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

Organisation:	School of Law, Faculty of Business, Government & Law University
	of Canberra
Name:	Asst Professor Bruce Arnold

Position: Assistant Professor

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

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

This submission responds to the Committee's call for public comment on the promotion of false or misleading health-related information or practices.

In summary, false/misleading information and practices has the potential to

- directly affect consumers of that information/practice and
- indirectly result in serious injury to people (particularly children) who are exposed to infections attributable to misleading information disseminated by 'anti-vaccination' advocates or who are dissuaded from engaging with science-based medicine.

it is desirable for the New South Wales Government, through the Council of Australian Governments and health-sector policy and standard-setting bodies, to foster a coherent national regime that deals with the promotion of false or misleading health-related information or practices.

Such a regime involves consistency across jurisdictions, public education, action by regulators such as the Australian Competition & Consumer Commission and Health Care Complaints Commission, and greater engagement by boards under the Australian Health Practitioner Regulation Agency with practitioners who promote false or misleading health-related information and practices.

Strengthening the powers of the Health Care Complaints Commission through the *Health Legislation Amendment Act 2013* (NSW) was appropriate. Protection of consumers in the state should be enhanced through resourcing of the Commission that ensures it is able to give effect to the legislation.

New South Wales has set an example for other governments through statements by ministers and senior officials that address community concerns regarding diagnoses/therapies that have no substantive basis. The Government has also demonstrated that it is prepared to address the promotion of false/misleading information by people who disregard more than a century of empirical data about vaccination and who appear to be indifferent to the harms associated with their propagation of what general practitioners regard as pernicious nonsense.

Investigation by the Health Complaints Commission on an own motion basis or in response to specific complaints does not inappropriately chill free speech. It complements the activity of the Australian Competition & Consumer Commission and the Complaints Resolution Panel under the *Therapeutic Goods Act 1989* (Cth). It offsets weaknesses in the national regime regarding heath products, services and information.

Basis

This submission is made by Bruce Baer Arnold.

I am an Assistant Professor in the School of Law & Justice Studies at the University of Canberra. I teach consumer protection and health law, with a particular interest in questions of regulatory capacity. My writing has appeared in a range of peer-reviewed Australian and international publications, including *Melbourne University Law Review* and *Journal of Medical Ethics*. I have made presentations in a range of fora regarding life-sciences regulation. I am a member of the OECD Health Information Infrastructure working party.

I have no commercial or other relationships that would be reasonably construed as a substantive conflict of interest. I am a member of Friends of Science in Medicine, reflecting the importance of an empirical basis for regulation and policy-making in the health and education sectors.¹

Background

The Commission embodies tensions in law and practice. There are no easy solutions to some of the issues that it, and the Committee, need to address. Both however have a valuable role in fostering public health and should accordingly express community concerns regarding false/misleading information and practice.

The Legal Framework

Australian law respects the autonomy of consumers. It assumes that consumers have some discernment (through the notion of common sense, through community awareness campaigns by government and other entities, and through the primary and secondary school curricula) in making decisions or advising their peers regarding decisions.² It assumes that consumers will differentiate between statements of fact and opinion, and in matters of particular importance will conduct research or seek advice.³ It also recognises that consumers may be misinformed and that governments in particular circumstances should intervene to prevent harm to those individuals or others.⁴

It provides for substantial self-regulation by the professions. It also provides for substantial self-regulation by 'bodies of practice' ⁵ such as chiropractors that seek

¹ This submission is independent of the Friends of Science in Medicine.

² That respect for autonomy and for discernment is evident in both common law and in the Australian Consumer Law, effective in the Commonwealth, states and territories.

³ A useful discussion is found in *Noone, Director of Consumer Affairs Victoria v Operation Smile* (*Australia*) & Ors (No 2) [2011] VSC 153 which deals with action by a Victorian regulator over problematical claims by a health service provider.

⁴ Tim Vines and Thomas Faunce, '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 & Medicine* 44

⁵ I specifically refer to bodies of practice rather than professions because there is substantive disagreement about the diagnostic/therapeutic basis and certification of occupations such as chiropracty, naturopathy, hypnotherapy and homeopathy. The absence of an evidential basis for reiki as a diagnostic practice and for homeopathy as a therapeutic practice was for example highlighted in submissions as part of the Australian Health Ministers Advisory Council 2011 consultation regarding Options for the Regulation of Unregistered

autonomy as professions under for example the *Health Practitioner Regulation* (*Adoption of National Law*) *Act 2009* (NSW) but that may not cover all practitioners and whose practitioner boards may have neither the will nor the resources to effectively discipline members.⁶

It protects the expression of opinion – including opinion that is wrongheaded and repugnant – as a foundation of civil society in a liberal democratic state. However, alongside that protection it restricts the dissemination of statements, particularly in the course of trade or commerce, that are deceptive or likely to result in harm.⁷ It also restricts the dissemination of goods and services that are likely to result in harm, including products that are claimed to have medicinal attributes or result in a well-being that cannot be substantiated through independent scientific testing.⁸

Such restriction is consistent with international law. It reflects what most Australians over the past century have identified as a key role of government. Independent research has consistently demonstrated that there is strong community support for consumer protection. Voters hold that government involvement in the health sector to ensure quality in pharmaceuticals and medical devices is axiomatic.

