THE PROMOTION OF FALSE OR MISLEADING HEALTH-RELATED INFORMATION OR PRACTICES

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Committee on the Health Care Complaints Commission Parliament House Macquarie St Sydney NSW 2000

Dear Chair

Civil Liberties Australia (CLA) thanks the Committee on the Health Care Complaints Commission for the opportunity to contribute to the Committee's inquiry into the Promotion of False or Misleading Health-Related Information or Practices.

CLA is a non-government organisation dedicated to the promotion of human and civil rights in Australia. It is funded by its members and donations, and does not receive funding from other sources. CLA monitors police and security forces, and the actions and inaction of politicians. It reviews proposed legislation to make it better, and keeps watch on government departments and agencies.

The subject matter of this inquiry touches upon a number of rights and freedoms, including the freedoms of religion, speech and association and the right to privacy and protection of family, the latter in the context of the ability for an individual to be free to exercise autonomy in their choice of health service provider and treatment.¹

Attention must also be paid to the rights of the child and people with disabilities, which may also be affected by any recommendations of the committee.

Our submission is confined to outlining a set of principles that the Committee should keep in mind when developing any "measures to address the promotion of unscientific healthrelated information or practices which may be detrimental to individual or public health". Thus, our submission is focused on items (a)-(c) of the Committee's Terms of Reference. We have also attached an article written by our Vice-President that is relevant to this inquiry.²

Due to the interest of certain groups in this inquiry, we would like to clearly state our formal position on vaccination: vaccines work, are safe (both in terms of absolute and relative risk) and have saved the lives of millions of individuals and spared many more from life-long disabilities. The childhood schedule of vaccines should be encouraged as it promotes the 'best interests of the child', an obligation imposed on parents, guardians and the State by the Convention on the Rights of the Child.³

¹ Including refusal of treatment.

 ² Vines, T and Faunce, TA, Civil Liberties and the Critics of Safe Vaccination: Australian Vaccination Network Inc v. Health Care Complaints Commission (2012) NSWSC 110 (2012) 20 *Journal of Law and Medicine* 44.
³ A more detailed discussion of CLA's position can be found at <u>http://www.cla.asn.au/News/vaccination-the-choice-made-for/</u> As a child matures it should share decision making responsibility with its parents.

Notwithstanding our support for vaccination, CLA would oppose any proposal to outlaw associations that engage in anti-vaccination speech, or those that criticise 'western' medicine, encourage members of the public to seek alternative treatment or adopt an overly sceptical attitude towards registered health providers. Individuals and groups are entitled to express views that are genuinely held, even if they are scientifically or factually wrong. Where these individuals or groups are engaged in activities which critique or question government run programs and policies, such as the National Immunisation Program, then their right is even stronger.

Measures to restrict the activities or speech of such individuals or groups can only be justified if they are narrowly designed with the legitimate goal of preventing 'fraud' – which is more serious than 'misleading' conduct.⁴ Likewise, while public policy may justify measures that allow a Government body to require organisations to *not* use a particular name if that name is likely to 'deceive', this power should not extend to permitting that body to choose another name for the group or compel the use of certain words. Compelling speech is as repugnant as prohibiting it.⁵

CLA would also caution against measures that have the effect of privileging certain points of view, especially in an area field of evolving knowledge and where incorrect information is published by both 'sides', innocently or otherwise. For example, until the mid-1980s medical orthodoxy held that stomach ulcers were caused by stress and lifestyle. To express a different view was likely to invite criticism from the medical establishment. It was only through the research of Australian doctors Barry Marshall and J. Robin Warren (including Marshall's self-experimentation) that it was proved that this orthodoxy was wrong, and that the vast majority of stomach ulcers were caused by a bacteria.⁶ In this case, they advocated an approach that "depart[ed] from accepted medical practice".⁷

It is better to let views compete in the open – where they can be challenged and tested – rather than protect one by suppressing dissenting viewpoints. As the conclusion of the attached article argues, in the context of anti-vaccination groups:

Public immunisation programs represent one of the greatest achievements of medical science and public health policy. The success of vaccines in reducing infant mortality stands in stark contrast to "evidence" presented by organisations such as the AVN that vaccines place children at risk, offer little long-term benefit or are dispensed by practitioners pursuing financial advantage. ...[In] their response to organisations critical of vaccination, governments need not resort to laws which limit speech; rather they should themselves speak more and more pointedly in favour of science.

⁴ CLA does not advocate for the rights of corporations and, in any event, believes that human rights are for humans (and collectives of humans), not fictional legal persons: see, for example, section 6 of the *Human Rights Act 2004* (ACT). Consequently, laws that regulate the conduct of companies – such as s 18 of the *Australian Consumer Law* – are an acceptable remedy for misleading and deceptive business conduct because they do not impact on personal speech.

⁵ See further: Vines T, Donohoo A, Faunce TA, Government Controls over Health-Related Not-For–Profit Organisations: Agency for International Development v Alliance for Open Society International (2013) 21 *Journal of Law and Medicine* 278.

⁶ For this research the two Australians won the 2005 Nobel Prize for Medicine:

http://www.nobelprize.org/nobel_prizes/medicine/laureates/2005/press.html

⁷ Committee Terms of Reference.

Similarly, no measure should be adopted that reduces the incentive for individuals or groups to question the safety or efficacy of pharmaceutical interventions. Just because a person's motivation to challenge 'western medicine' or 'Big Pharma' springs from a religious view (e.g. Scientologists and psychiatry) or personal belief (e.g. anti-vaxers) does not negate the merit of their complaint or the social utility of their challenge to orthodoxy.

For instance, there remain significant, scientific concerns over the use of anti-depressants and questions over their efficacy and safety,⁸ vaccines can have adverse side effects [overwhelmingly minor and transient], and drugs have been released into the market on the basis of bogus safety data and an unquestioning medical community.⁹ Sceptics and whistle-blowers alike need freedom to question received wisdom and 'established' science or treatments. It may be necessary sometimes to raise "anxiety toward, accepted medical practice", especially where publishing bias frequently supresses negative clinical trial results, and where busy medical practitioners may not have the time to question the veracity of studies which support their prescribing practices.¹⁰

While the Committee may support proper scientific scepticism and whistle-blowers it is questionable whether Parliament could ever craft a law that protected the 'right kind of people' and only targeted the 'wrong sort'.¹¹ Protecting free speech means that the Government cannot pick a winning viewpoint.

Finally, CLA notes that item (b) of the Committee's Terms of Reference has the potential to capture advice that encourages people to refuse medical treatment, which is the legal and ethical right of all competent adults.¹² It is "unsafe" for a person suffering severe anaemia or trauma to refuse a blood transfusion, but it is the right of an individual to refuse such treatment.¹³ For a Jehovah Witness it is religious dogma to refuse a transfusion. Would the Committee propose to violate the right to the free expression of one's religion by banning Jehovah Witness publications or teachings that express this particular "medically unsafe" view? Does the Catholic Church's opposition to the use of condoms to prevent the spread of HIV constitute the dissemination of unsafe information on preventative health?

Ultimately, it may be difficult – if not impossible – for the Committee to find a principled approach to banning the dissemination of views by civil groups such as the AVN while protecting the views of religious groups. Equality before the law means that both groups should be treated equally.

http://www.theatlantic.com/magazine/archive/2010/11/lies-damned-lies-and-medical-science/308269/

⁸ See, for example: Kirsch I. Challenging received wisdom: antidepressants and the placebo effect. (2008) 12(2) *Mcgill J Med.* 219; Gunnell D, Ashby D. Antidepressants and suicide: what is the balance of benefit and harm? 2004 329 *British Medical Journal* 34; Gunnell D., Saperia J., Ashby D. Selective serotonin reuptake inhibitors (SSRIs) and suicide in adults: meta-analysis of drug company data from placebo controlled, randomised controlled trials submitted to the MHRA's safety review (2005) 330 *British Medical Journal* 385.

