From: Martin Quinlan [redacted]
Sent: Wednesday, 3 April 2019 8:06 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I believe that the proposed new regulations are wrong and that option one should be adopted.

I feel that in the proposed new regulations you would label many eminent doctors as being in error and hold them up to public ridicule or question.

Please refer your proposal to such organisations as Solaris Care, the Cancer Council and the Peter MacCallum Cancer Centre. Also refer to the volume of literature in the role of complimentary medicine in cancer care and other complaints both here and abroad.

Would you put labels such as proposed on Dr [redacted] of [redacted]?

If your proposal goes ahead I foresee many challenges to it and a groundswell of public reaction that will end up causing you grief.

By all means protect the public from Charlatans but take care that you do not deny the public from treatments that work in alleviating stress and side effects of their treatment. In the same vein be careful not to deny possible emerging treatments that may offer relief or maybe a cure to medical problems.

Kind Regards

Martin Quinlan

From:	Emily Radclliffe
To:	medboardconsultation
Subject:	'Public consultation on complementary and unconventional medicine and emerging treatments'
Date:	Thursday, 27 June 2019 9:01:24 PM

I prefer Option 1 and I support the reasoning outlined in the submission from ACNEM.

Dr Emily Radcliffe
GP
[redacted]

W. L. RANKEN
[redacted]

Monday, April 1, 2019

The Executive Officer, Medical,
AHPRA,
GPO, Box 9958,
Melbourne, VIC 3001

medboardconsultation@ahpra.gov.au

Dear Sir or Madam,

Consultation on Complementary and Unconventional Medicine and Emerging Treatments

Thank you for the opportunity to provide feedback on the issues and options outlined in the discussion paper. My feedback and recommendations are below.

I am concerned about a number of aspects of the discussion paper and the proposed action.

I recommend that no further action be taken to implement Option 2 for practice specific guidelines, and that the status quo be retained.

There is a serious risk in my opinion of unintended adverse health risks and consequences for some 13 million Australian consumers of the subject products and treatments.

In my respectful opinion the discussion paper does not provide sufficient evidence of the need for change based on the potential health economics benefits and costs of change, and in particular the paper does not give evidence that existing law, regulation and guidance in the subject areas are inadequate, dangerous or harmful.

In fact in the Statement of Assessment at page 2, paragraph 3A, the Board states: "The proposed draft guidelines do not propose significant changes to the current ethical and professional standards of conduct expected of medical practitioners and they complement the principles contained in the Board's current code of conduct 'Good medical practice: A code of conduct for doctors in Australia'."

It would seem to me that if there are "no significant changes", then it is difficult to support an argument for any change at all, especially without clear evidence on prevalence, severity and cost/benefit.

Will the Board's proposed action deliver demonstrable net health economics benefits to the whole community? The evidence provided does not seem to answer that question. Therefore, it is difficult to understand how a considered and prudent decision can be made at this time.

The five facts and other grounds in support of my recommendations are as follows:

1. Option 2 likely will reduce the capacity of practitioners to minimise harm, and thereby create a risk of more harm being incurred in the wider community. In other words, the community wide costs of Option 2 likely will exceed the benefits, by a large margin.

    a. Option 2 likely will reduce the number of practitioners who are willing or able to give any advice at all to patients regarding the subject treatments; thereby creating unintended adverse consequences for community wide health.
    b. This is because the practical effect of Option 2 likely will be to cause a large number of practitioners to cease giving any advice on the subject treatments - because of the additional costs and obligations involved in giving such advice. (Those who do choose to give such advice likely will incur considerable additional costs and time to comply with the administrative and other requirements of Option 2.)
    c. The resulting likely reduction in the willingness and capacity of many practitioners to advise patients on these matters likely will leave such patients "in the dark", without access to those who otherwise might warn them of potential harm.

2. The Board will be aware that there are large numbers of patients with chronic illnesses that can only be treated symptomatically. Such patients include those with life threatening illness and severely debilitating chronic conditions. Many such patients seek alternative approaches to symptomatic treatment.

    a. I have had personal experience of a senior physician advising that, 'by all means pursue any alternatives, but please ring me first and I will advise if I think it might harm you'. On page 16 of the discussion paper it is noted that the Oncology Society encourages practitioners to have such conversations with patients. Does the Board wish to inhibit the capacity of practitioners to have such conversations and give such advice?

3. The number of patients potentially adversely affected by this likely loss of practitioner advice is large, and indicates the significant potential for community wide adverse consequences.

    a. On page 6, the discussion paper notes that more than two thirds of consumers report using these medicines, and that annual sales in Australia are $3.5 billion.
    b. Two thirds of consumers are more than 13 million Australians, counting only those 16 years and over (ABS 3235). If Option 2 has the unintended outcome of making it more difficult for these 13 million consumers to obtain practitioner advice on the subject treatments, then the scale of harm which may be done is very large, and I submit should be very carefully considered before Option 2 is implemented.
    c. Another indication of the level of consumer interest in these products is the fact the sales of Blackmores products in Australia have grown dramatically over ten years. Growth in sales has been three times the rate of inflation over the ten years to 2018. This provides further evidence of the strongly growing level of

consumer interest in these products and hence the increased community wide need for trusted health advice.

4. Option 2 also seems unnecessary. It seems to me that existing law and regulation provide more than adequate guidance, protections and definitions (in the National Law) of 'professional misconduct', 'unprofessional conduct' and 'unsatisfactory professional performance' to ensure that all practitioners offering the relevant advice or treatments already are obliged to provide satisfactory professional advice, conduct and performance.

    a. In fact in the Statement of Assessment at page 2, paragraph 3A, the Board states: "The proposed draft guidelines do not propose significant changes to the current ethical and professional standards of conduct expected of medical practitioners and they complement the principles contained in the Board's current code of conduct 'Good medical practice: A code of conduct for doctors in Australia'." It would seem to me that if there are "no significant changes", then it is difficult to sustain an argument for any change at all, especially without any evidence on prevalence, severity and cost.

5. The case for additional regulation does not seem to be supported by adequate evidence, particularly community wide cost benefit analysis or health economics.

    a. Pages 6 – 12 of the discussion paper cite a number of potential harms which may be done by the use of the subject practices and some examples. No data is provided on community wide prevalence, severity or cost of these harms. Given the number of consumers involved, at some 13 million, it seems to me that the number of actual harms cited in the paper is very low. Moreover, there is no evidence cited as to the prevalence, severity or cost of those harms in the community.
    b. However, all appears speculation in the absence of proper research and evidence. It would be most unfortunate if the Board were to make a decision to change the rules without proper evidence, especially given the number of consumers involved, and given that a major concern about the alternative therapies is lack of evidence.

In conclusion I would like to thank you for taking the time to consider my feedback, and to pose a rhetorical question for you:

Will the Board's proposed action deliver demonstrable net health economics benefits to the whole community? The evidence provided does not seem to answer that question. Therefore, it is difficult to understand how a considered and prudent decision can be made at this time.

Yours Faithfully,

W. L. Ranken

From: [redacted]
Sent: Thursday, 27 June 2019 8:33 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

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 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.
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.
I also believe that the right of patients to determine their own medical care is under threat.

regards
Andrew Rayner

Submission to Medical Board

Dr James Tom Clarence Read

MBBS FRACGP MPH (Nutrition) FARGP FACNEM

JCCA Accredited GP Anaesthetist

Faculty Member and Ex Vice President of ACNEM

Ex Board Member Karl McManus Foundation

Questions for consideration

The Board is inviting feedback on the issues and options outlined in the discussion paper.

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?

The 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

This definition is so broad as to serve to include anything a specific practitioner or the medical board is personally uncomfortable with, does not agree with or has an objection to whether this objection is founded in science, personal experience or bias. There is no definition of what conventional medicine is and what body decides what is conventional and what is not. This is clearly open to misuse by organisations where there is a political bias against certain approaches where they may be perceived as a threat to the established paradigm, power base or dogma of a certain group. The various definitions of complementary medicine in the Medical Boards consultation paper document alludes to the potential for political bodies such as the AMA to define health care as anything that their hierarchy consider as alternative to their conservative approach. The AMA, NHMRC, the College of Physicians and Surgeons of Ontario and the Clinical Oncology Society Australia all refer to complementary health being not conventional medicine without referring to what *Conventional Medicine* is. The WHO definition of complementary medicine as practice *not integrated into the dominant health care system* alludes to the fact that there are **dominating** health care systems which do not necessarily relate to patient or community needs, or to an evidence base. To truly examine the danger in differentiating complementary medicine and unconventional medicine from conventional medicine based upon this definition we must deeply explore what this means how it can be misinterpreted and the surrounding biases.

