IMPORTANT NOTICE to all patients

The Medical Board of Australia is proposing to create a strict new set of regulations governing the practice of "Complementary and Unconventional and Emerging Medicine"

The effect of these proposed Regulations will be to significantly increase the burden on Integrative Medical Practitioners, and so to increase the cost to patients of consultations. Also, there is almost certainly going to be a reduction of medical practitioners willing to practice Integrative Medicine and there will be an increase number of cases to deregister practitioners who are willing to continue practicing in this specialised area of medicine. Furthermore, many therapies currently available, including Bio-identical hormones, intravenous nutritional therapies for serious conditions and antibiotic use for Tick-borne illnesses, will be curtailed.

The net effect of these regulations will be to increase the cost and reduce the free choice of patients to see registered Medical Practitioners for specialised advice and treatment with an Integrative medical approach using the best of both orthodox and natural therapies with the latest research.

The stated reason for making these changes is that there have been some complaints from some patients about the standard of care of a few particular practitioners. What is not stated is that these complaints are no more frequent, and generally with less severe outcomes, than complaints against other modalities of medical practice. There is also no case made for why such rare occurrences cannot continue to be dealt with under the existing guidelines for good medical practice.

The unstated reason stems from a bias against the use of non-pharmacological therapies, as well as against progressive ideas in emerging medicine, irrespective of the latest research findings. There are specific aims to limit the treatment of Tick-borne diseases such as Lyme disease, as well as to limit the use of Bio-identical hormones, Acupuncture and Stem cell therapies.

The new regulations will create a discriminatory regime of double standards within medical practice where one group of medical practitioners must practice under a stricter set of guidelines than the rest of medical practitioners.

We urge you to protect your rights, and especially the right of those of you who can least afford it, to have access to the medical treatment of your choice, including the professional and ethical use of Complementary and Unconventional and Emerging Medicine. The Medical Board has released a discussion paper and called for Public consultation and submissions to AHPRA. Follow this link:

- Public consultation on complementary and unconventional medicine and emerging treatments (330 KB,PDF), Word version (713 KB,DOCX)

We ask you to send a personal letter supporting the continuation of the current existing guidelines for medical practice to the Australian Health Practitioners Regulatory Authority as soon as possible (submissions close by ~~12th April 2019)~~ You may also chose to send the same letter to your local member of the Commonwealth Parliament.

With much appreciation

Your Integrative Medical Practitioner

How to make a submission to the MEDICAL BOARD of AUSTRALIA

Individually written letters carry far more weight than a copied format. We thus ask you to write your own submission and to:

Email it to medboardconsultation@ahpra.gov.au

Or mail it to The Executive Officer
Medical
AHPRA
GPO Box 9958
Melbourne 3001

NB Send as soon as possible. Submissions are due to close on the 30th of June 2019

We suggest that in your submission you should:

1 State your name and age and state of residency

2 Make known your interest and concern and preferred outcome. Issues that you may specifically wish to mention could include:
   a. That you have used Complementary or Unconventional or Emerging Medicine and that you value its availability and are happy with its practice.
   b. That your Doctor already provides discussion about options for treatment and their relative merits and potential problems.
   c. That you value free choice in making your decisions over your medical treatment.
   d. That your preferred choice of outcomes is:
      i. Option 1, retain the status quo
      ii. That if the Medical Board eventually decides to choose Option 2, for greater regulation, that it be modified from the current proposal, to ensure
         1. That it applies to ALL medical practitioners with the same onus of exhaustive exposition of all treatment options, research etc, and
         2. That the Board accept that Integrative Medicine, utilising Complementary or Unconventional or Emerging Medicine as well as conventional medicine, be recognised as a Speciality, in order to allow increased Medicare rebates to help cover the increased costs of fulfilling the new regulations.

3 Please do not state the name of your own Integrative Medical Practitioner

Signed by ..... A.A.

Dated ..... 29 May 2019

From: Maggie Adams <[redacted]
Sent: Saturday, 23 March 2019 4:11 PM
To: medboardconsultation
Subject: Consultation on Complementary and unconventional medicine and emerging treatments

To Whom It May Concern
I am concerned about The Medical Board attempting to impose practice restrictions on doctors who practice integrative medicine in Australia.
I do not want this to happen as I believe in complementary medicine and emerging treatments for myself and my family....Freedom Of Choice
Kind regards
Maggie

Maggie Adams
[redacted]

From: [redacted]
Sent: Tuesday, 26 March 2019 9:26 PM
To: medboardconsultation
Subject: Submission: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001
medboardconsultation@ahpra.gov.au

RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern

Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.

Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.

I cannot thank my doctors enough for the risks they take on themselves with Boards such as yours that are continually putting up road blocks when it is quite clear to the majority of patients, that the combined allopathic/complementary treatment protocols work.

Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses also. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?

I have used Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. My treating doctor already provides discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.

The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose (which has worked). Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.

As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that I should be able to attain the treatment of my choice, here at home.

Moreover, if the Medical Board eventually decides to implement Option 2 (greater regulation) I demand that: it applies to ALL medical practitioners with the same onus of exhaustive exposition of all treatment options, research etc; and that the Board accept that integrative medicine, utilising Complementary or Unconventional or Emerging Medicines well as conventional medicine, will be recognised as a Speciality, in order to allow increased Medicare rebates to help cover the increased costs of fulfilling the new regulations.

Your sincerely

Marcelle Ah-Wang
26/03/2019

From: Tash Alexander [redacted]
Sent: Thursday, 30 May 2019 8:41 PM
To: medboardconsultation
Subject: Support of EFT as complementary therapy

Hi
I support Emotional Freedom Techniques (EFT) as a complementary therapy that is evidence based.

https://www.thescienceoftapping.org

With around 100 randomised controlled trials of strong evidence supporting it's efficacy, it's impossible to dispute.
I've attended the "Evidence Based EFT" workshop with Doctors and psychologists as participants, all wanting to add EFT to their tool box.
Thank you for your consideration.
Kind regards
Natasha Alexander

From: Anna Alexander-Reid [redacted]
Sent: Monday, 15 April 2019 12:45 PM
To: medboardconsultation
Subject: 'Public consultation on complementary and unconventional medicine and emerging treatments'

MY RESPONSE TO : 'Public consultation on complementary and unconventional medicine and emerging treatments'

Dear AHPRA

Our family of 6 (2 adults, 4 children) attend the two practices of Integrated Physicians for our medical care.

Along with these Physicians, my partner and I make informed, considered decisions regarding our medical and health care for ourselves and our family.

Our Physicians practice evidence based medicine using nutrition and supplement advice where it is warranted and pharmaceutical drugs at other times when necessary.

Our Physicians are supportive of holistic healthcare that views the whole bodily organism as connected. They look for the root cause of illness, disease and dysfunction and seek to reverse this.

As a family we appreciate the choice to choose a Physician who aligns with our beliefs and practice. We expect our Integrated Physicians to maintain their professional learning and treat us with ALL tools available to them. This includes complementary and emerging medicines.

We DO NOT SUPPORT restricted healthcare.
We DO NOT SUPPORT restricted choice.
We DO NOT SUPPORT caveat healthcare.
We DO NOT SUPPORT healthcare tampering.

Our family has moved to the care of Integrated Physicians due to being unable to achieve optimal wellness under the traditional healthcare model. DO NOT RESTRICT our healthcare choices here in Australia. This is draconian cronyism and barbaric bullying of Australian citizens. PLEASE MAINTAIN HEALTH CARE CHOICE and complementary experimental emerging medicines must be left in the toolbox of Integrated Physicians.

Regards
Anna Alexander-Reid

From: Edward Allardice [redacted]
Sent: Friday, 5 April 2019 11:05 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Good morning Medical Board,

Trust this finds you well.

I'm writing to you, expressing dissatisfaction on limiting medical practitioners scope of resources to just conventional/mainstream medicine. I do believe this will decrease the numerous amounts of effective health solutions for diseases that patients present with.

I can understand why this decision would have been made when reviewing a limited body of evidence that doesn't capture the full impact of complementary medicine and its full potential when supporting patients with many different health needs. Its the large body of evidence that has been collected for thousands of years, that captures the full health potential methods for numerous patient needs, that can be used to best support the future of the medical system in Australia.

In response to the submission, I am informing you that I urge you to adopt option 1; *Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.*

Thank you for taking the time to read my note amongst the mass of many other submissions.

Kind Regards,

Edward Allardice

From: Gail Allen [redacted]
Sent: Thursday, 4 April 2019 11:17 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

I support Option 1 of this consultation paper
Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Having seen various Doctors over many years I have found the Doctors who include a complementary medicine framework in their approach to patients to have provided me with the sort of medical care that has resulted in the improvement of my health. I would find it very distressing to find this sort of care become unavailable.

Kind regards,
Gail Allen

From: [redacted]
Sent: Wednesday, 10 April 2019 5:58 PM
To: medboardconsultation
Subject: Public Consultation on Complimentary Medicine and Emerging Treatments

To whom it may concern,

Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.

Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.

Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is.

Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.

The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.

As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Yours sincerely,

Renee Jennifer ALLEN
[redacted]
10th April 2019

From: Heather [redacted]
Sent: Sunday, 17 March 2019 5:08 PM
To: medboardconsultation
Subject: 'Consultation on complementary and unconventional medicine and emerging treatments'

To Whom It May Concern

I am writing as a retired Director of Nursing to express the importance of an integrative approach to healthcare.

I have witnessed excellent results with patients cared for under the broader approach of incorporating both conventional and integrative care. Through implementation of holistic strategies the body's healing process is greatly enhanced, going beyond just eliminating symptoms.

Effective less invasive treatments can easily be incorporated with excellent results. Chronic health problems require assessment and treatment of the whole person and not just the disease. The importance of understanding and focusing on nutrition and gut health (which is often overlooked) and the skills to implement strategies for patients has a major influence on health and promotes wellness.

There can be an appropriate use of both conventional and integrative medicine and I believe that those that practice this are at the forefront of healthcare.

I have seen this time and time again not only with patients, but indeed in my own personal wellness journey.

Heather Alley

From: Kate Amos [redacted]
Sent: Monday, 15 April 2019 1:14 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

In consideration of protection of the public, I refer to the public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

As an allied health practitioner (Dentist) working in a regional area of NSW, I have been fortunate to work closely with medical practitioners who combine 'conventional medicine' and 'complementary and unconventional medicine.'

I must say that on the whole, I have found those practitioners who practice 'complementary and unconventional medicine' to be incredibly diligent with respect to the co-ordinated management of patients under their care.

Although some of the methods employed are emerging or complementary, in discussions with patients being treated in this way, they appear universally well-informed about the treatment being undertaken and I have never perceived duress to comply with an alternative medicine regimen. Many of the practitioners in our region appear to use conventional medicine as their major reference, depending only on complementary and alternative methods to address conditions that are not well understood or managed otherwise.

An example that comes readily to mind in my own field is in management of neuropathic and atypical orofacial pain. Seldom do Dentists manage these conditions, instead, we work with our medical colleagues to do so. Unfortunately, many of these conditions are poorly understood and do not have reliable conventional management strategies. They can also be extremely debilitating for those affected. With evidence only slowly emerging for the appropriate 'conventional' management of such conditions, complementary therapies remain in many instances the only solace for these patients.

And yet, despite the lack of knowledge around these conditions, the approaches that I have witnessed when medical colleagues have used complementary approaches has been as rigorous in its diagnostic, titration and review strategies as any reasonable member of the public could expect.

It has been my experience that practitioners who adopt complementary and alternative medicine as part of their clinical armamentarium appear to maintain a high standard of communication and collaboration with their allied health colleagues, are focused on patient wellbeing, and seek evidence for efficacy as would be expected of their level of training and trust placed in them by the community.

In reading the Code of Conduct (*Good medical practice: A code of conduct for doctors in Australia)* I believe the Australian public is already protected by a robust framework for professional conduct among Medical

Practitioners. The same standards should apply to any practitioner performing any form of medicine as a registered health professional. Further definitions or segregations appear unnecessary at this time based on my personal experience. An approach which aims to maintain a close connection between conventional, emerging and complementary medicine with universal principles for professional conduct regardless of the domain would seem in keeping with the expectations of the public as well as health professional colleagues.

Yours Sincerely,

Dr Kate Amos

From: Sarah Andrews [redacted]
Sent: Wednesday, 10 April 2019 11:23 PM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology. As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Sarah Andrews
8/4/2019

From: Lisa Apostolides <campaigns@good.do>
Sent: Friday, 17 May 2019 2:20 PM
To: medboardconsultation
Subject: I oppose your changes or additions to the existing Code of Conduct 2014

Dear Sir / Madam,

I believe your proposals contained within your current Consultation Paper violate my right of self determination and protection of the rights to freedom of thought, conscience and to freedom of opinion and expression. (Articles 18 and 19 of the International Covenant on Economic and Social Rights & Cov on Civil and Political Rights (Ratified by Aust in 1995)

I also believe the proposals to limit my health care options by way of redefinition and restriction of complementary and alternative health practices is a violation of my fundamental rights as an Australians to have the 'highest attainable standard of health'. This right is recognized by the World Health Organisation Constitution (1946).

I hereby exercise my right under the Aust Charter of Healthcare (2007-8) to be included in decisions about my healthcare.

I have had several positive experiences and outcomes from complementary and alternative health practitioners and I wish to continue to have a choice over my treatment.

Yours sincerely,
Lisa Apostolides
[redacted]

_____

Dr Peter C. Arnold OAM
BSc, MBBCh Witwatersrand, *BA* New England

[redacted]

Friday, 22 February 2019

Re: 'Consultation on complementary and unconventional medicine and emerging treatments'

The Medical Board of Australia
Melbourne

Thank you for the invitation to make a submission.

Declaration of interest
Former Deputy President, NSW Medical Board
Former Chair, Professional Standards Committees of the NSW Medical Board
Former Chair, Registration Committee of the NSW Medical Board
Former Member, Medical Tribunal of NSW (District Court)
Former Member, Disciplinary Committee, Law Society of NSW
Former Member, Tribunal, NSW Bar Association
Former Chair, Federal Council, Australian Medical Association
Former President, AMA New South Wales
Chief Editor, Friends of Science in Medicine

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?
No, because the word 'treatment' is misleading. These non-evidence-based interventions are not 'treatments'. They are the very opposite of treatments; they are placebos.
This misleading term should be corrected throughout the document.
If not, what term should be used and how should it be defined?
'Health Interventions' – defined as "any intervention in a person's state of health, where that intervention is not based on valid and reproducible evidence"

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging **treatments** – 'any assessment, diagnostic technique or procedure, diagnosis, practice,4 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**.'
No, because the words 'therapy', 'treatment' and 'therapies' are misleading. 'Intervention' covers all three.
If not, how should it be defined?
By avoiding those words and substituting 'interventions'.
Footnote 4 ('Practice') is well-worded.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?
The concept of 'emerging' treatments needs clearer definition. There is a difference, on the one hand, between a newly explored treatment which, in well-controlled trials, is showing promise, and the claim, on the other hand, by a medical practitioner that one or other intervention he or she is using is 'emerging', because he or she is advocating it.
Evidence about new treatments is 'emerging', if not daily, then weekly, in reputable medical journals.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?
Yes. This statement is incorrect:
Tests and treatments are generally funded privately by patients (**not covered by Medicare or private health insurance**) and can be expensive with uncertain results.
Medicare funds acupuncture by registered medical practitioners, as do some health insurance funds, despite the total lack of evidence of efficacy other than as a placebo. I attach the exhaustive commentary by Professor of Neurophysiology at Flinders University, Marcello Costa. I also draw your attention to the debunking of acupuncture by Professor Edzard Ernst, Emeritus Professor of Complementary Medicine at the Peninsula School of Medicine, University of Exeter.
If the Medical Board of Australia is not to show a bias towards registered medical practitioners who practise acupuncture, it should press the Commonwealth to cease paying rebates for consultations by registered medical practitioners where acupuncture is administered.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?
More relevant would be the banning of claims (including advertising) by registered medical practitioners through 'false advertising' legislation. The Medical Board of Australia should investigate any such claims by registered medical practitioners, as it does for other areas of unprofessional conduct or professional misconduct.

6. Is there other evidence and data available that could help inform the Board's proposals?
I have alluded to the work of Professors Costa and Ernst. There is a vast amount of highly relevant information on the website of Friends of Science in Medicine, of which Professor John Dywer was Founding President, now succeeded by Professor Ken Harvey.

7. Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?
Not at all.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?
Guidelines would not suffice unless the Board were to back the guidelines with action, by investigating allegations as they do allegations of unprofessional conduct and professional misconduct.

Sincerely,

[redacted]

Friends of Science in Medicine
PO Box 631 • Morayfield • QLD 4506
scienceinmedicine@bigpond.com

***Endorsed by the RANZCOG - 29 July 2016**

Is there any place for acupuncture in 21st century medical practice?

Introduction

Acupuncture is an integral part of traditional Chinese medicine (TCM). Over the past few decades, acupuncture has become popular in a number of countries as a stand-alone intervention. As part of TCM, acupuncture needs to be considered as a pre-scientific modality, and, as such, unlikely to be accepted by global modern medical science. As a separate technique it has received much attention. However, after much promise and extensive investigation, it is now becoming clear that there is no evidence based support for its use in modern medicine. This paper examines the evidence for this conclusion. Acupuncture is examined as a part of TCM and the results of research studies asking if acupuncture has the potential for contributing to modern scientific medicine are reviewed.

Traditional Chinese Medicine

What is traditional Chinese medicine?

TCM, also present in Japan, where it is called *Kampo*, is, together with Indian Ayurveda and pre-Enlightenment European medicine, one of the major pre-scientific medicines. They share common roots, probably from ancient Indian philosophies, according to which the equilibrium of the healthy human body is believed to be the result of a balance of a number of elements. Diseases are thought to be due to their imbalance.

In TCM, these elements are wood, water, fire, earth and metal, a belief similar to that of ancient Indian Unani medicine, with its four humours (*akhlaat*) – air, earth, fire and water, and Indian Ayurveda medicine's air, water and fire. Pre-scientific European (from Greco-Roman) medicine proposed four humours, each associated with the four natural universal elements (blood – air; phlegm – water; yellow bile – fire; black bile – earth). Although these theoretical constructs represented an initial attempt to unify knowledge about the world and ourselves, none has any scientific foundation.

The history of traditional Chinese medicine

TCM involves imaginary structures and undemonstrable 'vitalistic' forces. An undetectable, immaterial life force, *qi*, is said to flow through channels ('meridians') in the body. Circulating within these channels is the hypothetical *qi*, which regulates bodily function, modulated by 12 bilaterally distributed channels (six Yin and six Yang channels), supplemented by two midline channels (one in the front, and the other in the back, of the body). Disease is said to occur when the flow of *qi* becomes blocked. TCM uses several approaches to correct such blockage, including acupuncture, moxibustion and multiple herbal and animal extracts.

The politics of traditional Chinese medicine

TCM, as is true for many other traditional medicines, plays important cultural and political roles in modern geopolitics.

In the 19th century, China started to accept the emerging scientific bases of medicine. In 1822, Emperor Dao Guang issued an imperial edict, stating that acupuncture and moxibustion should be banned forever from the Imperial Medical Academy. Indeed, the teaching of acupuncture was banned by the Imperial Medical Academy in 1882 and its use banned in 1929. In parallel, modern medicine had developed rapidly. The four humours theory had long been discredited by evidence-based developments and TCM was being superseded. Acupuncture continued as a minor activity in China till the Chinese Civil War finally ended in 1950. Not surprisingly, the Chinese Communist Party, based on the materialist philosophy of Marxism, rejected TCM, including acupuncture, as superstitious.

However, Chairman Mao Zedong revived TCM as part of the Great Proletarian Cultural Revolution of 1966, giving medical authority to peasant doctors still using TCM and establishing 'barefoot doctors' with a comprehensive manual. The revival was a useful way to increase Mao's authority amongst peasants and has since become part of Chinese nationalism.

Despite the overwhelming importance of modern medicine in modern China, supported by the vast majority of health workers, the emergence of China as a political and economic giant has given the traditionalists a further impetus, by supporting TCM with cultural pride, to expand China's influence in the world.

The Chinese government has started to promote TCM heavily, both in China and abroad. The WHO in 2008 endorsed an international agreement drawn up in Beijing to support the safe and effective use of traditional medicine within the modern healthcare system of member states**.** In 2011, China signed 91 TMC partnership agreements with more than 70 countries with the aim of promoting greater recognition of TCM around the world. Recently the trade agreement with China and Australia (2015) included a special agreement to enable TCM professionals to practice, and TCM methods to be fostered in Australia.

This process of globalising aspects of TCM is also finding it way into the most important scientific journals such as *Nature*, which sponsored an entire section on 'Traditional Asian Medicine'. Interestingly, in China, a bachelor of medicine is only conferred currently on students of modern scientific medicine. Today, Western medicine is highly respected in China, while TCM (including acupuncture and herbs) is mainly used by those with lower socio-economic status. Since the early 20th century, the number of TCM practitioners in China has dropped from 800,000 to 270,000, and the number of Western-trained physicians has risen from 87,000 to about 1.75 million. In China, 'medicine' always implies 'modern medicine', not TCM.

The history of acupuncture

"An ancient Chinese method"?

Acupuncture is said to be 3,000 years old, but the earliest Chinese medical texts don't mention it. The earliest reference to 'needling' is from 90 BC and apparently refers to lancing abscesses with large needles or lancets made of stone and bone; early diagrams of lines on the body corresponded to visible veins, not 'meridians,' and were probably guides for bloodletting.

The total number of 'acupoints' changes over time. It was only 160 in *The Inner Classic of the Yellow* under Emperor Huangdi Neijing (between 200 and 100 BC - "The inner classic of the yellow emperor – plain questions"). After its report in the Yellow Emperor's *Manual of Corporeal Medicine* (Huang Di Nei Jing, also known as *Inner Canon*) in the 2nd century BC, acupuncture became widely used (J.L. Needham Science and civilization in China).

In addition, there seems to be little agreement about acupuncture. There is disagreement about the location and number of meridians: different texts mention 9, 11, or 12, or even as many as 36 meridians along with sub meridians. Some systems of acupuncture disregard meridians entirely and only use points on the tongue, scalp, ear or hand. There is disagreement about the location and number of acupoints. Originally there were 365, symbolically corresponding to the number of days in a year (acupuncture's origins are tied to astrology). Now over 2,000 have been described. In Korean acupuncture, there are 300 acupoints, but these are all on the hand. In auricular acupuncture, there were originally 30 acupoints, but now there are more than 120, all on the ear. If you add up all the acupoints described in all the different systems of acupuncture, it's hard to find an area on the skin that has *not* been designated as an acupoint.

Furthermore, historians have suggested that the ideas behind the use of acupuncture might have originated in ancient Greece and travelled to China via trade routes. The first European accounts of Chinese medicine in the 13th century didn't mention acupuncture. Before the 20th century, needles were commonly inserted directly into the site of pain rather than into acupoints. One popular version of acupuncture, ear acupuncture, was invented by a Frenchman, Nogier, as recently as 1957.

The place of acupuncture in traditional Chinese medicine

Acupuncture within TCM is believed to balance the energy flows of Yin and Yang, the two major 'negative' and 'positive' forces governing the body. By inserting a needle followed by its appropriate manipulation, it is believed that one can unblock the channel, thereby re-establishing the free flow of *qi*, relieving the pain and correcting imbalances and thus removing illness (e.g. D. Ehling Oriental medicine: an introduction, Eastern concepts of acupuncture (Veterinary Acupuncture (2nd ed.)), and Traditional and evidence-based acupuncture: history, mechanisms, and present status.

Why acupuncture has become popular in the rest of the world

As globalisation began to meld international relations, so interest in other cultural enclaves grew. During Nixon's visit to China in 1972, an accompanying reporter commented on symptomatic relief by acupuncture of pain after an appendicectomy operation. This event triggered interest in possible drug-free-induced anesthesia. The National Institutes of Health (NIH) gave the first grant to study acupuncture in 1972. Despite the significant interest in potential useful applications of ancient traditional medicines, the American Medical Association Council in 1981 (Reports of the Council on Scientific Affairs of the American Medical Association, and in 1991, the National Council Against Health Fraud: Acupuncture Position Paper, concluded that acupuncture has no scientific basis. But the attraction to 'miracle cures' of diseases was too strong, and the interest in acupuncture did not abate.

In Taiwan, only 6% of the population has used acupuncture (compared to 6.5% in the US). One could argue that acupuncture might just as well be called 'Californian' as 'Chinese.' And ear acupuncture, the kind being taught to American military doctors as 'battlefield acupuncture' is more 'modern French' than 'ancient Chinese'.

What could be the mechanisms by which acupuncture might work?

The proponents of acupuncture have postulated possible mechanisms involving neurovascular bundles, trigger points, connective tissue fascial planes, electrical impedance, migration of nuclear tracers, and other factors. These studies are flawed, inconclusive, contradict one another, and have not been replicated.

However, interest in acupuncture, particularly for analgesia, has been related to the 'gate control' theory (R. Melzack and P.D. Wall, *"*Pain mechanisms: a new theory*"*). According to this theory, the activation of large sensory fibres (touch pressure and vibration) inhibits transmission of nociceptive (pain recognising) pathways carried by small unmyelinated nerve fibres. This was postulated to occur in the spinal cord and might explain the effect of 'rubbing' the skin to reduce acute pain, the use of 'counter irritants', defined by the USA FDA as "externally applied substances that cause irritation or mild inflammation of the skin for the purpose of relieving pain in muscles, joints and viscera distal to the site of application". It has been suggested that acupuncture could act as a counter irritant.

Interest grew, in the 1970s, with the discovery of brain endogenous opioid peptides, which mimic the actions of morphine on pain. These discoveries triggered extensive research, both in China and around the world, on the involvement of endogenous opioid peptides and a plethora of many neuropeptides and purines in acupuncture-induced analgesia (H.M. Langevin et al., "Mechanical signaling through connective tissue: A mechanism for the therapeutic effect of acupuncture," N. Goldman et al., "Adenosine A1 receptors mediate local anti-nociceptive effects of acupuncture," Z.Q. Zhao "Neural mechanism underlying acupuncture analgesia".) The discovery of novel neurotransmitters capable of affecting nociception gave extra impetus to explain some analgesic responses to sensory stimulation (e.g. mini-review on *"*Acupuncture and endorphins*"* in *Neuroscience Letters*).

However while the concept that sensory stimulation affects pain sensation is well established, efforts to date have not established that this phenomenon is responsible for acupuncture induced analgesia.

Although acupuncture is supposed to be a very specific intervention involving skin penetration with needles and manipulation (twirling), many studies include a plethora of other interventions, assumed to be, to a lesser or greater degree, equivalent**.** These include acupressure, electro-acupuncture, transcutaneous nerve electrical stimulation (TENS), laser acupuncture, tiny gold beads implanted under the skin, and injection of homeopathic

remedies into acupoints. Electro-acupuncture, manipulated by passing electric currents through implanted needles, is widely used and allows a more objective control over stimulating parameters. Electro-acupuncture appears to be able to activate or deactivate a variety of brain regions and promote the release of endogenous opioid peptides, which are responsible for mediating its analgesic effects.

Other non-penetrating methods include stimulation with sound, pressure, heat (moxibustion, sometimes with deliberate burn injury), electromagnetic frequencies (laser stimulation, capsicum plaster, an acu-stimulation device such as Electro-acupuncture of Voll [EAV]), chemical (capsicum plaster and Sweet Bee Venom Pharmaco-puncture), vacuum (cupping), color, waving hands over acupoints, and striking the appropriate meridian on an acupuncture doll with a metal hammer (Tong Ren). Even some forms of bloodletting are thought to involve activation of acupuncture points.

Because of the aforementioned scientific studies on the neuroscience of nociception, acupuncture seemed to gain somewhat more plausibility than other forms of alternative medicine. Acupuncture has even been said to have positive effects on animals' cognitive functions.

Acupuncture and the proven principles of Brain Science

Any hypothesis on the mechanism of action of acupuncture and equivalent interventions needs to be placed within the well established, proven principles of the brain sciences. Brain activity is due to the activity of billions of nerve cells, each generating small electrical currents which carry signals from one end to the other of each nerve cell; and, due to communication through the release of small amounts of chemicals, called neurotransmitters, with other nerve cells and with muscle and glands. These electrical and chemical aspects of the nervous system represent the most important foundations of modern brain science.

This principle of organisation and function of the nervous system became well-established by the middle of the 20th Century, thanks to the research of the Australian neuroscientist, Sir John Eccles, Nobel prize-winner in Medicine because of this discovery. Since then, a plethora of neurotransmitter substances have been identified in the brain and in peripheral organs. Amongst these are endogenous opioids, as mentioned above, and other neuropeptides; these are recognised as important potential modulators of brain function. Not surprisingly, the idea that activating sensory inputs might affect central neural circuits and that, in particular, acupuncture might well work for analgesia, has triggered extensive research.

While there is evidence for the release by various sensory stimuli, including manual acupuncture, of some endogenous opioids and other endogenous chemical mediators potentially capable of modifying pain stimuli, there is little evidence that this is a specific effect related to any anatomical organisation which could correspond to the 'meridians' of TCM. In most cases, any physical or chemical sensory stimulus is likely to result in the release of some endogenous anti-nociceptive substances. The highest quality studies have shown that it doesn't matter where you insert the needles (acupoints or non-acupoints), and that it doesn't matter whether the skin is penetrated (in one study, touching the skin with a toothpick worked just as well). The one thing that does seem to matter is whether the patient believes in acupuncture.

It is becoming increasingly clear that the brain processes underlying the physiological 'placebo effect' in reducing pain perception share similar neurochemical mechanisms with the sensory stimulation caused by acupuncture and other sensory stimulations.

Thus the placebo effect is likely to explain many of the subjective improvements of many interventions, including acupuncture. This similarity explains, in part, why it has been so difficult, in practice, to perform satisfactory clinical trials to test the effectiveness of acupuncture separate from the placebo effect.

Another myth is that acupuncture *must be effective* because it works on animals, and they wouldn't respond to a placebo. But animals can't talk to tell us to how they feel; their owners must interpret their responses by observing the animal's behaviour, and the owners *are* susceptible to suggestion. They might inadvertently influence the animal's behavior by giving it more attention or treating it differently in some way. They might be convinced that they see a change in the animal's behavior and think that it means the animal feels better.

Using acupuncture for its placebo effect

Recently, the weight of evidence has convinced some acupuncturists that acupuncture works no better than placebo, but they still advocate using it for its placebo effect. Medical ethicists universally condemn using placebos intentionally since it amounts to lying and can destroy trust in the doctor/patient relationship. In reality, placebos don't do much; their effects tend to be small in magnitude and short in duration. Patients who use them might defer or reject necessary effective treatment. Placebos can waste time and money, and harm can result when patients are deluded into thinking they are getting better when they really are not. One study found that patients with asthma had the same positive subjective responses to placebos as to an asthma inhaler; but objectively, only the patients in the asthma inhaler group had improvements in lung function. The response to placebos was no better than that of patients in a no-treatment control group. This could have serious consequences, since difficulty in perceiving the severity of an asthma attack is a risk factor for asthma-related death.

Is there clinical evidence for effectiveness of acupuncture in clinical medicine?

The proponents of acupuncture, whether as part of holistic TCM or as a separate technique, advertise that acupuncture can cure a wide range of diseases. Acupuncture has been claimed to be effective for addiction (such as alcoholism), allergies, asthma, bronchitis, carpal tunnel syndrome, chemotherapy-induced nausea and vomiting, constipation, depression, diarrhoea, endometriosis, facial tics, fibromyalgia, gastro-esophageal reflux, headaches, high blood pressure, infertility, irregular menstrual cycles, kidney infections, memory problems, multiple sclerosis, pre-menstrual syndrome, polycystic ovarian syndrome, low back pain, menopausal symptoms, menstrual cramps, osteoarthritis, pain of various natures, pharyngitis, post-operative nausea and vomiting, psychological disorders such as anxiety, sciatica, sensory disturbances, sinusitis, spastic colon (often called irritable bowel syndrome), stroke rehabilitation, tendonitis, tennis elbow, tinnitus, urinary problems such as incontinence, sports injuries, sprains, strains, ulcers, and whiplash.

Acupuncture trials and pitfalls

Clinical research on acupuncture is inherently difficult. The practice of acupuncture is not standardised, and some studies of 'acupuncture' are actually of electro-acupuncture, ear acupuncture, or other variants. It's next to impossible to do double-blind studies, so confounding factors cannot be eliminated. The best studies use a retractable needle in a sheath, so that the patient can't tell whether the skin has been penetrated or only touched by the needle. The results are highly variable: it's easy to find studies to support a belief in acupuncture, but it's even easier to find studies showing that it doesn't work.

The rationale for acupuncture's acceptance in some aspects of clinical medicine, particularly in emergency medicine and pain clinics, has begun to crumble on closer examination of the evidence, mostly because of the excessively variable nature of the interventions involved in various studies which did not clarify the nature of the sham interventions used and any placebo effects.

Recent reviews of the effectiveness of acupuncture on pain in general are rather damning. There have, over several decades, been several thousand acupuncture studies. After all this clinical research, acupuncture has not been clearly demonstrated to be effective for any indication. In short it is more than reasonable to suggest that acupuncture doesn't work being no more than "a theatrical placebo".

Traditional Chinese acupuncture is no better for treating menopausal symptoms than a 'sham' version using blunt needles, according to a University of Melbourne study, published in the *Annals of Internal Medicine*, involving 327 Australian women over 40 who had at least seven moderately hot flushes daily. Half were given ten sessions of standard Chinese medicine acupuncture, where thin needles were inserted into the body at specific points. The others had their skin stimulated with blunt-tipped needles, which had a milder effect without penetrating the skin. After eight weeks of treatment, both had led to a 40% improvement in the severity and frequency of hot flushes; this was sustained six months later. However, there was no statistical difference between the two therapies. The authors said that both groups might have improved as a result of the placebo effect or because attending a clinic to talk about symptoms helped.

The authors also noted that hot flushes tended to improve spontaneously with time adding "This was a large and rigorous study, and we are confident there is no additional benefit from inserting needles compared with stimulation from pressuring the blunt needles without skin penetration for hot flushes."

The most positive results from acupuncture have been for pain and post-operative nausea and vomiting (PONV). But even for those, the evidence is unconvincing. For PONV, the most recent meta-analysis indicated a small effect of P6 acupoint stimulation, but it mixed studies of acupuncture with electro-acupuncture, transcutaneous nerve stimulation, laser stimulation, capsicum plaster, an acu-stimulation device, and acupressure. There were questionable randomisation procedures, incomplete data, and the conclusion of the reviewers (that P6 acupoint stimulation "prevented PONV") was not justified by the data. There is a lot of 'noise' in the data from these studies, but there doesn't appear to be any 'signal' mixed with the 'noise'.

It has been shown that the analgesic benefits of acupuncture are partially mediated through placebo effects related to the acupuncturist's behavior. It is becoming increasingly clear that any reported benefits of acupuncture are largely due to the surrounding ritual, the beliefs of patient and practitioner, and the other non-specific effects of treatment, not to the needles themselves.

The team studying PONV also examined 'Acupuncture for pelvic and back pain in pregnancy: a systematic review'. They concluded "limited evidence supports acupuncture use in treating pregnancy-related pelvic and

back pain. Additional high-quality trials are needed to test the existing promising evidence for this relatively safe and popular complementary therapy".

A systematic review of acupuncture for various pain conditions found a mix of negative, positive and inconclusive results. Out of 57 systematic reviews, there were only 4 pain conditions for which more than one systematic review reached the same conclusion: in 3 cases, they agreed that it was ineffective, and in only one (neck pain) was it agreed that it was effective.

That finding is suspect, because it doesn't make sense that a treatment could relieve pain only in one part of the body but not elsewhere.

Over the past 10-15 years the **Cochrane collaboration** has addressed the efficacy of acupuncture for many of these indications. When clinical trials have been performed properly, **lack or insufficient evidence of effectiveness for acupuncture** was demonstrated in most cases. The following is a list, not exhaustive, of such trials.

- In thirty trials for depression, with 2,812 participants, manual and electro acupuncture were compared with medication; they found no difference between the two groups.
- A review by the Cochrane Collaboration on the question 'Do acupuncture and related therapies help smokers who are trying to quit' "did not find consistent evidence that active acupuncture or related techniques increased the number of people who could successfully quit smoking".
- A study by RMIT researchers in 2016 showed that acupuncture is no better than placebo for menopausal symptoms such as hot flashes.
- A Cochrane Collaboration study (2014) demonstrated no effects on functional dyspepsia. A similar lack of effect on rheumatoid arthritis was demonstrated in 2005.
- Even proponents of acupuncture from the team at the RMIT in Melbourne, in their attempt to prove that acupuncture is effective in a "range of health conditions", admitted, "No solid conclusion of which design is the most appropriate sham control of Ear-acupuncture/ear-acupressure could be drawn in this review".
- Very clear experimental work performed by a University of Melbourne team on one of the projects funded by the NH&MRC on laser acupuncture, "Acupuncture for Chronic Knee Pain published A Randomized Clinical Trial on chronic knee pain", showed that neither needle nor laser acupuncture significantly improved pain and concluded that their findings did not support acupuncture for these patients.
- A paper in *Obstetrics & Gynecology* in 2008 "Acupuncture to Induce Labor: A Randomized Controlled Trial" concluded "Two sessions of manual acupuncture, using local and distal acupuncture points, administered 2 days before a scheduled induction of labor did not reduce the need for induction methods or the duration of labor for women with a post-term pregnancy".

Trials not performed sufficiently well and therefore "need to be repeated"

Despite the several decades of significant funding for, and research on, acupuncture and, in general, on alternative medicines in Australia and around the world, far too often the conclusion from clinical trials is "more research is needed". The excuses given in the numerous reviews, mostly by the proponents, are

insufficient numbers of patients or trials or insufficient control subjects. The reality is more likely due to the reality that there is an absence of effectiveness.