It is also a given that voters, with rare exceptions, want restrictions on what used to be characterised as 'snake oil' or 'quack medicine', especially where that false or misleading practice is promoted as having a diagnostic/therapeutic value rather the entertainment value associated with for example the ouija board or horoscope found in the mass media.

Put most simply, if the forecast in 'stars' in a tabloid newspaper is incorrect, there is little harm. If someone is persuaded to forego immunization or antiretrovirals or surgery in favour of 'magic touch', homeopathy, nutritional supplements or a green tea diet there are likely to be grave consequences for both that individual and for other people.

Condemnation by government representatives and requirement by the Health Care Complaints Commission for correction of misleading statements is accordingly appropriate. It is desirable that the Committee acknowledge the work of the Commission and encourage its future effectiveness through enhanced resourcing.

The Need for Regulation

Public and private sector entities on occasion fail to meet accepted standards of care in providing products and services, thereby causing transient or ongoing harm to consumers.

Health Practitioners and in the 2010 UK House of Commons Science & Technology Committee *Homeopathy* report.

⁶ From a consumer perspective that regulatory incapacity is of great concern, as the unduly permissive approach of some boards under the AHPRA is likely to result in harm to consumers and to erode the legitimacy of professions where there is meaningful self-discipline.

⁷ That restriction for example encompasses a range of law regarding fraud, vilification of collectives, defamation of individuals and false claims in product labelling.

⁸ The scope for vendors of nutraceuticals to engage in regulatory arbitrage between the Australian Competition & Consumer Commission (ACCC), the Therapeutic Goods Administration (TGA) and Food Standards Australia New Zealand (FSANZ) is of concern.

That failure is evident in litigation over injuries that for example involve work by surgeons and dentists or products such as Thalidomide, defective joint implants, the Dalkon shield, Filshie Clip and PIP breast implants.⁹ It is evident in a succession of major inquiries that acknowledged performance by gatekeepers such as the Therapeutic Goods Administration¹⁰ and Queensland Health Commission¹¹ was inadequate.

It is also evident in action by regulatory bodies such as the Australian Competition & Consumer Commission¹² and the Complaints Resolution Panel regarding the marketing of products that are claimed to have a therapeutic value.¹³ They complement action – by practitioner boards and in the courts – regarding behaviour by practitioners that brings a profession or body of practice into disrepute, ¹⁴ given that disrepute discourages members of the public from seeking diagnoses and therapies that are of benefit to specific individuals and the community at large.¹⁵

The Commission

The work of the Health Care Complaints Commission is important and should be recognised as such by the Committee and the New South Wales Government.¹⁶

It is not work that can be effectively relegated to other agencies or private sector bodies (eg practitioner boards under the AHPRA regime) or subsumed by the Australian Competition & Consumer Commission. It cannot superseded by education, practitioner self-regulation or tort law. From the perspective of national productivity and the burden on the state public/private health systems the Commission represents value for money.

⁹ Wendy Bonython and Bruce Arnold, 'Class Actions and Regulatory Failures – Medical Devices and the TGA' (Current Issues in Civil Justice, Melbourne University) (February 2013) demonstrated that the cost to government and the taxpayer – and to national productivity – of regulatory incapacity regarding breast and joint implants was significantly greater than the budget of the TGA. As a nation we have mismanaged risk; in essence Australia has been 'penny wise and pound foolish'.

¹⁰ The 2011 *TGA Reforms: A Blueprint for the TGA's Future* document for example notes the review to improve the transparency of the Therapeutic Goods Administration, the Auditor-General's report on Therapeutic Goods Regulation, several public consultations on the medical devices regulatory framework, separate public consultations on the regulatory framework for advertising therapeutic goods, an informal working group examining the regulation of complementary medicines and reasons for low compliance rates, the Working Group on Promotion of Therapeutic Products, and the Health Technology Assessment Review. Other examinations include the Senate Community Affairs Reference Committee report on the *Regulatory standards for the approval of medical devices in Australia.*

¹¹ Queensland Public Hospitals Commission of Inquiry, *Queensland Public Hospitals Commission of Inquiry final report* (2005)

¹² The ACCC's powers in relation to the health sector relate to the *Competition & Consumer Act 2010* (Cth).

¹³ The Panel deals with the *Therapeutic Goods Advertising Code*, the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth).

¹⁴ See for example *Chiropractic Board of Australia v Hooper (Review and Regulation)* [2013] VCAT 878; A Practitioner v The Medical Board of Western Australia [2005] WASC 198; HCCC v Peatling [2010] NSWCHT 1.

