Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

Submission to Australian Medical Board

Who are we?

We are group of academics and practitioners from various disciplines who have been working together to examine the regulation of innovative interventions in healthcare. Prof Cameron Stewart was the main author of the submission and any errors contained within are his responsibility.

Prof Cameron Stewart Sydney Law School University of Sydney	Prof Ian Kerridge Sydney Health Ethics University of Sydney
Prof Catherine Waldby Director of the Research School of Social Sciences Australian National University	Prof Dianne Nicol Faculty of Law University of Tasmania
Assoc Prof Wendy Lipworth Sydney Health Ethics University of Sydney	Assoc Prof Megan Munsie Stem Cells Australia University of Melbourne
Dr Jane Nielson Senior Lecturer Faculty of Law University of Tasmania	Dr Lisa Eckstein Lecturer Faculty of Law University of Tasmania
Dr Wally Jammal Conjoint Senior Lecturer School of Medicine Western Sydney University	Dr Narcyz Ghinea Research Fellow Sydney Health Ethics University of Sydney
Dr Jennifer Kaldor Research Fellow Law School University of Tasmania	Dr Christopher Rudge Research Fellow Sydney Law School University of Sydney

The functions of AHPRA and the National Boards and why we need more guidance

Our submission supports Option 2. We believe that there is a need to strengthen current guidance for medical practitioners who provide unconventional treatments through 'practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's *Good medical practice: A code of conduct for doctors in Australia*.'

AHPRA and the National Boards play a crucial role in regulating the profession, and that role can be broken down into three broad functions:

1. Permissive regulation - meaning, in a broad sense, the function of licensing and registering health professionals to work within specific scopes of practice and providing information to the public about those registrations;
2. Negative Regulation – the enforcement of minimal standards to protect the public from forms of undesirable professional conduct (for example, through professional discipline and findings of unsatisfactory professional conduct, unprofessional conduct and professional misconduct); and
3. Positive regulation – providing information on standards and best practice to encourage the health professions to improve safety and quality of health services (for example through guidelines and policies).

While the current approach adopted by AHPRA and the Boards goes some way towards fulfilling these functions, we believe that a specific policy dealing with non-conventional departures from standards of practice would be incredibly helpful and add to the effectiveness of both the negative and positive aspects of the *National Law*.

Currently, one of the stated aims of the *National Law* is to:

> (f) to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.[1]

Equally, in the protection of the public, the *National Law* strives to control departures from accepted standards of behaviour and treats them as grounds for disciplinary action under the *National Law*. Moreover, the *National Law* requires that registered practitioners notify authorities when another practitioner has placed the public at risk of harm because the practitioner has practised the profession in a way that constitutes a significant departure from accepted professional standards. This creates a tension between accepted standards and innovative approaches that may involve a departure from conventional medicine.

There are some policies created by AHPRA Boards which shed further light on the tension. The Medical Board of Australia's *Good Medical Practice: a code of conduct for doctors in Australia* states that patients need to provide information to patients in ways 'they can understand before asking for their consent'.[2] Additionally the Code states that any research must be 'based on an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research.'[3]

AHPRA's guidelines on advertising also makes it clear that advertising is prohibited when it:

- is false, misleading or deceptive or is likely to be so;
- offers a gift, discount or other inducement to attract a user of the health service without stating the terms and conditions of the offer
- uses testimonials or purported testimonials
- creates an unreasonable expectation of beneficial treatment, and/or
- encourages the indiscriminate or unnecessary use of health services.[4]

When using scientific information in advertising practitioners should:

- be presented in a manner that is accurate, balanced and not misleading
- use terminology that is understood readily by the target audience
- identify clearly the relevant researchers, sponsors and the academic publication in which the results appear, and
- be from a reputable (e.g. peer reviewed) and verifiable source.[5]

These policies help to create a web of regulation regarding non-conventional treatments but we believe that there is an advantage in specifically dealing with these issues in a dedicated

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[1] *National Law* s 3
[2] Part 3.5.
[3] Part 11.2.6.
[4] Medical Board of Australia, Guidelines for advertising regulated health services, 2014 http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Guidelines-for-advertising-regulated-health-services.aspx at 6.2
[5] Medical Board of Australia, Guidelines for advertising regulated health services, 2014 http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Guidelines-for-advertising-regulated-health-services.aspx at 7.6.

policy statement, that strengthens the MBA's position and that helps the state -based Boards (and Council) and Tribunals to protect the public.