For example, a review on "Acupuncture to treat common reproductive health complaints: An overview of the evidence" concluded "Acupuncture to treat premenstrual syndrome or polycystic ovarian syndrome and other menstrual related symptoms is under-studied, and the evidence for acupuncture to treat these conditions is frequently based on single studies. Conclusion: Further research is needed".

In a review, "Pain Research in Complementary and Alternative Medicine in Australia: A Critical Review", the authors concluded that, because of the poor design and execution of research papers on pain and alternative medicines, "The quantity and the quality of CAM pain research in Australia is inconsistent with the high utilization of the relevant CAM therapies by Australians. A substantial increase in government funding is required. Collaborative research examining the multimodality or multidisciplinary approach is needed".

It has been claimed that surgery can be performed using only acupuncture anesthesia. A widely publicised picture of a patient allegedly undergoing open-heart surgery under acupuncture anesthesia appears to be a fake: it shows her with an open chest cavity that would make her lungs collapse, she is not on a respirator and a heart-bypass machine does not appear to be in use. Also, the incision is in the wrong place for the procedure being described, and the photo is curious in other respects (such as the position of the patient's head). A recent BBC video of surgery on a conscious patient anaesthetised with acupuncture was similarly misleading.

Researchers at the Centre for Complementary Medicine Research at the University of Western Sydney, commenting on studies of acupuncture for menstrual problems stated, "Five systematic reviews were included, and six RCTs. The symptoms of the menopause and of dysmenorrhea have been subject to greater clinical evaluation through RCTs, and the evidence summarised in systematic reviews, than any other reproductive health complaint. The evidence for acupuncture to treat dysmenorrhea and menopause remains unclear, due to small study populations and the presence of methodological bias.

For example, a review on "Acupuncture to treat common reproductive health complaints: An overview of the evidence" concluded "Acupuncture to treat premenstrual syndrome or polycystic ovarian syndrome and other menstrual related symptoms is under-studied, and the evidence for acupuncture to treat these conditions is frequently based on single studies. Conclusion: Further research is needed".

Many other studies by the Cochrane Collaboration concluded that there was insufficient evidence for recommending the use of acupuncture for the conditions investigated, as listed as follow: ADHD in children and adolescents (2011); autism spectrum disorders (ASD) (2011); Bell's palsy (2010); cancer-related pain (2015); glaucoma (2013); depression (2010); dysphagia in acute stroke (2008); tennis elbow (2002); 'fibromyalgia' (2013); induction of labour (2013); menopausal hot flushes (2013); mumps (2014); near-sightedness in children (2011); hypoxic ischemic encephalopathy in newborn babies (2013); pain in endometriosis (2011); period pain (2011); chronic asthma (1999); urinary incontinence (2013); stroke rehabilitation (2006); uterine fibroids (2010); labour pains (2011); vascular dementia (2007)**;** nausea and vomiting in early pregnancy (2015); obesity (2015). Even TENS appears to give insufficient evidence for improving dementia (2003).

Reasonable trials with evidence for small effects.

A Cochrane study on acupuncture and dry needling for low back pain, based on 35 randomised clinical trials in 2005, reported a very small effect.

Another Cochrane study in 2009 suggested that acupuncture should be considered a treatment option for migraine prophylaxis, despite finding that "there was no evidence of an effect of true acupuncture over sham interventions".

A Cochrane study in 2006 found moderate evidence for a small improvement in chronic neck pain while a review in 2009 suggested that there was benefit from the use of acupuncture to treat Tension-type headache

Almost all trials of alternative medicines seem to end up with the conclusion "more research is needed". After more than 3,000 trials, we should recognise that the need for more trials is dubious.

Acupuncture in Australia

The reader is referred to the excellent review "Acupuncture in Australia".

Publicly funded Australian research on acupuncture

In recent years, with significant NH&MRC funding, research might have been be expected to result in some experimental evidence for acupuncture effectiveness if it existed. Starting from 2009, there were 7 NHMRC-funded CAM projects on pain. Four out of six projects were on chronic pain, one on acute pain, and the remaining one on experimental pain in rats. In all of them, acupuncture was the study intervention. All projects involved collaborative research.

In that year, the NH&MRC awarded over $2.5 million for seven grants for acupuncture research; one to Griffith University, four to RMIT University, one to the University of Queensland and one to the University of Melbourne. It has since been difficult to trace publications stemming from these projects. Only one paper was published from the team at the RMIT ("Acupuncture analgesia for temporal summation of experimental pain: a randomised controlled study"), but this had not been supported by the NH&MRC. Paradoxically, while electro-acupuncture was mildly effective when compared with a sham intervention, the result of traditional manual acupuncture (MA) was not different from that of the sham treatment (SA). Yet the authors dismiss this negative finding because "the lack of difference between the MA and SA groups in this study is likely a type II error due to a small sample size" .

Most publications published by leading Australian workers in this field were **reviews** rather than research papers, with very few acknowledging their NH&MRC funding. Many are simply papers on developing "Study protocols" to be applied some time in the future.

In a review in 2013, supported by the NH&MRC, the authors stated "It is suggested in our theoretical model that, in adult subjects with allergic rhinitis, acupuncture may down-regulate certain pro-inflammatory neuropeptides and neurotrophins as well as Th2 cytokines and pro-inflammatory cytokines, thereby producing a shift in the Th1/Th2 balance of T helper cells towards Th1".

Following a meeting in 2015 on "Acupuncture and Immunity", a team from Melbourne RIMT published a review on "Mediators, Receptors, and Signaling Pathways in the Anti-Inflammatory and Antihyperalgesic Effects of Acupuncture" (Evidence-Based Complementary and Alternative Medicine, Volume 2015, Article ID 975632), a special issue published by the Hindawi Publishing Corporation). No experimental evidence was provided.

The authors of a review article on "Factors Associated with Conflicting Findings on Acupuncture for Tension-Type Headache: Qualitative and Quantitative Analyses" admitted "Acupuncture is a complex intervention. Its active ingredients are not well defined." But the work concludes that results from meta-analysis "showed no statistically significant difference between real and sham acupuncture on headache days" and attributed this to the problem that "stimulation mode, needle retention, and treatment frequency are important factors contributing to the outcome of acupuncture treatment for TTH". No funding from the NH&MRC was acknowledged.

Another review article by an RMIT team "The Anti-Inflammatory Effects of Acupuncture and Their Relevance to Allergic Rhinitis: A Narrative Review and Proposed Model" concluded "more research is needed to elucidate specifically how immune mechanisms might be modulated by acupuncture in allergic rhinitis". Another review by the main author from the RMIT team ("Pain Research in Complementary and Alternative Medicine in Australia: A Critical Review") found that half of the acupuncture studies were conducted by medical doctors or physiotherapists. Multidisciplinary collaboration was uncommon.

The issue of performing proper trials, taking into account the placebo effect by using suitable 'sham' treatments, appears insurmountable, as the very proponents of acupuncture admit in yet another review article from the team of the RMIT ("Sham Control Methods Used in Ear-Acupuncture/ Ear-Acupressure Randomized Controlled Trials: A Systematic Review"). They concluded, "No solid conclusion of which design is the most appropriate sham control of EAP could be drawn in this review" .

The team funded by the NH&MRC at Griffith University also published mostly review articles ("Mediators, Receptors, and Signaling Pathways in the Anti-Inflammatory and Antihyperalgesic Effects of Acupuncture"). As with other review articles, this review conflates the complexity of the endless list of molecules known to be associated with pain and inflammation to hide the lack of sensible evidence for a clear relation between acupuncture and pain therapy.

The team funded by the NH&MRC set up collaborations with Chinese companies and universities and managed to have such collaboration included in the Memorandum of Understanding during the Australian-China free trade agreement ceremony. These companies appear to mislead the public by citing the use of TCM in western medicine to generate public trust in the effectiveness of TCM. Because the TCM market is worth close to $170 billion, they received the backing of politicians. For China, this is excellent, because they can use Australia as a new export market for TCMs and, upon acceptance within Australia, with endless lobbying of the National Institute for Complementary Medicine (NICM), open up the more lucrative US and EU markets. These companies use the argument that China is the "biggest country in the world" and that TCM has been used for millennia, TCM will be effective and safe to use in Sydney clinics. It appears that the NICM plans to introduce TCM's via acupuncture clinics in Sydney, and they will use cancer as the disease of choice because the media would be reluctant to report negatively on cancer issues. This raises serious issues of safety, diverting unaware patients away from needed medical interventions, and shifting the public's need for healthy care away from scientific medicine.

Issues of safety

Safety issues apply to acupuncture or similar interventions, as to any other interventions. Some people have asserted that acupuncture is perfectly safe, but there are at least 95 published cases of serious adverse effects including infection, pneumothorax, and five deaths. In the UK, a total of 468 safety incidents was reported over a 3-year period for patients treated with acupuncture in the National Health Service; 95% of these were categorised as low or no harm. And there are contraindications to acupuncture: metal allergies, bleeding disorders, anticoagulant drugs, and skin infections. It is generally safe as long as disposable needles are used, proper infection-control procedures are followed, and the practitioner has a good understanding of anatomy; but mishaps do occur. Recently, the ex-president of South Korea had to undergo major surgery to remove a 6.5 cm acupuncture needle from his lung; they had no idea when or how it had lodged there.

Is there any justification for the use of acupuncture in modern medicine?

Despite the conceptual difficulties, an enormous number of investigations have been publicly funded and performed over the past few decades. However, as discussed above, examination of the efficacy of acupuncture for any diseases such as that conducted by the Cochrane Collaboration, has fundamentally failed to give any credibility to claims that acupuncture is an effective intervention for any illness. Some studies have concluded that acupuncture is not effective or that there is only a small and temporary effect or that there is insufficient evidence that it is effective. Pseudo-philosophical arguments have been made that these findings do not mean that acupuncture is ineffective, simply that "absence of evidence of an effect does not imply that there is no effect". However, failure to reliably demonstrate any effectiveness of acupuncture in the diseases tested in trials should send signs of significant doubt, even to the most dedicated supporters of acupuncture.

The World Health Organization (WHO) endorsed acupuncture, but challenged by evidence from the Cochrane Collaborative has taken down their website on acupuncture which had suggested effectiveness in more than 100 conditions. Cochrane emphasized that where acupuncture appeared to be effective, the studies were of poor quality (often with no sham acupuncture control group), and the evidence was weak. When studies included sham acupuncture, both true acupuncture and sham acupuncture groups had similarly positive results, indicating that they were measuring simply a placebo effect. And for many of the conditions being treated, there was no relevant published research at all.

The US Center for Inquiry Office of Public Policy issued a position paper on acupuncture in 2010. It concluded that recent research had unraveled nearly all acupuncture claims and noted, "The bulk of recent research strongly tends towards the hypothesis that acupuncture's positive effects are mainly due to a built-in expectation…"

A 2006 review in *The Medical Letter* stated that "Acupuncture alone has not been shown in rigorous, duplicated studies to benefit any defined medical condition".

In their book *Trick or Treatment*, Simon Singh and Edzard Ernst concluded that there was only "tentative" evidence that acupuncture "might" be effective for some forms of pain relief and nausea, that it failed to deliver benefits for any other conditions, and that its underlying concepts were meaningless.

Authors, editors, and journalists often put a spin on the results according to their preconceived opinions. For example, the CACTUS study was essentially negative, but was reported as positive. David Colquhoun said that it was published with conclusions that directly contradicted the data and was "the best evidence I've ever seen that not only are needles ineffective, but that placebo effects, if they are there at all, are trivial in size and have no useful benefit to the patient" .

As acupunctures loses support in Medicine, it is increasingly used as part of larger constellations of alternative treatments within private enterprises which mix together, almost randomly, any of the many pseudoscientific interventions under a generally attractive umbrella of 'wellness'. This makes acupuncture even less reliable and hides it from public scrutiny.

Conclusion

Acupuncture has been studied for decades and the evidence that it can provide clinical benefits continues to be weak and inconsistent. There is no longer any justification for more studies. There is already enough evidence to confidently conclude that acupuncture doesn't work. It is merely a theatrical placebo based on pre-scientific myths.

All health care providers who accept that they should base their treatments on scientific evidence whenever credible evidence is available, but who still include acupuncture as part of their health interventions, should seriously revise their practice.

There is no place for acupuncture in Medicine.

Prepared by FSM 25 July 2016

From: Grahame & Elsie Arnot [redacted]
Sent: Thursday, 11 April 2019 12:36 PM
To: medboardconsultation
Subject: proposed regulations on integrative Medical Practitioners.

To Whom it may concern at the Medical Board of Australia.

Dear Sir/Madam,

We are sending this letter to you regarding your proposed regulations and restrictions to some Medical Practitioners who may prescribe alternate types of treatment in a professional ethical way.
We are an elderly couple on the pension who are under the care of two different such Professional Medical Practitioners and have found great benefit from their prescriptions for both orthodox pharmacy lines and alternate type medications all of which are available at Pharmacies.
We strongly object to this privilege and right being discriminated against and many people like ourselves being at a severe disadvantage.

Kind Regards

Grahame and Elsie Arnot

[redacted]

From: Jenny Atkinson [redacted]
Sent: Thursday, 27 June 2019 4:34 PM
To: medboardconsultation
Subject: RE: 'Consultation on complementary and unconventional medicine and emerging treatments'

To Whom It May Concern

I am writing to express my following concerns regarding the proposed guidelines. I believe the proposed guidelines are detrimental to patient care and that they were produced without the necessary input and consultation with the integrative and complementary medicine community.

My strong concerns:

The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based

That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty

That the term 'complementary medicine' also includes access to traditional medicines
No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs ‘conventional’ medicine

That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release

That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach

That the right of patients to determine their own medical care is under threat

That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Regards

Jenny Atkinson
[redacted]

From: Jenny Austin [redacted]
Sent: Wednesday, 26 June 2019 11:21 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments'

I would like to provide my feedback as part of the public consultation process. I personally have experienced the health benefits of using integrative and complementary medicine. In regard to the current evidence base which confirms the therapeutic value of TCM, I recommend that the MBA consultation process should take into account all of the information/research presented in the WHO Global Report on Traditional and Complementary medicine.

As the following extract from the exec summary of the 2019 WHO report states, "Globally, the landscape for T&CM has been improving consistently. In line with the WHO Traditional Medicine Strategy 2002–2005 and the WHO Traditional Medicine Strategy 2014–2023, and relevant World Health Assembly resolutions, Member States took steps between 2005 and 2018 to promote the safety, quality and effectiveness of T&CM. They also took steps for the appropriate integration of T&CM into health systems (particularly health services) by developing national policies, regulatory frameworks and strategic plans for T&CM products, practices and practitioners. Based on current information, 88% Member States have acknowledged their use of T&CM which corresponds to 170 Member States. These are the countries that have, for example, formally developed policies, laws, regulations, programmes and offices for T&CM, and the actual number of countries using T&CM is likely to be even higher."

In light of the all existing evidence currently available in the literature that supports the increased the use of TCM , in addition to the aforementioned WHO report, I believe that rather than changing existing guidelines to restrict Integrative Medical Practitioners from using proven integrative and complementary medicine, that the existing guidelines should be broadened to support the growth of integrative medical and TCM practice.

Sincerely,
Jenny Austin

From: Mary Avery [redacted]
Sent: Thursday, 6 June 2019 10:18 PM
To: medboardconsultation
Subject: Medical care availability concern

To whom it may concern,

I have been made aware of a new set of guidelines put forward by one branch of the available health care options which seeks to diminish the reputation of other branches of health care. ‘Complementary medicine’, which includes traditional medicines, is described as ‘unconventional medicine’, with ‘emerging treatments’ and involving ‘inappropriate use’, terms which are critical without substantiation.

I am adamantly opposed to my health care choices being limited by a vested-interest body seeking to undermine the reputations of other modalities. I seek out practitioners who are open to integrate ‘traditional western medicine’ with other healing modalities as in the Integrative Medicine (IM) approach.

I write this in order to make it known I am opposed to the guidelines being proposed which could threaten IM and other health care modalities as we know them.

Sincerely,
Mary Avery

From: ayre michael [redacted]
Sent: Thursday, 13 June 2019 3:48 PM
To: medboardconsultation
Subject: Review of alternative medicine arrangements

Dear Board members,

I was recently made aware of the impending review of alternative and complementary medicine.

As a client and patient of an integrated health practitioner organisation, I want to add my voice to those who caution against this review being an opportunity to treat intergrated medicine services as non mainstream medicine.

Intergrated medicine utilises the best of western and traditional medicine to holistically treat a medical condition and as such offers greater opportunity for permanent cure than just treating the symptoms as is most often the case of today's medical care.

I have observed over many years the medical profession's seemingly unquestioning acceptance of big pharmaceutical companies chemical drug focussed treatments at the expense of working in the best interest of the patient through seeking holistic treatments that might involve simple lifestyle change and not a lifetime of unnecessary ingestion of drugs. (As a simple example, statins are almost ubiquitous amongst those over 50 and the evidence from the latest research suggests they might be unnecessary as cholesterol may not be a contributor to heart disease as originally thought)

Please don't disregard the often better outcomes realised from integrated medicine that combines natural therapies with a moderate and cautious application of tried and tested western drugs.

Mick Ayre
[redacted]

From: Louise Azzi [redacted]
Sent: Thursday, 11 April 2019 6:33 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern
I currrently see a doctor who uses complementary medicine as well as traditional to treat a range of ailments where I had no success with conventional medicine previously. My health has improved drastically and I am appalled to think that in a country which is meant to be progressive and world leading that we could even be considering this. I will not be voting for any government supporting this policy. Therefore I would like to see the following supported. Look to world leading practices in Europe and you will find intergrative medicine is the norm not the exception.

Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Yours sincerely
Louise Azzi

From: Stephen B [redacted]
Sent: Thursday, 16 May 2019 3:47 PM
To: medboardconsultation

To whom it may concern,
I'm emailing to express my concern that you are looking to limit and control what Integrative Doctors can perscribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illness, having seen no such success from my regular GP, I feel that this is abhorrent limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

I REQUEST OPTION 1.

From: Adrienne [redacted]
Sent: Monday, 13 May 2019 3:08 PM
To: medboardconsultation
Subject: proposed tighter control of Natural medicine practitioners

Good day ,

I am a one of many concerned citizens who would like to protest against the proposed tighter controls on Natural medicine & therapies & this modalities to be lumped together with other experimental and on the " fringe " medical therapies
It is alarming that our freedom to choose the type of therapies we believe are the best for our health is being more and more restricted . This is no doubt due to the lobbying of the pharmaceutical industry who sees natural therapies as a great threat

I and my family as well as many friends I know have used natural therapies like homeopathy , naturopathy , herbal medicine and the like successfully for over 40 years never have we had an adverse reaction or experience which is very common with orthodox medicine and drugs . No herbal of other natural products come with a disclaimer and a list of dangerous side effects which is attached to virtually every single pharmaceutical drug (including over the counter ones)
yet there is a constant threat to our freedom to choose this more gentle & effective type of treatments .

I would like my protest against this dictatorship noted

Kind Regards
Adrienne Bac

From: Lorraine Backhouse [redacted]
Sent: Saturday, 20 April 2019 8:07 PM
To: medboardconsultation

To whom this may concern

I am emailing to express my concern that you are looking to limit and control what integrative Doctors and prescribe and, by doing this, aer therefore looking to control and monitor their practice.

As someone who regularlysees an integrative Doctor, with great success and improvements to my ilnesses, having seen no such success from my regular GP, I feel that this is an abhottent limitataion on my rights to seek the appropriate medical attention.

To put these limitations in place is to not only deny my individual rights, but will also deny thousands of toerh patiennts their rights to appropriate treatment and also to thos professionals who have worked very hard to gain their accreditation in their respected field.

Your faithfully
Lorraine Backhouse

From: Karen Bailey [redacted]
Sent: Thursday, 27 June 2019 8:38 AM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

Subject: Consultation on complementary and unconventional medicine and emerging treatments

I prefer non-drug approaches for managing my family's and my own health or illnesses which is proven to be very effective as they give me a better range of diagnostic and treatment options. Natural options has also enabled me to get to the cause of any issues rather than just treating the symptoms.

From: [redacted]
Sent: Thursday, 27 June 2019 12:58 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Hello

I would like to support Option 1 that “no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine.”

I have chosen to see Integrative Medicine doctors because:

I want to be involved in my own care and this requires time in consultations and additional medical training that I found in my integrative medicine doctor.

I prefer non-drug approaches for managing my own health or illnesses.

I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.

I have concerns about the proposed regulations because:

There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.

The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.

The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.

There has been no transparency in the consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and have failed to disclose the details of why the new regulations are required.

Regards

Anne Bain

From: Fiona [redacted]
Sent: Sunday, 30 June 2019 4:09 PM
To: medboardconsultation
Subject: Consultation on complementary medicine

Surely some of the most intelligent people in society can utilise experience, training AND assessments of complementary medicine to deliver integrated, personalised medicine? Allopathic medicine offers wonderful benefits in many areas, and yet is lacking in terms of preventative treatments. Likewise complementary modalities have their shortfalls. Integrating both into general practice seems a safe and logical progression when pharmaceutical drugs fail.

My integrative doctor has managed to augment the side effects of drugs using herbs and other treatments, so that pharmaceuticals are more effective and less problematic. Surely the current system delivers a win-win to all parties?

Sincerely,
Fiona Banovic

From: Vic Barbeler [redacted]
Sent: Sunday, 30 June 2019 1:59 PM
To: medboardconsultation
Subject: Public Consultation on Complementary and Unconventional Medicine and Emerging Treatments

Dear Medical Board,

As a member of the public and a consumer,

I strongly support the maintenance of Option 1 to remain and reject any changes to Option 2.
I believe there are no grounds for regulating these medical approaches differently. I have often used these avenues for treatment of myself and my family with success where conventional medicine has significantly let us down with no options.
The combination of these avenues together with conventional medicine offers better care for my family.
The doctors we see are ethical,
educated, widely informed with better approach to health care and better engaged with my family then conventional doctors. They should not be penalised or treated differently from their peers.

Yours Sincerely

Vic Barbeler
[redacted]

From: Paige Barrand [redacted]
Sent: Thursday, 11 April 2019 2:50 PM
To: medboardconsultation
Subject: Feedback

To whom this may concern,

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice.

As someone who regularly sees an Integrative Doctor with great success and improvements to my illness - having seen no such success from my regular GP nor a multitude of specilists- I feel that this is a repugnant limitation of my rights to seek appropriate medical attention.

To place these proposed limitations on Integrative Doctors is not only denying my individual rights but will also deny thousands of other patients their rights to appropriate treatment. Further, the professionals who worked hard to gain their accreditations in this respected fields are not having their ability to holistically treat patients threatened.

Kind Regards,

Paige Barrand

--
Paige Barrand

[redacted]

From: [redacted]
Sent: Tuesday, 9 April 2019 1:24 PM
To: medboardconsultation
Subject: concerns regarding the Consultation on complementary and unconventional medicine and emerging treatments

I would like to formally lodge my concerns on the upcoming Consultation.

Some of my concerns include that grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of integrative medicine being "fringe" rather than evidence-based

That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty

That the term 'complementary medicine' also includes access to traditional medicines

No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs ‘conventional’ medicine

That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release

That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach

That the right of patients to determine their own medical care is under threat

That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Sincerely
Kris Barrett

From: Helen Bartlett [redacted]
Sent: Wednesday, 10 April 2019 3:47 PM
To: medboardconsultation
Subject: 'Public consultation on complementary and unconventional medicine and emerging treatments'

'Public consultation on complementary and unconventional medicine and emerging treatments'

I opt for Option 1 - to retain the status quo of providing general guidance about the Board's expectations of medisacl practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Questions for consideration.
1. I suggest complementary and alternative treatments.
2. Yes
3. No
4. No
5. No . Patients are capable of performing their own research.
6. No
Options:
7. Yes
8. Not required.
9. No
10. No
11. Option 1

Helen Bartlett

[redacted]

From: Lucy Bartlett [redacted]
Sent: Wednesday, 10 April 2019 9:30 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

AMA,

Please note my preference/vote, Re: Consultation on complementary and unconventional medicine and emerging treatments.

If it weren't for Integrative Medicine I would be a very sick woman. Please don't take this option away from us. Our health, our choice.

Option ONE: Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Kind regards,
Lucy Bartlett
[redacted]

From: Amy Basha [redacted]
Sent: Monday, 18 March 2019 9:55 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Hello Medboard ,

Patients have a right to seek alternative/natural treatments which have been proven for hundreds of years to be effective.

I have had personal experience of enormous benefit from integrative medicine with healing many health issues .

All pharmaceutical medications come with risks - that area needs to be policed just as much as alternative therapies .

Taking Panadol, antihistamines can cause terrible side effects and those are prescribed like candy .

Please allow patients the benefits of integrative medicine and focus on the horrific side effects of pharmaceuticals and abuse of pharmaceutical medications .

Sincerely,

Amy Basha

Sent from my iPad

From: Andre Bax [redacted]
Sent: Thursday, 4 April 2019 12:48 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Hello

Some of my concerns regarding your consultation as the above. I have seen such a push by big Pharma who obviously lobby Government with incredible amounts of money. I have seen this affect compounding Chemists in unfair and absolutely shocking ways.It seems like you have no regard for small businesses who employ most of the people in this country. I do hope you are not influenced by those whose lobby money you receive but about the welfare of people who really need these types of medicines. I being one of them.

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs 'conventional' medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practice and protects patient safety. There is no need or justification for a two-tiered approach
- That the right of patients to determine their own medical care is under threat
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Sincerely,

Andre Bax
[redacted]

From:	Lorraine Beard
To:	medboardconsultation
Subject:	Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments
Date:	Tuesday, 25 June 2019 3:08:00 PM
Attachments:	Complementary unconventional alternative Rx.docx Complementary unconventional alternative Rx.pdf

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

I am in favour of Option 1:
Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Please see the atatched file.

Many thanks
Lorraine Beard, MB,ChB, MD, FRACP

medboardconsultation@ahpra.gov.au

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

I am in favour of Option 1: Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

I consider that the current regulations are sufficient and that registered medical practitioners should have freedom to use their knowledge, experience and discretion with regard to the use or recommendation of complementary and emerging treatments, and to prescribe off-label provided that patients are made aware of possible adverse effects and are not promised that any of these treatments will necessarily be effective in a particular patient.

For some conditions, which in severe form can be extremely debilitating and yet are not uncommon, there are no valid double-blind controlled trials to enable doctors to offer evidence-based approved therapies. One such group of conditions is myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). In ME/CFS there is as yet no definitive diagnostic test and neither is there any treatment/therapy that has been proven to be effective by valid double-blind controlled trials. What is the caring medical practitioner to do when consulted by a patient whose symptoms lead to a diagnosis of ME/CFS after the exclusion of other relevant conditions? Is the patient just to be told, "I'm sorry, there is nothing we can do?" Can nothing be offered or tried to reduce the patient's symptoms? Currently, some such patients are being helped by medical practitioners who take an holistic and individual approach to managing each patient, and having considered the details of a patient's history and symptoms, suggest trials of complementary substances, emerging management strategies, or drugs prescribed off-label. Research is progressing, and in future, both diagnostic testing and evidence-based treatments are likely to become available for individuals ME/CFS, but in the meantime, it is surely in the best interests of patients to allow doctors freedom to use their knowledge, experience and skills to assist patients who are desperately in need of their help, and for patients to be free to select the doctors of their choice.

For other conditions, conventional medical treatments may fail to give sufficient relief, or have significant side effects, and alternative or complementary substances can be of real assistance, for instance, alpha lipoic acid for some neuropathic symptoms in some patients.

Thank you for considering these comments.

LJ Beard, MB,ChB, MD, FRACP

From: Jeanne Beatty [redacted]
Sent: Thursday, 4 April 2019 9:03 PM
To: medboardconsultation
Subject: Freedom of Choice

I am concerned about the changes that are being considered. I am a registered nurse and believe in Conventional Allopathic medicine and Complimentary medicine. Both Compliment each other. Many highly qualified, skilled specialists use Complimentary and alternative medicines in their practice. These changes will negatively affect the advice and use of complimentary medicine compromising patient care, choice and outcomes.

There should be only ONE set of good practice guidelines that ALL doctors should follow.

We need to be open to taking a holistic approach to treatment and embracing new and innovative medical practices.

Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Mrs J Beatty

From: Vanessa Beckitt [redacted]
Sent: Saturday, 29 June 2019 9:19 PM
To: medboardconsultation@ahpra.gov.au.
Subject: Integrative Medicine Recommendation

To whom it may concern,

I choose Option 1: "no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine."

I have chosen to see Integrative Medicine doctors mostly out of a desperate need to find solutions to complex health matters which have not been solved by general practice and because:
-I prefer to be involved in my own and my family's care and this requires time in consultations an additional medical training that I have found in my integrative medicine doctor.

Conventional medicine has often not provided answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options.
Due to a family history of allergies and sensitivities I prefer non-drug approaches for managing my family's and my own health or illnesses.
I am happy with my GP for simple treatments within brief consultations, but I want to go further with prevention and gain a deeper understanding of what I can do for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that.
I want more from my doctor. More time. More understanding of causes of illness and more basic advice on nutritional approaches to my wellbeing. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments.
My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.
I have concerns about the proposed regulations because:
There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.
The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.
The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.
There has been no transparency in consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations.
Yours sincerely
Vanessa Beckitt

[redacted]

From: Gordon James Benz [redacted]
Sent: Saturday, 29 June 2019 1:37 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

Sacketts's model of EBP is comprised of three parts, best available evidence, practitioner experience and patient desires. The last two are rarely mentioned yet are just as important as the first, and it is these two things this present action by the MBA is trying to eradicate. It is doing so under the false pretence of 'safety' and 'limiting harm'.

What a sick, evil, twisted joke.

Safety is a relative term and so needs to be compared to something else. Walking down the street is 'safer' than jumping in front of traffic, yet you can still be hit by a car walking down the street. Walking on the footpath is then 'safe'. The entire argument for vaccination rests on it being 'safer' than contracting the disease, though vaccines are NOT safe. Look at the product information, there is risk of harm.

The iatrogenic death toll in Australia is estimated to be 150,000 people killed every year. The true figure is of course hidden from the public because the government and the media refuse to disclose/report it. Figures aren't even accurately kept. Compare that to the rates of harm of natural medicines and those who practice it, including holistic GP's.

But of course, you don't for you are plainly evil.

Medical science has been bought out by pharmaceutical companies and interest groups. It has been in some journals. You might like to read some. Never mind the author bias, funder bias, publisher bias and conformational bias, there is just outright fraud and deceit. Look at the murderous, maiming behaviour around [redacted] and [redacted]. Despicable evil!!!

Those of us who work in the healthcare system know the truth, and we will continue to spread it. Despite the vicious attacks on the sovereign human rights of people, for that is all this is. GP's that aren't script writing monkey's will continue to be sought out, in spite of your efforts.

This is the very sad truth.

Regards

Dr Gordon Benz (chiropractor)

From: Kelly Bernard [redacted]
Sent: Monday, 27 May 2019 10:18 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments'

To whom this may concern,

I believe that Medical practitioners should retain the right to help their patients as best they can with unconventional medicine and new emerging treatments. Our family is one which has moved many times overseas for my husbands work and we have had medical situations that do not fit all the guidelines. The best medical practitioners that we have had have used their own common sense and experience from their practice rather than sticking to the rule book. One of my specialists told me that everything he had learned at Med School had been turned on its head once he started practising medicine, and I believe him. The human body is so sophisticated and medical schools have not been able to keep up with the progression of ills that affect families today. In that situation Medical Practitioners need to be able to operate in what they consider to be the patients best interest, providing they remain within an ethical context of "doing no harm". Families that come from overseas may be used to other ways of practising medicine that are not wrong, they are just different - family doctors need to be able to see how to adjust treatment to their patients needs.

Since returning to Australia, I have witnessed enough practitioners who prefer to stay in the comfort of the guidelines here when they can see the reasoning behind a different treatment. Forcing practitioners to remain within strict guidelines will limit the service/role of a family doctor and I think the aim of Medicare is to have the family doctor provide the lions share of health services. This way patients can find a family doctor that suits them and have continued treatment and proper follow up, as they both get to know each other.

It is also much better to have medically trained practitioners providing their best advice on these unconventional treatments rather than patients relying on less qualified practitioners. The family doctor should be aware of all treatments followed by their patients and what better way to do that than discussing and possibly prescribing these treatments in a way that compliments conventional medical treatments.

Thank you for your attention,

Kelly Bernard

From: kerrie [redacted]
Sent: Monday, 29 April 2019 7:14 PM
To: medboardconsultation
Subject: Regulations concerning complementary and unconventional medicine.

To the Executive Officer,
Medical
AHPRA

I understand the government is seeking to change the regulations concerning complementary and unconventional medicine and I wish to express my desire for this change NOT to take place. I would like for things to remain as they are.

I am a [redacted] year old Australian woman, a mother of 4 and a teacher. My husband and I have always valued health and fitness. I was raised to stick as close to nature as possible which included lifestyle practices of exercise, healthy eating and other wellness practices to ensure continued good health. [redacted] a GP/Naturopath for a number of years and loved the expertise that afforded me in maintaining good health for myself and my family. His advice was always very balanced and provided me with the options available without ever putting our health at risk. I would always attempt to care for our health with as little intervention as possible and I greatly value the right to choose how I manage my own medical treatment.

Best Regards
Kerrie Betlem

From: Karalyn [redacted]
Sent: Friday, 28 June 2019 12:16 PM
To: medboardconsultation
Subject: SUBISSION regarding Integrative Medicine Regulation

I choose Option 1: “no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine.”
I have chosen to see Integrative Medicine doctors because:
Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options.I have concerns about the proposed regulations because:
There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.
The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.
The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.
There has been no transparency in consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations.

Best Regards

Ms Karalyn Black

From: Kellie Blair [redacted]
Sent: Monday, 27 May 2019 10:05 PM
To: medboardconsultation
Subject: Unconventional medicine

Dear sir/madam

Please let it be known that we ate concerned with the view of Herbal Medicine being viewed as ‘unconventional medicine’ and not taken into account of both scientific and traditional evidence that shows evidence of herbal medicine efficacy and therapeutic activities.
This support is in conjunction with Bio Concepts and it’s substantiated research.

Kellie Blair

From: Olaf Bode [redacted]
Sent: Friday, 14 June 2019 1:35 PM
To: medboardconsultation
Subject: Integrative Medicine

Hi
I have a number of concerns regarding possible future changes to the policies and legal standing of Integrative Medicines (IM) and their practitioners.
I have personally experienced nothing but positive outcomes from treatments from IM practitioners who provide incredible support to people with needs that benefit from such treatments. My family members have benefitted and I am also aware of many others who have experienced and benefitted from IM treatments. My own IM experience has led me to treatments which have also included traditional medicines and my practitioner does not exclude these in preference to other options.
My concerns are that IM is grouped as "unconventional medicine" and "emerging treatments" which leads to ambiguity and uncertainty and further increases the likelihood of IM being regarded as fringe rather than evidence-based.
I have a choice to my medical care, not dissimilar to someone who decides that one doctor is more suitable than another and feel the rights of my decision for my medical care is potentially under threat.
Sincerely

Olaf Bode

ON COMPLEMENTARY AND ALTERNATIVE CARE

PROPOSITION

It should be regarded as **disingenuous** and, therefore, **unethical**, for a medical practitioner to provide complementary or alternative health care.

ARGUMENT

The province of medical practice is defined by what doctors have been **trained to do**.

Patients **trust** in their doctor because medical training is supposed to guarantee that their doctor has been properly trained, and has been shown by assessment to be able to practice correctly what they have been trained to do.

Complementary care is **not part of medical training**.

It is, therefore, disingenuous for a medical practitioner to practice complementary care because:

> complementary care is not in the training curriculum of a medical practitioner,
>
> yet they use their medical qualification as a licence to practice complementary care.

The sophistry involved in doing so is that the doctor **does not tell** the patient that they have not been trained and tested in complementary care, but **allows the patient to think** that because they are a doctor who is providing complementary care it must be "all right", i.e. as genuine, and as effective, as conventional medical care

This sophistry is an **abuse of trust**. The doctor earns the trust by qualifying in Medicine, but then relies on that trust to ply a trade in something that is not Medicine, and get paid to do so. Arguments could be raised that charging patients under these conditions constitutes fraud.

In principle, this situation is no different from a medical practitioner electing to provide financial advice under the auspices of a medical consultation, and relying on the trust of their clients to pay for that advice.

In as much as providing complementary care is disingenuous, relies of sophistry, and verges on fraud, the practice must surely become **unethical**.

DISCUSSION

Since there is no evidence for efficacy of complementary care, providing it cannot be a rational, objective decision. Those doctors who provide it must be doing so out of **fantasy**; or do so in order to appear **fashionable** and, thereby, attract "trade". Neither motive is worthy of the dignity and social status bestowed upon a medical practitioner by a medical qualification.

If a medical practitioner wishes to practice complementary care they should qualify and register as a homeopath, naturopath, chiropractor, iridologist, or whatever the appropriate classification may be. They should then publicise to their clients that they are practising as such. In so doing, they also divorce themselves from Medicare funding.

It is a specious argument that medical training qualifies a medical practitioner to evaluate new treatments and, therefore, that a medical practitioner is qualified to teach themselves complementary care, and incorporate it legitimately into their medical practice. The cardinal flaw in this argument is that the medical practitioner will not have been assessed in the evaluation of evidence for complementary care, by experienced peers, such as those who publish systematic reviews. Reading about something, and finding it attractive, is not the same as deeply analysing the biological plausibility of complementary care, its statistical validity, its safety, and its clinical validity. Adopting a treatment without doing so is irresponsible.