 ⁹ McLean T, Discontinuation of Vioxx (2005) 365 *The Lancet* 25 DOI: 10.1016/S0140-6736(04)17656-3.
¹⁰ Freeman H, 'Lies, Damned Lies, and Medical Science' (October 4, 2010) (*The Atlantic*)

¹¹ In a similar vein, we wonder if the Committee will also examine Australia's \$2 Billion per year Complementary and Alternative Medicine (CAM) industry. CAMs, including vitamins, are usually only assessed for 'quality' and 'safety' *not* for 'efficacy' (i.e. whether they work).

¹² See, for example: *Re C (Refusal of Medical Treatment)* [1994] 1 FLR 31; *Gardner; re BMV* [2003] VSC 173.

 $^{^{13}}$ And it would be a breach of their right to privacy to have treatment forced upon them.

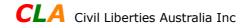
We appreciate the good intentions behind this inquiry. Ensuring the health and wellbeing of the community is a central role of government. But the suppression of speech is not an appropriate mechanism to achieve this. Rather the government and medical community should ensure their own message is loud and clear, that conflicts of interests in the industry are properly declared and that patients feel that they are receiving objective information from their health professionals.

Thank you for considering our submission.

Yours sincerely

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CIVIL LIBERTIES AND THE CRITICS OF SAFE VACCINATION: AUSTRALIAN VACCINATION NETWORK INC v HEALTH CARE COMPLAINTS COMMISSION [2012] NSWSC 110

Public immunisation programs have, time and again, demonstrated their effectiveness at reducing mortality and morbidity from vaccine-preventable diseases such as measles and pertussis. Governments, health agencies and almost all health practitioners regard vaccines as safe and cost-effective treatments with a low risk profile. Nevertheless, despite, or perhaps because of, their success, immunisation programs and vaccines have increasingly been questioned by various lobby groups, sceptical of the safety of vaccines and the motives of those who administer them. Whereas the reach of these aroups would have once been limited by the cost of postage, the internet has delivered a global audience. The extent to which these anti-vaccination advocates are expected to comply with the ethical and professional standards applied to registered health professionals remains unresolved in Australia. As demonstrated in the case of Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110, the ability of professional oversight bodies to regulate the information promoted by these lobby groups is limited by traditional conceptions of the doctor-patient relationship and the clinical setting in which medical advice is delivered. Acknowledging that vaccines, like all medical treatments, involve some level of risk, this article explores the relationship between the state, parents, family, medical professionals and such lobbyists within a human rights framework, suggesting that most public immunisation programs deliver benefits in "the best interest of the child" that, on balance, provide a good result for the civil liberties of Australians.

INTRODUCTION: THE GLOBAL PUBLIC HEALTH SUCCESS OF VACCINATION

Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 is a case concerned with the regulatory standards that should apply to anti-vaccination lobbyists in Australia. By way of general background to the issues involved, it should be emphasised that public immunisation programs are scientifically proven, cost-effective and safe medical interventions estimated to save three million lives worldwide each year.¹ Through such vaccination programs, humanity has banished the scourge of smallpox and is tantalising close to realising the long-held goal of a world free from polio.² The effectiveness of widespread childhood immunisation in Australia has seen the retreat of debilitating and frequently fatal childhood illnesses from the health system and public consciousness. Endemic measles transmission³ was eradicated in Australia between 2005 and

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¹ Australian Government, *Myths and Realities: Responding to Arguments Against Immunisation – A Guide for Providers* (4th ed, 2008) p 5; Campion EW, "Suspicions About the Safety of Vaccines" (2002) 347(19) NEJM 1474 at 1474; WHO, UNICEF and World Bank, *State of the World's Vaccines and Immunization* (3rd ed, World Health Organisation, Geneva, 2009) p xiv.

² WHO, UNICEF and World Bank, n 1, pp 137-139.

³ In 1960, 400 children died from measles in the United States: Campion, n 1 at 1475. 146 deaths from measles were certified in Australia between 1966 and 1975.

2007.⁴ Yet it is sobering to recall that more than 200,000 children worldwide continue to die from measles each year, mostly in developing countries.⁵ Many more die from other vaccine-preventable diseases such as rotavirus, diphtheria and pertussis.

Globally, countries have committed to reducing mortality in children under the age of five by two-thirds by 2015 as part of the United Nations' Millennium Development Goals.⁶ Public immunisation remains the key to achieving this goal, and reducing the suffering caused by preventable diseases that kill and maim. Significant progress has been made to date, with a 74% reduction in measles deaths globally (2000-2007)⁷ and endemic polio confined to four countries (down from 125 in 1988).⁸ However, with an estimated 19 to 24 million children remaining out of reach of vaccination programs, this goal remains optimistic.⁹

Yet, as an easy target for governments seeking short-term, low-risk "savings", foreign aid spending on vaccination has been curtailed to meet austerity targets or politically-driven budget surpluses.¹⁰ This is despite the benefits provided to the recipient nation and the donor country, eg, by reducing the number of individuals capable of transmitting a disease to a traveller or population group through migration. Indeed, so-called "imported cases" of measles now constituted the major source for local outbreaks in Australia and the United States.¹¹

A natural concern from such funding cuts is that, just as the memory of the scourge of childhood diseases recedes from the public's consciousness and with parents challenging their doctors with information obtained online about the alleged risks of vaccines, there is a danger that these diseases will again emerge. Misinformation can quickly lead to a drop in the coverage rate of vaccines below the level required to maintain herd immunity. Dr Andrew Wakefield's now infamous and flawed study linking gastrointestinal disease and developmental regression in a group of previously healthy children to "environmental factors"¹² (including the combined Measles, Mumps, Rubella (MMR) vaccine) saw vaccination rates decline in the United Kingdom.¹³ With weakened herd immunity, it is perhaps unsurprising that the United Kingdom has seen at least two significant outbreaks of measles since 1997.¹⁴ Despite the *Lancet* retracting the study,¹⁵ and other published research repeatedly

⁶ World Health Organisation, *Millennium Development Goals*, <u>http://www.who.int/immunization/newsroom/mdg/en/index.html</u> viewed 14 May 2012.

⁷ WHO, UNICEF and World Bank, n 1, pp 124-125.

⁸ WHO, UNICEF and World Bank, n 1, p 42.

⁹ WHO, UNICEF and World Bank, n 1, p xviii.

¹⁰ For example, in the 2012 Federal Budget, the Australian Government announced that it would delay increasing Australia's aid budget to 0.5% of Gross National Income by one year (to 2016-2017). This will achieve savings of \$2.9 billion over the forward estimates period (2012-2013 – 2015-2016): Australian Government, *Budget Paper No 2* (Australian Government, Canberra, 2012), <u>http://www.budget.gov.au/2012-13/content/bp2/html/bp2_expense-11.htm</u> viewed 14 May 2012.

¹¹ Heywood, Gidding, Riddell et al, n 4; Centers for Disease Control and Prevention, "Measles – United States" (20 April 2012) 61(15) *Morbidity and Mortality Weekly Report* 253.

¹² Wakefield AJ, Murch SH and Anthony A, "Retracted: Ileal-Lymphoid-Nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children" (1998) 351 (9103) *Lancet* 637.

¹³ In 2003-2004, 80% of children reaching their second birthday had been immunised with the combined MMR vaccine, down 2% from the previous 12 months and down from 92% in 1995-1996. Diphtheria, tetanus and polio vaccination rates were also down from their 1995-1996 peak (94% from 96%): National Health Service, *NHS Immunisation Statistics 2003-04*, <u>http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/StatisticalWorkAreas/Statisticalhealthcare/DH_4099576</u> viewed 21 May 2012. In 2007-2008 only 76.4% of pre-school aged children received their second MMR dose by age five.