Examples of the *National Law* and non-conventional treatment

The discussion paper gives some examples of how non-conventional treatment has been dealt with under the *National Law*.[6] We have added some further examples that we hope the MBA will find useful:

(a) Deliberately fraudulent or misleading and deceptive conduct

Some unconventional practices within a professional group are merely quackery, meaning that there is simply no evidence base at all which supports the practitioner's behaviour and there is no shred of any intention to improve practice or understanding. For example, in *Health Care Complaints Commission v Limboro*[7] a chiropractor was removed from the register after having plead guilty to charges of falsely advertising chiropractic as a cure for cancer, based on the traditional chiropractic belief that all human disease emanates from sublaxions in the spine. The chiropractor argued that it would eventually be proven that chiropractic treatments could cure cancer, and that he had left the contents of his website to others to manage. Nevertheless, NCAT found that the chiropractor was not a suitable person for registration in the profession of chiropractic and he was unfit in the public interest to practise as a chiropractor.

In *Medical Board of Queensland v Tarvydas*[8] a medical practitioner was deregistered for providing 'stem cell treatments' for adhesive arachnoiditis, which were effectively doses of steroids. Patients were told that they were part of a trial but they were never provided with information about the treatment and there was no follow-up with them. The doctor had refused to take part in the proceedings.

The making of false claims regarding the effectiveness of CAM treatments is grounds for disciplinary action. In *Medical Board v Barnes*[9] a doctor advertised on his website that he could provide a "non-toxic herbal and nutritional treatment as an alternative treatment for cancer." The treatment consisted of oral and intravenous administration of green tea polyphenols, genistein from soybeans, curcumin from turmeric, quercetin, vitamin C, selenium, anti-cancer herbs, "mineral replacements" following hair analysis and the observance of a particular diet. Importantly, the State Administrative Tribunal of Western Australian found that the advertisement stated or implied that the treatment could cure cancer. The doctor was reprimanded and fined $25,000. The doctor's practice was also subjected to conditions requiring that the doctor provide his patients with a document in which they acknowledge that they should continue with their standard oncological treatment and that Dr Barnes' approach was not supported by evidence.

(b) Use of existing treatments and devices in 'innovative' ways

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[6] Much of the following text comes from W Jammal, C Stewart, M Parker, ' "CAM-creep": Medical practitioners, professional discipline and integrative medicine' (2014) 22 *Journal of Law and Medicine* 221-232.
[7] [2018] NSWCATOD 117.
[8] [2010] QCAT 246.
[9] *Medical Board of Australia v Barnes* (unreported, State Administrative Tribunal of Western Australia, 2 August 2013).

In *Chiropractic Board of Australia v Hooper (Review and Regulation)*[10] a chiropractor was found guilty of professional misconduct for using a hyberbaric chamber and a Lokomat machine to treat cerebral palsy and other neurological conditions.

In *Health Care Complaints Commission v Chen*[11] a doctor was found guilty of professional misconduct for promoting ketamine to treat major depressive illnesses unresponsive to conventional treatments. Ketamine (a Schedule 8 medication used as a n anaesthetic) is not approved by the Therapeutic Goods Administration in Australia for depressive illnesses. There were no evidence-based treatment guidelines for ketamine in the treatment of depression. There are significant and recognised risks associated with the use of ketamine.

The drug was prescribed by the practitioner but the practitioner was effectively controlled by the clinic which was exercising commercial pressure on the doctor to prescribe ketamine. The NCAT found that the doctor failed to conduct an appropriate assessment when he prescribed ketamine for depression; he failed to exercise his own, independent clinical judgement; he failed to understand the responsibility incumbent on him when prescribing drugs in an experimental clinical setting with vulnerable patients; and he failed to provide supervision and ongoing assessment during the course of the ketamine treatment.

In *Chiropractic Board of Australia v Hooper (Occupational and Business Regulation)*[12] a chiropractor was disciplined for his provision of non-Chiropractic treatments for a patient with cerebral palsy, namely hyperbaric oxygenation and Lokomat (gait therapy) treatments. VCAT said at [29]:

> ...[I]t would be open to the tribunal to find that even if the health services constitute services outside the area in which Mr Hooper is registered, that he is still subject to the health professional regulations by virtue of his registration (at the time of the allegations) as a registered chiropractor.

(c) Diagnosing 'new' or non-extant conditions

In *Medical Board of Australia v Abi Haila (Review and Regulation)* [2017] VCAT 1627, the doctor was found guilty of unsatisfactory professional conduct for prescribing hormonal therapy for 'andropause' a supposed condition caused by a reduction in testosterone in men. The patients all had testosterone levels in the 'normal' range. It was argued by the Board that there was no therapeutic justification for the interventions. The doctor countered by saying that the patients had consented to the risk of harm.