Ironically, if and when something is so analysed and proves valid, it is rapidly incorporated into medical care, and medical training. Rarely has this been the case with complementary care. Most reviews of the existing literature show no evidence of efficacy, or expressly show evidence of no efficacy. Consequently, its use in medical practice is not valid, and can only be based on fashion and hearsay.

Reciprocally, there remain practices within Medicine that are wanting. They continue to be taught even though there is no evidence, or evidence of no utility. However, within Medicine such practices come under scrutiny. The definition of a profession is that (some) members feed back on what is practised, in order to improve the profession. Therefore, within Medicine there is a system by which, progressively sooner or later, the profession can rid itself of delinquent practices.

It is, therefore, absurd to allow inclusion into medical practice something that has already been shown to be delinquent, or reliant on no more than hearsay and wishful thinking.

The corollaries of this submission are:

- Complementary care should not be defined in terms of whether or not it is evidence-based care, but on the basis that it is not part of medical training and assessment.
- Simply being adopted by a medical practitioner does not make complementary care part of medical care.
- A practice becomes part of medical care only once it becomes part of medical training, be that undergraduate, postgraduate, or legitimate continuing professional development.
- Joining a Society or Association of like-minded, ill-informed fellows does not make complementary care a part of medical practice.
- It is a pity, and a shame, that some medical practitioners use their social popularity to legitimise their use of complementary care, and even be applauded for doing so.

Emeritus Professor Nikolai Bogduk AM

From: Janelle Bonato [redacted]
Sent: Sunday, 30 June 2019 12:57 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Hello there,

My name is Janelle Bonato
[redacted]
Recently heard about some changes to our Medical System which are not consistent with our rights to choose a medical professional. And which waste Taxpayers (mine included) money.

I choose Option 1: “no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine.”

I have chosen to see Integrative Medicine doctors because:

I want to be involved in my own and my family’s care and this requires time in consultations an additional medical training that I found in my integrative medicine doctor.

Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options.

I prefer non-drug approaches for managing my family’s and my own health or illnesses.

I am happy with my GP for simple treatments within brief consultations, but I want to go further with prevention and a deeper understanding of what I can do for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that.

I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.

I have concerns about the proposed regulations because:
There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.

The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.

The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.

There has been no transparency in consultation process. Freedom of

Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations

Kindest Regards
Janelle Bonato

From: [redacted]
Sent: Friday, 5 April 2019 8:16 AM
To: medboardconsultation
Subject: Censorship of Vitamins, natural hormones etc

I am writing to express my anger at the proposed censorship of things such as vitamin and herbal supplements and natural hormones.

I find it ridiculous that you would consider censorship of natural treatments meanwhile more people continue to die or face numerous side effects from medication which is considered okay.

Spend your time and money on an area where it is needed like finding cures albeit by natural or other methods. Let us have a choice.

Yours faithfully

Janine Bond

From: Jessica Bonniface [redacted]
Sent: Thursday, 18 April 2019 9:24 AM
To: medboardconsultation
Subject: Integrative General Practitioners

To whom this may concern,

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from my regular GP, I feel that this is an abhorrent limitation on my rights to see the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditation's in their respected field.

Kindest regards,
Jessica Bonniface
[redacted]

From: nadia booton [redacted]
Sent: Thursday, 11 April 2019 8:03 PM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001

medboardconsultation@ahpra.gov.au

RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.
As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Nadia Booton
11/04/2019

From:	[redacted]
To:	medboardconsultation
Subject:	Public consultation on complementary and unconventional medicine and emerging treatments
Date:	Saturday, 6 April 2019 10:22:21 AM

As a former medical expert, I struggle to understand why this is an issue. But then am reminded of what has been happening for decades, and the true political struggle which has resulted in such an impasse.

In 1991, during an international medical symposium, I was informed by a representative of the WHO that by 2000, anyone suitably qualified in 'alternatives' would be registered on par with a GP and some would become specialists.

The aim was to have doctors refer for natural health treatments. Instead, a concerted effort was implemented to destroy natural health. For anyone involved, it has been undeniable; by 2000 the PAN 'crisis' was constructed and implemented.

The dominoes fell and with it, more than half the careers of established, reputable natural health professionals. Even politicians who dared to speak out, with personal stories of cancer cures and so much more, their careers soon ended.

Scientific studies were warped and biased - if a natural therapy is proven to work, which is a huge ask thanks to the way studies are structured, it is soon banned, with matching fanfare and bad publicity. If a pharmaceutical study is proven to have questionable outcomes, it is covered up.

Soon, doctors began to at least try to fill in the gaping hole left by those leaving their careers. They took part in weekend courses to practice these modalities - rather than referring. And instead of seeing the big picture, the TGA and their buddies soon began focusing their sights on these 'renegade' doctors.

A good doctor will be honest when they determine that medicine has no answers; they will find answers elsewhere. Rather than reward them for their adherence to the Hippocratic oath, they are punished. Even if the cure is standing right in front for all to see.

The answer is simple; go back to the drawing board. Anyone who attempts to deny the efficacy of myriad natural therapies is either ignorant or a liar. I have had doctors, who do not know my background, tell me ALL natural therapies do not work. So, water does not hydrate? Aspirin, nutrition, digoxin, camphor, menthols, charcoal, atropine, quinine, morphine, penicillin, and the extensive line of botanicals should be outlawed? These are only a few natural therapies which have been embraced; there are thousands more.

Within pharmaceutical research it is generally accepted that efficacy of pharmaceuticals need only be around 30% while alternatives must be 100% to be considered effective. This witch hunt is responsible for much misinformation and could easily be blamed for thousands of deaths a year when people are told there are no cures, when valid cures are being ignored.

Doctors and nurses who work outside the medical paradigm should be awarded, not punished. As more than 70% of the population are now using natural therapies an intelligent governing body would see that outlawing can be a dangerous option as they are too afraid to seek professional guidance and self diagnose while often choosing the wrong therapy.

A smart government would integrate natural therapies into the Medicare system, while prescriptions would be available on the PBS. Registered natural health experts must be included in hospital based care. Clinics must have qualified natural health professionals. Rather than be cost prohibitive, it would save the nation billions as people are not waiting to become sick or masking symptoms with pharmaceuticals. Decisions need to be made without the input of pharmaceutical representatives while avoiding a conflict of interest via politicians with pharmaceutical investments.

Decisions must be made using as much common sense as scientific proof. It is a political game rather than medical honesty. Euphemisms which prevent the natural health professional from using real language, and symptom sets which are not permitted to be treated by a natural health professional regardless of whether every single case is cured, must be outlawed.

The push to integrate natural therapies into medical school should not go any further than an

understanding, allowing those who are actually experienced and qualified to teach and practice. Usurping any natural therapy proven to work while banning the use by natural health professionals must stop.

Additionally, the hostile takeover of natural products by pharmaceutical companies has resulted in substandard product; whether this is deliberate or not remains to be seen. Companies manufacturing natural products must be permitted to make their products rather than restricted and banned outright. Pharmacies are jumping on the bandwagon; the advice given is appalling and dangerous.

Only once a qualified natural health professional is permitted to practice with the freedom that a GP has within the medical realm, only then will perceived dangers be removed. Ignoring what the public want is a very real form of control and yes, even eugenic.

In regards to doctors, within my own circles, the war against these people who value ethics and honesty above kickbacks and ego, have been dragged through courts. In more than one case, once all avenues to destroy and silence them have failed, fake charges have been aimed at them which successfully destroys their careers. The charge of choice is often sexual which most would rather avoid, so do not fight. They simply go underground.

Any intellectual person could see the irony in the fact this is even an issue which needs to be debated. While modern medicine is funded to the tune of billions annually, natural therapies are devoid of all such subsidy, yet continue to cure every day; while the very word cure is forbidden.

Thousands of scientific studies are ignored. It is no secret that the one modality under constant fire, homeopathy, would have been the future of modern medicine but for political corruption in the early 20th century. Rather than embrace the common goal, real effort is waged every day to remove historical fact from the record. In the few decades that the internet has been in existence, more research has been destroyed than ever before in history; the only people who know the facts are those who have retained the original publications.

A dangerous precedent has been set. Right now, people are not using medical services for fear of control. While it is true that most ailments can comfortably be treated using natural therapies, as they always have done, in the cases where emergency medicine or even surgery are required, people are suffering and dying because they are fearful of reprisal. The public must have the choice. Blaming parents for medical failure while punishing them when natural therapies offer the only hope, is, or should be, criminal.

In a perfect world (and as we were originally advised would eventuate) an individual would have free choice of health care, with equal subsidy which allopathic medicine enjoys. The ongoing theft of wordage and cover ups must end. Euphemisms are misleading while prevention of accurate labelling prevents the user from understanding.

As a former medical expert, I am unable to understand the situation. Three out of five qualified natural health experts no longer practice, while 1 in 2 natural health colleges are now shut down. Many natural health professionals have degrees - including PhDs. It is no longer about health; I see little common ground with what once existed. From day one of medical school students are brainwashed against the use of natural medicine.

Yet all of this has failed - why? Why are people still seeking natural therapies? Because they work. Because medicine often has too many side effects and no answers. I fail to agree that if medicine has no answers that it is okay for a patient to be told they will die. The human body is not titanium or silicone or synthetic; it stands to reason that as we are 'natural' so too what we put into or onto our bodies should match.

Do not punish these brave doctors and nurses. You will never completely eradicate the use of natural modalities. Instead, bring it into the open and allow the same support that modern medicine is given. Teach doctors a basic truthful understanding about these modalities so they can refer accordingly. Having a seemingly intelligent doctor make a blanket statement such as 'natural therapies do not work' or 'are dangerous' shows how bad the system is today.

Imagine the scenario of a hospital patient (which many of us have taken part in albeit in secret); upon admission, a round table discussion takes place:

1. Natural, organic nutrition will be implemented to ensure cellular health.
2. Filtered water is given instead of heavy metal laden tap water. Hydration.

3. Sunlight, oxygen, hydrotherapy and all manner of external therapy is implemented to enhance each treatment choice.
4. The IV is used to administer safe therapies such as Vitamin C therapy, bicarbonate of soda therapy.
5. Modalities such as massage, chiropractic, osteopathic, acupuncture and so on are included to alleviate suffering.
6. Internal suitable therapies such as herbals, homeopathic, orthomolecular and so on are prescribed - an educated, experienced natural health professional will not only know what to use but will work alongside the doctors to ensure synergy and avoid any possible contraindications. It has never been an 'us and them' mentality - other than within the orthodox realm.

100% of treatments will not only experience expedient recovery, but the end result is health rather than following up side effects. Doctors must work alongside qualified natural health professionals, otherwise eventually the public will choose and modern medicine will be relegated only to the uneducated, dependent and those who cannot choose for themselves.

Let us be honest regarding the true reason for this invitation for submission. On the subject of chemotherapy and vaccination, choice must be made available. Herd immunity has failed. Chemotherapy has failed too many. How any doctor can choose surgery or toxic therapy which has a higher failure/injury rate than cure rate is impossible for a true health professional to grasp. How anyone can parrot the phrase 'correlation does not equal causation' is as mentally inept as they are ignorant/incorrect. It is only used in the topic of vaccine injury, yet the same medical expert, who has zero knowledge of natural therapies, will make the polar opposite claim if someone suggests an alternative.

The system is failing despite the onslaught of expensive continual advertising and brainwashing. People are choosing. Destroying the careers of people who only want to save lives is not the answer.

Honest practitioners and allied experts do not trust AHPRA - any formal report or complaint is assessed based upon the issue. If it involves pharmaceuticals of any type the outcome is always in favour of the doctor. However, if it involves successful use of natural therapies the outcome is catastrophic to the career and reputation of the individual. It is biased by default.

K Botes

From: Tessa C. Boucher [redacted]
Sent: Thursday, 4 April 2019 5:03 PM
To: medboardconsultation
Subject: Proposed guidelines for complementary and unconventional medicine

Hello,

Over the years I have gone to Integrative doctors, complementary practitioners, allied health professionals, compounding pharmacists and functional testing to address health issues which modern medical doctors were not able to do. I have found them very helpful in managing my health, often without the use of prescribed medication and therefore being less of a drain on health costs in Australia. I therefore have a few concerns about the implications of the guidelines which include:-

-The right of patients to determine their own medical care, which is under threat

-A range of medical treatments have been grouped together, including integrative medicine with unconventional medicine and "emerging treatments". This could create the impression that they are not evidenced based.

-Many of the terms used in the rationale, such as "inappropriate use" and "emerging treatments" lead to ambiguity and uncertainty.

-No evidence produced in the discussion quantifies risk in practicing complementary or integrative medicine vs conventional medicine

-There was no consultation with the Integrative medicine or complementary medicine community before the document's release

-The current Good Medicine Practice: a Code of Conduct for Doctors in Australia, already adequately regulates doctors' practice and protects patient safety. There is no need or justification for a two-tiered approach

There is a lack of clarity on how to determine what is "conventional" versus "unconventional" which can be easily misused by people with professional differences of opinion resulting in troublesome complaints.

I strongly urge you to reconsider these proposals and acknowledge members of the community, like myself, who want to continue having the choice to access these types of services,

Kind regards
Tessa Boucher

From: Julie Bourgeat [redacted]
Sent: Tuesday, 9 April 2019 2:48 PM
To: medboardconsultation
Subject: consultation on complementary med & emerging treatments

To the Board
I am very concerned to hear of a Consultation on Complementary Medicine and Emerging Treatments which fails to provide quantitative evidence of the efficacy or risks of complementary versus conventional medicine.
I am also alarmed that no consultation is being made with integrative or complementary medicine communities before the release of this document. …. Neither with the public. It seems a bit like being put on trial, but only listening to one side of the story.
Poor and dangerous practitioners of either complementary or conventional must be weeded out all the time to protect the community. However, practitioners must not be disallowed to practice because of differences of opinion. As a member of the general public and user of both conventional and complementary practices, I would be most appreciative if conventional medical practitioners would investigate alternatives for efficacy and risk. I have encountered helpful and unhelpful practitioners in both ways of practice and have had too many benefits from the complementary side of practice to be able to consider it all fringe or unhelpful. Much to the contrary.
And why do we have a mindset that postulates a "versus" situation ? Complementary practices are called such because they complement. Some areas of complementary approach have much to contribute and the public deserves their contributions.
Yours sincerely
Julie Bourgeat

From: Boyle, Calum [redacted]
Sent: Wednesday, 10 April 2019 12:32 AM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.
As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Calum Boyle
9/4/19

From: L-J Bradley [redacted]
Sent: Monday, 25 March 2019 5:58 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

I have seen the draft guidelines on the proposed changes to complementary and unconventional medicine and emerging treatments and I would like to voice my concerns regarding this, as a member of the public who has used both conventional and alternative medicine I ask that Option 1 be chosen from the proposed options.

The proposed new guidelines alarm me as it will bring about restricted access to alternative, emerging and integrative therapies, this outcome would be a travesty for any Australian wanting to experience good health. Alternative practitioners do an amazing job helping people overcome their health challenges, especially using natural therapies that have been around for thousands of years - modern conventional medicine is still in its infancy in comparison.

The integrative and alternative practitioners I've seen personally have done a much better job of improving my health than any conventional doctor I've gone to and I am not alone with this experience - many of my friends and family have had little success with conventional doctors and great success with alternative medicine.

Yet, should these changes to the guidelines occur it seems clear that our access and choice to use alternative therapies would be altered negatively - if it doesn't meet the standard criteria then it will be removed from our sphere - surely we as the Public can be given the respect that we are smart enough to make these choices for ourselves?

At this time I could choose to see a conventional doctor but I choose to see an alternative practitioner instead as I have had so much more success with my health this way - I do not want that choice restricted and my options narrowed to the more mainstream route - this has not worked for me in the past and I see no reason why it will work in the future as it is a different modality and one that is heavily pharmaceutical based rather than getting to the root cause of a problem and handling the issues without pharmaceutical medication.

I have never had ill effects of any kind from alternative medicine, in fact, I've never seen it harm anyone. Contrast that with the cascade of side effects, illness and irreversible harm I've observed from others undergoing conventional medical treatment - if anything needs to be better regulated it's those medical practices that seriously injure and kill thousands of people every year.

Modern medicine has its place and is useful in our society for certain ills but it's far from perfect and it is not the only answer.

Let us choose for ourselves the health therapies we wish to use by keeping the access open as it is now which will continue to grant us the freedom of choosing our own healthcare, this is a fundamental right for all Australians.

I urge you choose Option 1 and retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Thank for your time and consideration,

Regards,
Lorna-Jean Bradley

From: KARA BRAITHWAITE [redacted]
Sent: Thursday, 4 April 2019 7:52 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I do not support the Medical Board of Australia developing a separate guideline for medical practitioners who provide complementary medicine advice.
Complementary medicine is not ‘unconventional’ or ‘emerging treatment'.

I want my GP to extend themselves, and be able to support me with the best evidence based treatment. This is what they are trained to do.

Kind regards
Kara Braithwaite

From: Annie Bray [redacted]
Sent: Wednesday, 10 April 2019 12:04 AM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.
As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Ann Louise Bray

From:	janelle bray
To:	medboardconsultation
Cc:	[redacted]
Subject:	Public consultation on new guidelines for "complementary and unconventional medicine and emerging treatments".
Date:	Thursday, 4 April 2019 5:28:15 PM
Attachments:	[redacted]

Re: Public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

The Medical Board of Australia (MBA) has commenced a public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

Please be advised as to my concerns and **objection** to the new guidelines for ‘complementary and unconventional medicine and emerging treatments.

There is a concern that if adopted, a two-tiered system may arise that threatens Integrative Medicine (IM) and unreasonably targets practitioners.

The adoption of these guidelines must be stopped. As they stand the guidelines could impact doctors, complementary practitioners, allied health professionals, pharmacists, compounding pharmacists and functional testing labs.

Concerns include:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based.
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty.
- That the term 'complementary medicine' also includes access to traditional medicines.
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs ‘conventional’ medicine.
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release.
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach.
- That the right of patients to determine their own medical care is under threat.
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints.

This is an issue I deeply care about.

Janelle Bray
Remedial Massage Therapist, Reflexologist,
Reiki Master/Practitioner/Teacher
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

"Be the change you wish to see in the world." — Gandhi

From: Kerrie Broun [redacted]
Sent: Tuesday, 9 April 2019 11:31 PM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
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As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Kerrie Broun
9th April 2019

From: leanne.buchan [redacted]
Sent: Sunday, 7 April 2019 1:07 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To Whom It May Concern at The Medical Board of Australia…

Please, I implore you to resist from imposing greater regulation around the use of integrative, complementary and alternative medicines (CAMs), which will significantly restrain the practice of integrative medicine and the use of CAM modalities.

Restricting access to innovative and compounded natural therapies, would have substantial impact on the well-being of many Australians who use this treatment with great success.

On review of the proposal currently being reviewed, please choose “Option One (1)” as the preferred option, as I would miss the innovation and compounding of natural therapies in my own health care plan.

It is my right to have choices. It is your responsibility to make sure those choices are available to me.

From: [redacted]
Sent: Friday, 7 June 2019 1:39 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To Whom it may concern,

I am writing to you regarding the current laws in Australia regarding choice of health care. I would like to emphasis that Australians freedoms of choices are under threat from what kind of milk we can purchase to drink, to what we can rightfully believe! Now we are faced with the new guidelines for 'complementary and unconventional medicine and emerging treatments'. There is a concern that if adopted, a two-tiered system may arise that threatens Integrative Medicine and unreasonably targets practitioners, but also the right of patients to determine their own medical care is under threat.

Australian - The Free Country - We want to retain our freedom of unrestricted, uncensored health information, and retain the ability to choose the health care we want.

Kind regards,
Belinda Burtt

From: Kim Busuttil [redacted]
Sent: Tuesday, 30 April 2019 7:47 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear Sir/Madam,

I have recently had the opportunity to read about the proposed changes and consultation on complementary and unconventional medicine and emerging treatments.

I understand that the date of consultation has passed, however I request that this letter still be considered as I have only recently become aware of the changes as proposed.

I request that Option One be adopted by the Board, which will mean that no changes will apply.

In the past, I have seen two different medical professionals who practice in complementary medicine. Not only have these two individuals practiced to the highest standards of medical professionals, I have experienced positive improvements in my personal health.

As a practicing solicitor in NSW, I fully appreciate how regulated the medical profession currently is. I understand that such regulations have come about for good reason, however my position is that practitioners of complementary medicine should not be subject to extra regulations when compared with their peers, employing more traditional methods.

I find it most concerning that my health May suffer as a result of undue additional regulations.

Should you wish to contact me further, I supply my contact details below.

Kind regards,

Kim Busuttil
[redacted]

From: [redacted]
To: medboardconsultation
Subject: Submission to MBA
Date: Thursday, 27 June 2019 8:48:10 PM
Attachments: [redacted]

Please find attached three documents which require consideration when all the submissions are received and reviewed.

The first is a treatise on the treatment of thyroid disease and the value of TSH measurements, the measurement of Reverse T3 and the use of T3 in unrecognised thyroid deficiency.

I note that the Board has previously accused a doctor of treating a disease that "does not exist" relating to his use of SRT3 and that the College of Pathologists guidlines state that there is no indication to measure RT3. Their lack of an understanding of thyroid measurements and function is beyond belief. The above treatise is fully referenced and has to be accepted.

The second letter to me from the HIC in1998 approving my use of Kinesiology indicator muscle testing for a Medicare Rebate. This is an official approval and must be taken into account in your review of Kinesiology.

The third is a fully referenced abstract comparing bio-identical HRT with traditional forms.

I am an integrated Doctor and am prepared to consider all forms of therapeutic endeavour that do no harm. There are many examples of therapies that are not evidence based by today's scientific understanding and where double-blind crossover trials are impossible. There are also many mysteries of life that have to be uncovered and for the Board to impose its boundaries at this time of evolution is an unacceptable presumption.

Finally, the zealotry of [redacted] and friends has to be viewed judiciously.

Please acknowledge receipt.

Signed

Dr Edward Butterworth MB.Ch.B

Peripheral Thyroid Hormone Conversion and Its Impact on TSH and Metabolic Activity

February 23, 2015

Source: Journal of Restorative Medicine, Volume 3, Number 1, April 2014, pp. 30-52(23)

There have been recent advances in understanding of the local control of thyroid activity and metabolism, including deiodinase activity and thyroid hormone membrane transport. The goal of this review is to increase the understanding of the clinical relevance of cellular deiodinase activity.

Full Article >>

Peripheral Thyroid Hormone Conversion and Its Impact on TSH and Metabolic Activity

Kent Holtorf, MD

ABSTRACT

There have been **recent advances** in understanding of the local control of thyroid activity and metabolism, including deiodinase activity and thyroid hormone membrane transport. The goal of this review is to increase the understanding of the clinical relevance of cellular deiodinase activity. The physiologic significance of types 1, 2 and 3 deiodinase (D1, D2 and D3, respectively) on the intracellular production of T3 are discussed along with the importance and significance of the production of reverse T3. The difference in the pituitary and peripheral activity of these deidoidinases under a wide range of common physiologic conditions results in different intracellular T3 levels in the pituitary and peripheral tissues, resulting in the inability to detect low tissue levels of thyroid hormone in peripheral tissues with TSH testing. This review demonstrates that extreme caution should be used in relying on TSH or serum thyroid levels to rule out hypothyroidism in the presence of a wide range of conditions, including physiologic and emotional stress, depression, dieting, obesity, leptin insulin resistance, diabetes, chronic fatigue syndrome, fibromyalgia, inflammation, autoimmune disease, or systemic illness, as TSH levels will often be normal despite the presence of significant hypothyroidism. The review discusses the significant clinical benefits of thyroid replacement in such conditions despite having normal TSH levels and the superiority of T3 replacement instead of standard T4 therapy.

Keywords

HEALTH INSURANCE COMMISSION

Dr Edward Butterworth

[redacted]

[redacted]

Dear Dr Butterworth

[redacted]

Yours sincerely

[redacted]

[redacted]

The Bioidentical Hormone Debate: Are Bioidentical Hormones (Estradiol, Estriol, and Progesterone) Safer or More Efficacious than Commonly Used Synthetic Versions in Hormone Replacement Therapy?

Kent Holtorf, MD[1]

[1]Holtorf Medical Group, Inc., Torrance, CA

Abstract

Background: The use of bioidentical hormones, including progesterone, estradiol, and estriol, in hormone replacement therapy (HRT) has sparked intense debate. Of special concern is their relative safety compared with traditional synthetic and animal-derived versions, such as conjugated equine estrogens (CEE), medroxyprogesterone acetate (MPA), and other synthetic progestins. Proponents for bioidentical hormones claim that they are safer than comparable synthetic and nonhuman versions of HRT. Yet according to the US Food and Drug Administration and The Endocrine Society, there is little or no evidence to support claims that bioidentical hormones are safer or more effective. **Objective:** This paper aimed to evaluate the evidence comparing bioidentical hormones, including progesterone, estradiol, and estriol, with the commonly used nonbioidentical versions of HRT for clinical efficacy, physiologic actions on breast tissue, and risks for breast cancer and cardiovascular disease. **Methods:** Published papers were identified from PubMed/MEDLINE, Google Scholar, and Cochrane databases, which included keywords associated with bioidentical hormones, synthetic hormones, and HRT. Papers that compared the effects of bioidentical and synthetic hormones, including clinical outcomes and in vitro results, were selected. **Results:** Patients report greater satisfaction with HRTs that contain progesterone compared with those that contain a synthetic progestin. Bioidentical hormones have some distinctly different, potentially opposite, physiological effects compared with their synthetic counterparts, which have different chemical structures. Both physiological and clinical data have indicated that progesterone is associated with a diminished risk for breast cancer, compared with the increased risk associated with synthetic progestins. Estriol has some unique physiological effects, which differentiate it from estradiol, estrone, and CEE. Estriol would be expected to carry less risk for breast cancer, although no randomized controlled trials have been documented. Synthetic progestins have a variety of negative cardiovascular effects, which may be avoided with progesterone. **Conclusion:** Physiological data and clinical outcomes demonstrate that bioidentical hormones are associated with lower risks, including the risk of breast cancer and cardiovascular disease, and are more efficacious than their synthetic and animal-derived counterparts. Until evidence is found to the contrary, bioidentical hormones remain the preferred method of HRT. Further randomized controlled trials are needed to delineate these differences more clearly.

Keywords: bioidentical hormones; synthetic hormones; hormone replacement therapy; estriol; progesterone; conjugated equine estrogens; medroxyprogesterone acetate; breast cancer; cardiovascular disease

Correspondence: Kent Holtorf, MD,
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Torrance, CA 90505.
Tel: 310-375-2705
Fax: 310-375-2701
E-mail: kholtorf@cox.net

From: Dianne C [redacted]
Sent: Sunday, 10 March 2019 10:01 AM
To: medboardconsultation
Subject: Public

This is so wrong our bodies our choice

Sent from my iPhone

From: Kathy Calder [redacted]
To: medboardconsultation
Subject: public consultation on complementary and unconventional medicine
Date: Friday, 28 June 2019 10:20:04 PM

This letter is to provide feedback to the Medical board consultation paper regarding practitioners whom provide complementary, unconventional medicine or emerging treatment. I will limit my response to my area of knowledge and my own practice and observations as a General Practitioner of over 23 years. It is my understanding of my own practice and that of colleagues that integrative medicine is strongly anchored to conventional guidelines and accepted standards of care. Integrative approaches may also adopt evidence based research to assist patients with their health. The assertion that integrative practice may be harmful or inappropriate to patient care is concerning, and it appears that there has been a generalised attitude adopted in the consultation paper towards any practice which is considered 'unconventional'.

My observation has been that many patients present with complex conditions that are not always well addressed with traditional guidelines and models of care. These patients have often been through the gamut of orthodox treatments and on presentation are often well researched in a range of literature and evidence-based approaches relating to their condition. Integrative practitioners commit to further education in evidence based approaches to better help their patients, and most integrative training is conducted by ACNEM with training accredited with the RACGP. It is made clear to patients that integrative approaches, while not incorporated into current guidelines, should not conflict with recommended guidelines of care and patients are made aware of treatments which fall outside of conventional management approaches. It should also be noted that most conventional medical practitioners utilise ‘ off label’ medications and offer options which are not evidence-based nor part of clinical guidelines. This is arguably an accepted practice in medicine.

Pharmacological approaches are an integral part of patient care, and are predominately what is utilised within standard 10-15 minute consultations. While drug prescriptions comprise the most part of preventative health care - i.e managing risk factors – hypertension, metabolic disease, hyperlipidaemia, reflux etc, they do not address the underlying drivers for disease, and may sometimes be associated with long term health concerns i.e PPI’s. There is a growing public interest and scientific literature supporting a shift towards understanding drivers for disease, and personalised approaches to health. A concern with the Medical Board consultation paper is that that its implementation may erode patient choices and slow research. I see a need for a greater focus on preventative health and a better appreciation of the many antecedents that are underpinning increasingly challenging health issues. Areas of translational medicine and non-pharmacological evidence-based approaches to health have been somewhat overlooked in our overarching corporate pharmacological model which tends to dominate medical practice and training.

A systems thinking approach to complex conditions is optimal in understanding complex problems. Systems thinking has not yet weaved its way into the medical model, which is mostly based on reductionist approaches to research and medical trials. There are numerous studies around translational and personalised medicine, which are being supported in universities and institutions in many parts of the world. This involves a paradigm shift in the way we understand approaches

to health, where current models for research do not take into account the synergistic effects of nutrients, environment, genes etc, and are not designed to understand individualised responses to interventions. It appears that conventional medical models operate from a position of 'damage control'. It might be an opportune time for the medical profession to explore emerging thinking, and look at positive ways of incorporating a systems approach to health.
I believe the Medical board consultation paper listed concerns over safety, however these concerns were linked to practices that are not adopted by integrative practitioners i.e steroid use and stem cells. An integrative approach may help address the increasing safety concerns associated with some pharmacological approaches to patient care.
Dr Kathleen Calder
MBBS FRACGP
Member RACGP

Dr Kathy Calder
MBBS, FRACGP

A [redacted]
P [redacted] F
W [redacted]

[redacted]

From: RIKKI CALLAGHAN [redacted]
Sent: Sunday, 17 March 2019 10:40 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

It's been obvious for a long time now that the Medical Board don't have the support of Australians (patients and doctors) and it's all because of your obnoxious and arrogant priorities. While you may have your list of pathetic excuses you firmly believe in, the only legitimate reason the medical board has an issue with Docotors also treating with what you refer to is unconventional methods is because you feel inferior and let me tell you, you should! (insert your eye roll and immediate disbelief). You are inferior to these amazing doctors, I don't even like to call them doctors because that is degrading to who they are and what they do. Their priority is to actually treat people and not just give out bandaids in the form of prescription medicines. They treat people with a holistic approach which again is something you wouldn't know anything about. If you got your head out of your [redacted] for 5 seconds you'd realise you should be working with these highly trained medical proffessionals, include "alternative medicine" in hospitals and general medical centres and referring your patients to them. The save a buck now to cause more expensive health issues down the track approach has to stop and it has to stop now! You are costing the country a fortune and ruining innocent lives. Time for you to make health the priority since that is what WE PAY YOU far too much to do, especially considering you are failing.

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

To: The Medical Board of Australia

From: Mark Campbell

Telephone:

E-mail: [redacted]

Website:

Date: 29/06/2019

Consultation

I, Mark Campbell, appreciate the opportunity to participate in providing comments on the Medical Board of Australia's recent public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

It is noteworthy the MBA has undertaken an open and transparent consultation with all stakeholders to allow a considered and impartial document to be produced. I support the MBA continuing with its current code of Good Medical Practice, rather than producing an additional guideline document as an outcome of this consultation.

Question 1 – Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? If not, what term should be used and how should it be defined?

• Grouping the practice of integrative medicine (IM) with phrases 'unconventional medicine' and 'emerging treatments' implies that IM is fringe rather than an evidence-based and vital adjunct within the practice of healthcare.

• Grouping three disparate areas together in this proposal – complementary, unconventional and emerging is not scientific, and incorrectly aligns each area with the same degree of potential harm or risk.

• The inclusion of the umbrella term 'complementary medicine' in the proposed guidelines without an accepted definition presents a further problem. Internationally-recognised and nationally accepted definitions should be used in the proposed document being consulted on by the MBA. The definitions should be agreed to be government and key stakeholders from representative industry bodies such as the Therapeutic Goods Administration (TGA), Complementary Medicines Australia (CMA), the National Institute of Complementary Medicines (NICM) and the Australasian Integrative Medicine Association (AIMA). Current definitions include:

Definition of complementary medicines by the Therapeutic Goods Administration (TGA)[1]

In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the Therapeutic Goods Act 1989.

Definition of traditional and complementary medicine by the World Health Organization (WHO)[2]

Traditional medicine (TM):

Traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary medicine (CM):

The terms "complementary medicine" or "alternative medicine" refer to a broad set of healthcare practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant healthcare system. They are used interchangeably with traditional medicine in some countries.

Traditional and complementary medicine (T&CM):

T&CM merges the terms TM and CM, encompassing products, practices and practitioners.

Definition of Integrative Medicine by Australasian Integrative Medicine Association (AIMA).[3]

Integrative medicine is a philosophy of healthcare with a focus on individual patient care. It combines the best of conventional Western medicine with evidence-based complementary medicine and therapies.

Integrative Medicine reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing.

It takes into account the physical, psychological, social and spiritual wellbeing of the person with the aim of using the most appropriate, safe and evidence-based treatments available.

• There are many definitions of "integrative" and "complementary" healthcare, but all involve bringing conventional and complementary approaches together in a coordinated way. These definitions should be considered to be harmonious with national and international terminology.

Question 2 – Do you agree with the proposed definition of 'complementary and unconventional medicine and emerging treatments'?

• These terms 'unconventional medicine', 'inappropriate use' and 'emerging treatments' are not adequately defined which creates ambiguity and uncertainty.

• The term 'complementary medicine' also includes access to traditional medicines which is defined as a basic human right in Australia and by the World Health Organization.

• The amalgamation of three disparate groups into a single definition incorrectly implies they have many commonalities, which they do not. The only apparent component of the definition that provides cohesion is that the MBA sees these practices as non-conventional. This makes the definition political and therefore not scientific as it revolves around the concept of what evidence based medicine is in this age of evidence-based practice.

• More than two thirds of the Australian population use complementary medicines as a part of their self-care,[4] and it's estimated that one third of general practitioners incorporate some aspects of complementary medicine within their medical practice, therefore it could be argued that this constitutes current conventional medicine. The MBA would need to define conventional medicine to ascertain if this political definition has validity. The lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion.

• Complementary medicines, for the purpose of this consultation should be defined as, medicinal products containing such ingredients as certain herbs, vitamins and minerals, nutritional supplements, homoeopathic medicines and aromatherapy products and are regulated as medicines by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989.

• The terminology used should be nationally and internationally accepted, and agreed to amongst various industry stakeholders as outlined in response to Question 1. This assists in adopting a standardised process that can be transferred across different states and territories of Australia as well as internationally. Such standardised terms provides ease of communication across different frontiers.

Question 3 – Do you agree with the nature and the extent of the issues identified in relation to natural medicine practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

• There is no evidence produced in the discussion paper that quantifies risk or relative risk in practicing complementary medicines.

• Complementary medicines as defined in response to question 2, are regulated by the TGA and are low-risk under the therapeutic goods regulatory framework[5] and must be articulated separately from treatments or other alternative therapies for the purposes of this consultation.

• The reporting of Adverse Drug Responses (ADRs) via the Therapeutic Goods Administration shows that only 1% of ADRs are from complementary medicines, suggesting that the relative risk is low and does not warrant the proposed guidelines. These figures are reflective of similar patterns of adverse events reported in Singapore (considered by the TGA to be a comparable overseas regulator). According to a retrospective study of reported adverse events due to complementary health products between 2010 and 2016, only 0.6% were associated with complementary health products – with the remainder linked to chemical drugs, vaccines and biological drugs. This further reinforces the relative low risk of these forms of therapies.[6]

• The World Health Organization's Traditional Medicine Strategy 2014-2023 devotes attention to prioritising health services and systems including traditional and complementary medicine practices and practitioners.[7] Therefore the proposed guidelines could be perceived as being contradictory to the aims and objectives of the WHO strategy, violating the human rights of all Australians, particularly indigenous peoples.

Question 5 – Are safeguards needed for patients who seek complementary and unconventional medicine and emerging treatments?

• All aspects of the proposed guidelines are adequately covered through the existing "Good Medical Practice: A Code of Conduct for Doctors in Australia" as seen by the detailed analysis in Appendix 1,

performed by the Australasian Integrative Medicine Association (AIMA) and included in their letter to Dr Anne Tonkin on 20th March, 2019.

• The structure of the proposed guidelines which specifically divides the scope of intent into "guidance for all registered medical practitioners" and then "Guidance for registered medical practitioners who provide complementary and unconventional and emerging treatments' creates a two-tiered divisive system which is open to being challenged, onerous, restrictive and anti-competitive. This may in turn, impact service availability, additional costs to the patient, and restriction of consumer choice.

• A review conducted by the Australasian Research Centre in Complementary and Integrative Medicine, based at the University of Technology Sydney, determined that two thirds of complementary medicine users don't inform their healthcare provider about their use.[8] This was linked to the patient's perception of the level of knowledge and acceptance by their healthcare provider, and to their fear of being judged. By enforcing an additional set of guidelines the implication is that these therapies are 'unconventional' which could serve to further perpetuate this consumer concern. This in turn, presents safety implications whereby the lack of disclosure could lead to unwanted side effects, nutrient/herb/drug interactions, or reduced treatment effectiveness. These are all risks that can be easily managed if the patient feels comfortable and is encouraged to share their use with all of their healthcare professionals. As the code highlights there are many ways to practice medicine in Australia, reflecting a linguistically and culturally diverse society of which the core tasks of medicine are caring for people who are unwell and seeking to keep people well.