¹⁴ Health Protection Agency, "Measles Figures Soar", *Media Release* (28 November 2008), <u>http://www.hpa.org.uk/NewsCentre/NationalPressReleases/2008PressReleases/081128measles</u> viewed 21 May 2012; Leask J, Booy R and McIntyre PB, "MMR, Wakefield and the Lancet: What Can We Learn?" (2010) 193(1) MJA 5.

⁴ Eradication is defined by the World Health Organisation as less than one case per million in a population: Heywood AE, Gidding HF, Riddell MA et al, "Elimination of Endemic Measles Transmission in Australia" (2009) 87 *Bulletin of the World Health Organisation* 64.

⁵ WHO, UNICEF and World Bank, n 1, p 125. This is down from 600,000 in 2002. Higher mortality rates have been reported by others: Campion, n 1 at 1475.

contradicting Dr Wakefield's findings,¹⁶ the study continues to bolster the claims of several anti-vaccination groups. Not even the removal of Dr Wakefield from the register of medical practitioners for multiple counts of serious professional misconduct, including research misconduct, has diminished the credibility of this study to some.¹⁷

Perversely, the low incidence of childhood mortality, rather than being a cause for celebration, has increased the attention paid to the rare adverse events associated with vaccines,¹⁸ whether or not there is medical evidence linking the event to the vaccine.¹⁹ These reports often downplay the overall safety of a given program and the significantly higher risks presented by the disease.²⁰ It is incumbent on health practitioners to counter misleading information, while providing clear and accurate information on the risks and benefits of vaccination.

Doctors, nurses and other health practitioners are under a legal and ethical obligation to conduct themselves in a professional manner. Such requirements are prescribed under legislation,²¹ professional codes,²² and extend beyond the conduct of the doctor within their surgery. Deviation from those guidelines can lead to loss of registration and practising rights,²³ professional sanctions, liability in negligence and even criminal punishment.²⁴ The power of professional registration bodies to sanction members has been described as a "protective" rather than "punitive" function, placing the wellbeing of the community at the centre of the proceedings.²⁵

As trusted sources of medical information, doctors and nurses must ensure they provide accurate health information to their patients and to anyone who might be expected to make a clinical or treatment decision on the basis of that information.²⁶ With the enactment of a national law for the

²⁰ Centers for Disease Control and Prevention, n 19.

²¹ For example, s 139B(1)(a)(i) of the *Health Practitioner Regulation National Law* adopted by New South Wales through the *Health Practitioner Regulation (Adoption of National Law) Act 2009* (NSW).

²² "[Nurses] are entitled to participate in decisions regarding a person's nursing care and are obliged to question nursing care they regard as potentially unethical or illegal": Australian Nursing and Midwifery Council et al, *Code of Ethics for Nurses in Australia*, <u>http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx</u> viewed 15 May 2012; "Nurses provide impartial, honest and accurate information in relation to nursing care and health care products": Australian Nursing and Midwifery Council et al, *Code of Professional Conduct for Nurses in Australia*, Conduct Statement 6, <u>http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx</u> viewed 15 May 2012.

²³ Health Practitioner Regulation National Law 2009 (NSW), s 55.

²⁴ For example, *Criminal Code 1899* (Qld), ss 282, 288; *R v Patel* (2010) 202 A Crim R 53; [2010] QSC 198 (subject to an appeal to the High Court).

²⁵ Pillai v Messiter (No 2) (1989) 16 NSWLR 197; Medical Board (Qld) v Martin [1998] QSC 230; A Practitioner v Medical Board (WA) [2005] WASC 198 at [88] (Commissioner Kenneth Martin QC).

²⁶ See eg *Health Care Complaints Act 1993* (NSW), s 7(1)(a), (b); Australian Nursing and Midwifery Council et al, Conduct Statement 6, n 22.

¹⁵ Editors, "Retraction – Ileal-Lymphoid-Nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children" (2010) 375 (9713) Lancet 445.

¹⁶ See a list of references in Leask, Booy and McIntyre, n 14.

¹⁷ United Kingdom, General Medical Council, *Determination on Serious Professional Misconduct (SPM) and Sanction* (24 May 2010), <u>http://www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf</u> viewed 21 May 2012.

¹⁸ Adetunji J, "Schoolgirl Dies After Cervical Cancer Vaccination", *The Guardian* (29 September 2009), <u>http://</u> www.guardian.co.uk/uk/2009/sep/28/hpv-cervical-cancer-vaccine-death viewed 21 May 2012.

¹⁹ Bowcott O, "Girl Who Died After Cervical Cancer Injection had Tumour in Her Chest", *The Guardian* (1 October 2010), <u>http://www.guardian.co.uk/society/2009/oct/01/cervical-cancer-vaccination-tumour-natalie-morton</u> viewed 21 May 2012. As of 15 September 2011, 40 million doses of Gardasil® have been distributed in the United States, with 20,096 reports of adverse events. 92% of reported adverse events were non-serious: Centers for Disease Control and Prevention, *Reports of Health Concerns Following HPV Vaccination*, <u>http://www.cdc.gov/vaccinesafety/Vaccines/HPV/gardasil.html</u> viewed 21 May 2012.

registration of many health practitioners (including, controversially, chiropractors and from 1 July 2012 traditional Chinese medicine practitioners),²⁷ a similar obligation is presumed to apply to these practitioners.²⁸

But the debate over immunisation continues outside the surgery and involves a range of individuals, groups and forums that are not regulated or subject to a level of professional oversight. One such group purporting to provide information about vaccination is the Australia Vaccination Network (AVN). In 2009, an effort was made to bring the leadership of the AVN and the organisation itself within the legislative framework for handling health care complaints in New South Wales.

THE AUSTRALIAN VACCINATION NETWORK, DOREY AND THE HEALTH CARE COMPLAINTS COMMISSION

In 2009, two complaints were lodged under the *Health Care Complaints Act 1993* (NSW) (the Act) with the New South Wales Health Care Complaints Commission (HCCC) against the AVN and its president Ms Meryl Dorey. The first complainant, Mr McLeod, alleged that both parties had engaged, and continued to engage, in "misleading or deceptive conduct in order to dissuade people from being, or having their children, vaccinated".²⁹ Mr McLeod is a member of an online group titled "Stop the AVN".³⁰

The misleading or deceptive conducted alleged included, inter alia, statements on the AVN's website that "measles, mumps, and rubella are '*non-life threatening illnesses in early childhood*'; the incidence of diphtheria 'decreased well before the use of mass vaccination'; and that 'research has suggested there is a connection between vaccination and autism, Crohn's Disease and Irritable Bowel Syndrome'".³¹

Mr and Mrs McCaffery lodged a similar complaint with the HCCC. In March 2009, Dana McCaffery, aged 32 days, died of complications arising from pertussis. The McCafferys live only a few kilometres from the AVN's headquarters and in a region where 33% of children are not fully vaccinated,³² 8% of the population are registered vaccination "conscientious objectors" (national average 1.5%) and between 9.9% and 10.7% of children born between January 2003 and December 2008 have received no recorded vaccines (national average 3.1%).³³ A coverage rate of 90% or more is considered necessary to afford strong herd immunity.³⁴

²⁷ Australian Health Practitioner Regulation Agency, Chinese Medicine Board, "New Legal Requirements Apply to Chinese Medicine Practitioners from 1 July", *Media Release* (19 April 2012), <u>http://www.chinesemedicineboard.gov.au/News/2012-04-18-Media-release.aspx</u> viewed 22 May 2012.

 $^{^{28}}$ The extent to which a chiropractor, who honestly provides information consistent with the (contested) basis of their discipline, can be taken to have provided inaccurate advice (and thus engaged in professional misconduct) is beyond the scope of this article. However, cf the statement of the Chiropractic Tribunal of New South Wales in *Health Care Complaints Commission v Eather (No 2)* [2011] NSWCHT at [7] that "The trust placed in chiropractors is analogous to that placed in medical practitioners because of the necessity for the patient to come into close physical contact with the practitioner and frequently to disclose highly personal information to the chiropractor in the course of treatment".

