that the issue of vaccination is not black and white and that it is important for people to make educated decisions about vaccination. The AVN must be open about the position it holds so that the information it provides can be properly understood.

#### **Notices**

There are a number of organisations similar to the AVN. For the purposes of the investigation, the Commission reviewed the websites of these organisations.

Vaccination News has the following notice on its website:

'All information, data and material contained, presented or provided here is for general information purposes only and is not to be construed as reflecting the knowledge or opinions of the publisher, and is not to be construed or intended as providing medical or legal advice. The decision whether or not to vaccinate is an important and complex issue and should be made by you, and you alone, in consultation with your health care provider. 130

Vaccine Awareness Network has the following notice:

<sup>128</sup> Karp S, Monroe AF. Quality of healthcare information on the Internet: caveat emptor still rules. Manages Care Q. 2002;10(2):3-8. <sup>129</sup> Ibid

<sup>130</sup> www.vaccinationnews.com

'DISCLAIMER: We do not give medical advice as we are not GPs. We merely provide information and research studies surrounding vaccination to enable parents to make a fully informed decision. VAN UK is not responsible for any vaccination, birthing or infant feeding decision you may make. That is your responsibility as a parent. 131

Vaccination Risk Awareness Network has this notice:

'The contents of this website are for informational purposes only. Opinions expressed should not be construed as medical advice. The particulars of any person's concerns and circumstances should be discussed with a qualified health care practitioner prior to making any decision which may affect the health and welfare of that person or anyone under his or her care.

Anybody undergoing any medical treatment should consider the following:

- 1. Are you fully confident in the ability and qualification of your health care professional or specialist?
- 2. Are you completely informed about the procedure in question, its desired effect as well as its potential for short and long term side-effects? There is no medical procedure without possible side-effects and there is no guaranteed success either.
- 3. Are you prepared to accept all the potential side-effects of the procedure and convinced that the potential benefits outweigh the potential risks?

If in any doubt, we suggest you ask your healthcare practitioner for clarification, find additional information from other sources (such as the medical literature, support groups, the internet) or get a second opinion from another health care professional.

It is your right to be informed. 132

The AVN has the following paragraph on its website:

'The Australian Vaccination Network recommends that we all become fully informed about the relevant risks and benefits of vaccines - and all medical procedures - and make the best possible choices for our families and ourselves. We ask everyone to remember that vaccination is not compulsory in Australia so the decision to vaccinate is always must be yours and yours alone. 133

This paragraph is placed at the end of the vaccine information section regarding HPV and not in a prominent place on the website, such as the Home page.

In the course of the investigation, the Commission raised with Ms Dorey the possibility of the AVN featuring an appropriate notice on its website.

In response, Ms Dorey said the AVN already had one but that when a new website was launched in December 2009, the notice was not transferred correctly.

Ms Dorey said that the AVN remedied this in February 2010 and the notice is located via a link titled 'Legal Notice' at the bottom of the home page.

<sup>131</sup> www.vaccineriskawareness.com

<sup>132</sup> www.vran.org

<sup>133</sup> www.avn.org.au - Vaccination Information - HPV

This was further remedied in March 2010, with the link renamed 'Disclaimer'. The text of the notice that can be accessed by using the link is as follows:

'The AVN makes no guarantees of any kind with regard to any products and other materials contained on this site. No warranty or guarantee is expressed or implied with any information at this site.

The AVN has, as far as it is possible, taken care to ensure that the information given on this site is accurate and up to date. However, this information is provided with the understanding that the AVN is not liable for the misconception or misuse of information provided. This information is continually being updated and so may not be accurate, current or complete and is subject to change without notice.

The information on this site is intended and applicable for Australian audiences only and adheres to Australian legislation and regulatory notice. 133

This does not advise the general public of the apparent purpose of the AVN in providing information about vaccination and that other sources of information, including medical advice, should be taken into account when making decisions about vaccination.

The inclusion of a prominent statement on the website which articulates clearly the antivaccination stance of the AVN, would obviate the need for a public statement to be issued by the Commission, however if the Commission is not satisfied that sufficient steps have been taken by the AVN to implement this it will issue a public statement under section 94A of the Act.

#### Recommendation:

The AVN should include an appropriate statement in a prominent position on its website which states:

- The AVN's purpose is to provide information against vaccination in order to balance what it believes is the substantial amount of pro-vaccination information available elsewhere;
- 2. The information provided should not be read as medical advice; and
- 3. The decision about whether or not to vaccinate should be made in consultation with a health care provider.