In finding the doctor guilty of unsatisfactory professional conduct VCAT stated that the existence of the condition had not been accepted by any of the medical experts. VCAT also found that the doctor could not use patient consent to relieve himself of the professional obligation to ensure that proper clinical justifications existed for the treatment and for the prescribing of a poison.

In *Mayne, Peter*[13] a professional standards committee found a doctor liable for unsatisfactory professional conduct for diagnosing and treating a patient with Lyme disease, without using he standard test for the disease and knowing that there is no evidence of the disease's existence in Australia. Relevantly, the doctor had also employed intramuscular Penicillin

[10] [2013] VCAT 878.
[11] [2018] NSWCATOD 73.
[12] [2012] VCAT 1042.
[13] [2017] NSWMPSC 3.

injections in a way that was 'completely experimental' and had done so without informed consent.

Similarly in *Ladhams v Medical Board of Australia (No 2)*[14] QCAT upheld immediate actions conditions being placed on a doctor who was diagnosing and treating Lyme disease in unconventional ways.

(d) Non-conventional diagnostics

A recurrent problem for the *National Law* is where a doctor abandons conventional diagnostics tests in favour of non-conventional approaches. In *Health Care Complaints Commission v Cooke*,[15] Dr Cooke was a GP who 'functioned as a Medical Practitioner with a particular interest in nutritional medicine, environmental medicine, herbal medicine, Chinese medicine, Ayurvedic medicine and mind/body medicine.'[16] It would appear that she was practising within what she thought was an appropriate model of care:[17]

> I follow principles of conventional medical practice, with the additional assistance of tools from complementary medicine, to make a medical diagnosis. I then seek to instigate a comprehensive treatment protocol for my patient, using dietary intervention, nutritional and herbal supplementation, lifestyle modification and stress management.[18]

A patient complained after seeing the doctor and requesting advice about breast screening given her family history of breast cancer. The doctor referred the patient for an ultrasound but not a mammogram. A breast mass was discovered via the ultrasound, but Dr Cooke did not examine the patient and instead ordered a thermogram.[19] She neglected to follow conventional guidelines, which stipulated that this kind of patient required a mammogram and/or a biopsy. The doctor later failed to order a biopsy after being advised to do so by the radiologist after a lesion was discovered. A second patient was referred to Dr Cooke by an osteopath for hardening in her abdomen. The doctor did not perform an abdominal examination but instead put the patient on a liver detoxification program for two weeks and later a "lipotrene" treatment. The patient had a large fibroid which encompassed most of her uterus and was later removed. The tribunal reprimanded the doctor and ordered her to undergo retraining stating:

> Dr Cooke has revealed habits in practice of medicine that are deeply ingrained over 30 years. These will only be modifiable gradually over the course of her retraining. Until her retraining is complete, the Tribunal is of the view she will not be able to weigh up judiciously the appropriate role of conventional and complementary medicines in the individual management of her patients. The Tribunal is concerned the doctor's personality and persuasive skills could derail the benefits of retraining if she continues to blur the boundaries between conventional medicine and complementary medicine as she seems to have done throughout her 30 years practice. That would put the public at risk. There must be attitudinal change accompanying the retraining.[20]

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[14] [2014] QCAT 286
[15] [2012] NSWMT 12.
[16] *Cooke* [2012] NSWMT 12 at [13].
[17] *Cooke* [2012] NSWMT 12 at [27].
[18] *Cooke* [2012] NSWMT 12 at [14].
[19] Thermography is an imaging technique that has been marketed by some as a screening and diagnostic tool for breast cancer. In the US it is approved as an adjunct to conventional imaging techniques and has no role to play in the diagnosis or screening of breast cancer. See http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499 htm (accessed at 6 April 2013).
[20] *Cooke* [2012] NSWMT 12 at [50].

Importantly, the Tribunal judged the doctor's behaviour against conventional standards of general practice. Given the concern raised about her lack of insight, they ordered her to practice under direct supervision in a hospital-based programme, and thereafter gaining several years of retraining in conventional (GP) medical practice.[21]

Another case example of improper diagnostic testing is *Fluhrer*.[22] Dr Fluhrer practised as a GP but he also had qualifications in naturopathy. In 1996 he became a Fellow of the Australasian College of Nutritional and Environmental Medicine. Dr Fluhrer's interest was in IM, particularly in environmental medicine. While he undertook the Royal Australian College of General Practitioners QA and CME program and was also a member of the Australian College of Nutritional and Environmental Medicine and the Australian Integrative Medicine Association.