Question 6 – Is there other evidence or data that may help inform the Board's proposals?

There is additional concern that the proposed guidelines have not been developed in conformance with COAG principles for best practice regulation as there is no evidence presented in these guidelines on the 'magnitude (scale and scope) of the problem', there is no demonstration that the current guidelines are inadequate nor any cogent argument given as to the need for additional regulation. Also of concern is the Board's attempt to pre-justify a preferred solution stating 'the Board prefers Option 2'.

Conclusion

We support that the current regulation (i.e. the Board's Good Medical Practice) of medical practitioners who provide complementary and unconventional medicines and emerging treatments (option 1) is adequate to address the issues identified and protect patients. The proposed guidelines are unnecessary and provide no added value in terms of patient safety or clarity of practice for doctors.

I appreciate the MBA consideration of the points I have raised in this document and look forward to a positive outcome where the final document represents the comments and concerns from all stakeholders including those shared here.

1. Therapeutic Goods Administration. An overview of the regulation of complementary medicines in Australia. Available from: http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
2. World Health Organization (WHO). WHO traditional medicine strategy: 2014-2023. Geneva, Switzerland 2013. Available from http://www.who.int/medicines/areas/traditional/definitions/en/
3. Australasian Integrative Medicine Association. What is Integrative Medicine? Available from https://www.aima.net.au/what-is-integrative-medicine/
4. NPS Medicinewise, NPA Annual Consumer Surveys: Findings about complementary medicine use, 2008, available at: http://www.nps.org.au/about-us/what-we-do/our-research/complementary-medicines/npsconsumer-survey-cms-use-findings
5. Therapeutic Goods Administration. An overview of the regulation of complementary medicines in Australia. Available from: http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
6. Xu Y, Dhavalkumar N, et al. Retrospective study of reported adverse events due to complementary health products in Singapore from 2010 to 2016. Front Med (Lausanne) 2018;5:167.
7. World Health Organisation (WHO). WHO traditional medicine strategy: 2014-2023. Geneva, Switzerland 2013. Available from http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf
8. Foley H, Steele A, Cramer H, Wardle J, and Adams J. Disclosure of complementary medicine use to medical providers: a systematic review and meta-analysis. Scientific Reports. 2019:9; 1573.

From: rhonda e campbell [redacted]
Sent: Wednesday, 3 April 2019 7:31 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Hello

The proposed new draconian regulation is simply unnecessary. It is nothing more than an attack on complementary and integrative medicine.

Furthermore, it is wrong for the Medical Board to group complementary medicine with unconventional medicine and emerging treatments. Complementary medicine is safe and has nothing in common with these treatments.

One of the options that the proposal considers is:

Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

I want option one as above to be selected.

Regards
Rhonda Campbell

From: Jane [redacted]
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments
Date: Saturday, 30 March 2019 12:09:29 PM

Dear Sir/Madam,

I support the adoption of Option 2: Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines.

Option 2 provides enhanced safeguards for patients, and clearer guidance for all medical practitioners.

Regards,
Dr Jane Canestra MBBS, MPH, FACEM

From: John Cantarella [redacted]
Sent: Sunday, 30 June 2019 3:42 PM
To: medboardconsultation
Subject: submission to AHPRA regarding changes in regulation effecting the legitimacy of Integrated Medicine

Dear Sir / Madam
I would like to make a submission challenging the
Medical Board of Australia (MBA) proposed consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments' based on the below concerns

Some concerns to address and bring up to include:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs ‘conventional’ medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach
- That the right of patients to determine their own medical care is under threat
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Sincerely

John Cantarella
[redacted]

From: Annalisa Capurro [redacted]
Sent: Monday, 8 April 2019 1:02 PM
To: medboardconsultation
Subject: Proposal to create strict governing of "Complementary and Unconventional and Emerging Medicine"

To whom it may concern,

I am writing to state my concern for the proposal to create strict governing of Complementary, Unconventional and Emerging medicine.

My name is Annalisa Capurro. I am [redacted] years old and I live in [redacted].

I have been using Complementary, Unconventional and Emerging medicine for the past few years and both value it's availability and am very happy with its practice.

My doctor always provides information about options for treatments and their relative merits and potential problems. I very much value my fee choice in making decisions regarding my own medical treatment.

My preference is Option 1, to retain the status quo regarding this issue.

If the Medical Board eventually decides to choose Option 2 I would hope that first, it applies to ALL medical practitioners with the same onus of exhaustive exposition of all treatment options, research etc...

Second, that the Board accept that integrative medicine, utilising Complementary, Unconventional and Emerging medicine as well as conventional medicine, be recognised as a Speciality in order to allow increased Medicare rebates to help cover the increased costs of fulfilling the new regulations.

Thanking you for taking this into consideration.

Yours Faithfully,

Annalisa Capurro

From: Cilla Carden [redacted]
Sent: Thursday, 4 April 2019 4:07 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may Concern

I have been made aware the Medical Board of Australia is planning to impose greater regulation around the use of integrative, complementary and alternative medicines (CAMs).

I embrace prevention as a first principle of healthcare. I take a strong stand and of the opinion:-

Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Let us go forward not backwards.

With concern

Cilla Carden

From: [redacted]
Sent: Friday, 28 June 2019 1:30 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments.

To whom It may concern.

We, as a family have been, over many years, using complementary medicine, suggested by our doctor, to treat various non- life threatening ailments.

I ask please, that you do not hamper our doctor's treatments for us, both traditional and complementary.

Your sincerely.

The Carey family.

From: Romina Cavagnola [redacted]
Sent: Thursday, 27 June 2019 4:38 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1. I prefer a holistic approach to my family's health
and have been served well by integrative medicine doctors in determining the causes of ailments and holistic, non-drug approaches to resolve these where possible. I believe that all Australians reserve the right to choose how they seek advice and manage their own health, and make an informed decision about which treatments and therapies to implement.

From: [redacted]
Sent: Tuesday, 9 April 2019 12:27 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine etc

Dear Sirs,
I am amazed you are trying to do away with anything that does not fit in your outdated ideas of medicine.
Many people do not trust general GPs because all they do is give out drugs without trying to find the root cause of illness.
With so many people choosing to use integrative GPs you have no right to try to limit our access and perhaps try to disbar these wonderful doctors.
Like so many things today, ideas of what is right have moved on. Please do not alter the guidelines to stop these doctors.
I vote to leave things as they are.
Joan Chandler

From: Jeremy Chaplin [redacted]
Sent: Friday, 28 June 2019 11:30 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

- I choose **Option 1:** "no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine."

- I have chosen to see Integrative Medicine doctors because:
    - I want to be involved in my own and my family's care and this requires time in consultations an additional medical training that I found in my integrative medicine doctor.
    - Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options.
    - I have been harmed by conventional medical treatment, and needed to find other options.
    - I prefer non-drug approaches for managing my family's and my own health or illnesses.
    - I am happy with my GP for simple treatments within brief consultations, but I want to go further with prevention and a deeper understanding of what I can do for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that.
    - I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.
- I have concerns about the proposed regulations because:
    - There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.
    - The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.
    - The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.
    - There has been no transparency in consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations.

Kindest Regards,

Jeremy Chaplin

[redacted]

[redacted]

From: MsChappie . [redacted]
Sent: Wednesday, 26 June 2019 5:23 PM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

Subject: Consultation on complementary and unconventional medicine and emerging treatments

I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.
The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.

From: Glenda Charles [redacted]
Sent: Monday, 8 April 2019 6:20 PM
To: medboardconsultation
Subject: Integrative Doctor restrictions

To whom it may concern

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from my regular GP, I feel that this is an abhorrent limitation on my rights to seek the appropriate medical attention.

To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

I would appreciate an update on what measures are being put in place to maintain the current Integrative Doctors' practices.

Your sincerely,

Glenda Charles

Email: [redacted]
Mobile: [redacted]

From: [redacted]
Sent: Wednesday, 26 June 2019 1:39 PM
To: medboardconsultation
Subject: Public Consultation on complementary and unconventional medicine and emerging treatments

Public Consultation on complementary and unconventional medicine and emerging treatments

I am forwarding the below submission in relation to the above topic. I support Option 1 as described by the MBA – *Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.*

I am concerned that the proposed changes to regulations have been put forward by the MBA without prior consultation with relevant stakeholders, such as representatives of medical colleges, and or academics in the fields of Integrative Medicine and, further, that the "stakeholders" have not been identified or any concerns raised. How can this be a credible outcome without consultation? Some of the concerns regarding the proposed regulations are:-

- Unnecessary guidelines; there is a current Code of Practice that addresses all safety and efficacy issues related to Integrative Medicine
- Restriction of consumer choice outside "conventional" medical practice
- Failure to consult with stakeholders and state in the development of the regulations
- Failure to identify significant concerns about safety of Integrative Medicine or risk to the public

Surely, qualified doctors who have adopted integrated medicine into their everyday practice, should be congratulated in their open-minded approach towards their patients. The use of pharmaceuticals for many conditions may not necessary, nor do they always work. Sometimes, it is simply a change of lifestyle, eg simply what we eat. It is well known that many doctors over-subscribe pharmaceuticals.

To sanction doctors who use safe and effective Integrative Medicine in their day-to-day medical practice by imposing a new set of guidelines on their practice, is neither fair nor effective. Why complicate it with a two-tier medical system, ie, different guidelines for conventional and complementary medicine. One set of good practice guidelines is all that is required for ALL doctors.

Integrative medical doctors can combine the best of conventional and complementary medicine into clinical practice.

I work in the health food and supplement industry, and speak to many people in my day to day work.

A customer relayed her story to me. She was suffering with intense upper abdominal pain. After visiting her doctor and specialists on numerous occasions, and multiple tests later, she had no resolution or definitive answer for her painful condition. The specialist did mention the gall bladder was bulging with no presence of stones, however no medical treatment options were offered. I suggested she see a local integrative GP. Her condition was completely resolved within two weeks following one visit, with the use of only nutraceuticals, herbs and some simple dietary recommendations. She is still symptom free and simply follows a maintenance plan. She no longer experiences pain after meals. This has allowed her to function much better on a daily basis, without the use of any prescription medications.

This is not an isolated case. I literally hear numerous stories like this from customers who are frustrated with a lack of interest, or definitive answers, from main stream medicine. Sometimes they are people who are simply suffering niggling symptoms from nutritional deficiencies, or in some more extreme cases like auto-immune conditions and cancer. I have heard of some astonishing results and transformation of lives, simply

with making lifestyle changes, use of supplements and a change in diet. Most conventional doctors do not have specific training in nutrition. Integrated doctors have an understanding and passion for alternative options. Sometimes it is just a matter of changing your lifestyle, diet and correcting a few nutritional imbalances to return to health.

Australians who utilise GPs practising some aspects of complementary medicine within their practice, is on the rise. There is clearly a demand for a more holistic approach Why would general practitioners they do this if it didn't work for some of their patients?

There is no doubt, there is room for both conventional and complementary medicine. No-one is doubting the value and effectiveness of pharmaceuticals, of course they are necessary for many conditions, but not for all conditions.

Most of all, the changes to these regulations will severely limit Australians' freedom of choice for their health care.

Regards

Nicole Chester

From: Jocelyn [redacted]
Sent: Thursday, 27 June 2019 10:14 AM
To: medboardconsultation
Subject: Complementary medicines

Dear Sir/Madam

I write to express my opposition to the proposed changes to regulations that would have the effect of discrimination against medical practitioners who practise complementary medicine. Such changes would threaten my freedom of choice.

Most of the GPs that I have consulted over a lifetime use some aspect of complementary medicine. They have all been properly qualified doctors, but ones with open minds as to effective ways of treatment and the benefits of healthy lifestyles. I have also received similar advice from highly trained , specialist doctors educated beyond their medical tertiary qualifications.

The proposed changes would be very backward and not in line with practice in many other countries. Australia should take a holistic approach to treatment and embracing new and innovative medical practices.

I understand that if these regulations go through, any doctor practicing safe and effective Integrative Medicine might find himself or herself breaching the regulations and might therefore be subject to disciplinary action or even deregistration. Such a threat would deter practitioners and limit patient choice.

Yours sincerely

Jocelyn Chey AM FAIIA
[redacted]

Dr Roberta Chow AM
MB BS (Hons) FRACGP FAMAC M.Appl.Sci PhD Grad Cert Pain M'ment

[redacted]

9th April 2019

Medical Board of Australia

My submission to address the following issues:

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? If not, what term should be used and how should it be defined?

Complementary medicine is defined as non-evidence based medicine but does not define how much evidence is enough evidence. Until that is adequately defined, there should be no categorsing of treatments into the "complementary" or whatever. Define them by the evidence levels….on the currently understood levels of evidence, then there is no judgemental component. If there is consensus based it is low level evidence to the highest systematic review and meta-analysis. "Integrative medicine" might be acceptable for some doctors.

Defining something as "unconventional" is not an evidence based term because people who use acupuncture like myself would not regard it as "unconventional". I don't believe there is an adequate definition for "unconventional". Furthermore, conventional does not necessarily safe or effective. See above and below.

For the Chinese who live in Australia and seek Traditional Chinese Medicine treatments using acupuncture and herbs this form of medicine is not unconventional it is traditional. "Unconventional" would be a divisive term and how would the definition change. I have been using acupuncture in my medical practice since 1988, does that make it conventional or unconventional? Ditto "emerging treatments"… how will decide when they "emerge" and become "standard" or conventional. It is likely that stem cells will emerge as a standard treatment in the future, just like the treatment of Helicobacter Pylori. Prof Marshall had to fight a lot of opposition to get the concept of bacterial induced duodendal ulceration accepted. It was regarded as unconventional by many people. Is the use of mesh for prolapse repair that hasn't been tested fall into the innovative, complementary, emerging medicine etc etc definitions.

2. *Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – '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.'* No.

If not, how should it be defined? See above – define by levels of evidence only and don't use emotive terms.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

No.

4. *Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments by medical practitioners that the Board has not identified?*

The point is being missed that doctors need to do have across the Board standards of care whatever they do. Don't define these within in a great or less degree of conventionality. A lot of "bad" doctors practice conventional medicine and patients are not protected by that label.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'? No more than any procedure or medicine that they are offered in so-called conventional medicine.

"The available information indicates that patients are being offered treatments for which the safety and efficacy are not known. They may be having treatments which may be unnecessary or may result in delayed access to more effective treatment options. Unnecessary treatments may expose patients to adverse side effects. Harm may occur directly from the treatment resulting in an adverse outcome or it may be indirect, associated with delays in accessing other treatment or from the promises of 'false hope'. While there may be benefits - treatment and therapies may also have no effect, the benefit may be uncertain, or the effect may potentially be harmful. The harm can be physical, psychological and/or financial." Page 6

6. Is there other evidence and data available that could help inform the Board's proposals?

Please see my comments above concerning currently use "evidence-based" treatments which are known to cause harm and are not being policed. Why single out things like acupuncture?

Some examples to illustrate known harmful but evidence-based treatments which the Board regards as conventional.

i) **Knee arthroscopy** has been found to be not effective for relieving pain of knee osteoarthritis. In fact, there is a suggestion that it accelerates the need for knee arthroplasty at the end of two years (1, 2). Following is the RACGP 2018 knee OA guideline for knee arthroscopy.

PICO 3.1 (knee): What are the benefits and harms of arthroscopic lavage and debridement interventions in the management of patients with knee OA?
SUMMARY (3.1 Arthroscopic, lavage and debridement,3.2 meniscectomy and 3.3 cartilage repair). There is very low-quality evidence that there is no apparent benefit in terms of pain, function or quality of life for joint lavage, debridement and meniscectomy in the setting of knee OA. Arthroscopy occurs more commonly in the private hospital setting than public hospitals. It is important to note that arthroscopy rates in knee OA have been declining in the past few years. In the context of an intervention where there is a debatable benefit, measurable costs and potentially serious harms, the working group strongly recommends against the use of arthroscopy for lavage and debridement in the setting of knee OA. The Australian Orthopaedic Association and the Knee Society position statement (www kneesociety.org.au/resources/aksarthroscopy-position-statement.pdf) strongly states that arthroscopy is not indicated for the treatment of knee OA. In the infrequent instance where exercise fails to release the locked knee, arthroscopy could be indicated. OVERALL QUALITY OF EVIDENCE: ⊕□□□VERY LOW

Q: Does the Board intend to ban orthopaedic surgeons from performing knee arthroscopies given that it is expensive has no benefit and is likely to cause harm?

ii) **Paracetamol** – not effective in back pain and knee osteoarthritis pain. Paracetamol is currently accepted as a treatment for these indications (3).

Q: Does the Board intend to ban prescribing of paracetamol by GPs?

iii) **NSAIDs** – not only are these medications available over the counter but are still widely prescribed with the potential for serious side effects especially in patients with polypharmacy, such as the elderly (4-15)

Q: Does the Board intend to ban prescribing of NSAIDs by GPs

iv) Lumbar spine facet joint corticosteroid injection

There is evidence that such injections have no benefit and have potential harm though the risk is small, though as with acupuncture there some excellent responders as well as non-responders (16).

Q: Does the Board intend to ban the use of facet joint injections by radiologists?

Options

7. Is the current regulation (i.e. the Board's Good medical practice) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Yes, and only if you equally identify issues in conventional practice which cause harm as listed above. The number of patients admitted to hospital for adverse drug reactions is in the 10s of thousands and costs a lot more money than "unconventional" medicine. Many more patients are injured by "standard" treatments. Use evidence as the marker by experts in the field, not by uninformed Committees.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

"Poor patient management, including:

i) inadequate or inappropriate testing or investigation – this is not a problem with the doctor and not with the complementary medicine – the doctor should be reprimanded appropriately.

ii) missed, incorrect, or delayed diagnosis – this is a problem with the doctors and not with the medicine delayed or inadequate referral to appropriate specialists - this is a problem with the doctors and not with the medicine

iii) inadequate or inappropriate follow-up/monitoring or review (including lack of long term follow-up after experimental procedures) – this is a problem with the doctor and not the medicine or procedure

iv) inadequate co-ordination of care - failed to obtain medical history from the patient's existing treating practitioners/failure to notify other treating practitioners of concurrent treatments

v) inadequate, inaccurate or misleading health records: examinations are not recorded and/or not routinely performed. this is a problem with the doctor's practice and procedures not the medicine itself"

All the above "issues" are all relevant to all medical practitioners e.g. surgeons who use mesh, undertake insertion of neurostimulators etc etc. To single out complementary medicines for specific regulation is wrong. Doctors doing these other "things" should be under the same degree of scrutiny for patient care as others doing conventional medicine.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

The draft guidelines miss the point that doctors practice a variety of treatments with greater or less degrees of evidence. Many "conventional" medicines cause a great deal of harm and result in negative consequences for patient and doctor. Labelling something as unconventional doesn't protect the people from any greater degrees of harm.

The same requirements of care for patient, communication etc etc should apply to all medicines and practices.

10. Are there other options for addressing the concerns that the Board has not identified?

I believe that the Board has focused wrongly on the medicine and not the doctor and requirement for good medical practice. Evidence is the criteria and trying to label a treatment has one thing or another is clumsy and not necessary.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

 Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct. Yes.

 Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging 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.

No, the code of conduct should apply to all doctors and not those who are using techniques other doctors are not familiar with. Friends of Medicine has a great deal of bias in pushing these changes through.

 Other – please specify. Nil specific.

Yours sincerely,

Dr Roberta Chow

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29 June 2019

[redacted]

Martin Fletcher
Chief Executive Officer
Medical Board of Australia
GPO Box 9958
Melbourne
VICTORIA 3001

By email: medboardconsultation@ahpra.gov.au

Dear Sir

CONSULTATION ON COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENTS

This submission refers to the submissions from the Australian Integrative Medicine Association (AIMA) and from Australian Lawyers for Human Rights (ALHR). I am writing to add some further comments to those submissions from a personal perspective.

In this submission I refer to complementary medicine, unconventional medicine and emerging treatments jointly as 'the relevant practices.'

1. ASSUMPTIONS UNDERLYING THE CONSULTATION

The relevant practices are not defined separately in the Consultation Paper. The grouping together of the relevant practices is apparently informed by a particular view of the nature of scientific evidence which appears to:

- reject the validity of anecdotal evidence as a reliable basis for decisions in respect of the clinical management of particular patients (or, more generally, health policy or the allocation of research funds), and
- entail a presumption as to the invalidity of all complementary medicine.

While drawing from insights gathered from careful clinical observation, mainstream medicine appears to consider that medical knowledge and trustworthy evidence is most reliable when produced under controlled experimental conditions, and view with suspicion other types of evidence, anecdotal or empirical experience and extraneous factors (such as spontaneous remission or placebo effects) as threats to genuine knowledge claims about the efficacy of mainstream treatments.

The views underlying the Consultation would appear to derive from this model of mainstream medicine, and the collective grouping of the relevant practices would appear to be informed by the belief that there is no sufficient evidence-base that supports any of the relevant practices. However it is submitted that such beliefs are questionable (particularly in light of the debates around what constitutes evidence-based

medicine), and are inimical to the open, unfettered discourse and exchange of information that rests at the heart of scientific inquiry.[1]

There are of course valid concerns about the safety or efficacy of some types of non-conventional treatment. However to put all 'non-conventional' and emerging treatments in the one basket is effectively to treat valid integrative medical services and medical discoveries on the same basis as charlatanism.

Historically, mainstream medicine has opposed complementary medicine.[2] But despite the epistemological and practical differences between the two, mainstream and complementary medicine both unquestionably share the goal of promoting patient health and well-being and avoiding harm. It is axiomatic that both should respect the human right of competent patients to make therapeutic choices in consultation with health practitioners.

Complementary medicine is a heterogenous collection of diverse medical beliefs and healing practices often defying easy identification of commonalities between them. Chiefly, however, advocates of complementary medicine proceed within a theoretical framework validated by human experience on the basis both that patients are the best authority of what works for them and that individuals differ in their medical needs and responses in ways that cannot be taken into account in double blind placebo trials. As Hallam Stevens says, the traditional type of evidence-based medicine may indicate what is "on average best for patients," but this is "not necessarily helpful in deciding what to do in any given case."[3]

Often complementary medicine beliefs and practices are sourced to the teachings of an esteemed founder or a canonical text. Central to the development of complementary medicine is the view that simple observation and experience corroborates and expands the original theories and healing practices - often without concern for validation of them by experimental controls, blind assessment, and placebo comparisons, although such methods are viewed as essential for mainstream medical practitioners wanting to evaluate complementary medicine.

It should be noted that the implication underlying the Consultation Paper (and particularly the crucial joint definition of the relevant practices) that 'conventional' medicine is in all cases preferable to non-conventional medicine ignores the substantial worldwide evidence of misinformation from drug companies, hospital errors and inappropriate treatment that occur within 'conventional' medicine.[4]

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1 See Paul A. Komesaroff, Amber Moore and Ian H. Kerridge, 'Medicine and science must oppose intolerance and censorship' *Med Journal of Aust* 2012; 197 (2): doi: 10.5694/mja12.10500 and Hallam Stevens, "Evidence-based medicine from a social science perspective," *AJGP* Vol 47(2) December 2018, 889 at 889, available at: https://www1.racgp.org.au/ajgp/2018/december/evidence-based-medicine-from-a-social-science-pers.

2 Gevitz N, 'The chiropractors and the AMA: reflections on the history of the consultation clause', *Perspectives in Biology and Medicine*. 1989; 32: 281-99; 'Quackery progress to be reported in Chicago', *JAMA*. 1962; 180:53; Kaptchuk T and Miller F, 'What is the Best and Most Ethical Model for the Relationship Between Mainstream and Alternative Medicine: Opposition, Integration, or Pluralism?', *Academic Medicine*. 2004; 80(3): 286.

3 Hallam Stevens, 'Evidence-based medicine from a Social Science Perspective', *AJGP* Vol 47, No 12, December 2018, 889 ff at 889.

4 See for example: John T James, "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care", *Journal of Patient Safety*: September 2013 - Volume 9 - Issue 3 - p 122–128 at https://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Pati

The implication that 'conventional' medicine is always better also ignores a public desire for medical pluralism. Complementary medicine would not be popular if it did not respond to a need. As Burford notes,

> *Medical pluralism develops because the public 'votes with its feet' for complementary systems of medicine. This usually results from the failure of biomedicine to find cures for certain chronic diseases, and the accompanying determination of patients and their family members to seek effective treatments that do not produce debilitating side effects*.[5]

2. THE CHILLING EFFECT OF AN ADDITIONAL LAYER OF REGULATION ON INNOVATION AND MEDICAL PRACTICE

The joint definition effectively assumes that traditional or conventional medicine cannot develop from within, by treating new or developing practices as necessarily being 'outside' conventional medicine. In this way, the joint definition encourages the traditional discouragement of 'new' ideas in medicine - which are – like new ideas in other spheres - often fiercely opposed and may take decades to become accepted into the mainstream.

The joint definition necessarily discourages 'conventional' practitioners from expanding their horizons and learning about alternative treatments - even though much of what can be categorised within the relevant practices is not necessarily unscientific.

It is clear that an additional layer of regulation would discourage practitioners from engaging in, or exploring, the relevant practices.

As Stevens notes in his discussion of the problems arising for practitioners in relation to medical and hospital systems which rely purely on conventional "evidence-based medicine" (EBM):

> *Of particular concern … is not simply the loss of the authority or independence of the physician, but also the subjecting of the doctor (and to some extent, the patient) to regimens of measurement, quantification and accountability. Clinical guidelines are effectively implemented by imposing cost differentials on hospitals and patients (insuring some treatments but not others) … The 'suppression of clinical freedom' associated with these measures is not only something of concern for doctors; it is an issue for every patient, since the corporations that are increasingly making clinical decisions*

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ent_Harms.2.aspx, Martin A Makary and Michael Daniel, "Medical error—the third leading cause of death in the US", B*MJ* 2016;353:i2139, *World Health Organisation Assembly Report* 25 May 2019 at: https://www.who.int/news-room/detail/25-05-2019-world-health-assembly-update, Peter Whoriskey, "As drug industry's influence over research grows, so does the potential for bias", *Washington Post*, 24 November 2012, at https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html?noredirect=on&utm_term=.3a9f0af130c7. Thanks to Zoe Cotterill-Rogers for assistance with these references.

[5] Op cit.

> *are concerned more with their own reputations (and legal liabilities) and profits above patient care*.[6]

Stevens adds that "perhaps most problematically," EBM has become associated with a move from disease management to risk management.

I note also the comments of the AIMA that the existing Code "Good medical practice: A code of conduct for Doctors in Australia"[7] and the AMA *Code of Ethics*[8] would appear to cover all relevant issues contemplated in the proposed regulations.

In addition, it is implicit in the imposition of an additional level of regulation in relation to the relevant practices that additional scrutiny from internal and external medical regulatory organisations will be applied in relation to the relevant practices. Whether or not this happens in practice, the possibility of this occurring will itself also have a 'chilling' effect upon use of the relevant practices.

Discouragement of practitioners from working in non-conventional areas through such over- regulation will effectively limit the understanding and development of practitioners, diminishing the range of treatments available to Australian patients (so limiting their right to choose their preferred treatment), and ultimately limiting the progress of Australian medicine.

Given that patient demand from non-conventional treatment is largely driven by dissatisfaction with the efficacy and cost of conventional medicine, it is likely that the reduction in the range of available treatments will have deleterious effects upon Australians' health and well-being.

3. HOW THE CONSULTATION COULD BE REFRAMED

At is issue in the Consultation are questions about the best and most ethical model for the relationship between mainstream and complementary medicine.

It is submitted that the binary ('either/or') framework of the Consultation excludes the possibility of developing regulatory initiatives for the better enhancement of public health, safety and well-being that acknowledge and are more appropriately responsive to the different characteristics, benefits and risk profiles of the relevant practices.

A model based on 'opposition' contains shortcomings which would be institutionalised were the Board's 'preferred choice' implemented and it to adopt the proposed guidelines. An 'oppositional' model, unlike a human rights model, would fail to prioritise and respect the patient and their needs.

It has been suggested that the remit of conventional evidence-based medicine should be broadened to include knowledge and expertise from diverse fields including cognitive psychology, sociology and

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6 op cit.

7 https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx, https://ama.com.au/sites/default/files/documents/AMC_Code_of_Conduct_July_2009.pdf

8 https://ama.com.au/position-statement/code-ethics-2004-editorially-revised-2006-revised-2016. See also the Australian *Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*.

economics.[9] I submit that the additional of a human rights framework, as explained in more detail in the ALHR submission, will also benefit both practitioners and patients.

I submit that a human rights based model of 'medical pluralism' is the best and the most ethical model, which respects patient choice while fostering co-operation between mainstream and complementary medicine at the same time as it recognises epistemological and practical differences between the two, in a relationship of mutual respect.

In order to develop the most appropriate regulatory initiatives in relation to the relevant practices, it is at the same time surely necessary to clearly define the different characteristics and risk profiles, the benefits and the possible dangers, of all of the relevant practices in detail, in order to achieve appropriate tailored regulation.

Only in this way can any regulations truly respond to an appropriately evidence-based paradigm.

Yours faithfully

Tamsin Clarke, LLB (Hons), LLM, PhD

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9 Stevens, op cit, p 891.

From: Anna Coats [redacted]
Sent: Saturday, 4 May 2019 4:03 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

TO WHOM IT MAY CONCERN:
I wish to object to the imposing of restrictions on the practice of doctors who wish to practice integrative medicine.
Evidence based practice using vitamin and mineral supplements, Hormone supplements and herbal medicines should be allowed and approved by the Medical Board of Australia.
Clinical trials have been done on many herbs and supplements showing their efficacy. Many such supplements have also been empirically shown to be efficacious.
Mediherb is an organization that has much compiled research evidence. Do your homework and have an open mind.
Where is the same concern shown for the iatrogenic effect of pharmaceutical drugs on the population?
Given that antibiotic drugs are becoming less effective I would think that the Medical Board would be investigating the efficacy of many herbs and natural products in supporting the immune system.
As a concerned citizen I wish to have informed, well educated doctors. I also value my right to choose to use natural medicine products and not to be confined to the use of pharmaceutically manufactured drugs.
Kind Regards,
Anna Coats

From: Bob Coleman [redacted]
Sent: Friday, 28 June 2019 1:25 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

As an interested party, although not a health professional, please note my preference for Option 1 'No change to existing regulations'.

Proposed changes to regulation by the Medical Board of Australia will single out medical practitioners who practise supposed 'unconventional' medicine threatening patients' freedom of choice.

Effectively the Medical Board of Australia (MBA) is proposing one set of rules for 'conventional' medical practitioners and another more stringent set for those providing 'complementary and unconventional medicine and emerging treatments'.

The MBA proposal lumps together 'complementary medicine with unconventional medicine and emerging therapies' into a single definition. They're not the same.

About 30% of Australian GPs utilise some aspect of complementary medicine within their medical practice; it could even be argued that this is current conventional medicine. These are highly trained, specialist doctors educated beyond their medical tertiary qualifications.

As in any profession there are good and bad practitioners. We can't have one rule for some practitioners and one rule for others. The key is ensuring regulation is focussed on the health and safety of ALL Australians. There should be only ONE set of good practice guidelines that ALL doctors should follow.

This is a step backwards in time and an indictment on the progress of healthcare in Australia. We need to be open to taking a holistic approach to treatment and embracing new and innovative medical practices.

If these regulations go through, any doctor practicing safe and effective Integrative Medicine may find themselves breaching the regulations and may be subject to disciplinary action from the MBA's regulatory branch, AHPRA, including deregistration. What is clear is that such a threat will deter a number of practitioners and, ultimately, limit patient choice.

Regards, Bob

Bob Coleman
[redacted]

11 April 2019

Executive Officer
Medical
AHPRA
GPO Box 9958, Melbourne 3001.

The answers to discussion questions and additional comments are entirely my own views based on my training, further education, research, clinical experience as a Complementary/Alternative Medicine practitioner (Naturopath and Bowen Therapist) and personal experience as a patient consulting with Conventional and Integrative Medical Practitioners (General Practitioners) and Specialists in neurology, gastroenterology, urology, oncology, emergency medicine and radiology.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?
   If not, what term should be used and how should it be defined?

   I do NOT agree with this definition. This definition seeks to group practices that are very dissimilar into a "one-size-fits-all" definition that does not accurately define any of the practices. The practices must be defined separately; that is one definition for Complementary Medicine, a separate definition for Unconventional Medicine and a third definition for Emerging Treatments.
   Any other attempt to define these very different medical practices as one group is doomed to failure and will do a great disservice to medical practice, the Medical Board of Australia and the public.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice,[1] 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.'
   If not, how should it be defined?

   This is a highly inaccurate definition. The term "conventional medicine" is fluid and changes according to current practice and narrow practice guidelines as defined by consultants and administrators who are not necessarily engaged in current medical practice. For instance, 70 years ago, my doctors visited my home, advised sunshine and water and prescribed herbal medicine. This was "conventional medicine" 70 years ago. Each year,

[redacted]

the "conventional" practice of medicine changes significantly in the light of emerging therapies, drugs, surgical procedures and techniques disseminated through education modules, conferences, mentorship and student training. Without an accurate and acceptable definition of "Conventional Medicine", there can be no definition of any other branch of medicine relying on comparison with conventional medicine.
In order for the Medical Board of Australia to define "unconventional medicine" they must accurately define "conventional medicine". Furthermore, Complementary Medicine is, by its nature, tradition, guidelines and evidence base, quite conventional. Therefore Complementary Medicine cannot be defined with or grouped with "unconventional medicine". "Emerging Medicine" requires a separate definition. Even a casual read of medical journals and research papers will show many emerging treatments practised in conventional medicine clinics with the knowledge and support of the Medical Board of Australia, TGA and other health authorities. "Emerging medicine" requires a much more accurate and specific definition.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

There are certainly issues surrounding the practices of 'complementary and unconventional medicine and emerging treatments' but, as with my comments on definitions, the issues are largely different for each group and many of the nominated issues are also concerns with the practice of "conventional medicine". For instance, the issues highlighted below are presented as part of the MBA Discussion Paper and are as significant or more significant in "conventional medicine" as they are with 'complementary and unconventional medicine and emerging treatments'. All these issues have been experienced by myself in clinical practice or personal health care. I have included comments in parentheses as for instance *(off-label prescriptions .....)*

Issues and concerns about this area of practice

The information available to the Board indicates that the use of complementary and unconventional medicine and emerging treatments is increasing and includes a wide range of practices from minimally invasive to major complex interventions. The medicines and therapies may be used as alternatives to conventional medicine or used in conjunction with conventional medicine. They may be used with or without the knowledge of a patient's other treating practitioners.

The available information indicates that patients are being offered treatments for which the safety and efficacy are not known ***(off-label prescriptions and dietary advice from untrained medical practitioners)***. They may be having treatments which may be unnecessary or may result in delayed access to more effective treatment options. Unnecessary treatments may expose patients to adverse side effects. Harm may occur directly from the treatment resulting in an adverse outcome or it may be indirect, associated with delays in accessing other treatment or from the promises of 'false hope' ***(Personally experienced in conventional medicine)***. While there may be benefits - treatment and therapies may also have no effect, the benefit may be uncertain, or the effect may potentially be harmful. The harm can be physical, psychological and/or financial.

These treatments are provided by a variety of medical practitioners with varying qualifications and expertise in the therapy and/or the patient's underlying condition. There are reports of medical practitioners who are not specialists, providing treatments for complex conditions without necessarily having the specialist level knowledge of the disease and its progression ***(I see many People with Parkinson's disease diagnosed and treated by a General Practitioner without referral to a Neurologist and prescribed inappropriate medication)***. The lines between research and commercial advancement can be blurred and conflicts of

interest can arise if the provider has a financial interest in the product or service being offered ***(very common in medical practice)***. Some treatments are being offered on a commercial basis before the usual clinical trials have been completed. Patients don't have the usual protections where clinical trials have not been undertaken. Patients may also be offered treatments, tests or products which are available only through the practitioners offering them, or through other entities with which the practitioners have commercial associations, which may not be disclosed to the patients.

Many of these treatments are funded privately, can be expensive, and may have uncertain results. Patients may seek complementary and unconventional medicine or emerging treatments because of serious and/or chronic conditions and may be vulnerable to exploitation, including financial exploitation. Consumers who see direct-to-consumer marketing of 'therapies for health and wellness' may not realise that these are medical interventions with associated risks.

The risk to patients depends on a range of factors such as:

- the extent to which the practitioner is practising outside accepted practice
- the level of risk of the procedures and interventions, and
- the health and risk profile of the patient.

An added element of complexity in this area of practice is that many of the treatments offered are variations of existing accepted treatments. For example, stem cell treatments are being offered for a range of conditions, extending beyond those for which they are accepted treatments or for which there is a sound and established evidence base.

Concerns about therapies and treatments being offered include:

- safety and efficacy of treatments not known (experimental treatments outside clinical trials)
- unnecessary treatments, or treatments for which there is no clearly demonstrable need
- risk of harm associated with some treatments (unnecessary exposure to serious side effects)
- inappropriate prescribing - not in accordance with therapeutic guidelines (in particular, hormone therapy and antibiotic therapy)
- unconventional off-label prescribing
- recommending hormone, vitamin and mineral supplements without accepted indications ***(or training)***
- prescribing substances not approved by the TGA without scientifically defensible reasons
- prescribing substances not approved for human therapeutic use
- prescribing compounded products:
    - where a commercial product is available and suitable
    - where there is a lack of evidence to support the compounded product's use
    - that have been manufactured in circumstances that don't meet expected quality assurance processes[2]
    - that have been manufactured in bulk rather than to meet an individual's needs
- accepted treatments provided without indications/medical justifications ***(particularly antibiotics for viral infections)***
- accepted treatments provided beyond the accepted indications
- risks associated with route of administration of treatments
- methods used to harvest and administer stem cells

[2] Unlike medicines on the Australian Register of Therapeutic Goods, compounded medicines are not subject to the same rigorous assessment for product efficacy, quality and safety by the Therapeutic Goods Administration.