As an example of how a dominating health care system /conventional medicine will have unique biases which cause a failure to integrate evidence based alternative care I will examine a case related to mainstream anaesthetic practice. When recently attending an Anaesthesia conference in [redacted] I was shocked to learn that the use of Nitrous Oxide in labour was considered controversial and alternative to the "conventional'' medicine use of either opiates or epidurals only. There was a perception that it was dangerous, not evidence based and driven by midwives and hospital administrators trying to attract more patients. This despite the fact for over 25 years it has been

considered part of ''conventional'' practice in Europe and Australia, and although less efficacious than epidurals has a strong evidence base and long track record of being safe, efficacious and having very high levels of patient satisfaction as an intrapartum analgesic. I was even more shocked to learn that the objection of many of the anaesthetists seemed to relate to the fact that the use of nitrous oxide might be a threat to their income base from putting epidurals in. The speaker who despite being progressive and was supporting the use of Nitrous was still at pains to inform his anaesthetic colleagues that they did need to be concerned as the use of Nitrous oxide did not reduce the epidural rate. In-spite of being an advocate for the appropriate use of epidurals from my experience as both a GP anaesthetist and GP obstetrician I was concerned that a healthcare system could be embracing increased levels of need for an intervention as being a good thing rather optimum patient outcome. The US anaesthetists at the conference were good and caring physicians who cared about their patient outcomes and keeping up to date with evidence. Yet despite this they had an objection to an evidence based safe and established therapy for which there was a patient driven demand, supported by an alternative competing group of health practitioners (midwives) who would provide the service. This objection was because Nitrous oxide use was inconsistent with the doctors "tradition of practice'', their paradigm and at least subconsciously was a threat to their clinical role and financial wellbeing. This is an example of how ''conventional'' medical care may be biased by a paradigm which may have underlying political and financial motivators.

The acceptance of the medical board's definition supporting the acceptance of our current version of ''conventional'' care over and above other forms of care is fraught with ethical, moral and legal issues. There are numerous traditions of ''conventional medicine'' around the world where a different mix of traditions of health care and science/ evidence-based care are practiced. In China modern western based medical and surgical practice is practiced along-side well established safe traditions of traditional Chinese medicine and acupuncture which are being supported by an ever-increasing scientific evidence base. Simply type acupuncture in to Pubmed and there are 30289 hits displaying the extensive scientific basis for these interventions albeit based upon paradigms very foreign to our own. The investigation of Chinese herbal medicines artemisinin/ artemisia from Chinese wormwood led to the identification of the active compounds responsible for powerful anti-parasitic medications and the worlds currently most efficacious anti-malarial medications such as Riamet and artesunate. These discoveries led to the awarding of a Nobel Prize in Medicine to the respective researchers, and development of patented drugs but the traditional herbal medicines are still being used safely and efficaciously in China as they have been for hundreds of years. These are consequently part of conventional medical practice of 1/8 of the world's population and one of our fasting growing ethnic groups.

Having had the opportunity to be an invited speaker to a Nutritional Medicine Conference in India I was witness to the integration of Nutritional and Environmental Medicine, with traditional Ayurvedic Medicine and Western Allopathic Medicine including mainstream surgical and medical therapies in patient focussed evidence-based care. In a multicultural society such as Australia is it ethical to require a different expectation of level of evidence for other conventions of medicine that are different to our own tradition of "Conventional Medicine".

What further harms will be done to those already disempowered indigenous Australians by creating barriers to discussion of their traditional medicines as potentially efficacious tools as we are unfamiliar with their traditional use or evidence base as they are not part of our Medical Convention. I recall a medical colleague when we worked together in an Aboriginal Community Controlled Health Service validating the efficacy of numerous traditional medicines for skin sores as part of his Master of Public Health thesis. This knowledge despite being both based in traditional use, supported by local communities and evidence based is still not incorporated into *Conventional Medical* care even in the communities it has originated. In these communities the conventional doctors come and go and apply their ''conventional medicine'' therapies based on outdated or locally inappropriate 'Evidence based therapeutic guidelines to ever diminishing efficacy. In the face of different local patterns of antibiotic resistance. From a career spent working in Indigenous Health I have watched perpetuation of harm from application of the conventional medical guidelines not adapted to the local community. For years flucloxacillin was the therapeutic guidelines recommended anti-microbial for skin sores yet rates of MRSA in indigenous communities rendered it ineffective. Years later guidelines caught up and recommended considering cotrimoxazole which we had been using off guidelines and off label for an extensive time. Meantime, the evidence based local traditional remedies were being ignored by health

practitioners and rates of post streptococcal glomerulonephritis, skin sores and rates of rheumatic fever were some of the highest in the world. Who are we to impose our version of conventional medicine and worldview on to the world view of indigenous Australians.

The whole concept of health is different in different cultures and our western ‘’medical convention’’ continues to ignore the very meaning of health to those from other cultures particularly indigenous Australians. The WHO definition of health is *‘’a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity* ". Unfortunately, this concept of health is generally ignored by our imposition of our bio-medical model of ‘’evidence based’’ conventional medical care onto communities where the relevant research has not been performed nor does it apply. Yes, haemodialysis improves outcomes in renal patients but when an indigenous Australian is removed from their land community and culture the very foundation of their health (physical, mental and social well-being) and sent thousands of kilometres from their traditional homeland in the Kimberley to Perth for 3-6 months before being able to return to the Kimberley for more locally accessible dialysis does any of this evidence apply. Are we forgetting the ground-breaking work of Marmot demonstrating that most illness was not merely caused by proximal biomedical risk factors but rather the result of a complex interaction of underlying social and environmental factors? Biomedical factors such as dyslipidaemia and blood pressure are less significant than the underlying social and environmental determinants of illness which in the case of indigenous Australians run as deep as cultural and spiritual dispossession (loss of connection to culture, country and sense of meaning and purpose). Very little of these social environmental determinants come into the paradigm of Conventional Medicine. Does our biomedical model of conventional medicine have any consideration for the need of patients to have their traditional belief systems respected for them to maintain their health in the most holistic sense as defined by the WHO? Their version of wellbeing may be the need to choose to be die in country surrounded by loved ones rather than in a remote renal ward thousands of kilometres away. Similarly, health and well-being for all patients means having their need for spiritual care to be respected, whether it means to pray with their doctor in a consultation or to access energetic medicine such as Reiki which is consistent with their spiritual belief system.

Combining this biomedical bias of conventional medical practice with a different standard of scrutiny (as suggested by Option 2) for those providing alternate more holistic approaches to healthcare to those providing conventional biomedical care has the potential to impair the communities basic human right to freely access health care consistent with their own model of health. Barriers to accessing care which incorporates all the WHO considerations of what health is has the potential to greatly discriminate against other cultures and traditions. Similarly, it discriminates against those in Anglo-European cultures who may seek out more lifestyle and natural approaches to their health care such as nutrients, herbs, psychological and spiritual support.

The significant demand for holistic and complementary healthcare from a community perspective is illustrated by the size of the associated industries. The global complementary and alternative medicine market size is expected to generate a revenue of USD 210.81 billion by 2026, according to a new report by Grand View Research, Inc. Even acknowledging there may be influence of marketing and advertising, this industry must largely be driven by community demand and consequently reflects community needs and expectations. The established conventional medicine industry is also influenced by other non-community and patient focused factors including research and education funding by the pharmaceutical industry, pharmaceutical reps etc. There is a strong evidence base to suggest that conventional medical/ pharmaceutical industry influences Clinical guidelines beyond the existing evidence base and contributes to a publication bias. Consequently a Medical Board policy that differentiates scrutiny and regulation of provision of care that is holistic and integrates a model of health consistent with the WHO definition to a separate higher level of regulation to the conventional Biomedical model must be considered discriminatory and a threat to a basic human right to access health care.

The potential significant discrimination against both communities and healthcare providers whose paradigm extends beyond the biomedical paradigm when combined with the very broad definition of medical practice the potential for significant oppression of alternative belief systems is extreme. The medical board consultation document defines medical practice beyond clinical to include research, education advocacy and even policy development.