Dr Fluhrer saw Patient A in early 2009 after she had been diagnosed with breast cancer and had seen a medical oncologist. The patient consulted with Dr Fluhrer for advice about lifestyle and nutrition. Dr Fluhrer obtained buccal swabs from Patient A and ordered Genosense Polymorphism Assay testing (GPE). Dr Fluhrer later took blood from Patient A for the purpose of using a Circulating Cancer Cell test (CCCT). Patient A and her husband were told that these tests would provide a genetic profile with the strengths and weaknesses of particular genes, that could then be used to target her treatment. The patient was told that CCCT could identify how many circulating cancer cells there were in the blood and that this would help to measure the patient's susceptibility to metastases. Dr Fluhrer did not communicate these tests to the patient's oncologist and the patient had to pay for the test entirely out of her own pocket.

The NSWMPSC found Dr Fluhrer to have engaged in unsatisfactory professional conduct in employing the tests. While there was conflicting evidence, the Committee found that the tests were experimental and not part of accepted medical practice. On the issue of his failure to communicate with Patient A's oncologist, this was proven but not found to be unsatisfactory professional conduct. Similarly, the claims made against Dr Fluhrer for failing to properly disclose the costs of the test were proven but did not amount to unsatisfactory professional conduct. Dr Fluhrer was reprimanded.

In *Beilby, Michael*,[23] the practitioner was an integrative medical practitioner, specialising in 'bio-energetic medicine' who used his own diagnostic machines ('LISTEN Computer' and 'Cybertrone'/ 'CyberScan') whch were not proven to have any role in diagnosis or treatment. In finding the doctor guilty of unsatisfactory professional conduct, the PSC found that the doctor and failed to inform the patients regarding the devices' experimental nature in diagnostics and therapeutics.

(e) 'Innovative' drug therapies

In *Fraser v Health Care Complaints Commission*,[24] Basten JA upheld a finding of professional misconduct against a nurse who had administered intravenous vitamins and 'Insulin Potentiation Therapy,' a therapy used to treat cancer patients by intravenously administering insulin, to induce low blood sugar levels, together with low doses of conventional chemotherapy drugs. IPT is experimental and not scientifically proven. The

[21] *Cooke* [2012] NSWMT 12 at [54]-[58].
[22] [2012] NSWMPSC 6.
[23] [2016] NSWMPSC 25.
[24] [2015] NSWCA 421.

nurse argued that she was acting under the instructions of a medical practitioner but the 'practitioner' was not a registered medical practitioner and it was found that this was known to the nurse during the relevant period.

(f) 'Innovative' cellular therapies

In *Medical Board of Australia v Hocking*[25] it was alleged that a doctor had engaged in unsatisfactory professional conduct for his use of platelet rich plasma (PRP) on a child who had Perthes' disease. PRP is an autologous transplant of cells taken from the patient's own body. The doctor proposed the use of PRP as a trial prior to operating on the child's hip. After the procedure an anonymous notification was made against the doctor for administering an experimental therapy.

The expert evidence found that while the use of PRP was novel it was extremely unlikely to have caused any harm. However, the Tribunal found that the use of PRP for paediatric patients with Perthes' disease was novel and Dr Hocking had not sufficiently taken this into account in his administration of the treatment. Nevertheless, the Tribunal found that Dr Hocking had no case to answer from his use of PRP and that he did not knowingly misrepresent the safety of the treatment to the patient's mother (even though objectively his discussion of PRP was misleading).

In *Chinese Medicine Registration Board of Victoria v Ghaffurian* (*Occupational and Business Regulation)*[26] a Chinese medicine practitioner was found guilty of professional misconduct and unprofessional by holding himself out to be both Chinese Medicine practitioner (which he was) and a Western medical practitioner and surgeon (which he was not). The practitioner was found to have used "light" therapy, injected undiluted Vitamin C into a patient and offered stem cell therapies, none of which was supported by Chinese medicine (or Western medicine). The practitioner was reprimanded, fined, deregistered and disqualified applying for registration as a Chinese medicine practitioner for a period of three years.[27]

(g) Interventions performed in isolation from peers

In many of the above examples, the health practitioner has been acting in an isolated capacity without the support of peers. In *Medical Board of Australia v Siow*[28] a doctor was fund guilty of professional misconduct after having provided nutritional and detoxification advice to a terminally ill patient which had the effect of engendering an unreasonable expectation on the part of the patient and his family of a positive outcome. The patient had been advised by other doctors that he had a terminal prognosis and that he should seek palliative care. The doctor failed to seek informed consent regarding his treatment advice and did not provide counselling to the patient about his poor prognosis, options regarding palliative care or recommendations about related social issues. Additionally, the doctor continued to advise the patient while the doctor was overseas and the patient was in a palliative care setting. This advice conflicted with the advice being given by the palliative care team. The doctor had also made misleading statements about his qualifications.