²⁹ Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [2].

³⁰ Ms Dorey has characterised Mr McLeod's interest in the work of the AVN as "obsessive": AVN, "V is for Vendetta" (29 April 2012), <u>http://www.avn.org.au/2012/04/v-is-for-vendetta-no-compulsory-vaccination</u> viewed 21 May 2012.

³¹ Evans L (HCCC investigator), *Investigation Report Regarding the Australian Vaccination Network / Ms Meryl Dorey* (File No 09/01695 & 10/00002) (7 July 2010) p 2 (emphasis in original) (Investigation Report), <u>http://www.stopavn.com/documents/HCCC-Report.pdf</u> viewed 21 May 2012.

³² Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [54].

³³ Hull B, Dey A, Mahajan D et al., "Immunisation Coverage Annual Report, 2009" (2011) 35(2) *Communicable Diseases Intelligence*, Figures 14-18, <u>http://www.health.gov.au/internet/main/publishing.nsf/Content/cdi3502-1</u> viewed 21 May 2012.

³⁴ Hull, Dey, Mahajan et al, n 33.

In addition to alleging misleading and deceptive conduct, the McCafferys also complained about harassment directed towards them by the AVN, its representatives, and members following the death of their daughter.³⁵

The HCCC agreed to investigate the complaints as they "raised significant issues of public health and safety"³⁶ and focused on information set out on the AVN's website as "the website provides the main source of information to members".³⁷ The site was described as a "starting point" for a member of the public seeking information about vaccination.³⁸ An initial challenge to the jurisdiction of the HCCC to investigate the AVN was dismissed by the HCCC.³⁹

The final Investigation Report included a discussion and rebuttal of several statements of the AVN and Ms Dorey, whether made on the AVN's website or in public.⁴⁰ It is clear from the report that the HCCC believed that the AVN and Ms Dorey had made inaccurate statements,⁴¹ misstated research findings or government documents,⁴² failed to acknowledge contrary findings⁴³ or selectively quoted from sources.⁴⁴ Nor was the HCCC persuaded that the current "disclaimer" on the AVN website was satisfactory to "balance" the information on the website. A primary reason was that it "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".⁴⁵ In reaching this conclusion, the HCCC contrasted AVN's statement with those of other sites about vaccination organised with close involvement of registered health professionals: Vaccination Information South Australia, Vaccination News, Vaccine Awareness Network and Vaccination Risk Awareness Network.⁴⁶

In the absence of a clear disclaimer on the AVN's website and the anti-vaccination stance of the organisation, the HCCC upheld the complaint and made the following recommendation under s 42 of the Act (the Recommendation):

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

- 1. 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 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.⁴⁷

³⁵ Investigation Report, n 31, p 3. See also Cannane S, "Anti-vaccine Group Accused of Harassing Parents", ABC News online (13 July 2010), <u>http://www.abc.net.au/news/2010-07-12/anti-vaccine-group-accused-of-harassing-parents/901904</u> viewed 21 May 2012.

³⁷ Investigation Report, n 31, p 4.

³⁶ Investigation Report, n 31, p 3; Health Care Complaints Act 1993 (NSW), s 23(1)(b)(i).

³⁸ Investigation Report, n 31, p 4.

³⁹ Investigation Report, n 31, p 3.

⁴⁰ Investigation Report, n 31, pp 5-23.

⁴¹ For example, Investigation Report, n 31, pp 5, 22.

⁴² For example, Investigation Report, n 31, pp 7, 8, 22.

⁴³ For example, Investigation Report, n 31, pp 9-11, 22. "Ms Dorey submitted that it is not necessary to include complete information from articles that are linked to the AVN website, because a reader can access the full publication and read it for themselves" (p 11).

⁴⁴ For example, Investigation Report, n 31, pp 7, 8, 22.

⁴⁵ Investigation Report, n 31, p 25.

⁴⁶ Investigation Report, n 31, pp 22-24.

⁴⁷ Investigation Report, n 31, p 25.

The HCCC refused Mr McLeod's request to issue a prohibition order under Div 6A of the Act against Ms Dorey personally, as it was not convinced that the *Code of Conduct for Unregistered Health Practitioners* applied to Ms Dorey or, in the event that it did, that she had breached it.⁴⁸

The AVN did not implement the HCCC's recommendation and, on 26 July 2010, the HCCC issued the following public warning on its own website pursuant to s 94A of the Act (the Public Warning):

The AVN's failure to include a notice on its website of the nature recommended by the Commission may result in members of the public making improperly informed decisions about whether or not to vaccinate, and therefore poses a risk to public health and safety.⁴⁹

The Investigation Report and Public Warning were subsequently relied upon by the Minister for Gaming and Racing in an unrelated decision to revoke the AVN's fundraising licence issued under the *Charitable Fund Raising Act 1991* (NSW).⁵⁰

AVN'S APPEAL TO THE NEW SOUTH WALES SUPREME COURT

Following the Public Warning, AVN appealed to the New South Wales Supreme Court seeking a declaration that the HCCC's investigation, the Investigation Report, Recommendation and Public Warning were ultra vires on the ground that "neither of the complaints were a complaint within the meaning of the Act": see *Australian Vaccination Network Inc v Health Care Complaints Commission* [2012] NSWSC 110 at [5]. It also sought an order "in the nature of certiorari" to quash the HCCC's Public Warning and to overturn the decision to revoke its fundraising status (at [5]).

Argument before a single justice of the Supreme Court focused on the proper construction of the Act, and involved a discussion of fundamental principles of statutory interpretation. As the application of the Act depended on the AVN being a "health service provider" within the meaning of the Act, it is useful to set out some background about the AVN and the HCCC.

The Australian Vaccination Network

The AVN (originally named the Australian Council for Immunisation) (at [1]) is an incorporated association, formed in 1994 and based in northern New South Wales (at [1], [54]), although its presence on the internet and notoriety gives it a much broader public profile.⁵¹ For example, its president Ms Meryl Dorey recently delivered an address on vaccination at a popular music festival.⁵² According to the constitution of the AVN, the purpose of the association includes:

- (a) the advancement and promotion of education and learning amongst the public about all matters concerning human health and human physical and social well-being;
- (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.⁵³

This overarching purpose is distilled in the AVN's *Code of Ethics*, which is "binding on all AVN Office Bearers and such Members of the Committee".⁵⁴ Relevantly, the *Code of Ethics* states the mission of the AVN as:

⁴⁸ Investigation Report, n 31, pp 25-27.

⁴⁹ Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [3].

⁵⁰ Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [4].

⁵¹ Cannane, n 35.

⁵² Dunlop R, "Meryl Dorey at Woodford Folk Festival: A Hazard to Your Child's Health?", *The Conversation* (13 December 2011), <u>http://www.theconversation.edu.au/meryl-dorey-at-woodford-folk-festival-a-hazard-to-your-childs-health-4678</u> viewed 21 May 2012.

⁵³ Australian Vaccination Network Inc, *Model Rules*, <u>http://www.avn.org.au/wp-content/uploads/2012/04/ModelRulesNew.pdf</u> viewed 21 May 2012.

⁵⁴ AVN, *Code of Ethics Management Committee* (1998, modified 2008), <u>http://www.avn.org.au/wp-content/uploads/2012/04/</u> <u>Code-of-Ethics-Updated.pdf</u> viewed 21 May 2012.

- 1. To encourage all families to be fully informed with regards to medical procedures in general vaccination specifically enabling the [sic] to make educated decisions.
- 2. Making available the experience of families (with their permission) and the results of research to Members of the Association and to other interested persons and associations.
- 7. Encouraging State and Federal Governments to record the necessary vaccination information ... These records include:
 - (1) Monitoring the vaccination status of those contracting "vaccine preventable" diseases.
 - (2) Compulsory reporting, recording and investigation of possible vaccine reactions.
 - (4) Maintenance of a national toll-free number for parents and health professionals to report suspected adverse vaccine and drug reactions. These reactions are to be investigated by an independent panel which includes consumer representatives as the primary stakeholders.
 - (6) A new government committee to be set up to review all new vaccine licenses [sic]; this committee to include stakeholders from consumer groups such as the AVN.
 - (7) New legislation to be introduced in every State of Australia to guarantee that no child or adult can be discriminated against as a result of their vaccination status and that no school, preschool, childcare centre or employer can require vaccination for any reason.