- varied techniques and lack of standardisation and quality control, e.g. variable numbers of stem cells in the injections
- variable levels of training, skill and expertise in the administration of treatments and procedures ***(common in conventional medicine)***
- the providers offering treatments do not have experience or expertise in treating the underlying condition/disease ***(e.g. GP's and Parkinson's Disease)***
- practitioners using an identical treatment approach, including unconventional investigation and prescribing for most or all patients, and failing to make a proper diagnosis of each patient's specific condition
- practitioners encouraging indiscriminate or unnecessary use of regulated health services with limited evidence of benefits
- vulnerable patients (including patients with mental health conditions) who have tried conventional medicine and are willing to try anything are at risk of exploitation and unnecessarily exposed to risk of harm.

Concerns as to practices include:

Conflicts of interest, including:

- blurred lines between research and commercial innovation
- treatments marketed direct to consumers based on early research data which would normally lead to further research – insufficient to justify marketing direct to consumers outside formal clinical trials
- conflict of interest because of the commercialised nature of some procedures – where the provider has a pecuniary interest in a related company.

Concerns about inadequate consent including**:**

- known risks not fully disclosed ***(personally experienced in conventional medicine)***
- potential lack of benefit not communicated clearly ***(personally experienced in conventional medicine)***
- unsupported claims of efficacy and safety
- false claims of benefit ***(personally experienced in conventional medicine)***
- failure to inform patient of full costs (treatments are expensive and patients pay privately).

Poor patient management, including:

- inadequate or inappropriate testing or investigation ***(personally experienced in conventional medicine)***
- missed, incorrect, or delayed diagnosis ***(personally experienced in conventional medicine)***
- delayed or inadequate referral to appropriate specialists ***(personally experienced in conventional medicine)***
- inadequate or inappropriate follow-up/monitoring or review (including lack of long term follow-up after experimental procedures)
- inadequate co-ordination of care - failed to obtain medical history from the patient's existing treating practitioners/failure to notify other treating practitioners of concurrent treatments ***(common among my patients)***
- inadequate, inaccurate or misleading health records: examinations are not recorded and/or not routinely performed.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

   It is obvious that the Medical Board of Australia has sought an "easy way out" in submitting a generalised definition of practices which all have differing levels of benefits, safety and issues of concern. This consultation process cannot reach a valid conclusion until separate definitions are developed for each practice of medicine – Conventional Medicine, Complementary Medicine, Unconventional Medicine, Emerging Medicine.
   The Medical Board of Australia has also failed to provide an adequate definition or explanation of Integrative Medicine, a rapidly growing practice.
   A growing concern is the lack of standardised training for complementary medicine in Australia. Despite many efforts by the Complementary Medicine industry, appropriate Government bodies have not seen fit to pursue this matter in any cohesive way.
   As the situation stands now, we have doctors with qualifications from ACNEM and/or AIMA, but others who, because they are medical doctors, can practice Complementary or "Integrative" Medicine without appropriate post-graduate qualifications.
   Similarly, despite our best efforts to obtain suitable registration/regulation, almost anyone can call themselves a naturopath and practice unhindered until they hurt somebody.
   Without standardised education/qualification requirements, patients are put at risk from unethical practitioners.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

   Yes, of course. However, we must recognise that the tiny number of issues concerning Complementary Medicine pale into insignificance when compared with the enormous damage and cost of iatrogenic illness (650,000 hospitalisations, 40,000 deaths per year).
   All forms of medicine must be equally supervised by those qualified within the disciplines being supervised – that is <u>doctors supervise doctors, naturopaths supervise naturopaths</u>, etc.

6. Is there other evidence and data available that could help inform the Board's proposals?

   The Board must consult widely and openly with accredited and accrediting bodies representing all forms of medical practice, including Conventional Medicine, Complementary Medicine, Unconventional Medicine and Emerging Medicine, as well as Integrative Medicine, an area neglected in this discussion paper.
   Once these discussions are complete, and a new discussion paper prepared, the Board must allow adequate time for consumers to comment.

7. Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

As stated above, it is vital to define Conventional Medicine, Complementary Medicine, Unconventional Medicine, Emerging Medicine and Integrative Medicine separately and discuss safety issues within each discipline.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

   No, option 2 is totally inadequate.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

   The guidelines must be redrafted after the separate disciplines of medicine have been fully defined and discussed.

10. Are there other options for addressing the concerns that the Board has not identified?
11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?
    - **Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.**

<u>Option one</u> is preferred until a more comprehensive approach has been taken to both define and discuss 'complementary and unconventional medicine and emerging treatments' and, of course, Integrative Medicine, as indicated in my answers and comments above.

When redefining the various branches of medicine, it is vital to confer with "stakeholders" – that is practitioners practicing within each discipline as well as users/patients. The current discussion paper has been prepared with no consultation with stakeholders within the non-conventional disciplines.

In my view, the Medical Board of Australia needs to "go back to the drawing board" and create definitions and discussions more suited to its purpose. This task should be commenced without delay.

Yours sincerely

[redacted]

John C Coleman ND, MANPA

From: Kathy Coles [redacted]
Sent: Monday, 1 July 2019 8:03 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Re; Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1: “no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine.”

I have chosen to see Integrative Medicine doctors because:

I want to be involved in my own and my family’s care and this requires time in consultations an additional medical training that I found in my integrative medicine doctor.

I prefer non-drug approaches for managing my family’s and my own health or illnesses.

I am happy with my GP for simple treatments within brief consultations, but I want to go further with prevention and a deeper understanding of what I can do for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that.

I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments.
My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.

I have concerns about the proposed regulations because:

There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.

The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.

The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.

There has been no transparency in consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations.

Kathy Coles

From: [redacted]
Sent: Wednesday, 26 June 2019 1:56 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To the Executive Officer,
Medical,
AHPRA

Good afternoon,

I am writing in relation to the above matter and would request that registered doctors be allowed to continue practising as per Option 1 being considered by your organization.
As having received considerable help from medical doctors using conventional and complementary medicine, I would request that this option be put in place.

Thank you and kind regards,
Wendy Collett

[redacted]

[redacted]

1 April, 2019

The Executive Officer

Medical

AHPRA

GPO Box 9958

Melbourne Vic 3001

Dear Sir/Madam

I have been a patient of an Integrative Medical Practitioner for eighteen years. During that time, due to a range of medical issues, I have seen many medical practitioners and specialists.

The only consistent relief and understanding that I receive is from my Integrative Medical Practitioner.

I understand that the Medical Board of Australia is considering a proposal to create a strict new set of regulations and apply them to Integrative Medical Practitioners.

The result of such regulations will serve to significantly increase the burden of paperwork, thereby adding to patients' costs, and, in all likelihood, a reduction in the number of such practitioners.

To create double standards in medicine will be to the detriment of patients such as myself.

Only those patients who have benefited from the advice of an Integrative Medical Practitioner are in a position to provide first-hand experience, rather than the opinion of bureaucracy.

Yours faithfully

Anne M Collins

From: [redacted]
Sent: Saturday, 29 June 2019 9:56 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Medical Board of Australia, if you believe that nutrional deficiency, the environment and poor lifestyle choices have no impact upon the health of Australians then you should have no authority in our health care system.
No new regulations are required for doctors practising in the area of integrative and complementary medicine. I should be allowed to choose my health care practitioner without the restraints of the medical board dictating what treatments are acceptable. These doctors are highly trained, more thorough in their diagnostic skills, and extremely effective in treating the causes of disease and illness.
In my experience, your typical 10 minute appointment with a GP achieves nothing other than being handed a script for a pharmaceutical drug that will do nothing other than mask symptoms. I want answers and solutions when I am unwell, not necessarily a drug. If diet, exercise, or a nutrional deficiency are causes of my illness then I want to be given professional advice by a qualified doctor whose knowledge I can trust.
We need more Integrative Medicine, not to be putting restrictions on those practicing or threatening to prevent them from practicing at all. The safety of these practices should be the only concern of the Medical Board, the effectiveness of Complementary and Integrative Medicine should be left to me.
I have relied on Complementary Medicine for the past 25 years. I have rarely taken pharmaceutical drugs (on only one occasion following an accident) and therefore reduce the burden on the PBS and Medicare systems. Those that choose Complementary and Integrative Medicine are more likely to practice preventative measures and take responsibility for their own health rather than be a burden on the system.
The Medical Board of Australia should not be associated with political lobby groups and should act with transparency. The whole process has been flawed from the start. The general public has been kept in the dark and should be made aware that their right to choice is under threat.
Lisa Cook
[redacted]

From: Emma Cooper [redacted]
Sent: Monday, 11 March 2019 11:11 AM
To: medboardconsultation
Subject: A letter of concern

To whom this may concern,

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from my regular GP, I feel that this is an abhorrent limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

Please reconsider your actions.

Kind regards

Emma Cooper

From: manal coorey [redacted]
Sent: Wednesday, 27 February 2019 2:11 PM
To: medboardconsultation

To whom this may concern
I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from my regular GP, I feel that this is an abhorrent limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.
Best regards
Manal Coorey

From: Chris Coote [redacted]
Sent: Friday, 29 March 2019 2:53 PM
To: medboardconsultation
Subject: FW: Complementary & Emerging Medicine Review

Good Afternoon,

I have been attending a registered practitioner for at least the last 15 years.

My physician is not only a registered GP but also offers Complementary and Unconventional and Emerging Medicine.

For me personally this takes the form of non-prescribed supplements for my general health, together with the use of prescribed medicines when necessary, and as I am in my 70s this is a tremendous bonus to a healthy lifestyle.

Through the work of this physician I have maintained excellent health without dependence on pharmaceutical drugs, except in the odd instances.

I wish to express my grave concerns that the regulations would be so altered to affect the work of such physicians and I strongly support the continuation of the current existing guidelines for medical practice.

It concerns me greatly that such practices need to be further regulated against what the community in general want.

Who is promulgating this idea that the use of the ancient medical practice of Acupuncture, the emerging use of Stem cell therapy and limiting the treatment of such debilitating issues as Lyme disease, require any further regulation than what is current?

I regard any further regulation on these medical practices as a gross restriction on my democratic rights and especially against those in our community who can least

Yours faithfully

Christopher Coote

[redacted]

From: Rebekah Copas [redacted]
Sent: Tuesday, 12 March 2019 9:10 PM
To: medboardconsultation
Subject: Re complementary; unconventional; emerging treatments: Overseas study

To this maybe could concern,

I would like to draw your attention to this study completed in 2003 in the UK.
https://www.ncbi.nlm.nih.gov/pubmed/15022657?fbclid=IwAR3wmMfjChRW6x462dKkc3AjoaCzYxLeqlJ2LaAvHRMuHJEmNiYOKEzdT8E

The study corroborates a lot of anecdotal evidence that use of Complementary and Alternative Medicines (CAM) is primarily by persons who are already receiving more regular treatment, and who had felt dissatisfied with the result after a considerable period of time. Most people who approach CAM professionals have long term illnesses which they were already receiving treatment for from a GP and potentially also a specialist. Often these kinds of patients are not seeking to be treated by a GP who is knowledgeable in complementary and unconventional medicine, but prefer to keep their usual GP.

Potentially the outcome of the consultation and any ensuring changes, could reflect ill upon the medical profession if it appears that medical qualifications are less likely to ensure good practice when in combination with Complementary and Alternative Medicine, since so many patients already seek CAM treatment from another professional who specialises in this area, rather than speak to their GP regarding.

Rebekah Copas (incompleted Bachelor of Health Science from Endeavour College)

27 June, 2019

Zoe E. Cotterill-Rogers
[redacted]

The Executive Officer,
Medical,
AHPRA,
GPO Box 9958,
Melbourne
VICTORIA 3001 By email: medboardconsultation@ahpra.gov.au

Dear Executive Officer,

Consultation on complementary and unconventional medicine and emerging treatments - SUBMISSION

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SUBMISSION

Introduction and summary

I am a lawyer who, through the practice of law and personal experience, has become conversant with many of the issues surrounding the practice of medicine, including various complementary and alternate health practises.

I have also had the opportunity of reading the March 2019 submission to this Consultation from the Australian Integrative Medicine Association (AIMA) and endorse the arguments therein, including and additionally the following:

(i) that the proposal to have a section of medical practitioners adhere to an additional set of regulatory guidelines is uncalled for and unnecessary, and would have a contrary effect to the asserted desire of the Board of not wishing to "stifle innovation or research nor limit patients' right to choose their healthcare"

(ii) and in this instance, pursuing these additional regulatory guidelines breaches the application of 1 and 4 of the COAG principles.

(iii) The lack of clear definitions in the proposed guidelines creates uncertainty in responding to the public consultation paper; in the practice of medicine and in the enforcement of good medical practice;

(iv) Further, grouping together complementary medicine, unconventional medicine and emerging therapies is unscientific and is not evidence based

(v) Artificially and inappropriately aligns each area of practice with the same degree of potential harm or risk, as if they share unique commonalities.

(vi) The potential inconsistency of implementing the proposed guidelines with the objectives of the World Health Organisation's Traditional Medicine Strategy 2014-2023, wherein health services and systems including traditional and complementary medicine products, practices and practitioners is prioritised.

(vii) There is no reason given as to why integrative medical practitioners, of the kind these proposed additional guidelines are intended for (*in effect regulations, as they can be used in proceedings against practitioners*), would not abide by the current, thorough and adequate, guidelines required to be complied with by all medical practitioners.

(viii) Research would indicate that conventional mainstream medicine practised in the current paradigm is more inclined to harm patients than the kind of medicine practised in complementary, unconventional medicine and emerging therapies and would logically require less regulation;

(ix) Due to the lack of any necessity for effecting the additional guidelines, the proposal for such regulation suggests the potential for them to be used to set apart integrative medical practitioners from other medical practitioners for the ultimate purpose of:

I. compelling medical practitioners to abandon the integration of complementary medicine, unconventional medicine and emerging therapies into their practice, thereby, benefitting the current lucrative pharmaceutical industry paradigm, and, perhaps,

II. to avoid the profession and regulatory body of the profession (*in adoption of best medical practice*) having to become conversant with an emerging, changing and more holistic evidence-based medical paradigm (*some of which research, is examined below in this submission*), in addition to less costly and more traditional forms of medicine, that is, medicine that is not pharmaceutical and/or symptom based.

Accordingly, the option supported in this submission, is to retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's currently approved code of conduct.

Concerns regarding the Public Consultation paper

https://www.medicalboard.gov.au/News/Current-Consultations.aspx

Who were the stakeholders raising concern, do they have conflicts of interest or were they a significant proportion of patients who have received complementary care?

Has this Public Consultation Paper been properly brought to the attention of the public, whose input would provide pertinent information and valuable discourse, and in a manner that identifies the potential impact it may have on all Australian's future choice of medical care?

Proposed regulatory guidelines and how would the board use these guidelines?

I will for the most part, in this submission, refer to the proposed guidelines encompassed in the Public Consultation Paper as the 'proposed guidelines', refer to complementary medicine, unconventional medicine and emerging therapies as 'complementary medicine' and refer to those practitioners that the proposed guidelines are targeting as 'integrative practitioners'

Section 41 of the National Law states that an approved registration standard or a code or guideline approved by the Board is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the profession.

These guidelines can be used to assist the Board in its role of protecting the public, by setting and maintaining standards of medical practice. If a medical practitioner's professional conduct varies significantly from this guideline, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a medical practitioner's registration.

It is asserted in the Public Consultation Paper that innovation and research in new treatments is necessary to improve health outcomes, but there must be protections in place for patients and efforts to make advancements in treatments should not jeopardise patient safety. I am in agreement with both, however, consider that the current code of conduct applicable to all medical practitioners is sufficient protection.

The Medical Board also asserts that it does not wish to stifle innovation or research nor limit patients' right to choose their healthcare. Rather, it considers there is a need for additional safeguards to protect patients who seek complementary and unconventional medicine or emerging treatments (complementary medicine). I concur with the former, though, disagree with the latter.

It appears to me that additional regulation will actually tie the hands of physicians and reduce opportunity for integration of other modalities in patient medical care. Forcing practitioners of alternative or complimentary medicine out of medical practice, thereby, reducing choice and the benefits to patients that come from integrated medicine.

In my experience those choosing complementary medicine are much more informed of their options. Choosing a medical practitioner, who is also conversant with conventional medical practice, brings the benefit of an integration of both modalities, which is then overseen by a practitioner trained in evidence-based medical care. An additional advantage is that the patient is more likely to be participating in their own health care, which has been identified in the research to be the best way to prevent harm [5] rather, that is, than placing the fix in the hands of physicians and more regulation.

To discourage integrative practice, by implementing these oppressive additional guidelines, suggests that people have no ability or intelligence to be discerning and to participate in attaining their best health. When, in my experience, those choosing an integrative medical practitioner are much more informed than those who just go along with the majority, placing all their trust in a single conventional medical practitioner. When considering the research outlined below in this submission, the latter are likely the ones who require more protection, at least, in the form of information.

In supporting the retention of the current code of conduct and not supporting the additional proposed guidelines, I have examined two pertinent issues:

1. Is there a need for additional regulation for a subset of practitioners?

Are the asserted concerns any different to those raised in 'conventional medical practice'. Do they carry additional dangers to warrant additional regulation for a subset of integrative medical practitioners?

For the answer we must first look to the current guidelines and, secondly, to health outcomes, which I will address in more detail in the second part of this submission.

At the same time, we want to avoid keeping medicine in a straight-jacket and making it harder for people to access a variety of therapies and treatments, if they would so choose. Nor do we want to leave open a medical practitioner unnecessarily to prosecution, because of unclear and potentially onerous professional guidelines, which we are informed in the Public Consultation Paper is possible.

The inappropriate phrasing of the proposed guidelines will prejudice integrative practitioners and restrict the medical profession from developing from within, as any new idea by definition will be suspect. A means to eventually down regulate and erode access to complementary and developing protocols of medicine and oppress individual freedoms, such as self-determination of our own health and well-being.

Choosing to impose additional regulations upon integrative practitioners is concerning when conventional medical practice is impacted by significantly greater abuses than those complementary medicine is asserted to be in the consultation paper, such as: significant risks from adverse events *(bearing in mind consistent research identifies iatrogenic conventional medicine as possibly the 3rd leading cause of death)*; inappropriate practice and conflicts of interest (*at much greater financial cost to the public than complementary and alternative forms of medicine*).

By disregarding those risk, the consultation paper is demonstrating a bias against complementary medicine.

I have found the medical profession to take their responsibilities most seriously and, in this respect, a component of promoting patient safety is doctor well-being.

So why treat a subset of medical practitioners differently, particularly, when they have obtained the same qualifications and consequently familiarised themselves with the same ethical principles as those who don't incorporate complementary or like medical protocols in their practice?

Is science so settled it permits medical practice to remain stagnant and stifled in order to protect the dominant medical paradigm reliant upon extremely profitable pharmaceutical drugs and tools?

Sufficiency of current regulation of medical practitioners

https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx
https://ama.com.au/sites/default/files/documents/AMC_Code_of_Conduct_July_2009.pdf

Regulation of medical practitioners incorporated in the currently existing guidelines "**Good medical practice: A code of conduct for doctors in Australia**", is more than sufficient to deal with all the concerns raised in the Public Consultation Paper.

The concerns raised in the consultation paper in regard to medical practitioner's providing complementary medicine surely apply equally to those who don't choose to incorporate complementary therapies, so why treat them differently if the current guidelines are sufficient for the latter group.

The proposed guidelines lack clarity (*use of words such as: "conventional", "complementary" "alternative" "emerging", "therapeutic need" "more appropriate treatment")* and create uncertainty for the practitioner in their application and enforcement. Making it arbitrary as to the standard applied: on what basis and by whom is such standard to be determined and will this include respecting the patient's views in any decision making.

For example, at what point would incorporating some form of nutritional supplementation, such as Vitamin D, constitute practising in the field of complementary medicine. It would suggest a political agenda, if prescribing a pharmaceutical is considered conventional, but a mineral or vitamin (found in food, a necessity for survival and to signal our DNA) must be more strictly regulated.

The proposal for additional regulation of integrative medical practitioners is also in direct conflict with the current guidelines requiring: *"Doctors in Australia reflect the cultural diversity of our society, and this diversity strengthens our profession and that there are many ways to practise medicine in Australia".*

The proposed guidelines provide no additional protection for patients, as the current guidelines come into play anyway when taking a history of the patient and identifying their use of any complementary and unconventional medicine and emerging treatments.

Further, only a qualified practitioner with specific expertise and training in the area of use of complementary, unconventional and emerging therapies should be providing in-depth discussion and advice to patients, something the Medical Board of Australia alone is not qualified to do.

Part 2 of the proposed guidelines are covered by Part 1.4 and Part 2 of the current guidelines.

Part 3 of the proposed guidelines refers to conflicts of interest, which the research literature below in this submission demonstrates is inherent in mainstream conventional medical practice itself, beginning with the licensure of pharmaceuticals (*drug companies undertake their own studies to present to the TGA for licensure*) and facilitated by the revolving door between industry and regulatory bodies. The impact is reflected in drug failures like Vioxx, Avandia and Anaemia drugs.

Pharmaceutical drugs are not free, often involving long term dependency, they may appear to be cheap but are paid for indirectly by all of us through taxation.

The above comments are equally applicable when it comes to informed consent, whether it be conventional or other forms of medical practice, and patients are adequately covered by part 1.4, part 2 and part 3 of the current coded guidelines.

The term "conventional medicine" is not defined, and suggests it is based on usage alone. There is the argument, for example, that as more research on the importance of nutrition and exercise is acquired, medical practitioners are incorporating same into their practice of medicine, thereby, making it conventional medical practice. Further, a majority view is not authority alone, nor should it be when looking to past medical practice (*leaches come to mind)* and the emerging science, some of which is outlined below. Usage implies imposition by the dominant paradigm.

Convincing evidence-based science, which is in constant flux, requires an adaptable environment to flourish. Freedom of choice, permitting individual discernment, further ensures this.

Without evidence of harm, bearing in mind some alternative modalities in the practice of health are centuries old and from various cultures, why be concerned if patients are in the hands of a qualified medical practitioner adhering to current good practice guidelines.

Further, anecdotal evidence, or even an insufficiency of a scientific base of evidence (*as lack of evidence of benefit is not evidence of a lack of benefit*), should not necessarily be discounted. Asserted evidence-based medicine, as it is observed in today's setting, has been shown in the research literature to have limitations and cause significant harm.

Part 4 Though to some extent what is expected under part 4 can be said to be standard medical practice, it is already covered in part 1.4, part 2 and part 3 of the current guidelines. However, the degree to which a subset of practitioners will be expected to conform is far more than what is expected of other medical practitioners.

Part 5 Diagnostic methods and tests is superfluous, repetitive and covered by part 2 of the current guidelines

Part 6 already covered by parts 2 and 3 in the current guidelines.

Part 7 again is good medical practice and covered in parts 2 and 3 of the current guidelines.

Part 8 is superfluous as covered by the "guidelines for advertising regulated health services" and section 133 of the National Law.

Part 9 is superfluous as it is covered by the "Australian Code for the Responsible Conduct of Research" and "the National Statement on Ethical Conduct in Human Research", which practitioners are required to comply.

In regard to part 9.2 (*Where tests and treatments are experimental, being prepared to contribute to and share new knowledge with the profession*) why hold only a subset of medical practitioners to this standard.

Neither additional safe-guards or further regulation of the profession is called for as the current guidelines, "***Good medical practice: A code of conduct for doctors in Australia*"**, adequately and effectively address all the issues raised by the proposed guidelines, deeming them unnecessary. There is no demonstrable evidence presented that current regulation and guidance to medical practitioners is inadequate. Concerns raised are readily addressed by the current guidelines and law, further evidenced by those proceedings instituted that are referenced in the public consultation paper.

Instead, such unnecessary additional proposed guidelines are likely to impact detrimentally on both physicians practising integrative medicine and, consequently, their patients.

2 The premise of evidence-based medicine

Why, without good reason, set apart for regulation a subset of integrative medical practitioners, whose approach is generally less invasive and whose track record is insignificant compared to the practise of conventional asserted evidence-based medicine, and consequently, has much less chance of causing harm?

Recognised by the World Health Authority (WHO), *"better health is unquestionably the primary goal of a health system. Better health is of course the raison d'être of a health system, and unquestionably its primary or defining goal: if health systems did nothing to protect or improve health there would be no reason for them, we need to step back and consider what it is that the system as a whole is trying to do, and how well it is succeeding*". https://www.who.int/whr/2000/en/whr00_ch2_en.pdf?ua=1

If the criterion for imposing additional regulation is because of an insufficiency of evidence supporting the various modalities of complementary medicine, the research suggests that such an approach doesn't guarantee veracity or effectiveness.

The typical reductionist mechanistic view of life that mainstream practised medicine offers doesn't suit everyone, particularly those who seek to participate in their own health and well-being, which participation, research suggests, improves health outcomes. 5

Further, as Professor Jeremy Dunning-Davies observes, "*In whatever field someone works that person will be conditioned in all their thoughts by knowledge accumulated over the years and will remain influenced by the actions attitudes and beliefs of all who surround them. It follows that so called "conventional wisdom" will undoubtedly play a part in most thinking. This is probably inevitable, but it is easy to see that it can, and probably will, have a somewhat stifling effect on any researcher and could, in an extreme case, even prevent the discovery of the correct solution to a problem. In many instances, the problem is exacerbated by the trend for people to overspecialise. This often means that workers in one field are both unaware of developments in other fields and/or totally ignorant of that field*…." *(An alternative view of Redshift by Jeremy Dunning-Davies, PhD @2017, having held positions as Senior Lecturer in Mathematics at Hull University and Senior lecturer in Physics at Hull University, academic author).*

C. S. Lewis 45 had the foresight to perceive science as the ultimate threat to freedom in modern society, and a well-founded concern it seems, reflected in the significant adverse events occurring in the application of asserted conventional "evidence-based medicine" in the context of the pharmaceutical industry paradigm. Presenting good reason why we should not be constraining the wider practise of medicine.

Lewis declared that "*All through the eighteenth century, . . science was not the business of Man because Man had not yet become the business of science.*" (*1954 Inaugural lecture at Cambridge University*). Lewis did not view science as a source of neutral truths about nature, writing, "*the scientists go to work and discover the evidence on which our belief in that sort of universe would now be held to rest*." (*The Discarded Image*) and, viewing modern science as a reflection of its' age, rather than a method for finding truth: "..*every age gets, within certain limits, the science it desires." (Christian Reflections*).

Lewis feared that the reductionist tendency of modern science undermined moral reasoning, human dignity, and religious faith, reason is thus viewed as a product of non-rational nature. This undermines moral reasoning because our moral judgments depend on our reasoning, and if our reasoning is not grounded in the rational, then neither are our moral judgments: ".. *item after item is transferred from the object's side of the account to the subject's (until)… the subject himself is discounted as merely subjective; we can only think that we think. Having eaten up everything else, he eats himself up too. And where we 'go from that' is a dark question." (The Discarded Image)*

Science leads to technology, which Lewis believed would be utilized regardless of its detrimental impact on humans.

Lewis was convinced that scientific authority would be used to justify and facilitate political oppression, observing: "*The physical sciences, good and innocent in themselves, hard already . . . begun to be warped, and been subtly manoeuvred in a certain direction…"* Scientific planning is not necessarily evil, but *'Under modern conditions any effective invitation to Hell will certainly appear in the guise of scientific planning' as Hitler's regime in fact did*." *(That Hideous Strength)*

"*Again, the new oligarchy must more and more base its claim to plan us on its claim of knowledge. . . . I dread government in the name of science. That is how tyrannies come in. In every age the men who want us under their thumb, if they have any sense, will put forward the particular pretension which the hopes and fears of that age render most potent….. It has been magic, it has been Christianity. Now it will certainly be science*." (*God in the Dock)*

Further, to use the words of Bruce Lipton, Stem Cell Biologist, research scientist and author**:**

"*As science advances it begins to resemble ancient wisdom. Long ago in the age of Judean-Christianity, the Church was the provider of civilization's truth… at this time the Church's control of civilization was predicated on the belief in it's claim that the Church represented infallible knowledge, that is "absolute truth… Consequently any individual, and especially a scientist, that offered an opinion or belief that challenged Biblical dogma would be accused of being a heretic and face some severe penalties, including torture, drowning or being burned at the stake……Science could understand the mechanisms of the universe without invoking God or invisible forces (ie spirit)…."* and

"However, as physical science got older, it's "father" metaphysics has been recognized (in hindsight) to be quite smart…It was with the emergence of Quantum Physics in 1925 that science revised it's view of the nature of the Universe. Rather than being comprised of a duality, a physical realm and a material realm, quantum physics revealed the Universe to be a singularity, the Universe is made out of one thing… energy...Today, quantum physics is recognized as the most valid and truthful of all the sciences. A primary assertion of this physics is "consciousness creates out reality". (Newsletter May, 19).

Thus, identifying the paramount requirement for both diversity and choice in medical practice.

How then does evidence-based care operate today?

Is it reflective of the current politically dominant health system or truly scientific and independent of same?

Has that system proved itself to have better long-term health outcomes than others? What is the extent of the evidence for any favourable conclusion in this respect, and if that evidence is of sufficient quantity and quality, is it uncontested or cherry picked? The argument that "*it is the best we have*" is neither convincing nor scientific.

As outlined below in the sample of research provided and in the additional material contained in the Annexure with the reference sources: Evidence-based medicine, in the context of the current conventional medical paradigm, makes assumptions and has limitations. A large industry has developed and the motivator is significant profit. Consequently, mistakes are made, providing no guarantee that a drug, procedure, process or policy is either effective or free from harm.

Australian medical practitioners practise in the same medical paradigm, use the same pharmaceuticals and medical devices as does the US. Based on the US experience, we can expect to have similar outcomes as those described below, if we continue to follow a similar path in conventional medical practice, while constraining integrative medical practice and impeding diversity.

That is not to say that complementary and alternative forms of medical practice are not evidence based. 44 Also, when applying the same evidence-based model to complementary and alternate forms of health modalities, they are not reported as causing anywhere near the extent of harm as conventionally practised medicine.

Behaviour of the scientific and pharmaceutical industry in the current paradigm, as one might expect, leads to a lack of trust and reliance on conventional medical practice and pharmaceuticals as the sole provider of health and well-being. Consequently, medicine needs to be embracing of as many modalities as people themselves seek.

The medical paradigm is also shifting. As we learn more and more about the physical body, we see the connections between the gut, brain and immune system. Not to mention, the role our mind and belief systems play in creating and maintaining our health, the most obvious example being the placebo effect, which should not be discounted as it so often is, but studied, because it is effective.

What were once considered pathogens and scourges of our bodies, are now referred to as the beneficial "microbiome", "virome" or, overall, the 'holobiont'.

The research is indicating a whole-body or holistic connection to health, requiring us to nutritionally and emotionally feed the body and mind, rather than to treat the body as indivisible parts. The singular approach practised in conventional medicine of treating symptoms alone, using manufactured chemicals or relying upon surgery to remove what appears to be the offending body part, is becoming obsolete.

This is further conveyed by the failures of conventional evidence-based medicine as it is currently practised, where, as I set out in more detail below, it has become an industry that has the means and ability to protect itself. For there is not much money to be found in health, only in sickness.

We do not want the practice of medicine to fall behind, by stifling those practitioners open to integrating other modalities into their practice, particularly if they are more fitting to health and wellbeing

The sample research:

Hospitals 3rd leading cause of death in the US and underreporting of adverse events

Research in the US identifies hospitals and iatrogenic care as the 3rd leading cause of death.1, 3, 5 -10

With the release of the Institute of Medicine (IOM) report in November,1999, "***To Err Is Human***," millions of Americans learned, for the first time, that an estimated 44,000 to 98,000 among them die each year as a result of medical errors. 1, 2

Studies indicate that by the year 2000 as many as 20% to 30% of patients received contraindicated care and a total estimate of 225,000 deaths per year from iatrogenic causes, including 106,000 deaths from FDA-approved correctly prescribed medicines. Most of the data being derived from studies in hospitalised patients, the estimates do not include adverse effects that are associated with disability or discomfort. Though, one analysis estimated out-patient care and adverse effects, other than death, to be between 4% and 18% of consecutive patients, If the higher estimates are used, the deaths due to iatrogenic causes would range from 230,000 to 284,000. In any case, 225,000 deaths per year constitutes the third leading cause of death in the United States, after deaths from heart disease and cancer. 1 The findings aren't disputed and subsequent studies found the number of preventable deaths due to medical intervention to be higher. The US relative position for life expectancy in the oldest age group was also better in the 1980's than in the 1990s. 1

Further research published in 2013 in the Journal of Patient Safety, using a weighted average of 4 studies published from 2008 to 2011 associated a lower limit of 210,000 deaths per year with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the researchers reported the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.5

In this study, albeit assessing for the most part adverse events occurring in hospital, **the need was identified for patients to be thoroughly integrated into their care to reduce risk of serious harm and death**, rather than placing the problem and fix in the hands of physicians or additional regulation – "*Perhaps it is time for a national patient bill of rights for hospitalized patients that would empower them to be thoroughly integrated into their care, so that they can take the lead in reducing their risk of serious harm and death…*"5

A study published 3 May 2016 in the BMJ again proposes that medical errors are the third leading cause of death in the US 8 Analysing medical death rate data over an eight-year period, Johns Hopkins patient safety experts calculated that more than 250,000 deaths per year are due to medical error, surpassing the U.S. Centers for Disease Control and Prevention third leading cause of death, respiratory disease, which kills close to 150,000 people per year. According to the CDC in 2013, 611,105 people died of heart disease, 584,881 died of cancer and 149,205 died of chronic respiratory disease, the top three causes of death in the U.S. 9, 10

The poor performance of the United States was recently confirmed by the World Health Organization.1 World Health Organisation's top decision makers at the 72nd World Health Assembly in May 2019 recognized patient safety and reducing patient harm in healthcare settings as a key priority, pointing out that **adverse events are one of the leading causes of death and disability globally**, an estimated 134 million occur annually due to unsafe care in hospitals in low and middle income countries, contributing to 2.6 million deaths, **while 1 in 10 patients is estimated to be harmed while receiving hospital care in high income countries**.11

Money spent on health care doesn't necessary result in better outcomes of health: In 2016 the United States spent nearly twice as much as 10 high-income countries (including Australia) on medical care and performed less well on many population health outcomes. 21

Specialisation also doesn't necessarily confer more benefit: preliminary analyses even suggest that the higher the specialty physician–to–population ratios and of specialist–to–primary care physician ratios in US states, the worse health outcomes are. 1

Underreporting

Findings of a study published in the Journal of Healthcare Quality in 2016 reveal poor data monitoring and reporting, indicating there is potentially an underreporting of adverse events and**,** thereby**,** exacerbating both the collection of data and timely responses to any harm occurring, in addition to: hurting efforts to study disease, guide patient choice of optimal treatments, formulate rational health policies and track in a meaningful way how well physicians and hospitals perform. 19, 20 (and see 5)

According to Martin Makary, professor of surgery at the John Hopkins University School of Medicine, and an authority on health reform, the incidence rates for deaths directly attributable to medical care isn't recognized in any standardized method for collecting national statistics, the medical coding system was designed to maximize billing for physician services, not to collect national health statistics. 10

Professor Martin Makary considers that reporting of adverse events is hampered, amongst other things, by information sources on patient safety being hidden in an impenetrable maze of websites and hospitals failing to report fully on the outcomes of the care they provide. 18 Failure to measure and accurately track patient outcomes remains one of the greatest problems in modern health care, a sector that claims one-fifth of the nation's economy, curtailing our ability to understand disease and evaluate treatments. Most clinical registries collecting data on clinical outcomes are underdeveloped, underfunded and often not based on sound scientific methodology 20

In 2018 the Pharmaceutical Society of Australia (PSA) released a report: *Medicine Safety: Take Care,* which highlights the extent of the unsafe use of medicines in Australia. The report details the extent of harms in Australia as a result of medicine use, revealing that 250,000 Australians are hospitalised each year, with another 400,000 presenting to emergency departments, as a result of medication errors, inappropriate use, misadventure and interactions. **1**6a

Australia also has a passive reporting and surveillance system for adverse events. It is further impacted by difficulties using the system, limitations of the system and physician bias. The TGA has both a regulatory and licensing authority function, as well as having a reporting and surveillance role for adverse reactions or events to medicines, which obscures transparency. 20b

Pharmaceuticals adverse events, conflicts of interest and undue influence of industry

When we then look to pharmaceuticals used in conventional medical practice, the situation is even more dire. Since 2000 the death toll from hazardous prescription drugs alone has been far greater than the 106,000.00 reported above 3 Every year in the United States nonsteroidal anti-inflammatory drugs (NSAIDs) alone kill 16,500 people through gastrointestinal complications alone 16b

According to research, in 2012 adverse drug events stood at more than 25 million with over 100,000 deaths annually, with product recalls occurring about 15 times per week in medical devices (the number of patients reported injured in serious adverse events in the US increased by 17% per year from 2001-2009, topping 28,000 in 2009) and 20 times per week in pharmaceuticals in the U.S. alone (growing by 26% per year from 2005-2001, to more than 1,000 per year. The US FDA issued 18 Good Manufacturing Practice (GMP) warning letters to pharmaceutical manufacturers in 2005, and 53 in 2011, a nearly 200% increase. Many recalls still fail to remove all affected products from inventories or locate every exposed patient. In developed markets like U.S. and U.K., medication errors occur during 10-20% of all inpatient admissions. **Reported incidence rates of preventable ADEs vary from 2-7% of hospital admissions in developed countries** to as high as 18% in developing nations. These have led to thousands of patient deaths and millions of short- and long-term disabilities every year. 12

In a Cross-sectional survey study published in JAMA in 2018 use of prescription medications that have depression as a potential adverse effect was common and the use of multiple medications associated with greater likelihood of concurrent depression.13

Explored below, conflicts of interest abound in the medical and science industries. When the company is footing the bill, the opportunities for bias are manifold: they can select like-minded academics to perform the work; run the statistics in ways that make their own drugs look better than they are and where troubling signs about a drug arise, they can steer clear of further exploration.