*('**Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.)*

Consequently, as a healthcare provider I may end up in front of the medical board under a different level of scrutiny for even doing research on spiritual aspects of health care, for educating medical students about cultural safety because it is presumed to be not evidence based. Most frightening is that advocacy for patients right to access alternative approaches care can be regulated in a different manner to advocating for conventional drug related care. Is it morally or ethically right to have a different level of regulation on advocacy or research on areas that are considering non-conventional in a biomedical model? Can I be called up to the medical board for advocating for my aboriginal patients having their worldview respected or for a Chinese patient with advanced cancer to be able to access their traditional herbal medicine or acupuncture in hospital because the Oncologist does not believe in Acupuncture and reports me to AHPRA. Is it ethical to restrict a GP obstetrician rights to advocate for a patients right to have essential oils used topically or a Reiki practitioner present during her normal in hospital delivery so long as it does not do harm nor provide a barrier to accessing mainstream care, The fact that there may not be a strong evidence base or that I and most doctors have no knowledge of the evidence base or lack thereof of these modalities as we have not screened the relevant literature is irrelevant. At what point can I not advocate for patient centered care and shared decision making. Can I not support a patient's right to pray for their loved ones in a waiting room or a chapel in a hospital or does this require a different level of regulation as it is not evidence based. THIS IS TERRRIFYING and is a potential afront to religious freedoms, cultural freedoms and basic human rights to accessing health (*physical, mental and social well-being)* -care.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice,[2] 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?

The AIMA definition of complementary medicine is perhaps the most accurate of those in the Medical Board document *: a philosophy of healthcare…combining the best of conventional western medicine and evidence-based complementary medicine and therapies within current mainstream medical practice (Australasian Integrative Medicine Association).*[3]

Perhaps a more comprehensive definition or understanding is required. Complementary medicine is the practice of health care that complements western allopathic biomedical medicine and that provides a broader more holistic provision of health delivery than a biomedical approach alone. It addresses a broader definition of health acknowledging the need to provide patient centered health care in a shared decision-making context that addresses the physical, emotional, social, cultural and spiritual aspects of human wellbeing. It is guided by a scientific evidence base but also how this evidence base applies to the communities and individual patients it serves. It respects patient's belief systems, multiple cultural traditions of health care and the use of all resources available including but not limited to lifestyle change, environmental medicine, nutritional medicine, herbal medicine, traditional medicines including Chinese medicine and acupuncture, ayurvedic medicine and traditional indigenous medicines, manipulative musculoskeletal and body therapies including massage,

psychological, emotional and spiritual support, hypnotherapy, meditation visualization and mindfulness training, biofeedback such as neurofeedback, hyperbaric medicine, energetic and electromagnetic therapies: ranging from radiotherapy and ECT to scrambler therapy, pulsed electromagnetic frequency therapy, deep brain stimulation, TENS, nerve stimulators, light and phototherapy and transcranial magnetic stimulation.

3. [1]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 As per all therapeutic there will be some individual cases of harm. However many of the cases reported as issues to Medical Boards where restrictions have been placed on practitioners include the practice of healthcare where there is a reasonable evidence base to support use that is not widely known to the broader medical establishment and does not acknowledge the extensive benefit that other patients who have utilised these complementary and alternative therapies have benefited from but rather focusses on the limited number of cases of harm.

It is naïve to think traditional allopathic conventional medicine does not require the same degree of regulation or scrutiny as complementary health care. In a 2007 review of iatrogenic illness on internal medicine of the 445 patients included in the study 22.9% developed 121 iatrogenic events (Madeira, Melo et al. 2007). Forty-four patients were admitted for iatrogenic illness, (9.8%) developed life-threatening events, and in 6.8% iatrogenic conventional medicine was the cause of death. Eighteen percent of all iatrogenic disease was severe, 61.9% predictable, 54.5% avoidable, and 59% drug-related, 80% of which was due to side effects or adverse reactions. Infection and metabolic and electrolyte disorders were the most frequent effects. A 2018 study of over 4800 patients admitted to internal medicine wards in Sicily found that over 6% of admissions were due to adverse drug reactions and that in over 3% of hospital admissions a new adverse drug reaction occurred (Giardina, Cutroneo et al. 2018). If the development of iatrogenic illness from conventional medicine resulted in the degree of scrutiny by medical bodies such as this medical board submission it is unlikely that we would use opiates, aspirin, antibiotics, chemotherapy, radiotherapy anaesthesia or even perform surgery.

Because conventional medicine is broadly accepted without scrutiny by the dominating health care system complementary medicine which by the WHO definition is not integrated into this system is already under a higher degree of scrutiny. As adverse events are a part of all healthcare inadvertently some complementary health care practices will be associated with adverse events whether related and causative or just by coincidence. When a conventional medical practitioner identifies this the incident is much more likely to be reported to the HCCC or AHPRA as it is an affront to their paradigm and it is easy to blame the unknown. This is almost a form of medical xenophobia. However, when complications occur as a direct result of conventional care this is dismissed as a result of being routine practice irrespective of the appropriateness of the medical intervention or the evidence base. The individual cases that have triggered this process of creating a higher degree of scrutiny on complementary care given the incredibly high rates of iatrogenesis reported above.

This would be all very well if our conventional medicine was truly based on a foundation of unbiased evidence-based care in contrast to an alternative non evidenced based complementary paradigm we seemed to be so threatened by. However, neither of these perceptions held by the conventional medical fraternity is true. All cultures and systems of thinking inherently have a cultural bias which they are blind to. [redacted] I have been brought up in a scientific paradigm [redacted] I am a strong believer for the application of science and evidence-based health care in science. However, we must combine this with the art of medicine where we apply this science to the patient in front of us and their individual situation as part of patient centred care and shared decision making.

Unfortunately, as is the case with almost all paradigms as a profession we fail to see the limitations of our perception that our version of conventional medicine incorporates all evidence-based health care and is based entirely on evidence-based practice. We fail to practice metacognition (thinking about

the way we think) having been indoctrinated into a certain way of thinking. One does not need to look to far to find scientific evidence in the peer reviewed literature which suggests otherwise. In terms of our perception that our ‘’conventional medicine is evidence based’’ let us us examine some evidence.

The Institute of Medicine in the USA estimates that 50% of routine medical practice is not evidenced based and despite this lack of evidence 90% of this practice is supported by moderate or strong consensus (Johnson and Stricker 2004). For example, the use of adrenaline in anaphylaxis or cardio-pulmonary resuscitation is not supported by controlled trials. Mainstream medical practice is dominated by guidelines and practice that are not supported by high quality evidence. A review of evidence underlying the ACC/ AHA clinical practice guidelines in JAMA in 2009 illustrate this point (Tricoci et al 2009). Only 314 of 2711 recommendations are supported by evidence of category A evidence and only 245 of the 1305 recommendations considered to be based on high quality level 1 data have strong evidence i.e. category A.

The medical profession is generally slow to take up new evidence-based practices particularly when it means giving up a significant part of a professions bread and butter workload to alternative health care providers. Let us examine this in the context of several common medical conditions. Firstly, let us examine operative and non-operative management of appendicitis. Most patients treated with antibiotics respond clinically with a reduction in white blood cell count (Eriksson et al 1995), avoidance of peritonitis (Vons et al 2011), and general symptom reduction (Hansonn et al 2009, Styrud et al 2006, Turhan et al 2009). Compared with those who underwent immediate appendicectomy, patients treated with antibiotics have lower or similar pain scores (Vons et al 2011, Hansonn et al 2009 Eriksson et al 1995), require fewer doses of narcotics (Eriksson et al 1995), have a quicker return to work (Hansonn et al 2009, Eriksson et al 1995), and do not have a higher perforation rate. Approximately 90 percent of patients treated with antibiotics are able to avoid surgery during the initial admission. The other 10 percent that fail to respond to antibiotics require a rescue appendectomy. Approximately 70 percent of those successfully treated with antibiotics during the initial admission are able to avoid surgery during the first year. The other 30 percent eventually require appendectomy for recurrent appendicitis or symptoms of abdominal pain (mean time to appendectomy 4.2 to 7 months (Vons et al 2011, Eriksson et al 1995, Styrud et al 2006). Follow-up data beyond the first year is available for one of the six trials. No patients suffered a major complication. Compared with the antibiotic group, the appendicectomy group had a higher five-year overall complication rate (24.4 versus 6.5 percent), required a longer sick leave (by 11 days), and had the same length of hospital stay. Given the both increased short and long-term complication rate of surgery it would appear reasonable and ethical to inform patients of this evidence and of the relative high recurrence rate to allow a patient centered care shared decision-making process. Yet in almost 20 years of work as a rural GP anaesthetist I am yet to observe this conversation.