10. Challenging media articles that give misleading information to the public.

11. Dealing with any and all threats to the AVN's ability to protect and inform the Australian public.⁵⁵

Office bearers and committee members are expressly reminded that "we cannot tell the parent to vaccinate or not to vaccinate their children or themselves", nor can they "give medical advice".⁵⁶ Practical advice to parents is provided on the AVN's "What you need to do" page, where they recommend:

Once you have read through this information [Product Information sheets on vaccines], *make a list of questions* that cover your concerns with vaccination. Ask your GP or clinic sister these questions. Then, ask a natural therapist and/or the AVN those same questions. Once you have gotten answers ... you will have the confidence to know that you've done the best possible thing by your precious child.⁵⁷

Even assuming that representatives of the AVN do not push an "anti-vaccination" view, the provision of information to parents about medical risks and therapeutic products with a view to influencing their decision to vaccinate would appear to constitute the "giving" of medical advice, contrary to the AVN's *Code of Ethics*. In any event the provision of health information could render them amenable to the jurisdiction of the HCCC.

The Health Care Complaints Commission

Responsibility for regulating the behaviour and conduct of health practitioners and health providers is fragmented in Australia, with State, national and professional bodies all exercising control over health care providers.⁵⁸ The introduction of a "national law" for health practitioners has had some success in improving the sharing of information between professional councils, albeit with some early problems.⁵⁹ There remains, however, the challenge of providing members of the public with a single avenue for lodging a complaint against a health service provider from whom they may not be receiving any treatment. Some jurisdictions have enacted laws in an attempt to ease this process.

⁵⁵ AVN, Code of Ethics Management Committee, n 54.

⁵⁶ AVN, Code of Ethics Management Committee, n 54.

⁵⁷ AVN, What You Need to Do (6 April 2012) (emphasis in original), <u>http://www.avn.org.au/making-an-informed-choice/what-you-need-to-do</u> viewed 21 May 2012.

⁵⁸ See generally the range of bodies the Australian Health Practitioner Regulation Agency (AHPRA) support: AHPRA, *What We Do*, <u>http://www.ahpra.gov.au/About-AHPRA/What-We-Do.aspx</u> viewed 22 May 2012.

⁵⁹ Parliament of Australia, Senate Finance and Public Administration Committee, *Report of the Inquiry into the Administration of Health Practitioner Registration by the Australian Health Practitioner Regulation Agency (AHPRA)* (2011), <u>http://www.aph.gov.au/Parliamentary Business/Committees/Senate_Committees?url=fapa_ctte/health_practitioner_registration/report/index.htm</u> viewed 22 May 2012.

- In New South Wales, the HCCC is responsible for:
- (a) receiving and assessing complaints ... relating to health services and health service providers in New South Wales, and
- (b) investigating and assessing whether any such complaint is serious and if so, whether it should be prosecuted, and
- (c) prosecuting serious complaints, and
- (d) resolving or overseeing the resolution of complaints.⁶⁰

In exercising its functions under the *Health Care Complaints Act 1993* (NSW), the HCCC must hold the "protection of the health and safety of the public" as its "paramount consideration".⁶¹ The HCCC must notify the relevant professional council of any complaint made "against or directly involving" a registered (or formerly registered) health professional as soon as practicable.⁶² Generally, an HCCC investigation will be accorded priority over an inquiry by a professional body,⁶³ although the Act does allow a professional body to take appropriate action to "protect the life or the physical or mental health of any person".⁶⁴

Under s 7 of the Act, a complaint can be made to the HCCC concerning:

(1) ...

- (a) the professional conduct of a health practitioner ..., or
- (b) a health service which affects the clinical management or care of an individual client.
- (2) A complaint may be made against a health service provider.⁶⁵

A "health service provider" means a person who provides a health service "being a health practitioner or a health organisation".⁶⁶ In typically circular drafting, a "health organisation" is defined as a body (not being a health practitioner) that provides a health service. Importantly, the definition of "health service" is expansive and includes, inter alia, the provision of the following services:

- (a) medical, hospital and nursing services,
- (d) pharmaceutical services,
- (f) community health services,
- (g) health education services,⁶⁷

Section 8 of the Act sets out a non-exclusive list of people who can make a complaint to the HCCC, including "the client concerned", "a parent or guardian of the client concerned" or "a member of parliament". While s 8 states that "a complaint may be made by any person", it is significant that "a member of the public" is not included in the list of examples.

The parties to the proceedings accepted (and the court agreed) that as "vaccination is a matter about health ... [the] provision of information about vaccination is a health education service" (at [10], [43]). Consequently, it was accepted that the AVN could be characterised as a "health service provider" for the purpose of the Act.⁶⁸

However, the central issue before the court was whether the complaints lodged by Mr McLeod and the McCafferys were "complaints" for the purpose of s 7 of the Act, such as to enliven the power

⁶⁷ Health Care Complaints Act 1993 (NSW), s 4.

⁶⁰ Health Care Complaints Act 1993 (NSW), s 3(1).

⁶¹ Health Care Complaints Act 1993 (NSW), s 3(2).

⁶² Health Care Complaints Act 1993 (NSW), s 10.

⁶³ Health Care Complaints Act 1993 (NSW), s 14(1).

⁶⁴ Health Care Complaints Act 1993 (NSW), s 14(2).

⁶⁵ *Health Care Complaints Act 1993* (NSW), s 7 (emphasis added). "Client" is defined broadly by s 4 of the Act and means "a person who uses or receives a health service, and includes a patient". A complaint can also be lodged against an unregistered health practitioner (s 7(3)).

⁶⁶ Health Care Complaints Act 1993 (NSW), s 4.

⁶⁸ The court agreed with the parties on this point: Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [10], [30], [43].

of the HCCC to commence an investigation,⁶⁹ jurisdiction over which is "conditioned on the existence of a 'complaint' within the Act".⁷⁰ The AVN sought to confine "complaints" to those arising under s 7(1)(a) or (b) of the Act. Conversely, the HCCC believed its jurisdiction extended to complaints raised under s 7(1)(a), (b) and 7(2), with the latter providing a broader power to investigate a complaint "against" a health service provider.

Counsel for the AVN submitted that only a complaint concerning the matters outlined in s 7(1)(b) provided jurisdiction for the HCCC to investigate a health service provider such as the AVN. On this basis, the AVN advanced that the two complaints did not fall within s 7(1)(b) of the Act, as the "health service" provided by the AVN "did not affect the clinical management or care of an individual client" (at [22]). It was contended that, for a complaint to validly fall under s 7(1)(b), the health service "must actually influence an individual". Furthermore, the AVN submitted (at [25]) that the phrase "clinical management or care" in s 7(1)(b) was limited by the traditional understanding of "clinical" as importing

an element of clinical judgment, which in turn would carry with it the requirement of some knowledge or understanding on the part of the health service provider of the client's personal circumstances and needs, and consideration by such a provider as to how the intended supply of the health service would affect those personal circumstances.

AVN argued that, as it had no direct contact with a visitor to its website, it could not have "affected" the clinical management or "clinical care" of that individual.⁷¹ The HCCC objected to this narrow interpretation of s 7(1)(b) and, furthermore, argued that the complaint was accepted as a valid complaint pursuant to s 7(2) of the Act.