¹⁵ Julie Leask, Simon Chapman, Penelope Hawe, and Margaret Burgess, 'What maintains parental support for vaccination when challenged by anti-vaccination messages? A qualitative study' (2006) 24(49) *Vaccine* 7238 and Shona Hilton, Mark Petticrew and Kate Hunt, 'Parents' champions vs. vested interests: Who do parents believe about MMR? A qualitative study' (2007) 7(11) *BMC Public Health*

¹⁶ Recognition by the Health Minister and Premier in the form of a media release announcing additional resources would send a welcome message to health specialists and the broader community.

The cost of running the Commission is less than costs attributable to misinformation or bad practice that results in death or other injury.

Education initiatives are a valuable mechanism for addressing harms attributable to false or misleading health information and practices.¹⁷ That education encompasses an emphasis in the primary and secondary school curriculum on articulation and understanding of science principles and practice. Given that some people choose to home-school their children or to use nongovernment institutions it is essential that an understanding of those principles and practices be induced through the state-wide secondary examination system rather than taken for granted.

Such a 'nudge' is constitutionally permissible. I accordingly suggest that the Committee specifically remind the Government of the need to expressly situate the Health Care Complaints Commission within the broader state and national policy framework regarding the K12 curriculum and certification. If the legal system relies on consumers reading critically and in particular appraising statements of opinion, as noted in *Noone*,¹⁸ we should endeavour to foster that sort of literacy.

I also suggest that the Committee note concerns regarding the inclusion in postsecondary curricula (ie within TAFEs and universities) of what might be dubbed 'junk science' units and courses, for example the Energy Medicine course that has been available at RMIT University as both a standalone course and part of a Masters of Wellness or the Acute Homeopathy unit at Holmesglen. It should be of real concern that funding stringencies are resulting in institutions catering to perceived demand for 'alternative' or 'complementary medicine' training by offering units/courses that lack a scientific basis, are typically delivered by people with problematical qualifications and should be appropriately marketed as entertainment rather than health education.

Education initiatives also involve community awareness campaigns that address people who have finished secondary schooling. Such campaigns over the past century have dealt with smoking, tuberculosis, whooping cough, poliomyelitis and HIV. They are constitutionally permissible. In retrospect they have been acknowledged by the community at large to be of general benefit.

Regrettably, education cannot be regarded as the only solution.

Some people disregard fact-based medicine because they are adherents of a particular ideology. Those people are a receptive audience for false or misleading information and practices, including practices that may result in substantial harm to themselves or – as in the case of anti-vaccinationists¹⁹ – to third parties.²⁰

¹⁷ Jon Wardle, Cameron Stewart and Malcolm Parker, 'Jabs and barbs: Ways to address misleading vaccination and immunisation information using currently available strategies' (2013) 21 *Journal of Law & Medicine* 159

¹⁸ A useful discussion is found in *Noone, Director of Consumer Affairs Victoria v Operation Smile* (Australia) & Ors (No 2) [2011] VSC 153

¹⁹ Gregory Poland and Robert M. Jacobson, 'The clinician's guide to the anti-vaccinationists' galaxy' (2012) 73(8) *Human immunology* 859.

²⁰ See for example Paul Offit, *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (Basic Books, 2011) and more broadly Archana Chatterjee (ed) *Vaccinophobia and Vaccine Controversies of the 21st Century* (Springer, 2013).

The Australian Competition & Consumer Commission for example in May 2012 referred to representations on the Homeopathy Plus! Pty Ltd website that were considered to be "misleading and deceptive and that could lead to serious health risks for consumers" –

"The combination of claims that the vaccine was ineffective and that the homeopathic remedies listed on the page were an alternative prevention and treatment regime elevated this matter to one of extreme concern," ACCC Chairman Rod Sims said.

The ACCC examined content on the Homeopathy Plus! website following a complaint from the medical profession. The ACCC considered that the Homeopathy Plus! claims that the current whooping cough vaccine is dangerous and ineffective, while the homeopathic remedy is a proven and safe alternative, were likely to be misleading or deceptive. Reliance on these claims may influence consumers to avoid the whooping cough vaccine and rely solely on the homeopathic approach for treatment and prevention of whooping cough.21

In that instance the ACCC had taken action in the federal Court under the *Competition &* Consumer Act 2010 (Cth), seeking an injunction to have the claims removed from the HomeopathyPlus site, along with penalties against the company and individuals.

Some people seek to profit from false or misleading information and practices, including the commercial distribution of substances that are toxic (eg 'Black Salve').²² products with claims that are not substantiated (eg magnetic beds, energy medicine²³ and wrist 'power bands'),²⁴ and statements that strongly discourage people from using therapies that are of proven efficacy.

An egregious example is Andrew Wakefield,²⁵ an individual proven to have engaged in research fraud, who had a substantial conflict of interest, who continues to profit from false or misleading information and practice, and who along with micropaleontologist Viera Scheibner²⁶ serves as an authority figure for Australian anti-vaccinationists. Some of those anti-vaccinationists have endorsed figures such as Matthias Rath, who has gained international condemnation for what the World Health Organisation, UNICEF

²¹ Australian Competition & Consumer Commission, 'ACCC tackles Homeopathy Plus! Whooping Cough claims' (Media Release NR 086/12)

²² See Therapeutic Goods Administration, 'Decision under regulation 9 of the Therapeutic Goods Regulations 1990 in relation to an advertisement about the product 'black salve' (Complaint No. 2012-04-022)' (16 May 2013) regarding advertising on the Australian Vaccination Network site of the caustic black salve product as a cancer treatment.