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[25] [2015] ACAT 44.
[26] [2012] VCAT 478.
[27] *Chinese Medicine Board of Australia v Ghaffurian (No 2) (Occupational and Business Regulation)* [2012] VCAT 1944.
[28] [2016] SAHPT 1.

The Tribunal said:

> The treatment program set up for the patient by the respondent did not comply with a conventional treatment modality as understood and utilised by medical practitioners of an equivalent level of training or experience in the management of patients with a condition equivalent to the patient's terminal illness. In addition the respondent failed to ensure that the treatment program was properly communicated to other treating doctors and the patient to ensure that it was not pursued in isolation or to the detriment of other treatment modalities including palliative care. As a consequence the patient focussed on completing the treatment program, had an imperfect understanding of the need to have palliative care and delayed acceptance of the need for such palliative care.[29]

(h) Failure to understand the risks of CAM treatments

Another problem which can emerge for doctors practicing in integrative medicine is their lack of medical knowledge about the effects of CAM treatments. An example of this is the case of *Varipatis*. [30] Dr Varipatis was a GP who practiced in IM. A complaint was brought before a NSWPSC in relation to Dr Varipatis treating a patient with intravenous vitamin C, and thereby precipitating a deterioration of his renal impairment. As an underlying premise, it was determined that in practising this style of medicine, Dr Varipatis needed to abide by the NSW Medical Council *Policy on Complementary Health Care*.[31] Due to his admitted lack of knowledge concerning side effects of intravenous vitamin C,[32] his lack of communication with the patient's specialists,[33] and failure to use conventional medical tests to assess the risk to the patient,[34] he was found guilty of unsatisfactory professional conduct and reprimanded.[35]

(i) Working at the direction of practitioners of other modalities of care

Doctors who train in CAM will naturally form professional associations with CAM practitioners and seek out their advice on the incorporation of CAM in their practice. Professional disciplinary problems can arise if the GP fails to apply their own medical knowledge and expertise, and instead work solely at the direction of the CAM practitioner.

In *Medical Board of Australia v O'Sullivan,*[36] Dr O'Sullivan (a GP) was suspended and had conditions placed upon her registration following her willingness to comply with the request of Ms Newlands, her patient (who was a naturopath), to infuse bicarbonate of soda for the treatment of her breast cancer.[37] Furthermore, Dr O'Sullivan then agreed to assist Ms Newlands with the infusion of other non-therapeutic substances into two patients of Ms Newlands, relying 'entirely on Ms Newlands to assess, advise and formulate a course of treatment for these two patients.'[38] Interestingly, this case shows that although the patient sought and obtained the help of this GP to have a treatment that she requested, the GP was found to have acted irresponsibly by not ensuring the patient was informed of the lack of scientific evidence for this treatment:

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[29] *Medical Board of Australia v Siow* [2016] SAHPT 1 at [22]
[30] *Varipatis* (unreported, New South Wales Professional Standards Committee, 15 September 2009).
[31] Medical Council of NSW, *Complementary Health Care Policy 2011* http://www.mcnsw.org.au/resources/1294/PCH9 v3 Complementary Health Care190911.pdf (accessed at 28 October 2012).
[32] *Varipatis* at [31] and [41].
[33] *Varipatis* at [8].
[34] *Varipatis* at [46].
[35] *Varipatis* at [63]-[64].
[36] [2011]QCAT 135.
[37] Ibid [3].
[38] Ibid [12].

> Ms Newlands may well have been resolute about her course of treatment and disinterested in any advice Dr O'Sullivan might have given. This did not absolve Dr O'Sullivan from her professional responsibility. Ms Newlands sought the services of a medical practitioner and they were provided. It was Dr O'Sullivan's responsibility to ensure that her patient was properly advised, regardless of how informed and resolute she appeared to be.[39]

Dr O'Sullivan was also found to have breached the Medical Board of Queensland's *Guidelines for Unconventional Medical Practice*.[40]

Another example of this form of behaviour is *Medical Board of Australia v Boyd*.[41] Boyd was a doctor who was asked to provide assistance to cancer patients seeking therapy invented by Mr Abdul-Haqq Sartori, a person who claimed to have invented a cure for cancer involving caesium and high pH substances. Sartori had been refused entry into Australia but, with the help of acquaintances, was giving directions to others about how to implement his treatment regime on Australian patients.