The AVN rejected the HCCC's contention that s 7(2) provided an additional category of complaints arguing that it simply clarified the meaning of s 7(1). The HCCC argued (at [30]) that this interpretation, if accepted, would leave s 7(2) with "no work ... to do" and would undermine a chief principle of statutory interpretation, namely, that "all words are to be given some meaning and effect".⁷²

Furthermore, the HCCC argued (at [34]) that if the narrow reading of "affect the clinical management or care" proposed by the AVN was adopted, then:

it [would be] difficult to see how a health education service could ever be said to "affect" the clinical management or care of an individual client and therefore be the subject of a complaint under s 7 since, by definition, a health education service will be from the actual provision of clinical management or care.

The HCCC proposed (at [44]) that "clinical management or care" could appropriately cover the scenario of "a cohort of persons reading [the AVN's] website and taking its contents into account in deciding whether to vaccinate their children". The court proffered a third interpretation during the hearings in which "clinical management or care" could extended to non-clinical settings where, eg, a mother relied on information on the website in the *care* of their child (at [27]). In this event, AVN might "affect" the care of a client, even if the AVN had "neither knowledge nor understanding of the particular circumstances of the mother or the child and notwithstanding that [the information on its website] might be regarded as 'information' rather than 'advice'" (at [27]).

FINDINGS OF THE SUPREME COURT

Ultimately, the Supreme Court was not persuaded by the HCCC's arguments and found in favour of the plaintiff, declaring that the two complaints were not "complaints" for the purpose of the Act and

⁷² Project Blue Sky Inc v Australian Broadcasting Authority (1998) 194 CLR 355 at 381 (McHugh, Gummow, Kirby and Hayne JJ).

⁶⁹ Whether under Pt 2, Div 5 or s 59 of the Health Care Complaints Act 1993 (NSW).

⁷⁰ Awad v Health Care Complaints Commission [2006] NSWSC 698 at [92] (Hall J), cited with approval in Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [7].

⁷¹ The AVN advanced the argument that "clinical management or care" should be read as "clinical management or *clinical* care", thus importing the same qualification on the term "care": *Australian Vaccination Network Inc v Health Care Complaints Commission* [2012] NSWSC 110 at [25].

that the subsequent investigation, Investigation Report, Recommendation and Public Warning were invalid for want of jurisdiction (at [69]).⁷³ The court rejected the submission that s 7(2) is an alternative source of jurisdiction to that provided under s 7(1), finding (at [40]):

on a reading of the Act as a whole,^[74] Parliament ought be taken to have intended that the HCCC be empowered only to deal with certain types of complaints, being the complaints concerning the subject matters specified in s 7(1).

Moreover, the court agreed (at [45]) that s 7(1)(b) was limited to complaints "concerning a health service that has a concrete (even if indirect) effect on a particular person or persons". It dismissed the HCCC's scenario of an individual being influenced by the contents of the website of a health service provider, finding (at [44]):

Had Parliament intended complaints regarding the contents of such websites to be covered by s 7(1)(b), it would, in my view, have used broader words. It might, in that instance, have provided for complaints "concerning a health service that affects medical decisions made by clients of the health service".

The court was not convinced that Parliament had intended the HCCC to investigate complaints about the actions of health services "that have a tendency to affect a person or group, but which cannot be shown to have had an effect" (at [45]). Moreover, if Parliament had sought to regulate conduct that has a "particular tendency, rather than having an actual effect", it could have modelled the Act on provisions of the *Australian Consumer Law* which prohibit "conduct that is misleading or deceptive or is likely to mislead or deceive" (at [46]).⁷⁵

A key weakness in the HCCC's case was that neither of the complaints could show that the AVN had affected the clinical management or care of themselves, or a "client". That they were concerned citizens was not sufficient to give their complaint the necessary standing (at [59]). That the AVN's website might have the tendency to affect the decision of an unknown party was also not sufficient, even if the AVN desired its website to have such an effect (at [59]).

CONSEQUENCES FOR FREEDOM OF EXPRESSION AND WHISTLEBLOWING

As a result of the court's decision, it is clear that the absence of an "affected" "client" will drastically curtail the HCCC's ability to investigate complaints against health service providers, especially those engaged in the provision of "health education". Notwithstanding the findings of the court, it is doubtful that Parliament anticipated such organisations would be excluded from the HCCC's oversight. Indeed, the imperative for the HCCC to consider the "protection of the health and safety of the public" as its foremost objective suggests a broader remit for the HCCC than the court allowed. A broader reading of s 7(1)(b) and 7(2) would have furthered the protective purpose to which the Act was directed.

The effect of this decision on future complaints remains unclear; however, it is possible that potential whistleblowers may be discouraged from disclosing conduct which places the public at risk in the absence of an "affected client" willing to come forward. For some conduct, such as "phantom billing" or poor corporate governance, it may be difficult to identify an "affected client". While the "exoneration from liability" afforded to a person "making" a good-faith complaint, or "reporting any matter or thing that could give rise to a complaint", might not depend on the existence of a valid "complaint" under the Act, the risk of civil litigation if the complaint does not satisfy s 7(1)(b) may still discourage disclosure.

 $^{^{73}}$ The court, however, refused to grant certiorari against the decision of the Minister for Gaming to revoke the AVN's fundraising licence: *Australian Vaccination Network Inc v Health Care Complaints Commission* [2012] NSWSC 110 at [66]-[67].

 $^{^{74}}$ And, in particular, the functions conferred on the HCCC by s 80 of the *Health Care Complaints Act 1993* (NSW): Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [40].

⁷⁵ See s 18 of the Australian Consumer Law set out at Sch 2 of the Competition and Consumer Act 2010 (Cth).

Nonetheless, the decision points to steps which Mr McLeod, the McCafferys or even the HCCC could take to successfully address the perceived risk of the AVN. First, as the court suggests,⁷⁶ the parties could identify a client "affected" by the information on the AVN's website. For example, a complaint could be lodged by or on behalf of a mother who decided not to immunise their child on the basis of the following AVN assertion:

Unlike vaccination (which offers only temporary immunity), the natural occurrence of each of these diseases (measles, mumps and rubella) (all non-threatening illnesses in early childhood) generally results in lifelong immunity.⁷⁷

This, however, may not address the AVN's argument that "clinical" should be given a narrow interpretation and exclude complaints against providers not in a position to know or understand the client's individual circumstances.

Secondly, any person (including the complainants) could bring an action against the AVN alleging deceptive and misleading conduct contrary to s 18 of the *Australian Consumer Law*. In a previous and unrelated case, the AVN accepted that, in relation to some of its activities at least, it was engaged in trade or commerce.⁷⁸ Such a suit would not require a plaintiff to establish that "any actual or potential consumer has taken or is likely to take any positive step in consequence of the misleading or deception".⁷⁹

Finally, the parties could lobby Parliament to amend s 7 of the Act to clarify that both s 7(1) and 7(2) confer a power to investigate complaints against health providers. Alternatively, Parliament could amend the Act to broaden the definition of "clinical" or "care" or to allow the HCCC to investigate complaints under s 7(1)(b) where there is a mere tendency for the conduct to affect *a* client. The court even suggested language for such a reform (at [44]).

However, the current authors do not support legislative reform of the HCCC in the manner proposed above or by the court. In a free society, the views and opinions expressed by Ms Dorey and the AVN should be protected against government interference. Arguments against public immunisation programs are not simply debates over health policy; they are also political discussions. As such, the AVN's website, and Ms Dorey's statements, ought to be protected from interference by Parliament or the Executive by the implied constitutional right of political communication.⁸⁰

Moreover, freedom of expression is an essential human right, protected under international and domestic human rights instruments,⁸¹ and should not be abridged except in the most limited of circumstances, such as a major pandemic.⁸² It would be inappropriate for a government agency to be given a standing mandate to censor debate or force an individual to include a statement on their website with which they do not agree. If the misleading information of the AVN is to be challenged, then it should be through the better dissemination of accurate information and the proper management of rare adverse events following immunisation.

⁷⁶ Australian Vaccination Network v Taycare [2004] FMCA 625 at [60].