²³ Australian Competition and Consumer Commission v Willesee Healthcare Pty Ltd (No 2) [2011] FCA

⁷⁵² ²⁴ See for example Australian Competition & Consumer Commission, 'Power Balance admits no reasonable basis for wristband claims, consumers offered refunds' (22 December 2010).

²⁵ See for example Fiona Godlee, Jane Smith and Harvey Marcovitch, 'Wakefield's article linking MMR vaccine and autism was fraudulent' (2011) 342(7452) British Medical Journal; Brian Deer, 'How the vaccine crisis was meant to make money' (2011) 342(c5258) British Medical Journal; and Owen Dyer, 'Wakefield admits fabricating events when he took children's blood samples' (2008) 336(7649) British Medical Journal 850. More broadly see Paul Offit, Autism's False Prophets: Bad Science, Risky Medicine. and the Search for a Cure (Columbia University Press, 2013).

²⁶ Julie Leask and Peter McIntyre, 'Public opponents of vaccination: a case study' (2003) 21(32) Vaccine 4700.

and Joint UN Programme on HIV/AIDS described as "wrong and misleading" advertisements regarding HIV/AIDS therapies.²⁷

I have specifically referred to ideology because some of the people who have embraced false or misleading information and practices have a deep personal (and on occasion financial) investment in the promotion of that information and practice. They are unlikely to be persuaded through education campaigns and along with many 'true believers' will ignore or accommodate facts that are contrary to their world view. Regulatory regimes in Australia are typically predicated on an assumption that people are rational and instrumental, ie people will not act to their own disadvantage. Sadly some anti-vaccinationists and others will construe regulation as validating their world view. Some construe criticism as confirmation that they uniquely possess a truth that is not available to their disbelieving peers. Some will be tireless in a cause and may even seek 'martyrdom' that validates a life that they otherwise consider unsatisfactory.

People who are convinced that Elvis is alive and flipping burgers in Wollongong, that Michael Jackson was assassinated by the CIA (or was it the Vatican Bank?), that the moon landings were faked or that the Queen is in fact a six foot tall green-skinned lizard from another planet are generally not going to be dissuaded from beliefs that have become fundamental to their personalities. Few of those people however are dangerous. Unfortunately some of the people addressed by the Health Care Complaints Commission **are** of substantive concern.

In this submission I have indicated that the Government is to be commended for strengthening the scope for action by the Health Care Complaints Commission regarding the promotion of false or misleading information by the body formerly known as the Australian Vaccination Network (AVN).

People associated with that body have been adept at gaining publicity, albeit on occasion through repellent statements such as that characterising a court-ordered vaccination as "rape" "with full penetration". They have been quick to claim that they are presenting a balanced view of matters of public concern. They have also claimed that restrictions on their dissemination of information are an inappropriate restriction of free speech.

Their energy is laudable but their statements, if accepted by consumers, are likely to result in substantive harm to minors and adults who –

- are vulnerable to a range of infections that could be prevented through the fact-based medicine that is so viscerally opposed by the AVN
- may be misled by promotion of harmful products such as laetrile and the black salve (aka cansema) escharotic.²⁸

²⁷ UNICEF Press Centre, 'UN condemns irresponsible attack on antiretroviral therapy' (30 March 2005). Recent increases in the number of young Australians with HIV are cause for concern and we should be wary of perceptions that nutritional supplements mean that people no longer need to act responsibly in stopping the spread of HIV.

²⁸ See for example Therapeutic Goods Administration, Black Salve - Australian Vaccination Network Inc -Complaint No. 2012-04-022 (Decision under regulation 9 of the Therapeutic Goods Regulations 1990 in relation to an advertisement about the product 'black salve').

• out of desperation and ignorance may be misled by claims that 'nutritional supplements' (especially those from a particular vendor) will cure cancer or HIV, meaning that those people avoid appropriate treatment.

Statistics regarding immunisation rates indicate that the promotion of the 'anti-vax' ideology – the promotion of false and misleading health-related information and practices – in Australia **is** posing a substantive risk of harm.²⁹

That risk is exacerbated when health sector practitioners, such as chiropractors, endorse the ideology in contact with consumers and are not disciplined by entities that have a regulatory function under the AHPRA regime.³⁰

As indicated in the preceding quotation from an Australian Competition & Consumer Commission media statement, the risk is recognised by the ACCC. It is also recognised by Australian courts. It is not a phantom or something that can be disregarded or left to the Commonwealth government, given that the ACCC and TGA have finite resources for investigation and enforcement.

New South Wales, through statements by Ministers and action by the Health Care Complaints Commission, has a role to play in dealing with such harms. The Government is not necessarily going to persuade people with closed minds. In responding on a considered and strategic basis to false and misleading information and practice it can however send a valuable message to the rest of the community.

Free Speech?