As the drug industry's influence over research grows so does the potential for bias and considerable harm, as clearly demonstrated with blockbuster pharmaceutical drugs such as Avandia, Vioxx, Celebrex and Anaemia drugs.14,15

Because of bias in the design of clinical trials and conclusions drawn, much of the industry funded research may be untrue and even fraudulent. 24 Particularly, as can be seen, when operating in the current conventional paradigm, reliant for the most part on surrogate endpoints to determine efficacy (*rather than real-world effectiveness*) and significantly affected by profit incentives, conflicts of interest, undue influence, lobbying of policy makers and, consequently, potentially ineffectual regulatory bodies.

Pharmaceutical companies aim is not just public health but part of a high-risk quest for profits and corporate interference has repeatedly muddled drug science sometimes with lethal consequences. 14

While funding a larger share of research, the Industry has shifted the job of conducting trials away from non-profit academic hospitals, universities and other academic centres to for-profit contract research organizations, who then compete to run the trials. Corporate sponsors are then able to dictate the terms. In effect, treating academic researchers like hired hands. 14

Abundant consistent evidence can be found demonstrating that the industry has created means to intervene and be intimately involved in all steps of the processes that determine healthcare research, strategy, expenditure, practice and education. To serve its interests, the industry masterfully influences evidence base production, evidence synthesis, understanding of harms issues, cost-effectiveness evaluations, clinical practice guidelines and healthcare professional. As a result of these interferences, the benefits of drugs and other products are often exaggerated and their potential harms downplayed. In addition clinical guidelines, medical practice, and healthcare expenditure decisions are biased. 22

There is seen to be a revolving door between regulatory bodies and those employed in the pharmaceutical industry. As examples: Dr Julie Gerberding (*named woman of the year in 2018*) was Director for the Centers of Disease Control and Population (CDC) from 2002 to 2009 when Joining Merck & C Inc and becoming executive vice president for strategic communications, global public policy and population health. Also holding stock in that company. Terry Nolan, chairman of the Australian Technical Advisory Group on Immunisation (ATAGI) 2005 to December 2014 declared having been a member of a CSL vaccine advisory board; receiving nominal payments as well as support for conference attendance from CSL Ltd, Novartis and GlaxoSmithKline. He was also the chief investigator of the clinical trial for CSL's Panvax influenza vaccine in 2009 while on the government's primary advisory boards for vaccination policy-decisions and deputy chairman of the National Health and Medical Research Council (NHMRC) that determines funding allocation for research projects. (No an McVe non Ske jo M R chmond P Wad a U ambe S e a mmunogen c y o a Monova en 2009 n uenza Vacc ne n n an s and Ch d en A Random sed a ama 2010 jan 6 303 (1) 37 46 Supp emen a y on ne con en)

Financial connections abound between drug makers and the research undertaken for licensure. It has become a common practice that medical journals feature research sponsored in large part by drug companies, co-written by drug companies or authored by academics with financial ties to drug companies, reflecting the growing role of industry money in research. For the diabetic drug Avandia, which was claimed to be associated with 83,000 heart attacks and deaths, the trial had been funded by GlaxoSmithKline, and each of the 11 authors had received money from the company. Four were employees and held company stock. The other seven were academic experts who had received grants or consultant fees from the firm. The New England Journal of Medicine NEJM promoting it's performance. The industry spending $39 billion in one year on research in the US. 14

All-in-all enabling drug companies to shape their research and design trials to obscure and hide dangerous side effect, which may not become apparent for years, and as exampled by Avandia and the Anaemia drugs. 14, 15

Other industry-funded papers published in NEJM have led to conclusions that were later contradicted, such as the anaemia drug Epogen and heart drug Natrecor, which were challenged later by studies performed by other researchers. 14

In this regard, editors of the world's most respected medical journals, **Dr. Richard Horton, Editor-in-chief of the Lancet** and **Dr. Marcia Angell,** physician and **long-time Editor-in-Chief of the New England Medical Journal,** have made public statements declaring a significant amount of published research is unreliable at best, if not false, even fraudulent. Being afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance. 24

Major pharmaceutical companies falsify or manipulate tests on the health, safety and effectiveness of their various drugs by taking samples too small to be statistically meaningful or hiring test labs or scientists where the lab or scientist has blatant conflicts of interest, such as pleasing the drug company to get further grants. While pharmaceutical dangers are withheld from the public. According to Dr Horton, corruption of the medical industry worldwide is a huge issue, perhaps more dangerous than the threat of all wars combined 24 Professor Joseph Ross of Yale Medical School, is reported to hold the view that the entire evidence base has been perverted. 14

Exposed in a **Washington Post** article 15: -

For a trio of pharmaceutically very successful **anaemia drugs** known as Epogen, Procrit and Aranesp, ranked among the best-selling prescription drugs in the United States, generating more than $8 billion a year for two companies, Amgen and Johnson & Johnson, potentially lethal side effects, such as cancer and strokes, were overlooked. Neither of these issues would have become public if not for the filing of a Freedom of Information Act.

4 out of the 8 authors of the New England Journal of Medicine journal article published in 1998 in support were employees of Amgen. Taxpayers put up as much as $3 billion a year for the drugs (*so pharmaceutical drugs are not free or cheap, we pay indirectly through taxation*).

Drug makers worked diligently to make sure that doctors had an incentive to give large doses, raising maximum dose levels as a consequence of lobbying, and made billions. The most commonly used dosing guidelines that doctors in the field used were issued by a group organised by the National Kidney Foundation, which Amgen was the founding and principal sponsor of. Moreover, in 2006, of the 16 members of the foundation's panel that created the new dosing guidelines, 10 reported receiving consulting fees, speaking fees or research funds from Amgen or Johnson & Johnson's subsidiary, Ortho Biotech, recommending doses at the high end of the FDA target recommendation.

Dialysis clinics were receiving as much as 25 percent of their revenue from using the drugs. According to a financial filing, Charles J McAllister, chief medical officer of DaVita, the dialysis company, was to receive a $200,000 bonus if the more stringent rules for the drugs' use being considered by regulators were dropped or delayed. He was to receive an additional $100,000 if the ten-new legislation, known as the Medicare Modernization Act, didn't cut into the company's revenue. The companies would even enlist the patients to lobby on their behalf.

The multibillion-dollar rise and fall of the anaemia drugs illustrates how the economic incentives embedded in the U.S. health-care system can make it not only inefficient but also potentially deadly. Through well-funded research and lobbying campaigns drugs can gain approval from a regulatory body.

It was a small Bethesda-based non-profit think tank, the Medical Technology and Practice Patters Institute, that challenged the conventional enthusiasm for the drug and the government policies that it said promoted anaemia drugs overuse, until contradictory research emerged in November 2006 when a study published in the NEJM reported that kidney patients targeted for higher doses were linked to higher risks of hospitalization, strokes and death and Danish researchers stopped a trial of Aranesp in cancer patients because of an increase in deaths and tumour growths.

Philanthropic power

Not only big business, but also **philanthropic power** has increasing significant influence on agenda-setting and the funding priorities of international organizations, including program priorities of the World Health Organisation's (WHO), governments and global development policy. Particularly large philanthropic foundations, through the sheer size of their grant-making, networking and advocacy capabilities (*most notably the Rockefeller Foundation and the Bill & Melinda Gates Foundation*). Australia's vaccination policies have been designed from the recommendations provided by the World Health Organisation (WHO) under Global Health Policies. 23

The WHO receives these recommendations from an advisory group called the Global Alliance for Vaccines and Immunisation (GAVI). This alliance includes the Federation of Pharmaceutical Companies, the International Monetary Fund, the World Bank, the Bill and Melinda Gates Foundation, the Rockefeller Foundation and many more private and public organisations, all with equal input into global health policies. 23

Bearing in mind my understanding that it is the manufacturer who compiles and presents the evidence relied upon for licensure of a pharmaceutical to the regulatory body, which in Australia is the Therapeutic Goods Administration (TGA). It is particularly concerning knowing the lengths industry has demonstrated it is willing to go to in making a profit. Another good reason to keep medical practitioners' methods of practise as free of constraint as possible, the last bastion in a patient's protection.

In conclusion, reliance upon the premise of evidence based medicine as a gauge of safety, effectiveness and wellbeing in the current medical and scientific paradigm, a system geared towards pharmaceuticals and surrogate end-points, encouraged by significant profit and abundant with conflicts of interest, is no guarantee of health and well-being.

Efficacy evaluated in a drug trial does not necessarily equate to effectiveness and overall good health and longevity in the real world (where recipient patients are themselves the guinea pigs). It is also my understanding that little, and only short term, follow up occurs for the most part after licensure)

The emerging science

Conventional medicine's current focus is pharmaceutical drugs as well as products, tests and equipment; a chemical and patent focused paradigm, treating symptoms, rather than the root cause of an illness or procuring overall health and well-being. A drug focused paradigm ignores a multitude of growing evidence directed towards the body's own ability to heal and achieved nutritionally or by other more natural and safer means.

Consequently, it is understandable why complementary and alternative forms of medicine are so appealing and why it is important not to constrain practitioners who integrate same into their medical practice. Retaining patient choices, in the safest of environments with doctors who are medically trained to evaluate them, can only raise the bar of health. Some traditional modalities of complementary medicine have been practised for hundreds of years and are not necessarily deficient in supporting evidence if you look in the right places.

While scientific journals, regulatory bodies and policies do not guarantee our protection, reliance upon surrogate endpoints 38, rather than real world effectiveness, in the practice of asserted 'evidence-based medicine' does not necessarily promote overall health and well-being either. 39 - 43.

Research published in 2011 revealed that in some cases no antibodies are required for immunity against some viruses. 39 High levels have even been found in the presence of active, even lethal infections. For example, high serum levels of antibodies against tetanus have failed to confer protection against the disease. 40, 41

The holobiont:

Janine Roberts, author has this to say about viruses:-

There are some basic facts about viruses all biologists agree on. Viruses have no metabolism so they cannot produce energy or eat. They have no nervous system, no sensory system, no intelligence that can facilitate any kind of invasion or hi-jacking of a cell a billion times larger.

Barbara McClintock, who won a Nobel Prize for finding that cells respond to the environment (contradicting the random theory of Darwin), operate with intelligence and seek to repair themselves. We have progressed from the constant Genome, subject only to random, localized changes at a more or less constant mutation rate, to the fluid Genome, subject to episodic, massive and non-random reorganizations capable of producing new functional architectures. This is a far cry from the reductionist, mechanical view of life reflected in the typical practise of conventional medicine.

We now know that our cells create multitudes of tiny transport particles (vesicles) to carry the proteins and genetic codes needed within and between cells. The ones that travel between cells communicating with each other, are puzzlingly just like those that we have long blamed for illnesses.

It seems we may have misconceived the virus; that most of them could well be simply inert messages in envelopes carried from cell to cell. In the last ten years scientists have begun to call them 'exosomes', 'particles that leave the body' of the cell, removing the inference that the word 'virus' carries, that is, of them being dangerous by nature. It has been discovered that our cells make them all in the same way, in the very same place. It also seems we cannot stop this process without risking severely damaging our cells. We need to know how we can strengthen the malnourished cell, rather than use the many medicines that try to prevent it from making particles by interfering with its essential processes. We need to know if a poisoned cell may produce unhealthy messengers or viruses. (*James A. Shapiro*) (*Janine Roberts, Journalist , Author Fear of the Invisible).*

Scientists have long known that the guaranteed way to make cells produce viruses in the laboratory, including flu and measles virus, is not by getting them infected, but by exposing them to stress and toxins. In 1928 the President of the Royal Society of Medicine's Pathology Section, A. E. Boycott, in a report on the '**nature of filterable viruses**,' stated that with toxins '*we can with a considerable degree of certainty stimulate normal tissues to produce viruses*.' 36

The Virgin laboratory formulated and proved the hypotheses that virus-plus-host-gene interactions define disease phenotypes. Mammals are best viewed as composite organisms in which the virome, and trans-kingdom interactions regulating and regulated by the virome, contribute to immunity, disease, and the genotype-phenotype relationship. 42

See in the reference source material attached to this submission for specific examples of research demonstrating how microbes help us, including**:** Lactobacillus casei has been found to decrease the mucosal damage done by aspirin; Saccharomyces boulardii prevents oral-poliovirus vaccine-induced IgA nephropathy in mice. 37

The relatively recent discovery of the microbiome, namely, the 100 trillion viruses, bacteria, fungi, parasites, which outnumber our own cells 10-1, proving we are more "germ" than "human," and in many respects, would not be alive without them: e.g. (up to) 90% of our immune system depends on bacteria in our gut. How, then, can these microorganisms be as deadly as we are told, while at the same time be responsible for making possible our life itself? If you take away the trillions of viruses, bacteria and fungi that co-exist with our human cells (the so-called **holobiont**), only 1% of the genetic material that keeps us ticking remains. The microbiome contributes towards sustaining functions like digestion, immunity, and brain function. Germs become less other and more self. The microbiome is a selective array of commensal microorganisms that ultimately originated from the environment: in the air we breathe, the soil we interact with, and the water and food, of course, we ingest. 42b

In light of revealing research of the holobiont, rather than an instrument of war against foreign entities, the immune system represents the master orchestrator of self-regulatory mechanisms, designed to participate in growth, maintenance, repair, signalling, and optimization of physiology. 42

Sample of the research demonstrating Viruses beneficial impact upon health:

Bearing in mind that the National Cancer Institute reported that about 1,735,350 new cases of cancer were diagnosed in the United States last year, 43 epidemiological studies have found an inverse association between acute infections and cancer development and science is now harnessing genes and viruses (potent cancer fighters) to infect and kill tumour cells. 28

Exposures to febrile infectious childhood diseases were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined. Epidemiological studies on common acute infections in adults and subsequent cancer development found these infections to be associated with reduced risks for meningioma, glioma, melanoma and multiple cancers combined. Consequently, Infections may play a paradoxical role in cancer development. 30

As the mounting research indicates, acute infections can be a means of cancer prevention: measles can prevent cancer 25,26,27 and mumps can prevent ovarian cancer in women 31 These childhood infections could be considered essential to our health.

Measles and mumps, especially in case of both infections, have also been associated with lower risks of mortality from atherosclerotic CVD." 29 The risk of Parkinson's disease is also lower from having had measles. 32

Bear in mind that there are over 200 viruses that cause influenza and influenza-like illness which produce the same symptoms (fever, headache, aches and pains, cough and runny noses, without laboratory tests doctors cannot tell the two illnesses apart.
https://www.cochrane.org/CD004876/ARI_vaccines-preventing-seasonal-influenza-and-its-complications-people-aged-65-or-older

Research indicates that most of what we believed about the purportedly deadly properties of viruses like influenza is based on nothing more than institutionalized superstition and myth. Discoveries in microbiology indicating how there is an abundance of host proteins in (flu) viruses and that viruses resemble exomes. There isn't even such a thing as "flu virus", in the sense of a monolithic disease vector existing outside of us, conceived as it is as the relationship of predator to prey.

Conserved and host-specific features of influenza virion architecture 33a "*was the first study ever to plumb the molecular depths of what influenza virus is composed of. Viruses use virions to spread between hosts and virion composition is therefore the primary determinant of viral transmissibility and immunogenicity. Virions are also known as "viral particles," and they are the means by which viral nucleic acids are able to move and 'infect' living organisms. Without the viral particle (taxi) to carry around the virus DNA (passenger), it would be harmless; in fact, viruses are often described as existing somewhere between living and inanimate objects for this reason: they do not produce their own energy, nor are transmissible without a living host. The authors are making it clear that virion composition* is also the primary determinant *in how or whether a virus is infectious (transmits) and what effects it will have in the immune system of the infected host."* 35

"*This distinction is important because we often think of viruses as simply pathogenic strings of DNA or RNA. The irony, of course, is that the very things we attribute so much lethality to, viral nucleic acids, are not even alive, and cannot infect an organism without all the other components (proteins, lipids, extra-viral nucleic acids) which are, technically, not viral in origin, participating in the process. And so, if the components that are non-viral are essential for the virus to cause harm, how can we continue to maintain that we are up against a monolithic disease entity "out there" who "infects" us, a passive victim? It's fundamentally non-sensical, given these findings*." 35

"The researchers found that the flu virus is as much comprised of biological material from the host the virus 'infects,' as the viral genetic material of the virus per se*. How then, do we differentiate influenza virus as fully "other"? Given that it would not exist without "self" proteins, or those of other host animals like birds (avian) or insects, this would be impossible to do with any intellectual honesty intact. It was never understood until now that "influenza" is so thoroughly dependent upon a host for its transmissibility and immunogenicity*. 35

What these researchers are talking about is the discovery that virion particles share stunning similarities to naturally occurring virus-like particles produced by all living cells called exosomes. 33

"*When we start to look at viruses through the lens of their overlap with exosomes, which as carriers of RNAs are essential for regulating the expression of the vast majority of the human genome, we start to understand how their function could be considered neutral as "information carriers," if not beneficial. Both exosomes and viruses may actually be responsible for inter-species or cross-kingdom communication and regulation within the biosphere, given the way they are able to facilitate and mediate horizontal information transfer between organisms. Even eating a piece of fruit containing these exosomes can alter the expression of vitally important genes within our body."* 35

"*Viruses could be described as pieces of information in search of chromosomes; not inherently "bad," but essential for mediating the genotype/phenotype relationship within organisms, who must adapt to ever-shifting environmental conditions in real-time in order to survive; something the glacial pace of genetic changes within the primary nucleotide sequences of our DNA can't do (it may take ~ 100,000 years for a protein-coding gene sequence to change* versus seconds *for a protein-coding gene's expression to be altered via modulation via viral or exosomal RNAs)*." 35

"This does not mean they are "all good", either. Sometimes, given many conditions outside their control, their messages could present challenges or misinformation to the cells to which they are exposed, which could result in a "disease symptom." It is said that these disease symptoms are often, if not invariably, attempts by the body to self-regulate and ultimately improve and heal itself." 35

"In other words, the virion composition of viruses appears to be the by-product of the cell's normal exosome (also known as microvesicle) production machinery and trafficking, albeit being influenced by influenza DNA. And like exosomes, viruses may be a means of extracellular communication between cells, instead of simply a pathological disease entity. This could explain why an accumulating body of research on the role of the virome in human health indicates that so-called infectious agents, including viruses like measles, confer significant health benefits". 35

Other researchers have come to similar discoveries about the relationship between exosomes and viruses, sometimes describing viral hijacking of exosome pathways as a "Trojan horse" hypothesis. 34

In conclusion

The practice of evidence-based medicine in the current conventional paradigm is no guarantee of veracity or long-term health and well-being. To constrain people's choices of health modalities in this context would be detrimental to health and well-being.

The above synopsis of the scientific research also demonstrates the changing face of medicine and science. What were once referred to as "germs" cannot with any certainty be for the most part considered causative or even opportunistic, but rather curative, of disease. Everything is mostly energy.

Further, treating the physical body may merely be a component of good health. This submission doesn't delve into what role the mind plays in orchestrating the human holobiont symphony or what the mind is truly capable of in that regard. Considering, however, the abovementioned research and the known impact of the placebo effect and how belief systems can play an important role in recovery, health and wellbeing, patients input in their care becomes an imperative for the attainment of same.

People are themselves becoming aware of the importance of whole-body health; identifying the root cause of illness and placing greater reliance on the body's own mechanisms to heal and produce well-being. Evidenced today, more than ever, by people incorporating into their lifestyles: exercise regimens, healthier diets and nutritional supplementation, in the expectation of enhancing and promoting the bodies' own ability to produce long-term health.

Consequently, such people are more inclined to turn to complementary or alternative therapies, rather than use pharmaceutical chemicals that merely supress symptoms and which can result in a cascade of other (side) effects. Common sense alone dictates which is likely to be the least harmful in the long run.

If you care to look, we are seeing the emergence of a whole new medical paradigm. One which in many ways reflects the belief systems of those that adopt or integrate conventional and complementary medicine.

Consequently, we should be making it easier, not more onerous, for practitioners to integrate those modalities into their practice, thereby, enabling patients to obtain the best from conventional and/or complementary medicine, in what would be the safest environment, under the care of a medically qualified practitioner.

Integrative practitioners of medicine are medically qualified and have an evidence based scientific background, thereby, providing patients with the best of both worlds, so to speak.

The Board's support and guidance in this respect would greatly benefit our health system.

Based on the course of conventional or mainstream practised medicine, and comparing it to less invasive complementary medicine, where there is significantly less risk of harm being caused, how can the board seriously be more concerned about the latter. The current code of conduct applicable to medical practitioners is quite adequate. Thus, there is no imperative to single out and additionally regulate this subset of medical practitioners.

In the circumstances, who can it be that seeks to stifle and constrain the practice and development of medicine rather than promote health and well-being of patients, other than those wishing to protect the status quo?

These additional guidelines may be touted merely as a means to protect patients choosing an integrative medical practitioner, but I see such proposal as a step towards, if not the actual means, to stifle and thwart the integrative practise of medicine, by further squashing medical practitioner's autonomy and so as to benefit it's competition: big business.

Surely, the wellbeing of patients must be the paramount consideration. Perhaps, fixing the apparent problems would have a much more observable benefit than pursuing the poorly conceived ones asserted in the paper.

SEE ANNEXURE FOR REFERENCE SOURCES AND ADDI IONAL RESEARCH MA ERIAL

Yours faithfully,

Zoe E. Cotterill-Rogers

ANNEXURE to SUBMISSIONS TO MEDICAL BOARD OF AUSTRALIA - Reference sources and additional research material

HOSPITALS - 3RD LEADING CAUSE OF DEATH IN THE US

1

JAMA 26.7.2000

COMMENTARY **Is US Health Really the Best in the World?**

Barbara Starfield, MD, M

JAMA, July 26, 2000—Vol 284, No. 4 *JAMA.* 2000;284(4):483-485. doi:10.1001/jama.284.4.483
https://jamanetwork.com/journals/jama/article-abstract/192908
https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-primary-care-policy-center/Publications_PDFs/A154.pdf

Author Affiliation: Department of Health Policy and Management, Johns Hopkins School of Hygiene and Public Health, Baltimore, Md. Corresponding Author and Reprints: Barbara Starfield, MD, MPH, Department of Health Policy and Management, Johns Hopkins School of Hygiene and Public Health, 624 N Broadway, Room 452, Baltimore, MD 21205-1996 (e-mail: bstarfie@jhsph.edu).

> *"Information concerning the deficiencies of US medical care has been accumulating. The fact that more than 40 million people have no health insurance is well known. The high cost of the health care system is considered to be a deficit, but seems to be tolerated under the assumption that better health results from more expensive care, despite evidence from a few studies indicating that as many as 20% to 30% of patients receive contraindicated care.[1] In addition, with the release of the Institute of Medicine (IOM) report "To Err Is Human,"[2] millions of Americans learned, for the first time, that an estimated 44,000 to 98,000 among them die each year as a result of medical errors*.
>
> *For example, US estimates 8-10 of the combined effect of errors and adverse effects that occur because of iatrogenic damage not associated with recognizable error include: • 12000 deaths/year from unnecessary surgery • 7000 deaths/year from medication errors in hospitals • 20000 deaths/year from other errors in hospitals • 80000 deaths/year from nosocomial infections in hospitals • 106000 deaths/year from non-error, adverse effects of medications. These total to 225,000 deaths per year from iatrogenic causes.*
>
> *Three caveats should be noted. First, most of the data are derived from studies in hospitalized patients. Second, these estimates are for deaths only and do not include adverse effects that are associated with disability or discomfort. Third, the estimates of death due to error are lower than those in the IOM report.1 If the higher estimates are used, the deaths due to iatrogenic causes would range from 230000 to 284000. In any case, 225,000 deaths per year constitutes the third leading cause of death in the United States, after deaths from heart disease and cancer*."
>
> *Of 13 countries in a recent comparison, 3 the United States ranks an average of 12th (second from the bottom) for 16 available health indicators. 3*
>
> *The poor performance of the United States was recently confirmed by the World Health Organization, which used different indicators. Using data on disability-adjusted life expectancy, child survival to age 5 years, experiences with the health care system, disparities across social groups in experiences with the health care system, and equality of family out-of-pocket expenditures for health care (regardless of need for services), this report ranked the United States as 15th among 25 industrialized countries.4*
>
> *One analysis overcomes some of these limitations by estimating adverse effects in out patient care and including adverse effects other than death.11 It concluded that between 4% and 18% of consecutive patients experience adverse effects in outpatient settings, with 116 million extra physician visits, 77 million extra prescriptions, 17 million emergency department visits, 8 million hospitalizations, 3million long-term admissions, 199000 additional deaths, and $77 billion in extra costs(equivalent to the aggregate cost of care of patients with diabetes).11*

The long-existing poor ranking of the United States with regard to infant mortality 14 has been a cause for concern; it is not a result of the high percentages of low birth weight and infant mortality among the black population, because the international ranking hardly changes when data for the white population only are used."

While available data indicate that specialty care is associated with better quality of care for specific conditions in the purview of the specialist,15 the data on general medical care suggest otherwise.16

The results of international surveys document the high availability of technology in the United States

YET…..Among 29 countries, the United States is second only to Japan in the availability of magnetic resonance imaging units and computed tomography scanners per million population.17 Japan, however, ranks highest on health, whereas the United States ranks among the lowest. It is possible that the high use of technology in Japan is limited to diagnostic technology not matched by high rates of treatment, whereas in the United States, high use of diagnostic technology may be linked to the "cascade effect"18 and to more treatment

Recent studies using physician-to-population ratios (as a proxy for unavailable data on actual receipt of health services according to their type) have shown that the higher the primary care physician–to–population ratio in a state, the better most health outcomes are.19 The influence of specialty physician–to–population ratios and of specialist–to–primary care physician ratios has not been adequately studied, but preliminary and relatively superficial analyses suggest that the converse may be the case

2
"To Err is Human "
https://www.ncbi.nlm.nih.gov/pubmed/25077248
https://www.ncbi.nlm.nih.gov/books/NBK225182/

3
AHRP 2000 referencing the abovementioned published **JAMA research**
US Healthcare Third Leading Cause of Death Barbara Starfield, MD
Is US Healthcare Really the best in the World? Starfield JAMA 2000
https://ahrp.org/us-healthcare-third-leading-cause-of-death_barbara-starfield-md/

"*The findings by Barbara Starfield, MD, of Johns Hopkins School of Public Health,*

12,000 deaths from unnecessary surgeries;
7,000 deaths from medication errors in hospitals;
20,000 deaths from other errors in hospitals;
80,000 deaths from infections acquired in hospitals;
106,000 deaths from FDA-approved correctly prescribed medicines.
The total estimated number of deaths caused by medical treatment in the US every year is 225,000.

Thus, the US medical system is the third leading cause of death, after heart disease and cancer.

The findings are not disputed. Indeed, subsequent studies found the number of preventable deaths due to medical intervention to be higher.

The US relative position for life expectancy in the oldest age group was better in the 1980's than in the 1990s. 13 The long-existing poor ranking of the United States with regard to infant mortality 14 has been a cause for concern; it is not a result of the high percentages of low birth weight and infant mortality among the black population, because the international ranking hardly changes when data for the white population only are used."

"Since 2000 when Dr. Starfield's analysis was published the death toll from hazardous prescription drugs alone has been far greater:

A sample includes the following:

Drug	Year Approved	Year Withdrawn
Pemoline	1975	2005
Darvon	1976	2010
Permax	1988	2007
Propulsid (cisapride)	1993	2000
Orlaam (levomethadyl acetate)	1993	2001—EU; 2003 US
Aprotinin (Trasylol)	1993	2007
Serelect (Sertindole)	1995	1998
Redux (dexfenfluramine)	1996	1997
Duract (bromfenac)	1997	1998
Raxar (grepafloxin)	1997	1999
Posicor (mibefradil)	1997	1998
Baycol (cerivastatin)	1997	2001
Sibutramine (Reductil/Meridia)	1997	2010
Trovan (Trovaloxacin)	1997	1999—EU; 2002–Pfizer stops mfg.
Avandia (Rosiglitazone)	1999	2010–EU
Rezulin (troglitazone)	1999	2000
Raplon (rapacuronium)	1999	2001
Vioxx (Rofecoxib)	1999	2004
Tequin (gatifloxacin)	1999	2006
Lotronex (alosetron)	2000	2000
Mylotarg (Gemtuzumab ozogamicin)	2000	2010
Xigris (Drotrecogin alfa)	2002	2011
Raptiva (Efalizumab)	2003	2009
Bextra (Valdecoxib)	2004	2005
Tysbari (Natalizumab)	2004	2005
Technetium fanolesomab)	2004	2005
Palladone (hydromorphone)	2004	2005
Zelnorm (tegaserod maleate)	2004	2007
Exubera (Inhaled insulin)	2006	2007

4 **List of drugs removed from the market for safety reasons at:**
https://www.ahrp.org/cms/content/view/861/9/

5
JOURNAL OF PATIENT SAFETY 2013
Review Article
A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care
James, John T. PhD Journal of Patient Safety: September 2013 - Volume 9 - Issue 3 - p 122–128
doi: 10.1097/PTS.0b013e3182948a69
https://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx
https://journals.lww.com/journalpatientsafety/Pages/ArticleViewer.aspx?year=2013&issue=09000&article=00002&type=Fulltext
Abstract J Patient Saf. 2013 Sep;9(3):122-8. doi: 10.1097/PTS.0b013e3182948a69.
https://www.ncbi.nlm.nih.gov/pubmed/23860193/

*"**Objectives** Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.*

***Methods** A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.*

***Results** Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm."*

6

SCIENTIFIC AMERICAN 20 SEPTEMBER, 2013 referencing the abovementioned published **JOPS study**
https://www.scientificamerican.com/article/how-many-die-from-medical-mistakes-in-us-hospitals/?redirect=1

> *"In 1999, the Institute of Medicine published the famous "**To Err Is Human**" report, which dropped a bombshell on the medical community by reporting that up to 98,000 people a year die because of mistakes in hospitals.*
>
> *Now comes a study in the current issue of the Journal of Patient Safety that says the numbers may be much higher 2014 between 210,000 and 440,000 patients each year who go to the hospital for care suffer some type of preventable harm that contributes to their death, the study says.*
>
> *That would make medical errors the third-leading cause of death in America, behind heart disease, which is the first, and cancer, which is second.*
>
> *By combining the findings and extrapolating across 34 million hospitalizations in 2007, James concluded that preventable errors contribute to the deaths of 210,000 hospital patients annually.*
> *That is the baseline. The actual number more than doubles, James reasoned, because the trigger tool doesn't catch errors in which treatment should have been provided but wasn't, because it's known that medical records are missing some evidence of harm, and because diagnostic errors aren t captured.*
>
> *An estimate of 440,000 deaths from care in hospitals "is roughly one-sixth of all deaths that occur in the United States each year," James wrote in his study. He also cited other research that's shown hospital reporting systems and peer-review capture only a fraction of patient harm or negligent care."*

7

LALEVA 10 DECEMBER, 2013 referencing the abovementioned published **JOPS study**
http://www.laleva.org/eng/2013/12/medical_errors_kill_enough_people_to_fill_4_jumbo_jets_a_week_-_7_tips_on_surviving_the_medical_industrial_complex-print.html

> *"With 200,000 - 400,000 deaths per annum Medical Errors are now the 3rd leading cause of death right behind Heart disease with 597,689 deaths per annum and Cancer with 574,743 deaths per annum.*
>
> *the Medical Industrial Complex has it's own spider web interconnecting Big Pharm, Big Agra the Personal Care Products Industry and their Lobbyists to Elected Officials, the FDA, EPA, WHO, the CDC, the AMA and Wall Street."*

8

BMJ 3 MAY 2016
Medical error—the third leading cause of death in the US
BMJ 2016; 353 doi: https://doi.org/10.1136/bmj.i2139 (Published 03 May 2016) Cite this as: *BMJ* 2016;353:i2139

Martin A Makary, professor1 , Michael Daniel, research fellow1
Author affiliations
[1]*Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA*
https://www.bmj.com/content/353/bmj.i2139.full

9a

John Hopkins article referencing the abovementioned published **BMJ study**

Study Suggests Medical Errors Now Third Leading Cause of Death in the U.S.

Physicians advocate for changes in how deaths are reported to better reflect reality

Release Date: May 3, 2016

https://www.hopkinsmedicine.org/news/media/releases/study_suggests_medical_errors_now_third_leading_cause_of_death_in_the_us

> *"May 3 in The BMJ, surpasses the U.S. Centers for Disease Control and Prevention's (CDC's) third leading cause of death — respiratory disease, which kills close to 150,000 people per year.*
>
> *In their study, the researchers examined four separate studies that analyzed medical death rate data from 2000 to 2008, including one by the U.S. Department of Health and Human Services' Office of the Inspector General and the Agency for Healthcare Research and Quality. Then, using hospital admission rates from 2013, they extrapolated that based on a total of 35,416,020 hospitalizations, 251,454 deaths stemmed from a medical error, which the researchers say now translates to 9.5 percent of all deaths each year in the U.S.*
>
> *According to the CDC, in 2013, 611,105 people died of heart disease, 584,881 died of cancer and 149,205 died of chronic respiratory disease — the top three causes of death in the U.S. The newly calculated figure for medical errors puts this cause of death behind cancer but ahead of respiratory disease."*

9b https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm

10

HUB ARTICLE referencing the abovementioned published **BMJ study**

https://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death/

> *"Analyzing medical death rate data over an eight-year period, Johns Hopkins patient safety experts have calculated that more than 250,000 deaths per year are due to medical error in the U.S. Their figure, published May 3 in The BMJ, surpasses the U.S. Centers for Disease Control and Prevention's third leading cause of death—respiratory disease, which kills close to 150,000 people per year….*
>
> *The Johns Hopkins team says the CDC's way of collecting national health statistics fails to classify medical errors separately on the death certificate.*
>
> *'Incidence rates for deaths directly attributable to medical care gone awry haven't recognized in any standardized method for collecting national statistics', says Martin Makary, professor of surgery at the John Hopkins University School of Medicine and an authority on health reform. 'The medical coding system was designed to maximize billing for physician services, not to collect national health statistics, as it is currently being used.'"*

11 **WHO ASSEMBLY REPORT 25 MAY 2019**

https://www.who.int/news-room/detail/25-05-2019-world-health-assembly-update

> "*More than 4,000 representatives from 194 member states gathered in Geneva, Switzerland during May 20-28, 2019 to discuss human-related health issues at the 72nd World Health Assembly, a meeting of the World Health Organization's (WHO) top decision-making body.*[1]
>
> *The World Health Assembly attendees recognized patient safety and reducing patient harm in healthcare settings as a key priority, and endorsed the establishment of an annual World Patient Safety Day, pointing out that:*
>
> *"**Patient harm due to adverse events is one of the leading causes of death and disability globally.** An estimated 134 million adverse events occur annually due to unsafe care in hospitals in low and middle income countries, contributing to 2.6million deaths, while 1 in 10 patients is estimated to be harmed while receiving hospital care in high income countries 22"*

12

STRENGTH IN UNITY REPORT OCTOBER 2012

McKinsey and company . Strength in unity: The promise of global standards in healthcare October 2012
https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

"…adverse drug events, which, according to our research, now stand at more than 25 million with over 100,000 deaths annually. Product recalls, now occurring about 15 times per week in medical devices and 20 times per week in pharmaceuticals in the U.S. alone…..

In the medical device sector, the number of patients reported injured in serious adverse events in the US increased by 17% per year from 2001-2009, topping 28,000 in 2009. The number of medical device recalls in the US grew 6% per year from 2003-2009, surpassing 700 in 2009.5

Pharmaceutical recalls have grown even faster: by 26% per year from 2005-2011, to more than 1,000 per year now.6 Not surprisingly, regulatory scrutiny has increased along with safety issues: the US FDA issued 18 Good Manufacturing Practice (GMP) warning letters to pharmaceutical manufacturers in 2005, and 53 in 2011—a nearly 200% increase. Regulators' response times also increased: the share of FDA warning letters issued within 4 months of inspection rose from 14% to 26%.