It is naïve to think that the conventional medicine is based upon the best evidence and not biased by our traditions, experience and a need to feel that what we are and have been doing is the right thing. It is natural for all people to protect their paradigm and ego related sense of purpose. One does not have to look far to see that the papers resisting a non-surgical approach to appendicitis are coming from surgeons with vested interests in continuing to operate. Similarly, the papers supporting radiotherapy for prostate cancer are supported by the radiation oncologists just as their urological colleagues tend to support advancing surgical approaches such as robotic prostatectomy. Almost all medical specialties have examples of this. In orthopaedics arthroscopy has been used in patients with knee osteoarthritis despite lack of evidence for outcome benefit. In cardiology patients without ongoing cardiac symptoms who are worked up from a single event that may have been coronary artery related are given angioplasty and drug eluting stents. This occurs despite no evidence of improved outcome compared to medical management alone, no ongoing symptoms to justify insertion and significant risk to patient and implications due to the need for dual anti-platelet therapy and both bleeding and anaesthetic implications. This is however accepted as part of conventional medical care and is quite lucrative for interventional cardiologists. All health care should scrutinised and if anything conventional care should be scrutinized more closely because it is followed due to convention not evidence.

Another example of the bias of conventional medicine to integrate evidence-based therapies whose use initially began beyond the established medical convention is our failure as a profession to integrate evidence base use of probiotics into our practice. The science supporting probiotic use in a

variety of clinical conditions is voluminous and includes numerous Cochrane reviews and numerous systematic reviews of randomized control trials in several clinical conditions the existence of evidence-based data bases such as probioticadvisor.com. As an example, the use of probiotics for the prevention of antibiotic associated diarrhoea has been the subject of systematic review of randomized controlled trials. Over 12 years ago McFarlands 2006 review of probiotics reported on Metanalysis of 25 RCTs where specific probiotics reduced the risk of antibiotic associated diarrhoea with a relative risk of 0.43 and a p value < 0.001 and systematic review of probiotics in eradication of H Pylori includes 7 metanalyses with over 10000 patients all of which support higher eradication rates when standard therapy is combined with probiotics. Further to this, probiotics have been the subject of numerous Cochrane reviews which support their use as having clinically meaningful evidence-based benefits. For example, the Cochrane review into the use of probiotics in acute infectious diarrhea concludes: *Used alongside rehydration therapy, probiotics appear to be safe and have clear beneficial effects in shortening the duration and reducing stool frequency in acute infectious diarrhoea. However, more research is needed to guide the use of particular probiotic regimens in specific patient groups*

One would think that this would mean that probiotics would be part of established conventional medicine and be included in all hospital ward stock and pharmacies to be dispensed to the large number of hospital inpatients having antibiotics. However, in the over 20 public hospitals I have worked in as a rural GP anaesthetist in the last 5 years in 3 Australian states I am yet to find a hospital that offers any evidence based probiotic use and the vast majority of my colleagues working in Emergency departments do not recommend probiotics to the patients they prescribe antibiotics. Further to this most of the both medical students, Junior doctors and both ED and GP registrars consider probiotics alternative or complementary medicine and are oblivious to the strong evidence base. Consequently what the ''Dominant Health System'' would consider as non-conventional medicine as the WHO defines complementary medicine is in fact strongly evidenced based but ignored due to our subconscious bias against therapies that appear to have been driven initially by the natural medicine practitioners and are not considered as drugs. Consequently the NSW Medical Board definition of complementary medicine as being ''non-evidence based care ''(Medical Council of New South Wales, 2015) appears to be in direct conflict with the evidenced based care such as probiotics which by the majority of definitions in the preamble to the Medical Board submission document including that of the WHO is defined as complementary medicine

It is concerning that the medical boards that are likely to oversee the regulation of complementary health care including doctors right to educate, research and advocate in this area own definition of what the broader profession considers to be complementary health care is that it is non-evidence based. The lack of understanding and inherent bias against complementary health care by the medical boards and the profession at large is reflected in the Submission document and all the broad inclusions that require a greater level of scrutiny and regulation than the profession at large including regulated health professions of chiropractic, osteopathy, Chinese medicine and acupuncture. Other areas of clinical practice where concerns have been raised but which do not fit within the definitions of complementary and/or alternative medicine as defined above, include: diagnosis of conditions which are not generally accepted, for example: Lyme disease (in patients who have not been outside Australia)

Consequently, deviation from standard practice should not be considered medical heresy if supported by the best available evidence and accompanied by informed consent. Unfortunately, the history of medicine and science is full of cases where new ideas were rejected and ridiculed by the established and revered experts. The ideas that Helicobacter Pylori caused gastritis, smoking caused lung cancer and that elevated cholesterol levels are a risk factor for heart disease were all initially rejected by the experts. Disagreeing with the establishment should not be considered dissent or punished but rather the natural process of good science. It is concerning that the Medical Board should consider that such a broad range of progressive healthcare should require a degree of scrutiny, a greater level of regulation or require additional guidelines than the existing Good medical practice: A Code of Conduct for medical practitioners

No ideas should ever be fixed. Even Sir Isaac Newton one of the world's greatest ever physicists held back the wave theory of light for 30 years and this only was accepted after his death. The famous scientist physicist Max Planck who pioneered quantum physics stated that "A new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die, and a new generation grows up that is familiar with it." In short, science

moves forward with its funerals. I hope we can change this but unfortunately this is not currently the case with tick borne illness in Australia. He also stated “New scientific ideas never spring from a communal body, however organized, but rather from the head of an individually inspired researcher who struggles with his problems in lonely thought”. This describes the isolation of the clinicians and researchers willing to adopt the non-accepted view of Lyme like illness and its management in Australia

Just as Semmelweiss was banished from the hospital for suggesting his esteemed colleagues wash their hands between doing autopsies on those dying from puerperal fever and examining labouring women so too Lyme treating doctors in Australia are being ridiculed and hauled up in front of medical boards and are having their practicing licenses restricted.

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 greatest concern we as a profession have is that we are not educated in evidence based complementary care or how to discuss with patients where and how to access good scientifically founded healthcare information. We ourselves generally are unaware of the clinical effects of many therapies such as herbs and cannot comment on the risk of herb drug interactions. Consequently, our patients often do not share their complementary healthcare use with their conventional healthcare practitioner. It is naïve to think that restricting medical professionals’ ability to discuss or recommend complementary health care will reduce the demand of the general public for these therapies. It will however drive these people away from conventional medical care and reduce the chance of them sharing their alternative treatments with their conventional allopathic medical practitioner. This is likely to lead to significant patient harm. The treatment if patients with suspected Lyme Like illness by the established medical profession has already been demonstrated in the Senate Enquiry into Lyme like illness in Australia to be causing significant patient harm and to be driving patients away from accessing mainstream care.

Are safeguards needed for patients who seek ‘complementary and unconventional medicine and emerging treatments’?

Yes these are the same safeguards that are required for mainstream conventional medical practice including their practitioners are continuously educated in their respective discipline, educated in communication, educated in ethics, shared decision making and patient centred care and educated in cross cultural healthcare practice and the need for cultural safety. It is important that their ongoing clinical ability is reviewed by those who have specific training in their respective area of practice. It is not appropriate for a doctor to be commenting on chiropractic practice or for a doctor with no training in clinical nutrition to be making judgements on nutritional medicine practice which they have not been educated anymore than it is appropriate for a psychiatrist to be assessing an anaesthetists practice.

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

Evidence for chiropractic and osteopathic Manipulative therapies

Cochrane Review

SMT appears to be as effective as other common therapies prescribed for chronic low-back pain, such as, exercise therapy, standard medical care or physiotherapy…. Furthermore, no serious complications were observed with SMT.