Submissions to the Committee will presumably include claims that restrictions on claims by advocates of 'alternative' or 'complementary' diagnostic and therapeutic schemes are impermissible under Australian law regarding free speech.

Put simply, some of people and organisations that are of particular concern to the Health Care Complaints Commission assert that they have a legally enforceable right to say what they like, irrespective of whether that expression is face to face, by mail, in print, in a broadcast or via the internet.³¹

That assertion is false. On occasion it is distinctly disingenuous, given that particular exponents repeat such assertions after having been recurrently alerted that they are

²⁹ For example, the rate for immunisation of five year olds in some parts of Australia is less than 85%. See recent data at

 $[\]label{eq:http://www.nhpa.gov.au/internet/nhpa/publishing.nsf/Content/EF033E4CEF532485CA257B1A00135974/\$ File/Immunisation%20report%20SA3s%20list%20FINAL%2008apr13.pdf$

³⁰ Weak regulation in some bodies of practice is unsurprising given that some practitioners adhere to beliefs such as subluxation (ie a range of learning difficulties, behaviours and organic states can be 'cured' through spinal manipulation). The legitimacy of the AHPRA is weakened by a permissive stance regarding acceptance by the Osteopathy Board of Australia of 'cranial osteopathy' in which osteopaths sense 'cranial rhythms', through a laying on of hands and thereby undertake diagnosis and treatment of problems that range from sinusitis and asthma to constipation and attention disorders. Expansion of the AHPR regime through recognition of bodies of practice such as reiki and homeopathy is, as noted above, undesirable.

³¹ Those assertions are often accompanied by claims that any restraints are an indication of a conspiracy that brings together the medical profession, the courts, officials, legal academics and pharmaceutical companies.

incorrect.

Australian law does **not** provide for a comprehensive right of free speech or free expression. Such a right is not an explicit feature of the national constitution, of the Commonwealth and state/territory human rights statutes or of Australian common law.³² The High Court has found that there is an implied freedom of political communication. The Court has however recurrently indicated that the freedom is circumscribed; it does not extend to all expression and accordingly does *not* invalidate legitimate restrictions regarding ethno-religious vilification,³³ victim identification,³⁴ defamation or product marketing.³⁵

The validity of such restrictions is irrespective of whether an individual has a sincere (albeit mistaken or fanciful) belief. It is also irrespective of whether the expression by an individual or organisation is on a commercial or non-commercial basis. I suggest that the Committee should be conscious that some individuals and entities that are engaging in the promotion of false/misleading information and practice appear to believe that they are able to do so because that promotion is labelled as 'not for profit' (somewhat at odds with revenue generation through the appearance of advertisements on websites) or as the raison d'etre of a charitable body.

A requirement under New South Wales law for organisations and individuals to correct health-related false or misleading information is appropriate. Action by the government to require a change of the misleading AVN name was commendable. The Health Care Complaints Commission is important because it represents a model for the other Australian jurisdictions. I suggest that the Committee note concerns within the medical, scientific and broader communities regarding false/misleading statements regarding vaccination – concerns that have been acknowledged by Australian courts as wellfounded – and encourage the Government to work with the other jurisdictions (through for example COAG) to ensure a coherent national regime.

Much of Australia's population is online and is acquiring information that is not mediated by editors or other gatekeepers who traditionally have filtered misleading information or indicated that particular statements are dangerous, poorly-based or nonsensical. A national approach is necessary to address regulatory arbitrage, ie people seeking to evade NSW law by simply tying a website to an interstate or overseas address.

Recognition of practitioners and practice

For over a century Australian law – along with that in the UK, New Zealand and Canada – has given a special status to health professionals. In essence, the law has restricted people from characterising themselves as professionals (in particular medical practitioners) unless they have been certified and abide by professional codes. Certification has involved a science-based training over a period of years, typically at a

³² The notion that restrictions on expression are necessarily inappropriate is problematical. Brian Martin, 'Debating vaccination: understanding the attack on the Australian Vaccination Network' (2011) 8 *Living Wisdom* 14 is unpersuasive.

³³ Monis v R; Droudis v R [2011] NSWCCA 231 and Man Horan Monis v The Queen & Anor and Amirah Droudis v The Queen & Anor [2013] HCA 4.

³⁴ Hogan v Hinch (2011) 243 CLR 506. See also AA v BB [2013] VSC 120.

³⁵ Rowe v Electoral Commissioner (2010) 243 CLR 1; [2010] HCA 46. See also JT International SA v Commonwealth of Australia [2012] HCA 43.

tertiary institution and with a period of familiarisation for novices under the supervision of senior practitioners). The expectation is that quality standards would be identifiable and maintained.

It has accordingly been an offence for uncertified practitioners to hold themselves out as having the identity and thus authority of recognised practitioners. Misbehaviour by practitioners has been addressed through removal of authority (eg formal deregistration) and through litigation under civil and criminal law where injury has occurred. In essence, practitioners had a higher status (and typically higher income) than nonprofessionals but were held to a higher standard than those non-professionals.

Overall that regime has served the needs of the Australian community.