The treatment was carried out, mainly by two nurses[42], at Dr Boyd's home. Boyd was asked to order tests on the patients and insert peripherally inserted central catheter (PICC) lines. For this she received nearly $40,000 but she denied being directly involved in the care of the patients. Boyd had no regard to the nature and effect of substances being administered and she had no knowledge about whether ethics approval had been given for the experimental treatment. Boyd also failed to take any patient histories or check on current medications that patients were taking.

Seven patients were treated with combinations of minerals including magnesium, caesium and laetrile (a restricted poison). The patients experienced severe side effects. Four of the patients died within two weeks of commencing treatment. A fifth died after six weeks, and a sixth patient died after nine weeks. The seventh patient ceased treatment after 11 days and then survived a further four and a half years. The Tribunal found that, during the treatments, Boyd had failed to refer patients for medical assessment or intervention where assessment or intervention was clearly called for. She failed to provide appropriate monitoring equipment or protocols for observing the patients' vital signs. She also was found to have failed to provide appropriate sterilisation equipment and implement safe practices in her home.

The Tribunal also found Boyd to have participated in the treatments to a far greater extent than she had maintained. The Tribunal stated that the patients were entitled to expect that Boyd would be "something more than a tool used to obtain tests."[43] Her failure to bring her expertise as a doctor to bear was found to be grossly careless and amounted to "infamous conduct," that being "conduct that would be reasonably regarded as disgraceful or dishonourable by other medical practitioners of good repute and competency."[44] This is a term from the older *Medical Practice Act 1894* (WA) which applied to Boyd because the events in question occurred in 2005 before the introduction of the *National Law*. The best approximate finding under the

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[39] Ibid at [6].
[40] Ibid at [14].
[41] [2013] WASAT 123.
[42] See generally Ian Freckelton, "Misplaced Hope: Misleading Health Service Practitioner Representations and Consumer Protection" (2012) 20 *Journal of Law and Medicine*, at 7.
[43] *Medical Board of Australia v Boyd* [2013] WASAT 123 at [50].
[44] *Medical Board of Australia v Boyd* [2013] WASAT 123 at [30].

National Law would be "professional misconduct," and its inclusion of conduct which is inconsistent with the practitioner being a fit and proper person to hold registration in the profession. The Tribunal ordered that her name be removed from the register of medical practitioners.

(j) The complete adoption of alternative modalities of care and the abandonment of standard medical practice

In the CAM-related cases discussed so above the doctors that have run afoul of professional rules have done so either because they have allowed CAM standards and practices to replace medical standards (as per the decisions in *Cooke*, *Fluhrer*, *Varipatis*) or because they had surrendered their professional judgment to other CAM practitioners (as per the decisions in *O'Sullivan* and *Boyd*).

At the extremes of CAM-creep, doctors completely abandon medical practice in favour of CAM–based treatment modalities. An example of this kind of case is *Health Care Complaints Commission v Gorman*.[45] Dr Gorman was an ophthalmologist who qualified as a GP in 2004.[46] He had a long history of disciplinary proceedings with the HCCC and (former) Medical Board of NSW, all of which were related to his medical philosophy. This philosophy essentially stated that all medical illness was related to cervical spine pathology, which can be corrected with spinal manipulation before resorting to orthodox medicine.[47] Gorman believed that '[e]very single patient who walks in the door of general practice is likely to respond beneficially to spinal manipulations.'[48] This approach eventually culminated in the removal of his name from the register for 3 years,[49] a decision he appealed to the New South Wales Court of Appeal, which dismissed his claim for lack of any appealable grounds.[50] Gorman's philosophy was so far removed from conventional medical practice that the Tribunal believed that he would be very unlikely to talk to patients about anything else but spinal manipulation, and that this 'misinformed consent'[51] would pose a risk to patients should he be allowed to practise medicine.