Evidence Based Use of Nutrients and Vitamins to Treat Conditions in the Absence of Deficiency e.g. Functional Deficiency Genetic Polymorphisms or Specific Evidence based Uses to treat conditions

(Cudkowicz, Titus et al. 2014)

(Dinicola, Fuso et al. 2018)

(Galeshkalami, Abdollahi et al. 2019)

(Huang, Huang et al. 1993)

(Kala, Neely et al. 2000)

(Mikirova and Hunninghake 2014)

(Nguyen and Takemoto 2018)

(Stevens, Obrosova et al. 2000)

(Traber, Buettner et al. 2018)

(Ziegler, Ametov et al. 2006)

(Ziegler, Low et al. 2016)

(Ziegler, Nowak et al. 2004)

(Kuwabara, Nakazawa et al. 1999)

(McCaddon, Regland et al. 2002)

(SUN, LAI et al. 2005)

(Talaei, Siavash et al. 2009)

(Watanabe, Kaji et al. 1994)

(Walker, Batterham et al. 2012)

(Schencking, Vollbracht et al. 2012, Hemilä 2017)

Cudkowicz, M. E., et al. (2014). "Safety and efficacy of ceftriaxone for amyotrophic lateral sclerosis: a multi-stage, randomised, double-blind, placebo-controlled trial." The Lancet Neurology **13**(11): 1083-1091.

Dinicola, S., et al. (2018). "Natural products–alpha-lipoic acid and acetyl-L-carnitine–in the treatment of chemotherapy-induced peripheral neuropathy." European review for medical and pharmacological sciences **22**(14): 4739-4754.

Galeshkalami, N. S., et al. (2019). "Alpha-lipoic acid and coenzyme Q10 combination ameliorates experimental diabetic neuropathy by modulating oxidative stress and apoptosis." Life sciences **216**: 101-110.

Hemilä, H. (2017). "Vitamin C and infections." Nutrients **9**(4): 339.

Huang, H., et al. (1993). "Glutathione as a cellular defence against arsenite toxicity in cultured Chinese hamster ovary cells." Toxicology **79**(3): 195-204.

Kala, S. V., et al. (2000). "The MRP2/cMOAT transporter and arsenic-glutathione complex formation are required for biliary excretion of arsenic." Journal of Biological Chemistry **275**(43): 33404-33408.

Kuwabara, S., et al. (1999). "Intravenous methylcobalamin treatment for uremic and diabetic neuropathy in chronic hemodialysis patients." Internal Medicine **38**(6): 472-475.

McCaddon, A., et al. (2002). "Functional vitamin B12 deficiency and Alzheimer disease." Neurology **58**(9): 1395-1399.

Mikirova, N. and R. Hunninghake (2014). "Effect of high dose vitamin C on Epstein-Barr viral infection." Medical science monitor : international medical journal of experimental and clinical research **20**: 725-732.

> Background Many natural compounds were tested for the ability to suppress viral replication. The present manuscript details an analysis of high dose vitamin C therapy on patients with EBV infection. Material and Methods The data were obtained from the patient history database at the Riordan Clinic. Among people in our database who were treated with intravenous vitamin C (7.5 g to 50 g infusions) between 1997 and 2006, 178 patients showed elevated levels of EBV EA IgG (range 25 to 211 AU) and 40 showed elevated levels of EBV VCA IgM (range 25 to 140 AU). Most of these patients had a diagnosis of chronic fatigue syndrome, with the rest being diagnosed as having mononucleosis, fatigue, or EBV infection. Results Our data provide evidence that high dose intravenous vitamin C therapy has a positive effect on disease duration and reduction of viral antibody levels. Plasma levels of ascorbic acid and vitamin D were correlated with levels of antibodies to EBV. We found an inverse correlation between EBV VCA IgM and vitamin C in plasma in patients with mononucleosis and CFS meaning that patients with high levels of vitamin C tended to have lower levels of antigens in the acute state of disease. In addition, a relation was found between vitamin D levels and EBV EA IgG with lower levels of EBV early antigen IgG for higher levels of vitamin D. Conclusions The clinical study of ascorbic acid and EBV infection showed the reduction in EBV EA IgG and EBV VCA IgM antibody levels over time during IVC therapy that is consistent with observations from the literature that millimolar levels of ascorbate hinder viral infection and replication in vitro.

Nguyen, N. and J. K. Takemoto (2018). "A Case for Alpha-Lipoic Acid as an Alternative Treatment for Diabetic Polyneuropathy." Journal of Pharmacy & Pharmaceutical Sciences **21**(1s): 192-199s.

Schencking, M., et al. (2012). "Intravenous vitamin C in the treatment of shingles: results of a multicenter prospective cohort study." Medical science monitor: international medical journal of experimental and clinical research **18**(4): CR215.

Stevens, M. J., et al. (2000). "Effects of DL-alpha-lipoic acid on peripheral nerve conduction, blood flow, energy metabolism, and oxidative stress in experimental diabetic neuropathy." Diabetes **49**(6): 1006-1015.

SUN, Y., et al. (2005). "Effectiveness of vitamin B12 on diabetic neuropathy: systematic review of clinical controlled trials." Acta Neurologica Taiwanica **14**(2): 48-54.

Talaei, A., et al. (2009). "Vitamin B12 may be more effective than nortriptyline in improving painful diabetic neuropathy." International journal of food sciences and nutrition **60**(sup5): 71-76.

Traber, M. G., et al. (2018). "The relationship between vitamin C status, the gut-liver axis, and metabolic syndrome." Redox biology **21**: 101091-101091.

Metabolic syndrome (MetS) is a constellation of cardiometabolic risk factors, which together predict increased risk of more serious chronic diseases. We propose that one consequence of dietary overnutrition is increased abundance of Gram-negative bacteria in the gut that cause increased inflammation, impaired gut function, and endotoxemia that further dysregulate the already compromised antioxidant vitamin status in MetS. This discussion is timely because "healthy" individuals are no longer the societal norm and specialized dietary requirements are needed for the growing prevalence of MetS. Further, these lines of evidence provide the foundational basis for investigation that poor vitamin C status promotes endotoxemia, leading to metabolic dysfunction that impairs vitamin E trafficking through a mechanism involving the gut-liver axis. This report will establish a critical need for translational research aimed at validating therapeutic approaches to manage endotoxemia-an early, but inflammation-inducing phenomenon, which not only occurs in MetS, but is also prognostic of more advanced metabolic disorders including type 2 diabetes mellitus, as well as the increasing severity of nonalcoholic fatty liver diseases.

Walker, J. G., et al. (2012). "Oral folic acid and vitamin B-12 supplementation to prevent cognitive decline in community-dwelling older adults with depressive symptoms—the Beyond Ageing Project: a randomized controlled trial." The American Journal of Clinical Nutrition **95**(1): 194-203.

Background: Evidence remains unclear as to whether folic acid (FA) and vitamin B-12 supplementation is effective in reducing depressive symptoms.Objectives: The objective was to determine whether oral FA + vitamin B-12 supplementation prevented cognitive decline in a cohort of community-dwelling older adults with elevated psychological distress.Design: A randomized controlled trial (RCT) with a completely crossed 2 × 2 × 2 factorial design comprising daily oral 400 μg FA + 100 μg vitamin B-12 supplementation (compared with placebo), physical activity promotion, and depression literacy with comparator control interventions for reducing depressive symptoms was conducted in 900 adults aged 60–74 y with elevated psychological distress (Kessler Distress 10–Scale; scores >15). The 2-y intervention was delivered in 10 modules via mail with concurrent telephone tracking calls. Main outcome measures examined change in cognitive functioning at 12 and 24 mo by using the Telephone Interview for Cognitive Status–Modified (TICS-M) and the Brief Test of Adult Cognition by Telephone (processing speed); the Informant Questionnaire on Cognitive Decline in the Elderly was administered at 24 mo.Results: FA + vitamin B-12 improved the TICS-M total (P = 0.032; effect size d = 0.17), TICS-M immediate (P = 0.046; d = 0.15), and TICS-M delayed recall (P = 0.013; effect size d = 0.18) scores at 24 mo in comparison with placebo. No significant changes were evident in orientation, attention, semantic memory, processing speed, or informant reports.Conclusion: Long-term supplementation of daily oral 400 μg FA + 100 μg vitamin B-12 promotes improvement in cognitive functioning after 24 mo, particularly in immediate and delayed memory performance. This trial was registered at clinicaltrials.gov as NCT00214682.

Watanabe, T., et al. (1994). "Ultra-high dose methylcobalamin promotes nerve regeneration in experimental acrylamide neuropathy." Journal of the neurological sciences **122**(2): 140-143.