Inappropriately permissive notions of inclusiveness and a failure to adequately appraise claims by advocates has unfortunately resulted in formal recognition under the AHPRA regime of bodies of practice that have weak internal discipline,³⁶ in some instances have a theoretical basis that the National Health & Medical Research Council characterises as implausible, and involve practices that appear to have no therapeutic efficacy apart from the placebo effect.³⁷

I suggest that the Committee should warn against privileging bodies of practice that are currently unrecognised as health professions under the AHPRA.³⁸ The National Health & Medical Research Council working committee on homeopathy, which several years ago was reported to have described use by medical practitioners of homeopathy as "unethical" on the basis that notions of 'similars' and 'extreme dilution' meant homeopathy was "inefficacious", has yet to report. The Australian Health Ministers Advisory Council has yet to release its report regarding consultation about unregistered health practitioners. Ongoing delays in provision of those reports is of concern.

As a society we should be concerned about acceptance of 'therapies' and 'diagnoses' that are at best implausible and that if provided outside the health sector would be held in Australian law to be fraudulent.

Exponents of homeopathy for example assert that homeopathic products are efficacious because of extreme dilution, ie the pharmacologically active chemicals are so dilute that they are undetectable in a laboratory. A court would hold that if those chemicals cannot be detected it means they are no longer present and thus unable to have any physiological effect.³⁹ Put crudely, consumers are paying for expensive flavoured water

³⁶ See for example controversy regarding Nimrod Weiner and about continuing professional development recognition highlighted by Michael Vagg, 'Concerns about chiros are about quality and safety, not some phoney turf war' (2013) *The Conversation* (12 March)

³⁷ Simon French, Melanie J Charity, Kirsty Forsdike, Jane M Gunn, Barbara I Polus, Bruce F Walker, Patty Chondros and Helena C Britt, 'Chiropractic Observation and Analysis Study (COAST): providing an understanding of current chiropractic practice' (2013) 199(10) *Medical Journal of Australia* 687 for example notes extensive use by chiropractors of the Activator (aka Clicky Stick), a device that one specialist argues does nothing more than click.

³⁸ Reference to practitioners – in for example *Sam, Thomas v R Sam, Manju v R* [2011] NSWCCA 36 and *R v Stuart* [1999] VSCA 41 – does not mean that homeopaths have the same legal privileges and duties of medical practitioners.

³⁹ Because there is no detectable agent there is no harm (eg no allergen or carcinogen) and homeopathic products accordingly fall outside the regulation by the Therapeutic Goods Administration of

that is misleadingly marketed as having a therapeutic effect that is attributable to chemistry rather than a placebo. Ultimately Australian consumers bear the cost of that practice because some private health insurance schemes pay for homeopathy and because Australian educational institutions, as noted above, feature courses that legitimise a practice that is inherently false and misleading.

If we going to subsidise homeopathy through the health insurance system on the basis that it 'makes people feel good' or simply 'does no harm' (unsurprising when there is no active compound) we should be consistent and similarly subsidise 'feel good' consumer purchases of chocolate or cupcakes, woolly slippers and videos.

We should similarly be situating homeopathy units outside health faculties, for example marketing them alongside units in Basket-weaving, Knitting and Justin Bieber Studies – ie as entertainment rather than medicine.

Causing general community mistrust or anxiety

The Committee's Terms of Reference refer to

The publication and/or dissemination of false or misleading health-related information that may cause general community mistrust of, or anxiety toward, accepted medical practice

Preceding paragraphs have highlighted concerns regarding the propagation of false/misleading information by people outside the health professions⁴⁰ and within bodies of practice or, less commonly, within the professions.⁴¹

Medicine is an imperfect science. On occasion diagnoses and therapies are ineffective. On occasion practitioners behave in ways that are appropriately condemned by peers, by the mass media and by the courts. Overall, however, medicine – and more broadly science – have had profound benefits for society. Most members of the Committee and most people reading this submission are alive because of acceptable medical practice that encompasses surgery for life-threatening conditions such as appendicitis and infections such as tetanus, poliomyelitis, whooping cough and diphtheria. That practice is empirical. It is founded on a willingness to rigorously identify and test dogmas in search of the truth.

pharmaceuticals. From a consumer law perspective an Australian court would presumably regard as fraudulent the promotion of a product that is falsely claimed to feature particular ingredients. If I sell what is claimed to be orange juice but in fact comprises sugared water with an orange tint, water in which any juice has been diluted several million times and is thus undetectable, I would be in breach of the Australian Consumer Law. The rationale of the Australian Competition & Consumer Commission in not taking action over homeopathic nostrums is presumably that it has to prioritise its enforcement of the Act and that action should be undertaken by the TGA or state health protection agencies such as the HCC.

⁴⁰ AVN founder Meryl Dorey for example does not appear to have a medical degree from an Australian university. Viera Scheibner has a degree in micropaleontology from an overseas university. Both operate outside the guidance and potential discipline involved in membership of a health profession.