⁷⁷ Australian Vaccination Network v Taycare [2004] FMCA 625 at [36].

⁷⁸ Australian Vaccination Network v Taycare [2004] FMCA 625 at [1].

⁷⁹ Taco Co of Australia Inc v Taco Bell Pty Ltd (1982) 42 ALR 177 at 199 (Deane and Fitzgerald JJ), cited in Australian Vaccination Network Inc v Health Care Complaints Commission [2012] NSWSC 110 at [47].

⁸⁰ Lange v Australian Broadcasting Corp (1997) 189 CLR 520; Australian Capital Television Pty Ltd v Commonwealth (1992) 177 CLR 106; Nationwide News Pty Ltd v Wills (1992) 177 CLR 1. This column does not suggest that private action under the Australian Consumer Law or negligence would necessarily be an inappropriate interference with free speech, as the public interest in protecting such speech would be one factor for a court to consider either in establishing liability or awarding damages.

⁸¹ For example, Art 19(1), (2) of the *International Covenant on Civil and Political Rights* (1980) ATS 23, opened for signature 16 December 1966, entered into force in Australia 13 November 1980 (except Art 41); s 15 of the *Charter of Human Rights and Responsibilities Act 2006* (Vic); s 16 of the *Human Rights Act 2004* (ACT).

⁸² Indeed, the right can be limited (under the ICCPR and the Victorian Charter) "for the protection of national security, public order, public health or public morality".

CONSEQUENCES FOR PUBLIC VACCINATION

Despite the media attention secured by groups such as the AVN, the Australian community almost universally accepts childhood immunisation programs. As shown above, only 1.5% of the population are registered as vaccination "conscientious objectors", although in some areas this figure rises to 8%. Low coverage rates are therefore more likely the result of traditional health determinants: socio-economic status, family size and distance from health services.⁸³ A better use of government health resources would, therefore, be to address these known barriers to accessing health care, rather than pursuing a minority who – in many cases – are afforded protection by the vaccinated community within which they reside.

Nonetheless, it is vital that governments, and health agencies, promote the benefits of vaccination, while also addressing public concerns provoked by media reports of adverse events attributed (rightly or wrongly) to vaccines.

In the course of any widespread medical intervention, adverse events or "adverse events following immunisation" occur and, occasionally, these adverse events result in temporary or permanent disability.⁸⁴ Unless these rare cases are treated in an appropriate manner, they can undermine support for public vaccination programs and provide support for those who run an anti-vaccination message. For instance, following several cases of febrile convulsions in children under five, associated with the Commonwealth Serum Laboratories' (CSL) FluvaxTM vaccine for seasonal influenza, WA Health suspended its program.⁸⁵ Media coverage at the time was critical of the timeliness of the WA Health and the Australian Government's response,⁸⁶ and the relationship between the Australian Government and CSL.⁸⁷ A "warning letter" from the United States Food and Drug Administration (FDA) critical of CSL's manufacturing standards compounded the stigma against Fluvax, and influenza vaccines generally, despite being issued a year after the event.⁸⁸ Media interest in this incident continues, with one family commencing legal action against CSL and the Western Australian Government.⁸⁹

Despite the overall low incidence of adverse events following immunisation for the seasonal influenza program generally, the ongoing scepticism towards the program is likely to have a negative impact on its effectiveness in the foreseeable future.⁹⁰ This is despite the fact that 20% to 40% of children are infected with influenza in a typical season, with the highest incidence in children under

⁸³ McIntyre P, Williams A and Leask J, "Refusal of Parents to Vaccinate: Dereliction of Duty or Legitimate Personal Choice?" (2003) 178 MJA 150; Barbaro B, Brotherton JML and Gertig DM, "Human Papillomavirus Vaccination and Cervical Cancer Screening by Socioeconomic Status, Victoria" (2012) 196(7) MJA 445.

⁸⁴ For example, paralytic disease from live polio vaccines or intestinal obstruction from early rotavirus vaccines: Campion, n 1.

⁸⁵ "Parents Hammer Hotline as 250 Adverse Flu Jab Reactions Reported", *The Australian* (27 April 2010), <u>http://www.perthnow.com.au/news/parents-hammer-hotline-as-250-adverse-flu-jab-reactions-reported/story-e6frg12c-1225858626065</u> viewed 15 May 2012; Tomson C, "Flu Vaccination Ban Goes National After Fever, Convulsions in Children", *WA Today* (23 April 2010), <u>http://www.watoday.com.au/wa-news/flu-vaccination-ban-goes-national-after-fever-convulsions-in-children-20100423-tglp.html</u> viewed 15 May 2012.

⁸⁶ The Australian Government conducted two reviews into the 2010 paediatric influenza vaccination program: Horvath J, *Review of the Management of Adverse Events Associated with Panvax and Fluvax* (Australian Government, Canberra, 2011); Therapeutic Goods Administration, "Investigation into Febrile Reactions in Young Children Following 2010 Seasonal Trivalent Influenza Vaccination" (2 July 2010, updated 24 September 2010), <u>http://www.tga.gov.au/pdf/alerts-medicine-seasonal-flu-100702.pdf</u> viewed 15 May 2012.

⁸⁷ Anderson B, "Government 'Too Cosy With Flu Vaccine Maker", ABC News Online (5 May 2010), <u>http://www.abc.net.au/news/2010-04-28/government-too-cosy-with-flu-vaccine-maker/413860</u> viewed 15 May 2012. The relationship between vaccine sponsor and governments is also explored in Colgrove J, Abiola S and Mello MM, "HPV Vaccination Mandates – Lawmaking Amid Political and Scientific Controversy" (2010) 363(8) NEJM 785 at 788-789.

⁸⁸ Malarkey MA (FDA), Warning Letter to CSL Biotherapies (15 June 2011), <u>http://www.fda.gov/ICECI/EnforcementActions/</u> WarningLetters/ucm259888.htm viewed 15 May 2012.

⁸⁹ Evans N, "Vaccine Family to Sue CSL Over Botched Flu Shots", *PerthNow* (23 June 2011), <u>http://www.perthnow.com.au/</u> <u>business/business-old/vaccine-family-to-sue-csl-over-flu-shots/story-e6frg2qu-1226080802868</u> viewed 15 May 2012.

⁹⁰ AAP, "Flu Vaccine with Side-effects Used Again", *WA Today* (16 February 2012), <u>http://www.watoday.com.au/national/flu-vaccine-with-sideeffects-used-again-20120216-1tafj.html</u> viewed 15 May 2012.

the age of two (who often require hospitalisation).⁹¹ Some have suggested the introduction into Australia of a no-fault compensation scheme for adverse events following immunisation, to minimise community objection to vaccination and to ensure "redistributive justice" for an injured party.⁹²

It would be wrong, however, to dismiss the "anti-vax" movement as Western vanity born of complacency. In developing countries, rumours over the motives of polio vaccination programs funded by the United Nations have hindered the eradication of the virus in some countries.⁹³ Attempts to rebuild confidence and trust have recently been undermined by the revelation that the United States Central Intelligence Agency (CIA) recruited Dr Shakeel Afridi to conduct a fake immunisation drive in Pakistan under the cover of humanitarian work. This work was part of the CIA's efforts to collect DNA evidence establishing Osama bin Laden's whereabouts.⁹⁴ Pakistan remains one of the four reservoirs of wild polio in the world and the CIA's efforts have reportedly led to significant hardship for the charity responsible for dispensing polio and other vaccines in the country.⁹⁵ Rather than denouncing this conduct (that undermines the foreign aid and health policy of the United States), politicians have introduced a Bill that would grant Dr Afridi United States citizenship.⁹⁶

Nonetheless, the refusal of parents to vaccinate their children can place their child at risk, and jeopardise the safety of members of the community (such as Dana McCaffery) who are too young to be vaccinated. While an adult, or competent young person, is presumed to be entitled to refuse medical treatment (whether life-saving or not), what obligations does a parent owe to an infant or young child who cannot consent to medical treatment on their own? Moreover, what responsibility does an intentionally unvaccinated individual owe to the community?