Ziegler, D., et al. (2006). "Oral treatment with α-lipoic acid improves symptomatic diabetic polyneuropathy: the SYDNEY 2 trial." Diabetes care **29**(11): 2365-2370.

Ziegler, D., et al. (2016). "Predictors of improvement and progression of diabetic polyneuropathy following treatment with α-lipoic acid for 4 years in the NATHAN 1 trial." Journal of Diabetes and its Complications **30**(2): 350-356.

Ziegler, D., et al. (2004). "Treatment of symptomatic diabetic polyneuropathy with the antioxidant α-lipoic acid: a meta-analysis." Diabetic Medicine **21**(2): 114-121.

Evidence for unconventional /Off Label Use of Hormones *hormone therapy and supplements in the absence of a hormone deficiency/identified therapeutic need*

(Stein 2001)

(Xiao, Wei et al. 2008)

J Clin Endocrinol Metab. 2001 Aug;86(8):3545-54.

Hypothalamo-pituitary-adrenal axis dysfunction in chronic fatigue syndrome, and the effects of low-dose hydrocortisone therapy.

Cleare AJ[1], Miell J, Heap E, Sookdeo S, Young L, Malhi GS, O'Keane V.

Abstract

These neuroendocrine studies were part of a series of studies testing the hypotheses that 1) there may be reduced activity of the hypothalamic-pituitary-adrenal axis in chronic fatigue syndrome and 2) low-dose augmentation with hydrocortisone therapy would improve the core symptoms. We measured ACTH and cortisol responses to human CRH, the insulin stress test, and D-fenfluramine in 37 medication-free patients with CDC-defined chronic fatigue syndrome but no comorbid psychiatric disorders and 28 healthy controls. We also measured 24-h urinary free cortisol in both groups. All patients (n = 37) had a pituitary challenge test (human CRH) and a hypothalamic challenge test [either the insulin stress test (n = 16) or D-fenfluramine (n = 21)]. Baseline cortisol concentrations were significantly raised in the chronic fatigue syndrome group for the human CRH test only. Baseline ACTH concentrations did not differ between groups for any test. ACTH responses to human CRH, the insulin stress test, and D- fenfluramine were similar for patient and control groups. Cortisol responses to the insulin stress test did not differ between groups, but there was a trend for cortisol responses both to human CRH and D-fenfluramine to be lower in the chronic fatigue syndrome group. These differences were significant when ACTH responses were controlled. Urinary free cortisol levels were lower in the chronic fatigue syndrome group compared with the healthy group. These results indicate that ACTH responses to pituitary and hypothalamic challenges are intact in chronic fatigue syndrome and do not support previous findings of reduced central responses in hypothalamic-pituitary-adrenal axis function or the hypothesis of abnormal CRH secretion in chronic fatigue syndrome. These data further suggest that the hypocortisolism found in chronic fatigue syndrome may be secondary to reduced adrenal gland output. Thirty-two patients were treated with a low-dose hydrocortisone regime in a double-blind, placebo-controlled cross-over design, with 28 days on each treatment. They

underwent repeated 24-h urinary free cortisol collections, a human CRH test, and an insulin stress test after both active and placebo arms of treatment. Looking at all subjects, 24-h urinary free cortisol was higher after active compared with placebo treatments, but 0900-h cortisol levels and the ACTH and cortisol responses to human CRH and the insulin stress test did not differ. However, a differential effect was seen in those patients who responded to active treatment (defined as a reduction in fatigue score to the median population level or less). In this group, there was a significant increase in the cortisol response to human CRH, which reversed the previously observed blunted responses seen in these patients. We conclude that the improvement in fatigue seen in some patients with chronic fatigue syndrome during hydrocortisone treatment is accompanied by a reversal of the blunted cortisol responses to human CRH.

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11502777

DOI:

10.1210/jcem.86.8.7735

[Indexed for MEDLINE]

DHEA IN CFS

A pilot study employing Dehydroepiandrosterone (DHEA) in the treatment of chronic fatigue syndrome.

(PMID:19078357)
Himmel PB , Seligman TM
Journal of Clinical Rheumatology : Practical Reports on Rheumatic & Musculoskeletal Diseases [01 Apr 1999, 5(2):56-59]

Abstract
Patients with chronic fatigue syndrome (CFS) frequently associate the disease onset with a period of high physical and/or emotional stress. Alterations in hypothalamic-pituitary adrenal axis (HPA) function have been demonstrated. Although Cortisol production in patients with CFS has proven to be low, Dehydroepiandrosterone (DHEA) production has not been measured. DHEA output may be altered in this population. The purpose of this uncontrolled, prospective, 6 month study of 23 white women, ages 35-55 was to identify CFS patients with suboptimal serum levels of DHEA-sulphate (DHEA-S), defined as DHEA-S <2.0 microg/mL, and to treat those patients with oral DHEA. DHEA-S levels were re-measured after 4-6 weeks of oral DHEA therapy (25 mg). If DHEA-S remained <2.0 microg/ mL, or if no clinical response was achieved after 4-6 weeks of therapy, then an increased dose of DHEA was given. Physical and psychological impairment and disability status were measured by the MHAQII before DHEA intervention and at 3-month intervals. Of initially screened patients with CFS, 76% (116 of 153) were ages 35-55, and 89% (103 of 116) had suboptimal (<2.0 microg/mL) production of DHEA-S.Supplementation with DHEA to CFS patients lead to a significant reduction in the symptoms of CFS: pain (improved by 18%, $p = 0.035$), fatigue (decreased by 21%, $p = 0.009$)), activities of daily living (improved by 8.5%, $p = 0.058$), helplessness (decreased by 11%, $p = 0.015$), anxiety (decreased by 35%, $p < 0.01$), thinking (improved by 26%, $p < 0.01$), memory (improved by 17%, $p < 0.05$), and sexual problems (improved by 22%, $p = 0.06$) over the period of the trial. Further study is necessary to determine the safety and efficacy of supplementation of DHEA to this population in a controlled setting.

A preliminary study of dehydroepiandrosterone response to low-dose ACTH in chronic fatigue syndrome and in healthy subjects

Psychiatry Research
Volume 97, Issue 1, 4 December 2000, Pages 21-28
Lucinda V Scotta Frank Svecb Timothy Dinanc

https://doi.org/10.1016/S0165-1781(00)00219-5

Abstract
Abnormalities of the production of dehydroepiandrosterone (DHEA), the adrenal androgen, have been linked with disorders such as obesity and psychological disorders such as major depression. Adrenocorticotropin (ACTH) is the primary stimulant of DHEA, and cortisol, from the adrenal. We chose to examine the DHEA and DHEA/cortisol response to the novel low-dose ACTH test in healthy subjects and a cohort with chronic fatigue syndrome (CFS): this test is useful in assessing subtle irregularities of pituitary-adrenal activity. Nineteen CFS subjects (diagnosed by CDC criteria) and 10 healthy subjects were examined. We demonstrated that 1 μg ACTH significantly elevates DHEA levels, with no difference in output between CFS and healthy subjects. The DHEA/cortisol ratio decreased in response to ACTH stimulation in healthy subjects but not in the CFS cohort. We suggest this divergence of response between the two groups represents an imbalance in the relative synthetic pathways of the CFS group which, if present chronically and if comparable to daily stressors, may manifest itself as an inappropriate response to stress. This difference may be important in either the genesis or propagation of the syndrome.

Stein, D. G. (2001). "Brain damage, sex hormones and recovery: a new role for progesterone and estrogen?" Trends in neurosciences **24**(7): 386-391.

Xiao, G., et al. (2008). "Improved outcomes from the administration of progesterone for patients with acute severe traumatic brain injury: a randomized controlled trial." Critical Care **12**(2): 1.