⁴¹ The Medical Board of Australia for example imposed a \$25,000 penalty on Perth general practitioner William Barnes who reportedly claimed he could cure cancer with green tea extracts and a special diet after hair analysis. The Board is reported as stating that "There was no sound scientific basis upon which the respondent could truthfully represent to patients, prospective patients and members of the public the claim that the treatment could cure cancer." The board indicated that statements by Barnes could mislead cancer patients, putting them at risk of delaying or refusing effective cancer treatment.

It is fundamentally different to the charisma of particular faith healers. It is fundamentally different to the unsubstantiated assertions made by 'anti-vax' exponents who comprehensively disregard over 200 years of impeccable research and practice. Those assertions are often accompanied by claims of conspiracies involving clinicians, medical researchers, pharmaceutical companies, lifesciences publishers and bogeys such as the Central Intelligence Agency.

I indicated above that some people will hold particular beliefs contrary to whatever evidence is presented. We should and can legitimately signal, through ministerial statements and public education and curriculum design and targeted enforcement, that misleading and false information likely to result in harm is abhorrent and in particular circumstances will incur a penalty.

The ideology that I have highlighted above is often couched in terms of 'alternative' medicine or 'complementary' medicine. Promotion of products and practices that fosters mistrust, anxiety and avoidance of legitimate medicine is reprehensible. It is legitimately condemned by Australian governments. That condemnation will on occasion involve one or more Ministers and/or agencies at the Commonwealth and state/territory levels.

I draw the Committee's attention to the decision by the Therapeutic Goods Administration regarding advertising on the AVN site of the Black Salve, ie promotion of an 'alternative' that should cause real concerns regard public health -

The Advertiser was not able to produce valid supporting evidence in relation to their claims, nor was there any referenced or highlighted medical evidence in the advertisement to support the representations. The advertisement promoted 'black salve' as a 'safe, effective, natural remedy ... used for over 2,000 years to treat skin cancers and other cancerous conditions, leading to a total remission of the disease.' The Delegate considered that, based on these statements, consumers would be entitled to expect that 'black salve' will cure them of cancer when, in fact, there is no credible, reliable clinical or scientific evidence to demonstrate that the product is effective in the treatment of any cancer. The Delegate found the advertisement was unverified, was not correct and raised unrealistic and unwarranted expectations of product effectiveness

The 'black salve' product was advertised both as a cure for cancer and as a legitimate alternative to 'Aldara' a conventional medicine. It was the Delegate's view that this comparison could mislead consumers into incorrectly believing that 'black salve' was a natural safe alternative which was more effective than conventional medicines and that the advertisement sought to give credibility to 'black salve' over clinically proven alternatives. The Delegate considered that statements made in the advertisement could lead to consumers inappropriately relying on 'black salve' to treat skin cancer to the exclusion of clinically proven conventional medicine and that the suggestion that 'black salve' will *'help people cure their own cancers'* may lead to self-diagnosis and a failure to seek out proper medical attention for a

potentially fatal disease. The Delegate found the advertisement was likely to lead to inappropriate treatment of a potentially serious disease.⁴²

Exploiting the fear, pain, desperation and gullibility of people with cancer and their associates is unconscionable.⁴³

It should be strongly and persistently condemned by the Committee and by the Government rather than ignored on the basis that it is trivial, or that it is contrary to free speech or that condemnation gifts cranks and con artists with a legitimacy that they do not deserve.

Encouraging unsafe refusal

In 2002 Brown FM in *T* & *M* commented that

it is in the interests of the community as a whole that endemic, life threatening diseases should remain eradicated in this country. For the last few decades the scourges of infectious diseases such as polio, tuberculosis and diphtheria and the horrifying birth defects arising from rubella have become relatively unknown in Australia. The community as a whole, and the parents of children in particular, have a legitimate interest in ensuring, as far as is possible, that this remains the situation.⁴⁴

The Committee's Terms of Reference refer to

publication and/or dissemination of information that encourages individuals or the public to unsafely refuse preventative health measures, medical treatments, or cures.

From a regulatory perspective the difficulty lies in the interpretation of "encourages". Is an expression of opinion the requisite encouragement? An expression that is presented as fact? Is expression couched as 'alternate' information on an advocacy site qualitatively different to a specific exhortation in an online forum, print newsletter or broadcast? What are the appropriate penalties if encouragement is to be restricted by law? Is enforcement of restrictions viable, for example because 'true believers' shelter behind firewalls – particularly firewalled for a that feature the sort of disingenuous boilerplate evident in some anti-vaccinationist sites?

There is disagreement about the appropriate answers to those questions. In principle a pharmaceutical company could take action for malicious falsehood regarding specific claims regarding particular therapies. In practice that does not occur, given that large

⁴² Therapeutic Goods Administration, Australian Vaccination Network Inc - Complaint No. 2012-04-022 (Decision under regulation 9 of the Therapeutic Goods Regulations 1990 in relation to an advertisement about the product 'black salve')

 $^{^{43}}$ The promotion of inefficacious supplements as cures for HIV, alongside claims that antiretrovirals are ineffective, is also unconscionable. It is likely to dissuade people from using effective treatments and – more subtly – to encourage irresponsible behaviour that puts many people at risk. (In essence, why bother with safe sex if you have been persuaded that HIV is a conspiracy by 'the chemical cartel' and that a few vitamins will make the HIV disappear?)