*Few healthcare organizations have responded to the rise in recalls by improving the efficiency or effectiveness of their recall processes. Many recalls still require hundreds of hours of manual labor and still fail to remove all affected products from inventories or locate every exposed patient. (page 15 of the **SIUR** report)*

*In developed markets like U.S. and U.K., medication errors occur during 10-20% of all inpatient admissions.11 .... Reported incidence rates of preventable ADEs vary from 2-7% of hospital admissions in developed countries15 to as high as 18% in developing nations.16 These have led to thousands of patient deaths and millions of short- and long-term disabilities every year.17 These injuries are also financially costly. The average cost per ADE in U.S. is $4,700-8,750,18 while in the U.K., the National Health Service (NHS) has reported £2 billion per year in avoidable hospital stays (page 29 of the **SIUR** report)"*

13

JAMA 2018

CROSS-SECTIONAL SURVEY STUDY

Prevalence of Prescription Medications With Depression as a Potential Adverse Effect Among Adults in the United States

Dima Mazen Qato, PharmD, MPH, PhD; Katharine Ozenberger, MS; Mark Olfson, MD, MPH
JAMA.2018; 319 (22): 2289-2298.doi:10.1001/jama.2018.6741
https://jamanetwork.com/journals/jama/fullarticle/2684607?appId=scweb

"*Question* *How frequently do US adults use prescription medications with depression as a potential adverse effect and is use of these medications associated with concurrent depression?*
Findings *In this cross-sectional US population-based survey study conducted between 2005 and 2014, the estimated overall prevalence of US adults using medications with depression as a potential adverse effect was 37.2%. The adjusted percentage of adults with concurrent depression was higher among those using more concurrent medications (eg, estimated 15% for ≥3 medications).*
Meaning *Use of prescription medications that have depression as a potential adverse effect was common and associated with greater likelihood of concurrent depression.*
CONCLUSIONS AND RELEVANCE *In this cross-sectional survey study, use of prescription medications that have depression as a potential adverse effect was common. Use of multiple medications was associated with greater likelihood of concurrent depression*."

14

WASHINGTON POST 2012 - AVANDIA

As drug industry's influence over research grows, so does the potential for bias

https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html?noredirect=on&utm_term=.be0869bdc673

"The billions that the drug companies invest in such experiments help fund the world's quest for cures. But their aim is not just public health. That money is also part of a high-risk quest for profits, and over the past decade corporate interference has repeatedly muddled the nation's drug science, sometimes with potentially lethal consequences.

In regard to the asserted effectiveness of Avandia in a trial conducted " For drug maker GlaxoSmithKline, the 17-page article in the New England Journal of Medicine represented a coup. The 2006 report described a trial that compared three diabetes drugs and concluded that Avandia, the company's new drug, performed best. "…financial connections between the drug maker and the research. The trial had been funded by GlaxoSmithKline, and each of the 11 authors had received money from the company. Four were employees and held company stock. The other seven were academic experts who had received grants or consultant fees from the firm…. A Food and Drug Administration scientist later estimated that the drug had been associated with 83,000 heart attacks and deaths.

over a year-long period ending in August, NEJM published 73 articles on original studies of new drugs, encompassing drugs approved by the FDA since 2000 and experimental drugs, according to a review by The Washington Post.

Of those articles, 60 were funded by a pharmaceutical company, 50 were co-written by drug company employees and 37 had a lead author, typically an academic, who had previously accepted outside compensation from the sponsoring drug company in the form of consultant pay, grants or speaker fees.

The New England Journal of Medicine is not alone in featuring research sponsored in large part by drug companies — it has become a common practice that reflects the growing role of industry money in research.

Last year, the industry spent $39 billion on research in the United States

Over a decade, controversies over blockbuster drugs such as Vioxx, Avandia and Celebrex erupted amid charges that the companies had shaped their research to obscure the dangerous side effects.

When the company is footing the bill, the opportunities for bias are manifold: Company executives seeking to promote their drugs can design research that makes their products look better. They can select like-minded academics to perform the work. And they can run the statistics in ways that make their own drugs look better than they are. If troubling signs about a drug arise, they can steer clear of further exploration.

Maybe the most widely reported research controversy arose over the arthritis drug Vioxx, which had been featured positively in a NEJM article. The article reported the results of a trial that was funded by Merck and was co-written by two company researchers.

Five years later, journal editors reported discovering that the authors had omitted key incidences of heart troubles, creating "misleading" conclusions about the drug's safety. Before the drug was pulled from the market, according to a review by an FDA investigator, it caused an extra 27,000 heart attacks and cardiac-related deaths.

Other industry-funded papers published in NEJM have led to conclusions that were later contradicted. Research published in NEJM regarding bestsellers such as the anemia drug Epogen and heart drug Natrecor has been challenged later by studies performed by other researchers.

"Unfortunately, the entire evidence base has been perverted," said Joseph Ross, a professor at Yale Medical School who has studied the issue.

Just because industry-funded researchers arrived at conclusions that were later discarded does not mean that money biased their findings. Researchers get things wrong for lots of reasons — errors are a part of science.

But Ross notes that corporate bias can be particularly strong. The odds of coming to a conclusion favorable to the industry are 3.6 times greater in research sponsored by the industry than in research sponsored by government and non-profit groups, according to a published analysis by Justin Bekelman, a professor at the University of Pennsylvania, and colleagues.

Moreover, at the same time that companies have been funding a larger share of research, they have shifted the job of conducting trials away from non-profit academic hospitals to for-profit "contract research organizations." Critics say that with this change, corporate bias is less likely to be challenged.

Academics have "contributed to the quality, intellectual rigor, and impact of . . . clinical trials," the editors of the nation's top medical journals, including NEJM, wrote in an editorial in 2001. "But, as economic pressures mount, this may be a thing of the past."

With the for-profit companies competing to run the trials, "corporate sponsors have been able to dictate the terms," the editorial said.

In recent years, more than half of the money the industry spends on outside research goes to for-profit organizations rather than universities and other academic centers.

"It used to be that drug companies would hand their new drug over to an academic center to have it tested, and then they sat back and waited," said Marcia Angell, who retired as editor in chief of NEJM in 2000 after more than 20 years at the publication. "Now they're intimately involved in every step along the way, and they treat academic researchers more like hired hands."

The result, Angell said, is that the research can be biased and that it can be difficult for medical journals to unmask the problems.

"I used to think that if studies were subject to rigorous peer review it would then be enough to simply disclose authors' commercial ties," she said. "But I no longer believe that's enough. It's too hard for anyone — editors, peer reviewers, readers — to tell whether that bias has affected the work…..

"peer reviewers" —typically assess the paper based on what is presented — they do not see all the data…

the New England Journal of Medicine….runs on advertising, subscriptions and other revenue… More than 600,000 people in 177 countries read it each week, according to the journal's Web site, and it influences the practice of medicine around the world

(Re Avandia) Interviews, FDA documents and e-mails released by a Senate investigation indicate that GlaxoSmithKline withheld key information from the academic researchers it had selected to do the work; decided against conducting a proposed trial, because it might have shown unflattering side effects; and published the results of an unfinished trial even though they were inconclusive and served to do little but obscure the signs of danger that had arisen…. Even when the company was ordered by the FDA to study potential dangers, it arranged a trial in which danger signs were muffled, or missed completely…

But as the FDA later noted, the ADOPT trial was not really designed to assess heart risks. For one thing, it excluded people most at risk of heart trouble, making it harder to spot a problem. Moreover, investigators did not have a group of doctors validate reports of heart attacks, as is customary because they can be difficult to detect. …… other data that suggested to him that Avandia could cause heart trouble. Another trial sponsored

by the company, known as DREAM, had shown a slight trend, he thought, but the number of patients was too small to be considered statistically significant. …. . In all, he discovered the summaries of 42 trials — 35 of them unpublished. Most of them had been sponsored by Glaxo.

After analysis, the results were stark: Avandia raised the risks of heart attack by 43 percent and of death from heart problems by 64 percent.

Those findings would stand up. But the reach of the pharmaceutical companies to influence the science would create three more years of uncertainty (the findings were leaked resulting in the company launching another trial).. would also launch (and funded) one other strategic counter to Nissen's paper: They would publish the results of another, separate trial of Avandia that they were conducting, known as the RECORD trial.

One of the reasons that the Glaxo executives could be confident that the RECORD trial would show no danger is that the trial did not have enough patients enrolled to judge the drug's heart-attack risks, as Glaxo scientists believed, according to the Senate report. It was, in the scientific jargon, " underpowered…. in turn hired a steering committee of prestigious academics to lead it…. many financial ties to the company, too…… .

"What it did was it falsely reassured practitioners and patients that [Avandia] might be safe when in fact it wasn't," Nissen said. "They got three more years out of it."

It was not until 2010 that Nissen was largely vindicated. An FDA reviewer indicated that the RECORD trial had been poorly designed and suggested that investigators had improperly missed heart problems suffered by Avandia patients.

In September 2010, the FDA announced major restrictions on the use of Avandia. On the same day, European regulators ordered it off the market."

15

WASHINGTON POST 2012 - ANAEMIA DRUGS
https://www.washingtonpost.com/business/economy/anemia-drug-made-billions-but-at-what-cost/2012/07/19/gJQAX5yqwW_story.html?utm_term=.816891fe94d4

"For years, a trio of anemia drugs known as Epogen, Procrit and Aranesp ranked among the best-selling prescription drugs in the United States, generating more than $8 billion a year for two companies, Amgen and Johnson & Johnson. Even compared with other pharmaceutical successes, they were superstars. For several years, Epogen ranked as the single costliest medicine under Medicare: U.S. taxpayers put up as much as $3 billion a year for the drugs.

The trouble, as a growing body of research has shown, is that for about two decades, the benefits of the drug — including "life satisfaction and happiness" according to the FDA-approved label — were wildly overstated, and potentially lethal side effects, such as cancer and strokes, were overlooked. And (no benefit) Medicare researchers issued an 84-page study declaring that among most kidney patients, the original and largest market for the drugs, there was no solid evidence that they made people feel better, improved their survival or had any "clinical benefit" besides elevating a statistic for red blood cell count…

How did this happen? To answer the question, The Washington Post obtained the agreements between the and the Food and Drug Administration, reviewed thousands of pages of transcripts and company reports, and relied on new academic research, some by doctors who once administered the drugs but now look askance at the drug makers' original claims…...

The multibillion-dollar rise and fall of the anemia drugs illustrates how the economic incentives embedded in the U.S. health-care system can make it not only inefficient but also potentially deadly.

Through a well-funded research and lobbying campaign, Amgen won far-reaching approvals from the FDA.

Both pharmaceutical companies conducted trials that missed the dangers and touted benefits that years later would be deemed unproven. The companies took more than a decade to fulfil their research commitments. And when bureaucrats tried to rein in the largest doses, a high-powered lobbying effort occurred until Congress forced the regulators to let the drugs flow… in some cases, the more they treat a patient, the more they earn. This was especially true in the case of the anemia drugs: The bigger the dose, the more they made. Unlike medications that a patient picks up at the store, drugs administered by a physician, as these were, can yield a profit for doctors if there is a "spread" — a difference between the price they pay for the drug and the price they charge patients.

In this case, drug makers worked diligently to make sure that doctors had an incentive to give large doses — that the spread was large…... The incentives drove remarkably high profits at Amgen — enough to elevate the small California firm into a Fortune 500 company… Amgen. They won. They made billions.

Anemia arises when the body produces too few red blood cells, which carry oxygen from the lungs to the rest of the body.

The drugs consisted of man-made versions of a natural hormone called erythropoietin, which stimulates the body to produce red blood cells.

.. The discovery, which grew out of research funded in part by the National Institutes of Health…

The trouble would arise as the drug makers won FDA approval for vastly expanded uses, pushing it in larger doses, for milder anemia and for patients with a wider array of illnesses. Very quickly, the market included nearly all dialysis patients, not just the roughly 16 percent who required blood transfusions. The size of average doses would more than triple. And over the next five years, the FDA would approve it to treat anemia in patients with cancer and AIDS, as well as those getting hip and knee surgery.

…funded by Amgen, the Normal Hematocrit Trial sought to explore the possibilities of raising the treatment target.. one of the largest trials to have been done on the drugs at the time… three years after the study began, the trial was halted. Patients in the higher dose group were dying or having heart attacks at a higher rate than those in the lower dose group..an indication the drugs could be deadly..but what could have been a clear warning turned murky as it was presented to the public.. the FDA added a summary of the results to the Epogen label, but didn't limit the recommended dosing levels and stated the reason for the "increased mortality" at the higher doses "is unknown". And when the results were reported to the New England Journal of Medicine in 1998 key informed was glossed over or omitted…(4 out of the 8 authors of the journal article were employees of Amgen)… Neither of these issues would have become public if not for Coyne, who filed a Freedom of Information Act request with the FDA asking for the actual results of the trial..(took the agency 2 years to respond to his request)…across the country, the dosages continued to rise.. When the agency first approved the drug, it recommended boosting a patient's haematocrit up to 33 percent.. a few years later, after Amgen's suggestion, it expanded the target range up to 36 percent…As hematocrits rise more of the drug is required to get it to rise again …would push the amount consumed from $7,000 to $10,000 annually… the average dose for the drugs more than doubled in the early to mid 90's..

The most commonly used dosing guidelines that doctors in the field used were issued by a group organised by the National Kidney Foundation..(which Amgen was the founding and principal sponsor of).. Moreover, in 2006, of the 16 members of the foundation's panel that created the new dosing guidelines, 10 reported receiving consulting fees, speaking fees or research funds from Amgen or Johnson & Johnson's subsidiary, Ortho Biotech. It recommended doses at the high end of the FDA target recommendation.

(Agency raised the max level as a consequence of lobbying, instead of the Medicare Limits that were sought. Amgen, already having a sizable in-house lobbying effort, turned to powerful outside help. It spent $2.4 million on lobbyists that year, according to OpenSecrets.org. Within months the Medicare bureaucrats had not only backed off the restriction but agreed to a higher limit.)

... Dialysis clinics were receiving as much as 25 percent of their revenue from using the drugs… According to a financial filing, Charles J McAllister, chief medical officer of DaVita, the dialysis company, was to receive a $200,000 bonus if the rules for the drugs' use being considered by regulators were dropped or delayed. He was to receive an additional $100,000 if the ten-new legislation, known as the Medicare Modernization Act, didn't cut into the company's revenue…. The companies would even enlist the patients to lobby on their behalf….. Amgen lobbying expenditures and political efforts jumped that year. The company ranked as the largest contributor to the campaign of House Speaker Nancy Pelosi(D-Calif), which got $42,050…

For years, a small Bethesda-based non-profit think tank, the Medical Technology and Practice Patters Institute, had been publishing studies that challenged the conventional enthusiasm for the drug and the government policies that it said promoted their overuse. Then in November 2006 a study published in the NEJM reported that kidney patients targeted for higher doses were linked to higher risks of hospitalization, strokes and death.. Danish researchers stopped a trial of Aranesp in cancer patients because of an increase in deaths and tumor growths… (then commenced) an FDA crackdown.. Amgen hit with whistleblower lawsuits alleging that the company engaged in illegal sales tactics…..setting aside $780 million to settle the lawsuits..

16a https://www.australianpharmacist.com.au/medicine-misadventure-common-reveals-psa/

16b

THE AMERICAN JOURNAL OF MEDICINE 27 JULY, 1998

Recent Considerations in Nonsteroidal Anti-Inflammatory Drug Gastropathy Singh Gurkirpal, MD

"*Every year in the United States nonsteroidal anti-inflammatory drugs (NSAIDs) kill 16,500 people through gastrointestinal complications alone*." (page 135)

UNDERREPORTING

17

SPRINGER 2018

April 2018, Volume 41, Issue 4, pp 403–413 | Cite as

Amyotrophic Lateral Sclerosis Associated with Statin Use: A Disproportionality Analysis of the FDA's Adverse Event Reporting System

Beatrice A. Golomb 1 Abril Verden 2 Alexis K. Messner 1 Hayley J. Koslik 1 Keith B. Hoffman 2

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https://link.springer.com/article/10.1007%2Fs40264-017-0620-4

"These findings extend previous evidence showing that significantly elevated ALS reporting extends to individual statin agents, and add to concerns about potential elevated occurrence of ALS-like conditions in association with statin usage."

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IT'S TIME FOR TRANSPARENCY Book 2012

Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care (Bloomsbury Press, 2012). Marty Makary, a surgical oncologist and gastrointestinal surgeon at Hopkins Hospital, instrumental in developing the World Health Organization's wide-ranging medical procedure safety checklist.

https://www.hopkinsmedicine.org/news/publications/hopkins_medicine_magazine/archives/fall_2012/its_time_for_transparency

https://www.hopkinsmedicine.org/news/publications/hopkins_medicine_magazine/archives/files/sebindoc/o/q/D3B1BDF3996E66F42682FEE8E44E10AA.pdf

"Many information sources on patient safety are hidden in an impenetrable maze of websites, he notes. Medical institutions and practitioners continue to mislead prospective patients with deceptive advertising, acting as salespersons for—or defensively overusing—potentially unnecessary treatments. What's more, hospitals fail to discipline errant physicians, and they don't report fully on the outcomes of the care they provide"

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THE JOURNAL FOR HEALTHCARE QUALITY (JHQ) JULY/AUGUST 2016

Prevalence and Data Transparency of National Clinical Registries in the United States

Lyu, Heather; Cooper, Michol; Patel, Kavita; Daniel, Michael; Makary, Martin A.
The Journal for Healthcare Quality (JHQ): July/August 2016 - Volume 38 - Issue 4 - p 223–234
doi: 10.1097/JHQ.0000000000000001
https://journals.lww.com/jhqonline/Citation/2016/07000/Prevalence_and_Data_Transparency_of_National.4.aspx

20a **JOHN HOPKINS 30 APRIL, 2015 referencing abovementioned JHQ study**

Study Questions Quality of U.S. Health Data

https://www.hopkinsmedicine.org/news/media/releases/study_questions_quality_of_us_health_data

> *"A new study by Johns Hopkins researchers concludes that most U.S. clinical registries that collect data on patient outcomes are substandard and lack critical features necessary to render the information they collect useful for patients, physicians and policy makers.*
> *Findings of the study, published ahead of print April 24 in the Journal for Healthcare Quality, reveal poor data monitoring and reporting that researchers say are hurting national efforts to study disease, guide patient choice of optimal treatments, formulate rational health policies and track in a meaningful way how well physicians and hospitals perform.*
>
> *"Our results highlight the acute need to improve the way clinical outcomes data are collected and reported," says senior investigator Marty Makary, M.D., M.P.H., professor of surgery at the Johns Hopkins University School of Medicine. "Failure to measure and accurately track patient outcomes remains one of the greatest problems in modern health care, curtailing our ability to understand disease, evaluate treatments and make the health-care industry a value-driven marketplace."*
>
> *In addition, the failure to track patient outcomes in a systematic way is tantamount to not measuring the performance of a sector that claims one-fifth of the nation's economy, the research team says.*
>
> *Clinical registries are databases of patient outcomes developed and maintained by medical organizations and medical specialty groups.*
>
> *To evaluate the quality of clinical registries, Makary and colleagues say they created "a registry of registries" to study the way the health care industry measures its performance.*
>
> *"We found it's the Wild West," Makary says. "With a few notable exceptions, most registries are underdeveloped, underfunded and often are not based on sound scientific methodology."*
>
> *The investigators assessed 153 U.S. clinical registries containing health service and disease outcomes data. On average, a registry contained information on more than 1,160,000 patients treated across more than 1,600 hospitals.*
>
> *A robust clinical registry can tell doctors in real time what medications work well and which are harming patients, yet the infrastructure to achieve that is vastly under-supported," says study co-author Michol Cooper, M.D., Ph.D., a surgical resident at the Johns Hopkins University School of Medicine. "The same rigorous standards we use to evaluate how well a drug does ought to apply to the way we report patient outcomes data."*

20b

Ministerial Review into the Public Health Response into the Adverse Events to the Seasonal Influenza Vaccine. Final Report to the Minister for Health July 2010 (WA Stokes report)

https://ww2.health.wa.gov.au/~/media/Files/Corporate/Reports%20and%20publications/PDF/Stokes_Report.pdf

This Review was ordered by the Western Australian (WA) Minister for Health. It's terms of reference were limited; they did not include investigating how decisions are made concerning acceptable levels and severity of AEFI's. The Review revealed what appears to be a serious deficiency in the current reporting mechanisms for adverse events.

The Review did not concur with the position of the NCIRS in their report of adverse events that the passive National surveillance system is robust or adequate. The NCIRS is conflicted by the function of performing research aimed at reducing the incidence of vaccine preventable diseases and improving vaccine uptake.

The Review reached the conclusion that the NIC had made little progress in implementing recommendations based on Who initiatives for AEFI monitoring and reporting to improve National AEFI surveillance and to ensure transparency and accountability.

"The TGA has both a regulatory and licensing authority function, as well as having a reporting and surveillance role for adverse reactions or events to medicines. From a governance perspective, these two functions should be separated. The recent announcement by the TGA to separate these functions within the TGA does go some way to achieve this goal, but in the Reviewer's opinion may not go far enough in this regard.

The separation of functions between licensing and regulation and monitoring and surveillance must be achieved so the process is open and transparent especially to those whom they serve, namely the public.

The ability to choose either a Commonwealth or State reporting mechanism is confusing and does not allow a real time collection of emerging events.

Whilst there is the current capacity for on-line reporting it is not well used and as demonstrated by the Review it is difficult to use and not operator friendly."

HEALTH SPENDING IMPACT

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JAMA March 13, 2018

Special Communication

Health Care Spending in the United States and Other High-Income Countries

Irene Papanicolas, PhD[1,2,3]; Liana R. Woskie, MSc[1,2,3]; Ashish K. Jha, MD, MPH[1,2]

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JAMA. 2018;319(10):1024-1039. doi:10.1001/jama.2018.1150

https://jamanetwork.com/journals/jama/article-abstract/2674671

> **"*Findings*** *In 2016, the United States spent nearly twice as much as 10 high-income countries (including Australia) on medical care and performed less well on many population health outcomes…..*
>
> *For some determinants of health such as smoking, the US ranked second lowest of the countries (11.4% of the US population ≥15 years smokes daily; mean of all 11 countries, 16.6%), but the US had the highest percentage of adults who were overweight or obese at 70.1% (range for other countries, 23.8%-63.4%; mean of all 11 countries, 55.6%). Life expectancy in the US was the lowest of the 11 countries at 78.8 years (range for other countries, 80.7-83.9 years; mean of all 11 countries, 81.7 years), and infant mortality was the highest (5.8 deaths per 1000 live births in the US; 3.6 per 1000 for all 11 countries)…… For pharmaceutical costs, spending per capita was $1443 in the US vs a range of $466 to $939 in other countries."*

22

REVIEW STUDY: 25 March 2013 European Journal of Clinical Investigation

Undue industry influences that distort healthcare research, strategy, expenditure and practice: a review

Emmanuel Stamatakis Richard Weiler John P.A. Ioannidis

First published: **25 March 2013** https://doi.org/10.1111/eci.12074
https://onlinelibrary.wiley.com/doi/full/10.1111/eci.12074
PDF: https://onlinelibrary.wiley.com/doi/epdf/10.1111/eci.12074

Emmanuel Stamatakis*,†, Richard Weiler‡ and John P.A. Ioannidis§,¶ *Department of Epidemiology and Public Health, University College London, London, UK, †Prevention Research Collaboration, School of Public Health, University of Sydney, Sydney, NSW, Australia, ‡University College London Hospitals NHS Foundation Trust, London, UK, §Stanford Prevention Research Center, Department of Medicine and Department of Health Research and Policy, Stanford University School of Medicine, Stanford, CA, USA, ¶Department of Statistics, Stanford University School of Humanities and Sciences, Stanford, CA, USA

"Abstract: Expenditure on industry products (mostly drugs and devices) has spiralled over the last 15 years and accounts for substantial part of healthcare expenditure. The enormous financial interests involved in the development and marketing of drugs and devices may have given excessive power to these industries to influence medical research, policy, and practice.

Results We located abundance of consistent evidence demonstrating that the industry has created means to intervene in all steps of the processes that determine healthcare research, strategy, expenditure, practice and education. As a result of these interferences, the benefits of drugs and other products are often exaggerated and their potential harms are downplayed, and clinical guidelines, medical practice, and healthcare expenditure decisions are biased.

Conclusion To serve its interests, the industry masterfully influences evidence base production, evidence synthesis, understanding of harms issues, cost-effectiveness evaluations, clinical practice guidelines and healthcare professional education and also exerts direct influences on professional decisions and health consumers. There is an urgent need for regulation and other action towards redefining the mission of medicine towards a more objective and patient-, population- and society-benefit direction that is free from conflict of interests."

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Philanthropic power significantly influences the setting of WHO's program priorities.
https://www.globalpolicy.org/component/content/article/270-general/52829-philanthropic-power-and-development-who-shapes-the-agenda.html
https://www.globalpolicy.org/images/pdfs/GPFEurope/Philanthropic_Power_online.pdf

> *"it is not only "big business" but also "big philanthropy" that has an increasing influence in global (development) policy, particularly large philanthropic foundations…Through the sheer size of their grant-making, personal networking and active advocacy, large global foundations, most notably the Rockefeller Foundation and the Bill & Melinda Gates Foundation, have played an increasingly active role in shaping the agenda-setting and funding priorities of international organizations and governments….The findings of the study range from the foundations' application of a business model to the measurement of results, their influence on policies and agenda-setting, the fragmentation and weakening of global governance, and the lack of transparency and accountability mechanisms."*

The U.S. government is the largest state member funder of WHO. The Gates Foundation is the largest non-state funder of the WHO, having donated more than $2B in earmarked grants to the international health agency since 1998. Because the Gates Foundation grant money is earmarked for specific programs, such as vaccine purchase, delivery and promotion, the Gates Foundation significantly influences the setting of WHO's program priorities.

[**NOTE** for example:

> Australia's vaccination policies have been designed from the recommendations provided by the World Health Organisation (WHO) under Global Health Policies. The WHO receives these recommendations from an advisory group called the Global Alliance for Vaccines and Immunisation (GAVI). This alliance includes the Federation of Pharmaceutical Companies, the International Monetary Fund, the World Bank, the Bill and Melinda Gates Foundation, the Rockefeller Foundation and many more private and public organisations, all with equal input into global health policies.
>
> The GAVI alliance cannot provide objective advice about disease control because many of these private-public organisations profit from the vaccines they recommend to the WHO.
>
> The majority of the research on vaccine safety and efficacy that is used by government regulators and advisory boards is carried out or sponsored by pharmaceutical companies. These are the companies that profit from selling vaccines. In addition, most representatives on vaccine advisory boards have financial or other conflicts of interests (COI) with pharmaceutical companies.
>
> For instance, prior to becoming the head of Gavi in 2011, Dr. Berkley worked for the U.S. Centers for Disease Control and Prevention (CDC), Rockefeller Foundation, the Carter Center and served on the Boards of Vaxinnate Corp, Napo Pharmaceuticals and Powderjet Pharmaceuticals.
>
> https://www.bloomberg.com/profile/person/2390911
> https://www.businesswire.com/news/home/20090506005234/en/VaxInnate-Corporation-Closes-30-Million-Financing-Wellcome]

24

NSNBC INTERNATIONAL Published 19 June, 2015
http://nsnbc.me/2015/06/19/shocking-report-from-medical-insiders/
https://journal-neo.org/2015/06/18/shocking-report-from-medical-insiders/
https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2815%2960696-1.pdf

> "*A shocking admission by the editor of the world's most respected medical journal, The Lancet, has been virtually ignored by the mainstream media.* ***Dr. Richard Horton, Editor-in-chief of the Lancet*** *recently published a statement. declaring that a shocking amount of published research is unreliable at best, if not completely false, as in, fraudulent.*
>
> *Horton declared, "Much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness.*
>
> *To state the point in other words, Horton states bluntly that major pharmaceutical companies falsify or manipulate tests on the health, safety and effectiveness of their various drugs by taking samples too small to be statistically meaningful or hiring test labs or scientists where the lab or scientist has blatant conflicts of interest such as pleasing the drug company to get further grants. At least half of all such tests are worthless or worse he claims. As the drugs have a major effect on the health of millions of consumers, the manipulation amounts to criminal dereliction and malfeasance.*
>
> *The drug industry-sponsored studies Horton refers to develop commercial drugs or vaccines to supposedly help people, used to train medical staff, to educate medical students and more.*
>
> *Horton wrote his shocking comments after attending a symposium on the reproducibility and reliability of biomedical research at the Wellcome Trust in London. He noted the confidentiality or "Chatham House" rules where attendees are forbidden to name names: "'A lot of what is published is incorrect.' I'm not allowed to say who made this remark because we were asked to observe Chatham House rules. We were also asked not to take photographs of slides."*

***Dr. Marcia Angell** is a physician and was **longtime Editor-in-Chief of the New England Medical Journal (NEMJ**), considered to be another one of the most prestigious peer-reviewed medical journals in the world. Angell stated, "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine."*

***Harvey Marcovitch**, who has studied and written about the corruption of medical tests and publication in medical journals, writes, "studies showing positive outcomes for a drug or device under consideration are more likely to be published than 'negative' studies; editors are partly to blame for this but so are commercial sponsors, whose methodologically well-conducted studies with unfavorable results tended not to see the light of day…"*

*At the **University of British Columbia's Neural Dynamics Research Group in the Department of Ophthalmology and Visual Sciences**, **Dr Lucija Tomljenovic** obtained documents that showed that, "vaccine manufacturers, pharmaceutical companies, and health authorities have known about multiple dangers associated with vaccines but chose to withhold them from the public. This is scientific fraud, and their complicity suggests that this practice continues to this day."*

*Lancet's **Dr. Horton** concludes, "Those who have the power to act seem to think somebody else should act first. And every positive action (eg, funding well-powered replications) has a counter-argument (science will become less creative). The good news is that science is beginning to take some of its worst failings very seriously. The bad news is that nobody is ready to take the first step to clean up the system.*

Corruption of the medical industry worldwide is a huge issue, perhaps more dangerous than the threat of all wars combined. Do we have such hypnosis and blind faith in our doctors simply because of their white coats that we believe they are infallible? And, in turn, do they have such blind faith in the medical journals recommending a given new wonder medicine or vaccine that they rush to give the drugs or vaccines without considering these deeper issues?"

Author: F. William Engdahl is strategic risk consultant and lecturer, he holds a degree in politics from Princeton University and is a best-selling author on oil and geopolitics, exclusively for the online magazine "New Eastern Outlook".

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Sources: Mayo Clinic Proceedings, 2014; 789: 926-33; **Viruses, 2016; 8: 294**
Measles to the Rescue: A Review of Oncolytic Measles Virus
Sarah Aref, Katharine Bailey, and Adele Fielding*
Richard K. Plemper, Academic Editor
Viruses. 2016 Oct; 8(10): 294.
Published online 2016 Oct 22. doi: 10.3390/v8100294 PMCID: PMC5086626 PMID: 27782084
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5086626/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5086626/pdf/viruses-08-00294.pdf PDF

> *"Many cancers remain incurable to modern therapy despite recent pharmacological advances. Oncolytic viruses are replicating viruses that preferentially infect and lyse cancer cells whilst leaving normal tissue unharmed. At least eleven viruses, including adenovirus, vaccinia virus, coxsackievirus, reovirus and measles virus (MV), are being extensively investigated and have entered clinical trials to treat a wide range of advanced cancers. Progress is highlighted by the acquisition of both the first Food and Drug Administration (FDA) licence and marketing authorization by the European Commission, for oncolytic virotherapy—talimogene laherparepvec—a herpes simplex virus that has been genetically engineered to express granulocyte macrophage colony stimulating factor (GM-CSF) to treat advanced melanoma.*
>
> *The idea that replicating viruses can kill malignant cells was first suggested in the early twentieth century. Reports that infection with wild type MV can have beneficial effects in cancer patients were published in the 1970s: dramatic improvements were reported in patients with acute lymphoblastic leukaemia [2], Burkitt lymphoma [3], and Hodgkin lymphoma [4]…. (Measles virus is a) natural tropism to cancer cells"*

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Stephen Russell PhD MD speaking regarding the measles virus cancer cure
https://www.youtube.com/watch?v=LImk-KdMT1w

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WDDTY interview with Dr Angela Dispenzieri speaking on measles virus cancer cure
https://www.wddty.com/news/2019/04/measles-is-a-natural-cancer-killer.html?fbclid=IwAR3l3vYuVeq_8UlQrH4pkB4LhKRAHmKxKCKKcFr-h57Knx4OBRM0NLzlt-4
https://www.mayo.edu/research/faculty/dispenzieri-angela-m-d/bio-00083433?_ga=2.203572180.552942431.1559793884-1335282834.1559793884

> *"The virus makes cancer cells join together and explode, explains Mayo Clinic researcher Dr Angela Dispenzieri. It also stimulates the immune system to detect any recurring cancer cells and 'mops them up'. Although it's been recognised for a long time that measles and other viruses are natural cancer fighters—it's known as virotherapy—the dose seems to be an important factor. Dispenzieri and her Mayo colleagues engineered, or genetically modified, the measles virus strain, and gave it in a dose strong enough to vaccinate 10 million people to a woman with end-stage multiple myeloma."*
>
> *Virotherapy was a last-resort therapy as the 49-year-old woman had endured every type of chemotherapy and two stem cell transplants without success.*
>
> *A response was immediate. Within five minutes, the doctors say she developed a splitting headache and a temperature of 105 degrees F. before she started vomiting and shaking. A tumor the size of a golf ball had disappeared inside 36 hours, and all signs of cancer had disappeared from her body within two weeks* "
>
> *Researchers at University College London agree that virotherapy could be a promising way forward in the fight against cancer. In a study titled 'Measles to the Rescue', the researchers say that "virotherapeutic agents are likely to become serious contenders in cancer treatment", and that the vaccine strain of measles virus holds special hope*."

28

Harnessing genes and viruses to fight cancer
https://www.mayo.edu/research/centers-programs/cancer-research/research-programs/gene-virus-therapy-program
https://www.mayo.edu/research/centers-programs/cancer-research/research-programs/gene-virus-therapy-program/research
https://www.mayo.edu/research/faculty/dispenzieri-angela-m-d/bio-00083433?_ga=2.203572180.552942431.1559793884-1335282834.1559793884

> *"Harnessing genes and viruses to infect and kill tumor cells offers a promising step forward in cancer treatment. Researchers in the Gene and Virus Therapy Program of the **Mayo Clinic Cancer Center** are finding novel ways to manipulate these potent cancer fighters and expand treatment options for patients with cancer.* "

29

Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study.
Atherosclerosis. 2015 Aug;241(2):682-6. doi: 10.1016/j.atherosclerosis.2015.06.026. Epub 2015 Jun 18.
Kubota Y[1], Iso H[2], Tamakoshi A[3]; JACC Study Group.
https://www.ncbi.nlm.nih.gov/pubmed/26122188

> "Conclusion: *Measles and mumps, especially in case of both infections, were associated with lower risks of mortality from atherosclerotic CVD."*

Note: This study from 2015 in the journal Atherosclerosis found that men had 29% fewer heart attacks and 17% fewer strokes if they had a history of childhood measles and mumps. Women suffered less events as well, but not to the same extent. 135,000 less people would suffer from a stroke per year if all of these people had measles and mumps as children. http://www.strokecenter.org/patients/about-stroke/stroke-statistics/ Every 40 seconds, someone in the United States has a heart attack https://www.cdc.gov/heartdisease/heart_attack.htm

30

Elsevier Cancer Detection and Prevention
Volume 30, Issue 1, 2006, Pages 83-93
Review Accepted 9 November 2005, Available online 21 February 2006
Acute infections as a means of cancer prevention: Opposing effects to chronic infections?
Stephen A.Hoption CannPhD[a] J.P.van NettenPhD[b] C.van NettenPhD[a]

a. Department of Health Care and Epidemiology, University of British Columbia, 5804 Fairview Avenue, Vancouver, BC, Canada V6T 1Z3
b. Department of Biology, University of Victoria, Victoria, BC, Canada

https://doi.org/10.1016/j.cdp.2005.11.001
https://www.sciencedirect.com/science/article/pii/S0361090X06000043

> *"**Purpose**: Epidemiological studies have found an inverse association between acute infections and cancer development. In this paper, we review the evidence examining this potentially antagonistic relationship. **Methods**: In addition to a review of the historical literature, we examined the recent epidemiological evidence on the relationship between acute infections and subsequent cancer development in adult life. We also discuss the impact of chronic infections on tumor development and the influence of the immune system in this process. **Results:** Exposures to febrile infectious childhood diseases were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined, significant in the latter two groups. Epidemiological studies on common acute infections in adults and subsequent cancer development found these infections to be associated with reduced risks for meningioma, glioma, melanoma and multiple cancers combined, significantly for the latter three groups. Overall, risk reduction increased with the frequency of infections, with febrile infections affording the greatest protection. In contrast to acute infections, chronic infections can be viewed as resulting from a failed immune response and an increasing number have been associated with an elevated cancer risk. **Conclusion**: Infections may play a paradoxical role in cancer development with chronic infections often being tumorigenic and acute infections being antagonistic to cancer."*

31

Cancer Causes Control. 2010 Aug; 21(8): 1193–1201.
Published online 2010 Jun 18. doi: 10.1007/s10552-010-9546-1
PMCID: PMC2951028 NIHMSID: NIHMS235805
PMID: 20559706

Mumps and ovarian cancer: modern interpretation of an historic association

Daniel W. Cramer, Allison F. Vitonis, Simone P. Pinheiro, John R. McKolanis, Raina N. Fichorova, Kevin E. Brown, Todd F. Hatchette, and Olivera J. Finn

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951028/

> *"Background. Epidemiologic studies found childhood mumps might protect against ovarian cancer. To explain this association, we investigated whether mumps might engender immunity to ovarian cancer through antibodies against the cancer-associated antigen MUC1 abnormally expressed in the inflamed parotid gland*.
>
> *In one of the earliest case–control studies of ovarian cancer, West observed that women with the disease were less likely to report having had mumps compared to women with benign ovarian cysts [1], suggesting that childhood mumps might protect against the subsequent development of ovarian cancer. Eight additional observational studies addressing mumps and ovarian cancer were published [2–9], and in all but two [2, 9], controls were more likely to report a history of mumps than cases, suggesting that mumps might be associated with lower ovarian cancer risk*.
>
> *Result* ***….****suggesting that mumps is significantly and inversely associated with ovarian cancer risk"*

32

Measles infection and Parkinson's disease.