Evidence for Off Label Use of Medication Evidence Base and Use of Antibiotics without confirmation of infection /Possibilities of Chronic Infection Underlying Chronic Diseases Including Neurodegenerative Diseases and Chronic Fatigue Syndrome

(Cudkowicz, Titus et al. 2014)

(Miklossy 2011)

(Shoemaker 2002)

(Harvey and Martz 2007)

(Ramesh, Meisner et al. 2015)

(Rudenko, Golovchenko et al. 2016)

(Kumar, Vashist et al. 2010)

(Bachs, Parés et al. 1992)

(Kraft, Cassell et al. 2002)

(Hahn, Bukstein et al. 1998)

Annals of Allergy, Asthma & Immunology
Volume 80, Issue 1, January 1998, Pages 45-49

Evidence for *Chlamydia pneumoniae* Infection in Steroid-Dependent Asthma

David L Hahn MD* Don Bukstein MD*Allan Luskin MD*Howard Zeitz MD†

https://doi.org/10.1016/S1081-1206(10)62938-9Get rights and content

Background
Chlamydia pneumoniae is an obligate intracellular respiratory pathogen capable of persistent infection. Seroepidemic studies and the results of open-label antimicrobial treatment of patients with non-steroid-dependent asthma have suggested a potential role for *C. pneumoniae* in asthma.
Objective To evaluate the results of antimicrobial treatment in patients with uncontrolled steroid-dependent asthma and serologic evidence suggesting *C. pneumoniae* infection.
Methods Three nonsmoking asthmatic patients (aged 13 to 65 years) whose symptoms remained poorly controlled despite daily administration of inhaled and oral steroid (10 to 40 mg/d). All met serologic criteria for current or recent *C. pneumoniae* infection
ResultsAfter prolonged treatment (6 to 16 weeks) with clarithromycin or azithromycin all three patients were able to discontinue oral steroids. All three patients have remained well controlled with inhaled antiasthma therapy only during 3 to 24 months of postantibiotic therapy observation.
Conclusion In adolescent and adult asthmatic patients, *Chlamydia pneumoniae* infection may contribute to symptoms of asthma that are poorly controlled by steroids. Serologic evidence for *C. pneumoniae* infection should be sought in such patients. A trial of appropriate antibiotic therapy may be helpful in those patients with high titers of anti-*C. pneumoniae* IgG antibodies.

(Hahn and McDonald 1998)

(Cunningham, Johnston et al. 1998)

Anti mycobacterial treatment in Crohns disease

(Borody, Bilkey et al. 2007)

(Borody, Leis et al. 2002)

Minocycline is safe and Effective in numerous conditions not primarily considered infective

Acne

Rheumatoid Arthritis

(Tilley, Alarcon et al. 1995)

Sarcoidosis

(Miyazaki, Ando et al. 2008)

(Marshall and Marshall 2004)

Minocycline is Neuroprotective

Recently, it has been reported that tetracyclines can exert a variety of biological actions that are independent of their anti-microbial activity, including anti-inflammatory and anti-apoptotic activities, and inhibition of proteolysis, angiogenesis and tumour metastasis. These findings specifically concern to minocycline as it has recently been found to have multiple non-antibiotic biological effects that are beneficial in experimental models of various diseases with an inflammatory basis, including dermatitis, periodontitis, atherosclerosis and autoimmune disorders such as rheumatoid arthritis and inflammatory bowel disease. Of note, minocycline has also emerged as the most effective tetracycline derivative at providing neuroprotection. This effect has been confirmed in experimental models of ischaemia, traumatic brain injury and neuropathic pain, and of several neurodegenerative conditions including Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, Alzheimer's disease, multiple sclerosis and spinal cord injury. Moreover, other pre-clinical studies have shown its ability to inhibit malignant cell growth and activation and replication of human immunodeficiency virus, and to prevent bone resorption. Considering the above-mentioned findings, this review will cover the most important topics in the pharmacology of minocycline to date, supporting its evaluation as a new therapeutic approach for many of the diseases described herein.

(Garrido-Mesa, Zarzuelo et al. 2013)

(Yong, Wells et al. 2004, Maier, Merkler et al. 2007)

(Plane, Shen et al. 2010)

Evidence For Safety of Use of Long Term Antibiotics in Absence of Chronic Infection

Prevention of Recurrent infection Triggering Autoimmunity

(Gerber, Baltimore et al. 2009)

Prevention of Infection in Immunocompromise

(Green, Paul et al. 2007)

Treating infections in Chronic Fatigue Syndrome

(Endresen 2003)

(Glaser and Kiecolt-Glaser 1998)

(Lerner, Beqaj et al. 2002)

(Lerner, Beqaj et al. 2007)

(Lerner, Zervos et al. 2001)

Consideration for Off Label Use of Pyridostigmine in Chronic Fatigue Syndrome

(Loebel, Grabowski et al. 2016)

Complex Multisystem Disorder in Chronic Fatigue Syndrome Requires an Individualised Holistic Approach where Individual Abnormalities are Assessed and Treated Accordingly

SYSTEMS APPROACH IN COMPLEX CHRONIC ILLNESS
Chronic Fatigue

Complex chronic conditions such as chronic fatigue have multiple contributing factors and effect multiple bodily systems and therefore require a systems approach to manage them.

HETEROGENOUS CONDITIONS

These conditions are syndromes that have multiple different contributing factors and multiple different consequences and therefore a one size fits all approach seldom works in enough people to reach statistical significance on clinical trials. This is no different to car accidents which have multiple contributing factors and multiple consequences but they still can be grouped together as a group. We manage motor accident victims by using history, examination and tests to identify their individual specific injuries and treat these specifically. Imagine if we trialled just treating them all the same eg by putting metal plates on their femur bones, removing their spleen and putting tubes in their chest because these treat common injuries in car accident victims we would help a few people and do a lot of harm to others where these treatment did not address their specific condition.

In chronic complex disorders such as chronic fatigue we must apply a systems approach to identify contributing factors and address the different factors contributing to illness in each individual. Ideally we need to identify both nurturing and toxic influences to a person's wellbeing so as to reinforce and strengthen the nurturing aspects and to eliminate the toxic influences. We do this ideally by identifying predisposing factors, triggering factors and illness perpetuating factors. To identify these in a complex being we need to use a system approach.

TSUNAMIS AND SYSTEM APPROACH

Imagine that the overwhelming breakdown of the normal functioning of your body is like the loss of function of a coastal town devastated by a tsunami. The tsunami wipes out the system or the infrastructure of the town which allows its normal functioning.

Its wipes out water and food supply (digestion and nutrition), sewage and sanitation systems, garbage collection and refuse control (detoxification and antioxidant systems), the police force (the immune system), health care (controlling inflammation and healing), electricity and power supply (cellular energy production and mitochondrial function), roads and transport (the musculoskeletal system), refrigeration and climate control (endocrine or hormonal system), communication system (neurological system including the autonomic nervous system), community recreation facilities (emotional wellbeing), places of worship and community spaces (spiritual wellbeing).

When this occurs we end up with lots of problems starving people looting as there is no law and order or food supply, untreated injuries and people with PTSD, dysentery and cholera due to the interruption of the water supply and sanitation, mosquitoes due to water sitting around, flies and rats and cockroaches due to no refrigeration or waste management and a weakened emotionally and physically crippled population. Each of the pests is akin to infections reactivating and getting out of control. Yes we need to address the pest i.e. kill the offending bacteria viruses and parasites but we will not succeed unless we repair the infrastructure. Putting rat sack and spraying insect spray alone will not fix these pest plagues. We need to nurture the population so as to help them to help themselves by rebuilding the infrastructure. We need to re-establish law and order ie support the immune system and minimise rioting ie settle inflammation and autoimmunity.

We certainly do not do nothing just because there has not been a trial of how to address the problem

before. Some in the medical profession would have us believe if there is no double blinded trial we should do nothing as we could make mistakes and do harm. We use our experience from previous similar situations on how to optimise resource management, we assess the specific problems unique to the situation, we engage with the local population and stakeholders and utilise local expertise and work within the existing culture. In a person this is akin to a shared decision making process and patient centre healthcare. And yes we do try and deal with the pests that have gone out of control i.e. we treat the infections that are contributing to the illness.

Systems Approach: Need to Heal the patients Infrastructure ie return homeostasis to multiple systems in chronic fatigue

Evidence Supporting Issues and Need to Intervene in each System

1. **Gut function and digestion**: Including elimination of food intolerances, healing gut wall and normalising gut microbial flora
   (Maes and Leunis 2008) (Maes, Mihaylova et al. 2007)

2. **Nutrition**
   (Heap, Peters et al. 1999) (Maric, Brkic et al. 2014) (Nicolson and Ellithorpe 2006) (Loblay and Swain 1992)

3. **Detoxification support and removal from ongoing toxin exposure**
   (Reid, Stokić et al. 1994)

4. **Antioxidant Support (including repair of oxidised cell membranes)**
   (Kennedy, Spence et al. 2005) (Maes and Twisk 2009) (Shungu, Weiduschat et al. 2012)

5. **Immune support and balanced healing without inflammation to treat immune deficiency (Lorusso, Mikhaylova et al. 2009) (Maes 2009) (Landi, Broadhurst et al. 2016) (Rajeevan, Dimulescu et al. 2015) (Sotzny, Blanco et al. 2018)**

6. **Energy support (Porter, Jason et al. 2010)**

7. **Optimising cellular energy production and mitochondrial function (your cell power stations)**

8. **Hormonal/ Endocrine Balance**: Optimising thyroid, adrenal and sex hormone function.