#### Application of the Code of Conduct for Unregistered Health Practitioners

Mr McLeod submitted that the Commission should make a prohibition order against the AVN and Ms Dorey on the basis that the AVN breaches a number of clauses of the Code of Conduct for Unregistered Health Practitioners (the Code of Conduct).

The Code of Conduct applies only to individual practitioners, rather than organisations that provide health services. Accordingly, the Commission's consideration of the application of the Code of Conduct in this matter is confined to examining whether Ms Dorey, as President and spokesperson of the AVN, may be in breach of it.

The Commission has set out below the clauses of the Code of Conduct that Mr McLeod has alleged have been breached by the AVN, together with the Commission's discussion of the applicability of these clauses to the circumstances of this matter.

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<sup>133 &</sup>lt;u>www.avn.org.au</u> - Disclaimer

Clause 3(2)(a) states 'a health practitioner must maintain the necessary competence in his or her field of practice'. 134

It is difficult to define with any clarity what constitutes 'necessary competence' in the field of the provision of information about vaccination.

Clause 3(2)(b) states 'a health practitioner must not provide health care of a type that is outside his or her experience or training 135.

This clause specifically refers to the provision of 'health care'. As president of the AVN, Ms Dorey does not provide health care. In addition, it is apparent that Ms Dorey is well read on the subject of vaccination and so there are difficulties in reaching a firm view that Ms Dorey does not have appropriate 'experience or training' in the provision of information about vaccination. An individual does not have to be a trained health practitioner to provide a health education service.

Clause 12(3) states: 'A health practitioner must not make claims, either directly or in advertising or promotional material, about the efficacy of or treatment or services provided if those claims cannot be substantiated.<sup>136</sup>

This clause appears to cover claims made by practitioners about their own treatments or services, not statements about the treatments provided by others as in the case of the AVN and Ms Dorey.

Clause 7 states, 'A health practitioner must not attempt to dissuade clients from seeking or continuing with treatment by a registered medical practitioner. <sup>137</sup>

While it could be argued that the effect of Ms Dorey's information, articles and statements is to dissuade people from having vaccinations, or seek advice from their general practitioners about vaccination, the Commission's investigation did not find clear evidence of specific statements made by Ms Dorey which establish a breach of this clause.

The Commission did consider whether statements made under Reason 7 amongst the '10 reasons why parents question vaccination' regarding doctors receiving payments for vaccinations (as discussed on page 11 of this report) was a breach of this clause by Ms Dorey. <sup>138</sup>

The statement: 'Doctors, as paid salesmen for vaccine products, are no longer considered to be trustworthy arbiters of their safety and effectiveness' and similar remarks made by Ms Dorey when she appeared on Channel Seven's 'Sunday Night' programme on 26 April 2009, appear to be referring to the GPII. In providing this information in this way, Ms Dorey is suggesting that it may not be appropriate to discuss the issue of whether or not to vaccinate with a medical practitioner. Ms Dorey's statement regarding doctors being untrustworthy arbiters of the safety and effectiveness of vaccination may undermine the trustworthiness of doctors with respect to vaccination generally.

This, however, is not considered sufficient to be a breach of the Code of Conduct as it is not a direct instruction not to seek vaccination from a registered medical practitioner to the extent that it may pose 'a risk to the health or safety of members of the public. 140

<sup>&</sup>lt;sup>134</sup> The Code of Conduct for Unregistered Health Practitioners, Public Health (General) Regulation, 2002

<sup>135</sup> Ibid

<sup>136</sup> Ibid

<sup>137</sup> Ibid

Ms Dorey, as the president of the organisation, bears the responsibility for authorship of unreferenced information presented on the website.

<sup>&</sup>lt;sup>139</sup>www.avn.org.au – General Vaccination Information – 10 Reasons why parents question vaccination

<sup>&</sup>lt;sup>140</sup> Health Care Complaints Act, 1993

There is also the difficulty of clearly legally establishing who Ms Dorey's client base is. The Act defines a client as 'a person who uses or receives a health service, and includes a patient. 141 It seems unlikely that it could be established that a person who either seeks advice directly from Ms Dorey or reads information posted by her on the AVN website is her client.

The context of this clause of the Code of Conduct is that it was largely to prevent unregistered practitioners potentially endangering the health or safety of their clients by advising them against conventional proven treatments by a registered medical practitioner. There is no evidence that Ms Dorey has done so and there is insufficient basis for the Commission to take action on this issue with respect to the Code of Conduct.

<sup>&</sup>lt;sup>141</sup> Health Care Complaints Act, 1993