In the Victorian case of *Traill v Medical Practitioners Board*, [52] Dr Traill was unsuccessful in overturning the Victorian Medical Board's previous findings of unprofessional conduct and cancellation of his registration.[53] In the period between 2000 and 2001, Dr Traill had treated three patients suffering from cancer, one of which was a child with a rare brain tumour, with unscientifically proven treatments such as hyperthermia and ultra-high frequency microwave treatment.[54] Despite agreeing with the overwhelming expert evidence that his treatments were unscientific and not shown to be effective,[55] Dr Traill claimed inherent bias in any criticism of

[45] [2012] NSWCA 251.
[46] *Health Care Complaints Commission v Gorman* [2011] NSWMT 7 at [11].
[47] Ibid at [26].
[48] *Health Care Complaints Commission v Gorman* [2011] NSWMT 7 at [26].
[49] *Health Care Complaints Commission v Gorman* [2011] NSWMT 7 at [423].
[50] *Health Care Complaints Commission v Gorman* [2012] NSWCA 251.
[51] *Health Care Complaints Commission v Gorman* [2011] NSWMT 7 at [410].
[52] [2006] VCAT 1920.
[53] *Traill v Medical Practitioners Board* [2006] VCAT 1920, at [1].
[54] *Traill v Medical Practitioners Board* [2006] VCAT 1920, also discussed in Ian Freckelton , "Unscientific Health Practice and Disciplinary and Consumer Protection Litigation" (2011) 18 *Journal of Law and Medicine* 645. See also *Chiropractic Board of Australia v Hooper (Review and Regulation)* [2013] VCAT 878; *Chiropractic Board of Australia v Hooper (Review and Regulation)* [2013] VCAT 1346 discussing a number of the authorities.
[55] *Traill v Medical Practitioners Board* [2006] VCAT 1920, at [55].

his treatment of these patients.[56] The Tribunal found that Dr Traill had not sought informed consent from his patients;[57] that he had misrepresented the efficacy of one of his treatments;[58] that he had overcharged for his treatments;[59] and that he had misrepresented himself as an oncologist when he was not.[60] The Tribunal were very disturbed by Dr Traill's attitude that he believed [his treatments] 'had a therapeutic effect, or, at least, a palliative effect, or, failing that, some unidentified beneficial effect, or that the patients asked for it, or were dying anyway, or that it would not do any harm.'[61] The Tribunal affirmed the Medical Board of Victoria's decision to cancel Dr Traill's registration for three years, stating that

> his lack of insight into his conduct, his ignorance of or contempt for the process of scientific verification and clinical validation of theories which is the hallmark of modern evidence-based medicine, his disregard for the standards set by his peers for the treatment of cancer patients, and his refusal to acknowledge his duty to conform to the standards required by the profession, we consider it appropriate in the circumstances to cancel his registration, in order to protect the public, to maintain the standards of the profession, and to protect the community's confidence in the profession.[62]

Another example of the total abandonment of medical practice in favour of CAM is the case of Dr Raddatz. Dr Raddatz believed in the merits of Mannatech, an unproven alternative product based on monosaccharides. In 2000 the (former) Queensland Health Practitioners Tribunal suspended Dr Raddatz's registration for two years on the grounds of unethical conduct, improper conduct, and incompetence in the practice of medicine.[63] Raddatz had come to believe in Mannatech even though there was no credible scientific evidence to support it. Raddatz offered the product as treatment for haemochromatosis, cancer, infertility and epilepsy. Raddatz also recruited a patient's daughter to sell the product and failed to disclose his own financial interests in the product.

Raddatz was granted conditional registration in 2008. The conditions included the restriction that he would refrain from unconventional medical treatment of patients and that he had to comply in all respects with the (then current) Medical Board of Queensland policy on unconventional medical practice. In 2008 Dr Raddatz was again found to have engaged in unsatisfactory professional conduct for, amongst other things, his unorthodox use of dietary testing and advice (in some cases based on the eating of offal), the unnecessary ordering of B12 injections and advising a patient with mental illness to change his drug regime.[64] He was ordered by the Tribunal to not "adopt or advocate unconventional investigations or treatments" and his practice was subject to a number of supervisory restrictions.[65]

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[56] Ibid, at [52].
[57] Ibid, at [80].
[58] Ibid, at [82]-[84].
[59] Ibid, at [87].
[60] Ibid, at [99].
[61] Ibid, at [110].
[62] Ibid, at [124].
[63] *Medical Board of Queensland v Raddatz* [2000] QHPT 001 at 5.
[64] *Medical Board of Queensland v Raddatz* [2008] QHPT 3.
[65] *Medical Board of Queensland v Raddatz* [2008] QHPT 3 at [49].