Human rights instruments afford special protection to the "family",⁹⁷ and so the legal starting point for decisions about vaccination is that "the united view of both parents is correct in identifying the child's welfare".⁹⁸ However, this does not mean that the question to be answered is whether the state's interest in vaccination outweighs the "right" of the parent to raise their child according to their wishes. Rather, in matters affecting the child, the child's rights outweigh both those of the state and their parents.⁹⁹ As such, the proper determination is what is in "the best interests of the child", having appropriate regard to the views of the parents. In keeping with the common law's concepts of the responsibilities of strangers¹⁰⁰ and biomedical ethics,¹⁰¹ the interest of the community in maintaining a high immunisation rate should never override the right of an individual to consent to medical

⁹¹ Isaacs D, "Should All Australian Children be Vaccinated Against Influenza?" (2005) 182(11) MJA 553.

⁹² Kelly HA, Looker C and Isaacs D, "A No-fault Compensation Scheme for Serious Adverse Events Attributed to Vaccination" (2011) 195(1) MJA 4.

⁹³ WHO, UNICEF and World Bank, n 1, p 137.

⁹⁴ Elliott F, "Pakistan Chains Spy Who Found Bin Laden", *The Australian* (2 May 2012), <u>http://www.theaustralian.com.au/</u>news/world/pakistan-chains-spy-who-found-bin-laden/story-fnb64oi6-1226344074916 viewed 15 May 2012.

⁹⁵ Crilly R, "Save the Children Pakistan Chief Under Pressure After 'Fake CIA Vaccination' Campaign", *The Telegraph* (3 May 2012), http://www.telegraph.co.uk/news/worldnews/asia/pakistan/9243243/Save-the-Children-Pakistan-chief-under-pressure-after-fake-CIA-vaccination-campaign.html viewed 15 May 2012.

⁹⁶ United States, HR 3901, 112th Congress (2nd Session), 2012, Mr Rohrabacher, "A Bill for the Relief of Dr Shakeel Afridi".

⁹⁷ For example, *Human Rights Act 2004* (ACT), s 11.

⁹⁸ McIntyre, Williams and Leask, n 83.

⁹⁹ Article 3 of the *Convention on the Rights of the Child* (1991) ATS 4, opened for signature 20 November 1989 (NY), entered into force in Australia 16 January 1991: "In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration." See also s 60CA of the *Family Law Act 1975* (Cth): "In deciding whether to make a particular parenting order in relation to a child, a court must regard the best interests of the child as the paramount consideration."

¹⁰⁰ Stovin v Wise [1996] AC 923 at 931 (Nicholls LJ); Stuart v Kirkland-Veenstra (2009) 237 CLR 215.

¹⁰¹ See eg National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee, *National Statement on Ethical Conduct in Human Research* 2007, esp Ch 2.2.

experimentation or treatment.¹⁰² However, it is not a necessary corollary to this principle that the community cannot exclude a non-vaccinated individual where necessary to prevent injury to others or to the child in question (eg during a measles outbreak at a school or to exclude an unvaccinated visitor from visiting a house with young children).¹⁰³

As vaccination does not usually constitute "life-saving" treatment, it may be reasonable for a parent to refuse to vaccinate their child.¹⁰⁴ Factors weighing in favour of a parent's decision to refuse to vaccinate their child would include the nature of the disease (seasonal influenza as opposed to rabies), the views of the other parent or child,¹⁰⁵ and the likelihood of the unvaccinated child contracting the disease. In Australia, if the mother is a carrier of a vaccine-preventable disease, the courts have been willing to intervene to order the vaccination of her child against the particular condition only.¹⁰⁶

CONCLUSION

Of course, if even a minority of parents decided to stop vaccinating their children, the community would suffer from a significant decrease in herd immunity. And, as immunisation from many vaccine-preventable diseases wanes over time, the incidence of these diseases would increase. Should such outbreaks reach "epidemic" levels, the Governor-General can "declare the existence in [a location] of that epidemic or of the danger of that epidemic" under the *Quarantine Act 1908* (Cth).¹⁰⁷ Once an epidemic is declared, the Minister for Health is authorised to "give such directions and take such action as he or she thinks necessary to control and eradicate the epidemic, or to remove the danger of the epidemic, by quarantine measures or measures incidental to quarantine".¹⁰⁸ Failure to comply with a direction is punishable by 10 years imprisonment,¹⁰⁹ and the Minister's power to give a "direction" is not restricted by "any other Commonwealth law, or of any law of a State or Territory".¹¹⁰ Quarantine measures include:

- (i) the examination, exclusion, detention, observation, segregation, isolation, protection, treatment and regulation of vessels, installations, human beings, animals, plants or other goods or things; or
- (ii) the seizure and destruction of animals, plants, or other goods or things; or
- (iii) the destruction of premises comprising buildings or other structures when treatment of these premises is not practicable.¹¹¹

The scope of the quarantine power, in relation to humans, has not been properly tested in the High Court although, like the defence power, it is assumed to be a broad head of power, limited only to considerations of what a particular circumstance involves. As a pandemic could lead to the temporary closure of parliaments, courts and other bodies of review and redress, the imposition of quarantine on

¹¹⁰ Quarantine Act 1908 (Cth), s 2B(2B).

¹⁰² Compare the experience of the British *Vaccination Act 1853*, which "made smallpox vaccination compulsory for all infants in the first three months of life, on pain of fine or imprisonment". Its passage "spawned riots in several towns and an active anti-vaccination movement": McIntyre, Williams and Leask, n 83.

¹⁰³ McIntyre, Williams and Leask, n 83.

¹⁰⁴ McIntyre, Williams and Leask, n 83. An exception is post-exposure vaccination against rabies.

¹⁰⁵ For example, "in the case of the human papilloma virus, the risk of contracting the virus depends on the behaviour of the child. Moreover, the vaccine is delivered at an age where the views of the child should be given equal (if not greater) weight than their parents": Massey PD and Durrheim DN, "Universal Human Papilloma Virus of Australian Boys – Neither Cost-effective Nor Equitable" (2012) 196(7) MJA 446 (letters); Isaacs, n 91.

¹⁰⁶ Director-General, Department of Community Services; Re Jules [2008] NSWSC 1193, although in this case the child was taken into hiding by the parents and the Department was unable to administer a vaccine in time. However, the court did not dispute its ability to "authorise" treatment of a child under its parens patriae jurisdiction (at [14]-[15], Brereton J); Re H [2011] QSC 427.

¹⁰⁷ Quarantine Act 1908 (Cth), s 2B(1). See also s 12A.

¹⁰⁸ Quarantine Act 1908 (Cth), s 2B(2).

¹⁰⁹ Quarantine Act 1908 (Cth), s 2B(3).

¹¹¹ Quarantine Act 1908 (Cth), s 4(1)(a).

any individual or community is likely to be far more harmful to human rights and liberties than efforts to encourage immunisation through government grants for practitioners and parents.¹¹²

Public immunisation programs represent one of the greatest achievements of medical science and public health policy. The success of vaccines in reducing infant mortality stands in stark contrast to "evidence" presented by organisations such as the AVN that vaccines place children at risk, offer little long-term benefit or are dispensed by practitioners pursuing financial advantage. More can, and should, be done to properly deal with rare adverse events following immunisation and to reduce the burden of vaccine-preventable diseases in Australian and abroad. However, in their response to organisations critical of vaccination, governments need not resort to laws which limit speech; rather they should themselves speak more and more pointedly in favour of science.

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¹¹² "Funding for the National Immunisation Register and for incentives to general practitioners to improve vaccine uptake are part of the total budget for Australia's vaccine program, estimated to exceed \$400 million annually": Kelly, Looker and Isaacs, n 92.