⁴⁴ *T* & *M* [2002] FMCAfam 277 at [9]. See also *Mains* & *Redden* [2011] FamCAFC 184; *Kingsford* & *Kingsford* [2012] FamCA 889; *Preston* & *Starkweather* [2012] FMCAfam 168; In re H [2011] QSC 427; *Howell* & *Howell* [2012] FamCA 903; and *Holloway* v *Coster* [1897] 1 QB 346.

corporations are typically advised 'do not feed the troll' or 'give legitimacy' to someone who craves media attention. It is unlikely that one of the professions would similar dignify fringe organisations and individuals characterised as cranks. There is disagreement within online and legal communities about the effectiveness of bans on 'advice sites', for example regarding euthanasia.

Action by the New South Wales Government therefore needs to be targeted, with an emphasis on exemplary action against egregious claims and in particular against claims (such as those noted above regarding Black Salve) that

- falsely assert therapeutic properties and
- discourage consumers from relying on clinically proven medicine and
- are made outside the professions and thus not susceptible to discipline by those professions.

Targeting acknowledges the sharing of responsibility by the Commonwealth, New South Wales and other state/territory governments: the HCC and more broadly the NSW Government is not expected to address every harm (although can set an example). It also acknowledges that the professional bodies have some suasion in articulating and fostering compliance with professional standards.

Targeting should particularly emphasise promotion that has a commercial element, whether on a directly for-profit basis (eg a site that exists to promote a specific product or service provider) or an indirect basis (eg an 'information' site that features advertisements regarding another entity's products/services).

As a corollary Australian governments should be wary about privileging advertisements that appear in social network services. Facebook for example recurrently displays advertisements for bogus therapies such as Black Salve. The Committee may wish to recommend that the NSW Government and Commonwealth Government call on Australian and overseas social network services (and placement services) to act responsibly by rejecting advertisements for products that are harmful to public health. The major online media exercise restraint (and comply with direct government restraints or industry codes) in rejecting advertisements for tobacco products. We should expect them to exercise restraint in rejecting advertisements for 'snake oil'.

This is a matter that should be progressed through meetings of the national consumer protection regulators and should be high on the agenda of the Australian Communications & Media Authority rather than just the Health Care Complaints Commission or the TGA.

HCCC institutional capacity

The Committee's Terms of Reference refer to

the capacity, appropriateness, and effectiveness of the Health Care Complaints Commission to take enforcement action against such organisations or individuals; and

In the absence of scope for action by consumers it is axiomatic that bodies such as the Health Care Complaints Commission act on behalf of the community as a whole in dealing with misleading or false statements and practices. Making a ministerial statement or passing an enactment is easy. True effectiveness requires work by the Health Care Complaints Commission and Health Department. That requires adequate resourcing by the Government on the basis of public good.

Much consumer protection in Australia is a matter of cardboard and tinsel because public/private sector regulators are under-resourced and accordingly emphasise 'conciliation' – often after delays of 12 or more months – rather than substantive action. That emphasis is ineffective in dealing with businesses that are well-resourced (ie have the money to abuse regulatory mechanisms through for example name changes or appeals to tribunals and courts) or individuals whose lives centre on saving the world from common sense. The Health Care Complaints Commission needs staff to deal with those enterprises and individuals. It needs funding for legal action. It needs a willingness elsewhere in government to hear what it says and work with it.

One response to that comment might be that the Government has finite resources and must exercise restraint in spending. I have suggested above that as a society we need to be wary of being penny wise and pound foolish in dealing with false/misleading statements and practices. Irrespective of the pain experienced by individuals and families when something goes wrong because of that information/practice, the cost to the taxpayer and national productivity is likely to be significantly greater that the cost of running the Health Care Complaints Commission and associated information campaigns. It is expensive, for example, to provide treatment and lifelong support for people who experienced injury that is attributable to the AVN.

Enhancement of the New South Wales regime regarding false/misleading information and practices will

- offset weaknesses in the national regime under the Australian Consumer Law, the *Therapeutic Goods Act 1989* (Cth) and *Food Standards Australia New Zealand Act 1991* (Cth), the health practitioner National Registration & Accreditation Scheme and the *Code of Conduct for Unregistered Health Practitioners* under *Public Health Regulation 2012* (NSW)
- provide a model for other jurisdictions and
- complement public information campaigns and the state's education curriculum

without impermissibly chilling the expression of opinion or exchange of information that emanates from inside/outside the state.

That enhancement should be complemented by statutory provision that expressly authorises exclusion of unvaccinated minors and adults from childcare and other facilities.⁴⁵ It is unlikely that some proponents of the anti-vaccination ideology will be persuaded through education campaigns. Their impact on minors and adults through the propagation of infection via particular facilities can and should, however, be minimised.

⁴⁵ Beattie (on behalf of Kiro and Lewis Beattie) v Maroochy Shire Council [1996] HREOCA 40