Suggested changes to the draft policy

(a) The definition of 'non-conventional practice'

The Board has proposed the following definition:

> **Complementary and unconventional medicine and emerging treatments** include any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.

With respect we believe that a more streamlined definition may prove more useful in the long term. The notion of 'not usually considered to be part of conventional medicine' is also somewhat imprecise. This is probably caused by the fact that the policy is trying to address three main problems – inappropriate use of CAM, unproven use of existing diagnostics and therapeutics, and unproven use of emerging medicine. What all three of these behaviours have in common is a departure from practices supported by responsible peers. This is the same problem that we see in law for questions about standards of care in negligence (the '*Bolam* test') so we would argue that this test could serve a similar purpose in the policy. The benefit of using a modified *Bolam* test is that it is understood both legally and medically. Once a practice has fallen into this category it can then be examined to see if it complies, in which case no disciplinary response will be needed. Alternatively, f the practice does not comply it can be investigated as a breach of the standards or conduct under the National Law.

We like the term 'unconventional medicine' but we believe the term 'non-conventional' might serve a similar function and avoid confusion with the more limited definition the MBA has provided of 'unconventional'. Argubaly it also sounds less judgmental than 'non-conventional'. Equally we prefer to shift the language away from 'medicine' and/or 'treatment' to 'practice' given practice is the focus of the *National Law*. We also think that it is important to exclude research approved by a human research ethics committee constituted under the regulations of the National Health and Medical Research Council, to avoid overlap with formerly regulated medical research.

So the definitions we propose are:

> **Non-conventional medical practice** means medical practice that is not supported widely in Australia by peer professional opinion as competent medical practice, including:
>
> > (a) the use of novel or emerging medical practices;
> >
> > (b) the use of health practices from other health disciplines (including complementary and alternative healthcare); and/or
> >
> > (c) the use of proven and/or accepted medical practice in unproven or non-approved ways,
> >
> > but which excludes research approved by a human research ethics committee in compliance with the regulations of the National Health and Medical Research Council.
>
> **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. Practice includes any assessment, diagnostic technique or procedure, diagnosis, medicine, therapy or treatment. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

(b) Knowledge and skills

One of the features of the cases mentioned above was the problem of a doctor completely departing from the practice of medicine in their pursuit of other modalities of care. We would add a sub-section to paragraph 2:

> 2.5 acknowledging the primacy of scientific medical knowledge and the requirement for medical practitioners to assess non-conventional practice and its place in the treatment of patients according to the standards of the medical profession.

(c) Conflicts of interest

The cases above illustrate many examples of problems with the non-disclosure of conflicts. We would add the following sub-paragraph:

> 3.3 Disclosing all potential conflicts of interest to patients in ways that they will understand both the potential for conflicts and their possible impact on treatment, prior to commencing any intervention.

Alternatively, this could be added to the list of factors required for informed consent

(d) Informed consent

We would add to the introduction to the paragraph (the part in italics)

> Patients have a right to know if the treatment they are being offered is not considered to be 'conventional medicine'. They have the right to know the evidence for its efficacy and safe use.
>
> Medical practitioners proposing complementary and unconventional medicine and emerging treatments must obtain informed consent from their patient. *Informed consent is a necessary (but not a sufficient) requirement for good medical practice.*

(e) Treatment

The lack of peer support and review is another common feature shared by those who breach the National Law. We would amend 6.2 as follows (amendment in italics)

> 6.2. Only recommending treatments where there is an identified therapeutic need, quality and safety can be reasonably assured and that have a reasonable expectation of clinical efficacy and benefit. *Whenever possible, medical practitioners must seek the advice of a qualified peer group to confirm the medical practitioner's assessments of therapeutic need, quality and safety, and expectation of clinical efficacy and benefit.*

(f) Advertising

We believe that non-conventional treatments should not be advertised at all. This may require an amendment to the *Guidelines* on advertising but, following the TGA's decision to forbid advertising of autologous stem cell therapies, we believe that there should be a ban on any advertising of non-conventional practices. Such a ban should relate to advertising particular practices (eg, 'stem cell transplants', 'live blood analysis' etc) which would still allow for a practitioner to state that they have integrated other modalities into their care (eg, "Dr X,

integrative medicine practitioner"). It should also be clear that 'advertising' includes posts to social media.

Conclusion

We are very supportive of the Medical Board of Australian pursing Option 2 and we hope that our suggestions prove useful to the Board when drafting the policy

Yours faithfully

[redacted]

Prof Cameron Stewart

Sydney Law School

On behalf of the submission team

30 June 2019