Sasco AJ, et al. Am J Epidemiol. 1985.

Authors Sasco AJ, Paffenbarger RS Jr.

Citation Am J Epidemiol. 1985 Dec;122(6):1017-31.
American Journal of Epidemiology, Volume 122, Issue 6, December 1985, Pages 1017–1031, https://doi.org/10.1093/oxfordjournals.aje.a114183
Published: 01 December 1985
PMID 4061437 [Indexed for MEDLINE]
https://www.ncbi.nlm.nih.gov/m/pubmed/4061437/?fbclid=IwAR1JjqZJ6v5j1LZKOmSi3GEG9YnxecAOHqQLe-Wzp32rypRHIG6B91s-fXc
https://academic.oup.com/aje/article-abstract/122/6/1017/72271?redirectedFrom=fulltext

> ***"Abstract***
> *A case-control analysis of Parkinson's disease and infections in childhood was conducted in a cohort of 50,002 men who attended Harvard College (Cambridge, MA) or the University of Pennsylvania (Philadelphia, PA) between 1916 and 1950 and who were followed in adulthood for morbidity and mortality data. Cases of Parkinson's disease were identified from responses to mailed questionnaires and death certificates through 1978. Four controls from the same population were selected for each case. A reduced risk of Parkinson's disease was associated with most childhood viral infections. The negative association was statistically significant for a history of measles prior to college entrance (exposure odds ratio = 0.53; 95% confidence limits: 0.31, 0.93). The reduced risk of Parkinson's disease among subjects with a positive history of measles in childhood may reflect an adverse effect of measles in adulthood or of subclinical or atypical measles. Furthermore, a negative history of measles, especially if associated with a lack of other common diseases, could be a marker for negative influenza history before 1918 and thus a higher risk of infection during the 1918 influenza epidemic, because of the lack of partial influenza immunity. These data may also suggest a truly protective effect of measles, compatible with some complex interaction between measles virus and the virus of the 1918 influenza epidemic."*

33a

Nat Commun. Author manuscript; available in PMC 2015 Mar 16.
Published in final edited form as: Nat Commun. 2014; 5: 4816.
Published online 2014 Sep 16. doi: 10.1038/ncomms5816
PMCID: PMC4167602 EMSID: EMS59800 PMID: 25226414

Conserved and host-specific features of influenza virion architecture

Edward C Hutchinson,[1,*] Philip D Charles,[1] Svenja S Hester,[1] Benjamin Thomas,[1] David Trudgian,[1,2] Mónica Martínez-Alonso,[1] and Ervin Fodor[1,*]

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4167602/ https://www.nature.com/articles/ncomms5816

"We show that a conserved influenza virion architecture is maintained across diverse combinations of virus and host. This 'core' architecture, which includes substantial quantities of host proteins as well as the viral protein NS1, is elaborated with abundant host-dependent features. Finally, we note that influenza virions share an underlying protein composition with exosomes…"

"Viruses can cause infected cells to produce virions"

"Viruses use virions to spread between hosts, and virion composition is therefore the primary determinant of viral transmissibility and immunogenicity."

"Host proteins, including those whose incorporation is species dependent, make a substantial contribution to influenza virion architecture."

"Influenza virions contain abundant host proteins." "Virion architecture is shaped by the host"

"Influenza virions share an underlying protein composition with exosomes, Influenza virions and exosomes share architectural features."

33b

Bacterial Microbiome Move Over: the Gut Virome Makes Its Debut – *Medscape* – Nov 19, 2014

Lara C. Pullen, PhD November 19, 2014 for publication details see reference 33c

https://www.medscape.com/viewarticle/835193

"A new study reveals that eukaryotic viruses are able to both shape mucosal immunity and support intestinal homeostasis in mice. Specifically, infection with murine norovirus (MNV) appears able to replace the beneficial function of bacterial colonization in the gut.

Scientists have long known that RNA viruses are commonly found in healthy infants and children, as well as in individuals recovering from acute gastroenteritis. Such viral infections have generally been assumed to be detrimental to the host. The new study turns that assumption on its head and hints that these viruses may play a role similar to that of the bacterial microbiome.

Elisabeth Kernbauer, PhD, from the New York University School of Medicine in New York City, and colleagues published the results of their murine study online November 19 in Nature. The investigators used germ-free mice that are microbiologically sterile, wild-type mice that had been treated with a cocktail of antibiotics, and mice whose gut tissue had been damaged by treatment with dextran sodium sulphate.

The new findings are the first strong evidence that viruses in the gastrointestinal tract can help maintain health and heal a damaged gut. Before this study, there had been very little investigation of the viruses that colonize the gut.

The team infected germ-free mice and antibiotic-treated mice with MNV and found that the infection triggered the repair of intestinal tissue damaged by inflammation, restored intestinal cell numbers, restored intestinal cell function, and normalized tissue architecture. The results were apparent after just 2 weeks of MNV infection.

Infection with MNV also helped restore the gut's immune system. The investigators do not yet know how the virus supports the immune system. They did find, however, increased signalling by antiviral type 1 interferon proteins, suggesting the virus was playing a key role in driving the immune response."

33c

An enteric virus can replace the beneficial function of commensal bacteria
Letter | Published: 19 November 2014
Elisabeth Kernbauer Yi Ding & Ken Cadwell
Nature **volume 516**, pages 94–98 (04 December 2014
https://www.nature.com/articles/nature13960
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4257755/

> *"Intestinal microbial communities have profound effects on host physiology1. Whereas the symbiotic contribution of commensal bacteria is well established, the role of eukaryotic viruses that are present in the gastrointestinal tract under homeostatic conditions is undefined2,3. Here we demonstrate that a common enteric RNA virus can replace the beneficial function of commensal bacteria in the intestine. Murine norovirus (MNV) infection of germ-free or antibiotic-treated mice restored intestinal morphology and lymphocyte function without inducing overt inflammation and disease. The presence of MNV also suppressed an expansion of group 2 innate lymphoid cells observed in the absence of bacteria, and induced transcriptional changes in the intestine associated with immune development and type I interferon (IFN) signalling. Consistent with this observation, the IFN-α receptor was essential for the ability of MNV to compensate for bacterial depletion. Importantly, MNV infection offset the deleterious effect of treatment with antibiotics in models of intestinal injury and pathogenic bacterial infection. These data indicate that eukaryotic viruses have the capacity to support intestinal homeostasis and shape mucosal immunity, similarly to commensal bacteria."*

34

The Trojan Exomes Hypothesis

https://www.pnas.org/content/100/19/10592.long
https://www.pnas.org/content/pnas/100/19/10592.full.pdf

35

including, videos:

"**what is an exome**"

https://www.youtube.com/watch?v=sE2krsErbwI&feature=youtu.be

and

"**The mammalian virome in genetic analysis of health and disease pathogenesis"**

https://youtu.be/TRVxTBuvChU

http://www.greenmedinfo.com/blog/why-only-thing-influenza-may-kill-germ-theory

36

Boycott AE.

The transition from life to death; the nature of filterable viruses. Proc. Royal Soc. Med. 1928;22:55-69.

37

Some examples of specific research demonstrating how microbes help us:

Bifidobacterium Bifidum is capable of degrading perchlorate.

> C Phillip Shelor, Andrea B Kirk, Purnendu K Dasgupta, Martina Kroll, Catrina A Campbell, Pankaj K Choudhary. **Breastfed infants metabolize perchlorate**. *Environ Sci Technol*. 2012 May 1 ;46(9):5151-9. Epub 2012 Apr 20. PMID: 22497505

Lactic acid bacteria strains isolated from the fermented cabbage dish known in Korean culture as kimchi were shown capable of degrading four different organophosphorous insecticides using these poisons as a source of carbon and phosphorus.

> ye Man Cho, Reukaradhya K Math, Shah Md Asraful Islam, Woo Jin Lim, Su Young Hong, Jong Min Kim, Myoung Geun Yun, Ji Joong Cho, Han Dae Yun. **Biodegradation of chlorpyrifos by lactic acid bacteria during kimchi fermentation** *J Agric Food Chem*. 2009 Mar 11;57(5):1882-9. PMID: 19199784
>
> Shah Md Asraful Islam, Renukaradhya K Math, Kye Man Cho, Woo Jin Lim, Su Young Hong, Jong Min Kim, Myoung Geun Yun, Ji Joong Cho, Han Dae Yun. **Organophosphorus hydrolase of Lactobacillus brevis WCP902 from kimchi is able to degrade organophosphorus pesticides**. *J Agric Food Chem*. 2010 May 12;58(9):5380-6. PMID: 20405842

Oral Saccharomyces boulardii, a beneficial form of yeast, has been found in an animal model to prevent oral polio vaccine-induced IgA nephropathy, a form of immune-mediated kidney damage. Additionally, probiotic bacteria have been found to positively regulate the two poles of immunity (TH1/TH2), which vaccines often upset by inducing hypersensitization via over-activation of the adaptive/humoral (TH2) pole of immunity

> Alper Soylu, Sema Berktaş, Sülen Sarioğlu, Güven Erbil, Osman Yilmaz, Belde K Demir, Yahya Tufan, Didem Yeşilirmak, Mehmet Türkmen, Salih Kavukçu. **Saccharomyces boulardii prevents oral-poliovirus vaccine-induced IgA nephropathy in mice.** *Pediatr Nephrol*. 2008 Aug;23(8):1287-91. Epub 2008 Apr 30. PMID: 18446380

Bifidobacterium breve and Lactobacillus casei have been found in the animal model to both reduce the intestinal absorption of BPA and facilitating its excretion.

> Kenji Oishi, Tadashi Sato, Wakae Yokoi, Yasuto Yoshida, Masahiko Ito, Haruji Sawada. **Effect of probiotics, Bifidobacterium breve and Lactobacillus casei, on bisphenol A exposure in rats**. *Biosci Biotechnol Biochem*. 2008 Jun;72(6):1409-15. Epub 2008 Jun 7. PMID: 18540113

There is evidence that the probiotic Bifidobacterium breve is capable of reducing the adverse effects on immune health induced by chemo-agents.

> Mariko Wada, Satoru Nagata, Masahiro Saito, Toshiaki Shimizu, Yuichiro Yamashiro, Takahiro Matsuki, Takashi Asahara, Koji Nomoto. **Effects of the enteral administration of Bifidobacterium breve on patients undergoing chemotherapy for pediatric malignancies**. *Support Care Cancer*. 2010 Jun;18(6):751-9. Epub 2009 Aug 14. PMID: 19685085

The bacteria known as Lactobacillus casei has been found to decrease the mucosal damage done by aspirin.

> Hiroki Endo, Takuma Higurashi, Kunihiro Hosono, Eiji Sakai, Yusuke Sekino, Hiroshi Iida, Yasunari Sakamoto, Tomoko Koide, Hirokazu Takahashi, Masato Yoneda, Chikako Tokoro, Masahiko Inamori, Yasunobu Abe, Atsushi Nakajima. **Efficacy of Lactobacillus casei treatment on small bowel injury in chronic low-dose aspirin users: a pilot randomized controlled study**. *J Gastroenterol*. 2011 May 10. Epub 2011 May 10. PMID: 21556830

Lactic acid bacteria extracted from kimchi have been found to degrade sodium nitrate.

> Chang-Kyung Oh, Myung-Chul Oh, Soo-Hyun Kim. **The depletion of sodium nitrite by lactic acid bacteria isolated from kimchi.** *J Med Food*. 2004;7(1):38-44. PMID: 1511755

Bifidobacteria may reduce the immuntoxic properties of gluten peptides by further degrading them into non-toxic peptides. Interestingly, the oral cavity has recently been found to contain bacteria capable of degrading gluten, indicating there may be other gluten-degrading microorganisms within the upper gastro-intestinal tract, and that thoroughly chewing your food would reduce the potential antigenicity/immunotoxicity of wheat gluten peptides.

J M Laparra, Y Sanz. Bifidobacteria inhibit the inflammatory response induced by gliadins in intestinal epithelial cells via modifications of toxic peptide generation during digestion. *J Cell Biochem*. 2010 Mar 1;109(4):801-7. PMID: 20052669

Eva J Helmerhorst, Maram Zamakhchari, Detlef Schuppan, Frank G Oppenheim. Discovery of a novel and rich source of gluten-degrading microbial enzymes in the oral cavity. *PLoS One*. 2010;5(10):e13264. Epub 2010 Oct 11. PMID: 20948997

Surrogate endpoints and Antibodies

38

Surrogate endpoint:

*In clinical trials, a **surrogate endpoint** (or **surrogate** marker) is a measure of effect of a specific treatment that may correlate with a real clinical **endpoint** but does not necessarily have a guaranteed relationship.*

*n clinical trials, a **surrogate endpoint** (or **surrogate** marker) is a measure of effect of a specific treatment that may correlate with a real clinical **endpoint** but does not necessarily have a guaranteed relationship.*

***surrogate** marker EBM A parameter (e.g., diastolic blood pressure) used to assess a drug's biological activity, which may serve as indicator of efficacy of a therapeutic agent, rather than a more serious but less common clinical **endpoint**, such as death.*

*The disease affects the **surrogate endpoint**, which in turn affects the definitive **endpoints**. Examples of **surrogate endpoints** include CD4 counts in AIDS patients, tumor size reduction in cancer patients, blood pressure in cardiovascular disease, and intraocular pressure in glaucoma patients.*

And in vaccinology, which is the science or method of vaccine development, vaccine effectiveness is often determined by the ability of a vaccine to increase antibody titers. Regulatory bodies, such as the US FDA and Australian TGA, often approve vaccines based on their ability to raise antibody titers, also known as "vaccine efficacy," without requiring proof of vaccine effectiveness in the real world.

Studies, however, call into question this theory: see reference 39

39

Research published in 2011 revealed that in some cases no antibodies are required for immunity against some viruses. Published in the journal *Immunity* in March, 2011, and titled, "**B cell maintenance of subcapsular sinus macrophages protects against a fatal viral infection independent of adaptive immunity [**Immunity. 2012 Mar 23 ;36(3):415-26. Epub 2012 Mar 1. PMID: 22386268]

https://www.ncbi.nlm.nih.gov/pubmed/22386268

40

The discovery that antibodies are not required for protection against infection is not unique, high levels have even been found in the presence of active, even lethal infections. For example, high serum levels of antibodies against tetanus have failed to confer protection against the disease. A report from 1992 published in the journal *Neurology* found severe tetanus in immunized patients with high anti-tetanus titers, one of whom died as a result of the infection. [**Severe tetanus in immunized patients with high anti-tetanus titers**. Neurology. 1992 Apr ; 42(4):761-4. PMID: 1565228]

https://www.ncbi.nlm.nih.gov/pubmed/1565228

41

Comparative efficacy of three mumps vaccines during disease outbreak in eastern Switzerland: cohort study

BMJ 1999; 319 doi: https://doi.org/10.1136/bmj.319.7206.352 (Published 07 August 1999)
Cite this as: *BMJ* 1999;319:352

1. *Matthias Schlegel, attending physician*[a],
2. *Joseph J Osterwalder, head*[b],
3. *Renato L Galeazzi, department chief*[a],
4. *Pietro L Vernazza, senior research fellow (*Pietro.Vernazza@kssg.ch)[c]

Author affiliations
1. [a] *Department of Medicine, Kantonsspital, 9007 St Gallen, Switzerland*
2. [b] *Emergency Department, Kantonsspital, 9007 St Gallen*
3. [c] *Institute for Clinical Microbiology and Immunology, 9001 St Gallen*

https://www.bmj.com/content/319/7206/352
https://www.bmj.com/content/319/7208/477 Corrections

Three mumps vaccines – Rubini, Jeryl-Lynn and Urabe (the one withdrawn because it caused encephalitis) all produced excellent antibody levels but those vaccinated with the Rubini strain had the same attack rate as those not vaccinated at all.

42a

For an in-depth discussion of how the virome is undermining classical, "us versus them" germ theory, watch **NIH lecture by Herbert W. Virgin, MD, PhD**. The Virgin laboratory formulated and proved the hypotheses that virus-plus-host-gene interactions define disease phenotypes. Mammals are best viewed as composite organisms in which the virome, and trans-kingdom interactions regulating and regulated by the virome, contribute to immunity, disease, and the genotype-phenotype relationship. Genetic analysis of disease risk, and the study of normal immunity, should incorporate consideration of the virome and trans-kingdom metagenomic interactions that control the virome:

https://videocast.nih.gov/summary.asp?live=16028&bhcp=1

https://oir.nih.gov/wals/2014-2015/mammalian-virome-genetic-analysis-health-disease-pathogenesis

42b

http://www.greenmedinfo.com/blog/germ-theory-more-theoretical-evidence-based
http://www.greenmedinfo.com/blog/how-microbiome-destroyed-ego-vaccine-policy-and-patriarchy

43

https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm

44

The State of the Evidence for Whole-System, Multi-Modality Naturopathic Medicine: A Systematic Scoping Review

The Journal of Alternative and Complementary Medicine 25(2):141-168 · February 2019
DOI: 10.1089/acm.2018.0340

https://www.researchgate.net/publication/331239381_The_State_of_the_Evidence_for_Whole-System_Multi-Modality_Naturopathic_Medicine_A_Systematic_Scoping_Review

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C S Lewis
Science as a Threat to Freedom in Modern Society
Edward J. Larson, University of Georgia and Discovery Institute
https://www.catholiceducation.org/en/culture/catholic-contributions/c-s-lewis-on-threats-to-freedom-in-modern-society.html

Consultation on complementary and unconventional medicine and emerging treatments

With respect, I submit that this consultation will best serve the interests of the Australian public by addressing these supplementary questions.

- **What constitutes unconventional medicine in Australia?**

The evolution of human healthcare involves various modalities and changeable theories. So called conventional, or western, medicine has a long and continuing history of recanting its conclusions and endorsing 'better' alternatives.

In the 21st c. terms like "unconventional medicine" are increasingly anachronistic, some may say hubristic. For instance, consider the Swiss government's decision to afford holistic medicine, homeopathy, herbal medicine, acupuncture and traditional Chinese medicine the same status as so called conventional medicine.[1]

- **Why do so many people choose to utilise supposed complimentary and unconventional medical care?**

Millions of Australians choose complementary or alternative, "unconventional" therapies. One common reason is an aversion to pharmaceuticals and their side effects. For many, the frequent ingestions of chemical compounds is unconventional and unsafe. Denying such people the freedom of choice is unlikely to alter their opinions about efficacious healthcare.

- **Has the Medical Board of Australia (MBA) reviewed all "clinical practice where concerns have been raised about insufficient information being provided to patients, inappropriate tests being ordered, inappropriate prescribing and inappropriate treatments being provided to vulnerable consumers"?**

The valid regulation of healthcare practise in Australia ought to prioritize and focus on any inappropriate clinical practices.

Abuse of prescription drugs in Australia requires urgent attention. In 2016 over 1,200 Australian were killed by these drugs: "About 550 of those deaths were related to prescription painkillers such as oxycodone, morphine and codeine (a 168 per cent rise in a decade) and 663 to tranquillisers and sleeping pills called benzodiazepines."[2] How is the MBA addressing this crisis?[3]

---

[1] https://aurumproject.org.au/3816-2/: https://www.swissinfo.ch/eng/society/complementary-therapies_swiss-to-recognise-homeopathy-as-legitimate-medicine/42053830, both accessed 22.02.19.

[2] https://www.smh.com.au/national/a-million-australians-abuse-prescription-drugs-20171218-h06rgu.html: accessed 21.02.19.

[3] https://www.sbs.com.au/news/the-feed/australia-s-addiction-to-prescription-meds-is-nearing-crisis-point: accessed 21.02.19.

The over prescription of antibiotics, at around nine times the recommend rate, is an equally disturbing practise.[4] As are the 'inappropriate', sometimes harmful, surgeries that increasingly waste healthcare expenditure. A recent analysis of 21 procedures by HCF "found up to 34 per cent of 32,900 admissions in 2016-17 were "low-value", unhelpful, and in some cases, potentially harmful".[5] Surely, these matters warrant MBA's urgent attention.

- **Does the MBA adequately represent the reality of healthcare practices throughout our society?**

In order to diligently serve Australians in the 21st c healthcare policy makers have a duty of care to undertake balanced deliberation, which necessitates engaging with the compass of what we Australians deem real and useful medical practises. A composed approach also tempers those who seek to impose the exclusive authority of a specific medical modality.

As for this consultation, it seems somewhat incongruous that the MBA announced a preferred outcome prior to the objective dialogue upon which that preference purportedly rests.

L.M.J. Coulson DipLangStud, BA (Hons), PhD

[4] https://www.smh.com.au/national/extreme-australian-gps-prescribing-antibiotics-at-up-to-nine-times-recommended-rates-study-finds-20170709-gx7p81.html: accessed 22.02.10.
[5] https://www.smh.com.au/healthcare/how-inappropriate-surgeries-are-pushing-up-your-health-insurance-premiums-20180829-p500gl.ht: accessed 22.02.19.

From: Jeremy Cowan [redacted]
Sent: Tuesday, 25 June 2019 12:49 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I want to go to my doctor and have CHOICE. It is really important to me.

I want ONE doctor (not 2, 3, 4) who can give me a holistic view of all natural, synthetic, other options to treat me. I want to work with that one person who knows me best to find the right natural solution with proven credentials OR a synthetic / lab made pharmacy drug for a specific treatment. I see myself as the patient (effectively customer) I want to go to my doctor and have all options open ….. I don't have time or knowledge to shop around to 2 or 3 or 4 different "specialists" each of whom are trying to push their own portfolio of solutions - that is not patient / customer centric approach.

I therefore fundamentally disagree with any action which would plan to impose greater regulation around the use of integrative, complementary and alternative medicines.

Thanks you

Jeremy Cowan

From: Sally Cowper [redacted]
Sent: Friday, 1 March 2019 9:30 PM
To: medboardconsultation
Subject: Integrative Doctors

To Whom It May Concern,

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice. As someone who regularly sees an Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from other doctors, I feel that his is an abhorrent limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

Sally Cowper

[redacted]

From: Neesa Craber [redacted]
Sent: Wednesday, 26 June 2019 5:08 PM
To: medboardconsultation
Subject: 'Consultation on complementary and unconventional medicine and emerging treatments'

Dear Sir,

I am writing about the very serious matter that has the potential to severely restrict the use of integrative medicine in Australia by the Medical Board of Australia.

I hereby dispute the plan to impose greater regulation around the use of integrative, complementary and alternative medicines (CAMs), which will significantly restrain the practice of integrative medicine and the use of CAM modalities.

I content that the Board's public consultation paper on "Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments" is born of prejudice and ignorance and, therefore, must be seriously challenged.

The proposal would see a split between conventional doctors and integrative medicine doctors. It would sanction doctors who use safe and effective integrative medicine in their day-to-day practice.

Integrative medicine doctors combine quality conventional medicine with safe and effective complementary medicine to improve health and reduce unnecessary medical treatments.

They embrace prevention as a first principle of healthcare, help manage complex illness and care for patients for whom conventional medicine has not assisted.

The Medical Board already has a strong code of conduct on good medical practice which sets out what is expected of all doctors registered to practice medicine in Australia.

The proposed new draconian regulation is simply unnecessary. It is nothing more than an attack on complementary and integrative medicine.

Furthermore, it is wrong for the Medical Board to group complementary medicine with unconventional medicine and emerging treatments. Complementary medicine is safe and has nothing in common with these treatments.

The Therapeutic Goods Administration has never been able to confirm a single death in Australia that directly resulted from using complementary medicine.

By contrast, it is estimated that there are around 650,000 hospital presentations/admissions every year due to medication-related problems.

Yours sincerely,
Neesa Craber

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

To: The Medical Board of Australia

From: Teresa Crisp

Telephone: [redacted]

E-mail [redacted]

Website: [redacted]

Date: 14/6/2019

Consultation

I, Teresa Crisp, appreciate the opportunity to participate in providing comments on the Medical Board of

Australia's recent public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

It is noteworthy the MBA has undertaken an open and transparent consultation with all stakeholders to allow a considered and impartial document to be produced. I support the MBA continuing with its current code of Good Medical Practice, rather than producing an additional guideline document as an outcome of this consultation.

Question 1 –I don't agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

• Grouping the practice of integrative medicine (IM) with phrases 'unconventional medicine' and 'emerging treatments' implies that IM is fringe rather than an evidence-based and vital adjunct within the practice of healthcare.

• Grouping three disparate areas together in this proposal – complementary, unconventional and emerging is not scientific, and incorrectly aligns each area with the same degree of potential harm or risk.

• The inclusion of the umbrella term 'complementary medicine' in the proposed guidelines without an accepted definition presents a further problem. Internationally-recognised and nationally accepted definitions should be used in the proposed document being consulted on by the MBA. The definitions should be agreed to be government and key stakeholders from representative industry bodies such as the Therapeutic Goods Administration (TGA), Complementary Medicines Australia (CMA), the National Institute of Complementary Medicines (NICM) and the Australasian Integrative Medicine Association (AIMA). Current definitions include:

Definition of complementary medicines by the Therapeutic Goods Administration (TGA)[1]

In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the Therapeutic Goods Act 1989.

Definition of traditional and complementary medicine by the World Health Organization (WHO)[2]

Traditional medicine (TM):

Traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary medicine (CM):

The terms "complementary medicine" or "alternative medicine" refer to a broad set of healthcare practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant healthcare system. They are used interchangeably with traditional medicine in some countries.

Traditional and complementary medicine (T&CM):

T&CM merges the terms TM and CM, encompassing products, practices and practitioners.

Definition of Integrative Medicine by Australasian Integrative Medicine Association (AIMA).[3]

Integrative medicine is a philosophy of healthcare with a focus on individual patient care. It combines the best of conventional Western medicine with evidence-based complementary medicine and therapies.

Integrative Medicine reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing.

It takes into account the physical, psychological, social and spiritual wellbeing of the person with the aim of using the most appropriate, safe and evidence-based treatments available.

• There are many definitions of "integrative" and "complementary" healthcare, but all involve bringing conventional and complementary approaches together in a coordinated way. These definitions should be considered to be harmonious with national and international terminology.

Question 2 –What is the definition of 'complementary and unconventional medicine and emerging treatments'?

• These terms 'unconventional medicine', 'inappropriate use' and 'emerging treatments' are not adequately defined which creates ambiguity and uncertainty.

• The term 'complementary medicine' also includes access to traditional medicines which is defined as a basic human right in Australia and by the World Health Organization.

• The amalgamation of three disparate groups into a single definition incorrectly implies they have many commonalities, which they do not. The only apparent component of the definition that provides cohesion is that the MBA sees these practices as non-conventional. This makes the definition political and therefore not scientific as it revolves around the concept of what evidence based medicine is in this age of evidence-based practice.

• More than two thirds of the Australian population use complementary medicines as a part of their self-care,[4] and it's estimated that one third of general practitioners incorporate some aspects of complementary medicine within their medical practice, therefore it could be argued that this constitutes current conventional medicine. The MBA would need to define conventional medicine to ascertain if this political definition has validity. The lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion.

• Complementary medicines, for the purpose of this consultation should be defined as, medicinal products containing such ingredients as certain herbs, vitamins and minerals, nutritional supplements, homoeopathic medicines and aromatherapy products and are regulated as medicines by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989.

• The terminology used should be nationally and internationally accepted, and agreed to amongst various industry stakeholders as outlined in response to Question 1. This assists in adopting a standardised process that can be transferred across different states and territories of Australia as well as internationally. Such standardised terms provides ease of communication across different frontiers.

Question 3 –I don't agree with the nature and the extent of the issues identified in relation to natural medicine practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

• There is no evidence produced in the discussion paper that quantifies risk or relative risk in practicing complementary medicines.

• Complementary medicines as defined in response to question 2, are regulated by the TGA and are low-risk under the therapeutic goods regulatory framework[5] and must be articulated separately from treatments or other alternative therapies for the purposes of this consultation.

• The reporting of Adverse Drug Responses (ADRs) via the Therapeutic Goods Administration shows that only 1% of ADRs are from complementary medicines, suggesting that the relative risk is low and does not warrant the proposed guidelines. These figures are reflective of similar patterns of adverse events reported in Singapore (considered by the TGA to be a comparable overseas regulator). According to a retrospective study of reported adverse events due to complementary health products between 2010 and 2016, only 0.6% were associated with complementary health products – with the remainder linked to chemical drugs, vaccines and biological drugs. This further reinforces the relative low risk of these forms of therapies.[6]

• The World Health Organization's Traditional Medicine Strategy 2014-2023 devotes attention to prioritising health services and systems including traditional and complementary medicine practices and practitioners.[7] Therefore the proposed guidelines could be perceived as being contradictory to the aims and objectives of the WHO strategy, violating the human rights of all Australians, particularly indigenous peoples.

Question 5 – Are safeguards needed for patients who seek complementary and unconventional medicine and emerging treatments?

• All aspects of the proposed guidelines are adequately covered through the existing "Good Medical Practice: A Code of Conduct for Doctors in Australia" as seen by the detailed analysis in Appendix 1,

performed by the Australasian Integrative Medicine Association (AIMA) and included in their letter to Dr Anne Tonkin on 20th March, 2019.

• The structure of the proposed guidelines which specifically divides the scope of intent into "guidance for all registered medical practitioners" and then "Guidance for registered medical practitioners who provide complementary and unconventional and emerging treatments' creates a two-tiered divisive system which is open to being challenged, onerous, restrictive and anti-competitive. This may in turn, impact service availability, additional costs to the patient, and restriction of consumer choice.

• A review conducted by the Australasian Research Centre in Complementary and Integrative Medicine, based at the University of Technology Sydney, determined that two thirds of complementary medicine users don't inform their healthcare provider about their use.[8] This was linked to the patient's perception of the level of knowledge and acceptance by their healthcare provider, and to their fear of being judged. By enforcing an additional set of guidelines the implication is that these therapies are 'unconventional' which could serve to further perpetuate this consumer concern. This in turn, presents safety implications whereby the lack of disclosure could lead to unwanted side effects, nutrient/herb/drug interactions, or reduced treatment effectiveness. These are all risks that can be easily managed if the patient feels comfortable and is encouraged to share their use with all of their healthcare professionals. As the code highlights there are many ways to practice medicine in Australia, reflecting a linguistically and culturally diverse society of which the core tasks of medicine are caring for people who are unwell and seeking to keep people well.

Question 6 – Is there other evidence or data that may help inform the Board's proposals?

There is additional concern that the proposed guidelines have not been developed in conformance with COAG principles for best practice regulation as there is no evidence presented in these guidelines on the 'magnitude (scale and scope) of the problem', there is no demonstration that the current guidelines are inadequate nor any cogent argument given as to the need for additional regulation. Also of concern is the Board's attempt to pre-justify a preferred solution stating 'the Board prefers Option 2'.

Conclusion

We support that the current regulation (i.e. the Board's Good Medical Practice) of medical practitioners who provide complementary and unconventional medicines and emerging treatments (option 1) is adequate to address the issues identified and protect patients. The proposed guidelines are unnecessary and provide no added value in terms of patient safety or clarity of practice for doctors.

I appreciate the MBA consideration of the points I have raised in this document and look forward to a positive outcome where the final document represents the comments and concerns from all stakeholders including those shared here.

1. Therapeutic Goods Administration. An overview of the regulation of complementary medicines in Australia. Available from: http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
2. World Health Organization (WHO). WHO traditional medicine strategy: 2014-2023. Geneva, Switzerland 2013. Available from http://www.who.int/medicines/areas/traditional/definitions/en/
3. Australasian Integrative Medicine Association. What is Integrative Medicine? Available from https://www.aima.net.au/what-is-integrative-medicine/
4. NPS Medicinewise, NPA Annual Consumer Surveys: Findings about complementary medicine use, 2008, available at: http://www.nps.org.au/about-us/what-we-do/our-research/complementary-medicines/npsconsumer-survey-cms-use-findings
5. Therapeutic Goods Administration. An overview of the regulation of complementary medicines in Australia. Available from: http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
6. Xu Y, Dhavalkumar N, et al. Retrospective study of reported adverse events due to complementary health products in Singapore from 2010 to 2016. Front Med (Lausanne) 2018;5:167.
7. World Health Organisation (WHO). WHO traditional medicine strategy: 2014-2023. Geneva, Switzerland 2013. Available from http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf
8. Foley H, Steele A, Cramer H, Wardle J, and Adams J. Disclosure of complementary medicine use to medical providers: a systematic review and meta-analysis. Scientific Reports. 2019:9; 1573.

From: alicia crowhurst [redacted]
Sent: Thursday, 21 March 2019 6:01 PM
To: medboardconsultation
Subject: Objection to stopping integrative medicine practices

To whom this concerns,

How can you possibly restrict access to complementary medicine and integrative medicine practices. People have a right to choose which health practices they would like.

What is one good reason for getting rid of it?

It's not all about the big pharmaceutical companies and people's lives depend on integrative medicine.

Don't be ridiculous and don't restrict access to complementary and integrative medicine.

How to make a submission to the MEDICAL BOARD of AUSTRALIA

Individually written letters carry far more weight than a copied format. We thus ask you to write your own submission and to:

Email it to medboardconsultation@ahpra.gov.au

Or mail it to The Executive Officer
Medical
AHPRA
GPO Box 9958
Melbourne 3001

NB Send as soon as possible. Submissions are due to close on the 30th of June 2019

We suggest that in your submission you should:

1 State your name and age and state of residency

2 Make known your interest and concern and preferred outcome. Issues that you may specifically wish to mention could include:

a. That you have used Complementary or Unconventional or Emerging Medicine and that you value its availability and are happy with its practice.
b. That your Doctor already provides discussion about options for treatment and their relative merits and potential problems.
c. That you value free choice in making your decisions over your medical treatment.
d. That your preferred choice of outcomes is:
    i. Option 1, retain the status quo
    ii. That if the Medical Board eventually decides to choose Option 2, for greater regulation, that it be modified from the current proposal, to ensure
        1. That it applies to ALL medical practitioners with the same onus of exhaustive exposition of all treatment options, research etc, and
        2. That the Board accept that Integrative Medicine, utilising Complementary or Unconventional or Emerging Medicine as well as conventional medicine, be recognised as a Speciality, in order to allow increased Medicare rebates to help cover the increased costs of fulfilling the new regulations.

3 Please do not state the name of your own Integrative Medical Practitioner

Signed by .....

Dated 28/5/2019

From: Samantha Curro [redacted]
Sent: Monday, 27 May 2019 12:04 PM
To: medboardconsultation
Subject: Re: Public Consultation on Complimentary and Unconventional Medicine and Emerging Treatments

Dear Sir/Madam,
Simply, I would argue that people have the right to choose and/or consider complimentary and/or unconventional medicine and/or emerging treatments when they and/or their care givers are properly notified of any potential risks and/or whether the risks are unknown and in circumstances where they can be properly monitored by a treating practitioner with adequate qualifications.
One would think more caution may arise with the treatment of individuals when potential risks of such medicines are unknown, however again the circumstances of these individuals and the choices available to them at the time may then become relevant.
Samantha Curro

From: [redacted]
Sent: Thursday, 4 April 2019 1:47 PM
To: medboardconsultation
Cc: [redacted]
Subject: Public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

Re: Public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

The Medical Board of Australia (MBA) has commenced a public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

Please be advised as to my concerns and **objection** to the new guidelines for 'complementary and unconventional medicine and emerging treatments.

There is a concern that if adopted, a two-tiered system may arise that threatens Integrative Medicine (IM) and unreasonably targets practitioners.

The adoption of these guidelines must be stopped. As they stand the guidelines could impact doctors, complementary practitioners, allied health professionals, pharmacists, compounding pharmacists and functional testing labs.

Concerns include:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based.
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty.
- That the term 'complementary medicine' also includes access to traditional medicines.
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs 'conventional' medicine.
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release.
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach.
- That the right of patients to determine their own medical care is under threat.
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints.

This is an issue I deeply care about.

Robbie Curtis

[redacted]

[redacted]

From: Sarah Curtis [redacted]
Sent: Saturday, 6 April 2019 8:13 PM
To: medboardconsultation
Subject: Re: Public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

Re: Public consultation on new guidelines for 'complementary and unconventional medicine and emerging treatments'.

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- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints.

This is an issue I deeply care about.

Sarah Curtis
[redacted]

From: David Cutlan [redacted]
Sent: Friday, 29 March 2019 9:02 AM
To: medboardconsultation
Subject: Submission to the Medical Board of Australia

Dear Sir

I am an [redacted]yo male who has lived on [redacted] for the past 25 years. I have been seeing my GP, for the whole time I have lived in the area. During this time, he has treated me for many conditions, including some which had the potential to be life-threatening, using a variety of Conventional, Complementary and Unconventional procedures, all of which have contributed to my continuing good health including overcoming some serious conditions which did not respond to purely conventional treatments.

I am extremely happy with the holistic nature of the treatment I have received from my GP over the many years I have been his patient and would be very concerned if he were not able to continue to use whatever medical methods are necessary for my continued well-being.

My GP always discusses proposed treatments for my conditions and the options available to me. In this way, I am able to make an informed decision whether or not to adopt the preferred treatment. He provides me with a hand-written summary of the matters discussed after each consultation.

My GP has been bulk-billing me the whole time I have been seeing him due to my being dependent on the basic aged pension.

I would urge you to maintain the status quo so that my GP can continue to attend to my holistic needs as he has done for the past 25 years.

If, for any reasons, the Medical Board of Australia chooses to change the regulations as they apply to GPs, I would prefer:

1. That is applies to ALL medical practitioners with the same onus of exhaustive exposition of all treatment options, research, etc., and
2. That the Board accept that Integrative Medicine, as well as conventional medicine, be recognized as a Speciality, in order to allow increased Medicare rebates to help cover the increased costs of fulfilling the new regulations.

Kindest regards

David Cutlan
[redacted]