9. **Optimising neurological function**: Including healing nerves and myelin sheaths, and blood brain barrier, balancing autonomic nervous system that controls heart, blood pressure, digestion and bladder function/ fight flight system

10. **Identify and treat infections**
(Nicolson, Gan et al. 2003) (Underhill 2015) (Werbach 2000)

11. **Optimise sleep and Neurological Function**
    (Cook, Light et al. 2017) (Finkelmeyer, He et al. 2018)

12. **Improving emotional wellbeing**

13. **Spiritual wellbeing**: Staying connected to your sense of meaning and purpose and connection to your loved ones

(Teitelbaum, Bird et al. 2000)

Effective Treatment of Chronic Fatigue Syndrome and Fibromyalgia—A Randomized, Double-Blind, Placebo-Controlled, Intent-To-Treat Study

ABSTRACT

Background: Hypothalamic dysfunction has been suggested in fibromyalgia (FMS) and chronic fatigue syndrome (CFS). This dysfunction may result in disordered sleep, subclinical hormonal deficiencies, and immunologic changes. Our previously published open trial showed that patients usually improve by using a protocol which treats all the above processes simultaneously. The current study examines this protocol using a randomized, double-blind design with an intent-to-treat analysis. Methods: Seventy-two FMS patients (38 active:34 placebo; 69 also met CFS criteria) received all active or all placebo therapies as a unified intervention. Patients were treated, as indicated by symptoms and/or lab testing, for: (1) subclinical thyroid, gonadal, and/or adrenal insufficiency, (2) disordered sleep, (3) suspected neurally mediated hypotension (NMH), (4) opportunistic infections, and (5) suspected nutritional deficiencies. Results: At the final visit, 16 active patients were “much better,” 14 “better”, 2 “same,” 0 “worse,” and 1 “much worse” vs. 3, 9, 11, 6, and 4 in the placebo group ($p < .0001$, Cochran-Mantel-Haenszel trend test). Significant improvement in the FMS Impact Questionnaire (FIQ) scores (decreasing from 54.8 to 33.2 vs. 51.4 to 47.7) and Analog scores (improving from 176.1 to 310.3 vs. 177.1 to 211.9) (both with $p < .0001$ by random effects regression), and Tender Point Index (TPI) (31.7 to 15.5 vs. 35.0 to 32.3, $p < .0001$ by baseline adjusted linear model) were seen. Long term follow-up (mean 1.9 years) of the active group showed continuing and increasing improvement over time, despite patients being able to discontinue most treatments. Conclusions: Significantly greater benefits were seen in the active group than in the placebo group for all primary outcomes. An integrated treatment approach appears effective in the treatment of FMS/CFS.

Evidence for Off Label Use of Nutrients and Detoxification and Antioxidant Support in Other Conditions Such as Mental Health

(Berk, Dean et al. 2011)

(Gawryluk, Wang et al. 2011)

(Kidd 1997)

(Magalhães, Dean et al. 2011)

(Millea 2009) (Morris, Anderson et al. 2014)

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Cook, D. B., et al. (2017). "Neural consequences of post-exertion malaise in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome." Brain, Behavior, and Immunity **62**: 87-99.

Post exertion malaise is one of the most debilitating aspects of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, yet the neurobiological consequences are largely unexplored. The objective of the study was to determine the neural consequences of acute exercise using functional brain imaging. Fifteen female Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients and 15 healthy female controls completed 30min of submaximal exercise (70% of peak heart rate) on a cycle ergometer. Symptom assessments (e.g. fatigue, pain, mood) and brain imaging data were collected one week prior to and 24h following exercise. Functional brain images were obtained during performance of: 1) a fatiguing cognitive task – the Paced Auditory Serial Addition Task, 2) a non-fatiguing cognitive task – simple number recognition, and 3) a non-fatiguing motor task – finger tapping. Symptom and exercise data were analyzed using independent samples t-tests. Cognitive performance data were analyzed using mixed-model analysis of variance with repeated measures. Brain responses to fatiguing and non-fatiguing tasks were analyzed using linear mixed effects with cluster-wise (101-voxels) alpha of 0.05. Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients reported large symptom changes compared to controls (effect size ≥0.8, $p<0.05$). Patients and controls had similar physiological responses to exercise ($p>0.05$). However, patients exercised at significantly lower Watts and reported greater exertion and leg muscle pain ($p<0.05$). For cognitive performance, a significant Group by Time interaction ($p<0.05$), demonstrated pre- to post-exercise improvements for controls and worsening for patients. Brain responses to finger tapping did not differ between groups at either time point. During number recognition, controls exhibited greater brain activity ($p<0.05$) in the posterior cingulate cortex, but only for the pre-exercise scan. For the Paced Serial Auditory Addition Task, there was a significant Group by Time interaction ($p<0.05$) with patients exhibiting increased brain activity from pre- to post-exercise compared to controls bilaterally for inferior and superior parietal and cingulate cortices. Changes in brain activity were significantly related to symptoms for patients ($p<0.05$). Acute exercise exacerbated symptoms, impaired cognitive performance and affected brain function in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients. These converging results, linking symptom exacerbation with brain function, provide objective evidence of the detrimental neurophysiological effects of post-exertion malaise.

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Objective Investigate global and regional grey and white matter volumes in patients with Chronic Fatigue Syndrome (CFS) using magnetic resonance imaging (MRI) and recent voxel-based morphometry (VBM) methods. Methods Forty-two patients with CFS and thirty healthy volunteers were scanned on a 3-Tesla MRI scanner. Anatomical MRI scans were segmented, normalized and submitted to a VBM analysis using randomisation methods. Group differences were identified in overall segment volumes and voxel-wise in spatially normalized

grey matter (GM) and white matter (WM) segments. Results Accounting for total intracranial volume, patients had larger GM volume and lower WM volume. The voxel-wise analysis showed increased GM volume in several structures including the amygdala and insula in the patient group. Reductions in WM volume in the patient group were seen primarily in the midbrain, pons and right temporal lobe. Conclusion Elevated GM volume in CFS is seen in areas related to processing of interoceptive signals and stress. Reduced WM volume in the patient group partially supports earlier findings of WM abnormalities in regions of the midbrain and brainstem.

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Recently, differences in the levels of various chemokines and cytokines were reported in patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) as compared with controls. Moreover, the analyte profile differed between chronic ME/CFS patients of long duration versus patients with disease of less than 3years. In the current study, we measured the plasma levels of 34 cytokines, chemokines and growth factors in 100 chronic ME/CFS patients of long duration and in 79 gender and age-matched controls. We observed highly significant reductions in the concentration of circulating interleukin (IL)-16, IL-7, and Vascular Endothelial Growth Factor A (VEGF-A) in ME/CFS patients. All three biomarkers were significantly correlated in a multivariate cluster analysis. In addition, we identified significant reductions in the concentrations of fractalkine (CX3CL1) and monokine-induced-by-IFN-γ (MIG; CXCL9) along with increases in the concentrations of eotaxin 2 (CCL24) in ME/CFS patients. Our data recapitulates previous data from another USA ME/CFS cohort in which circulating levels of IL-7 were reduced. Also, a reduced level of VEGF-A was reported previously in sera of patients with Gulf War Illness as well as in cerebral spinal fluid samples from a different cohort of USA ME/CFS patients. To our knowledge, we are the first to test for levels of IL-16 in ME/CFS patients. In combination with previous data, our work suggests that the clustered reduction of IL-7, IL-16 and VEGF-A may have physiological relevance to ME/CFS disease. This profile is ME/CFS-specific since measurement of the same analytes present in chronic infectious and autoimmune liver diseases, where persistent fatigue is also a major symptom, failed to demonstrate the same changes. Further studies of other ME/CFS and overlapping disease cohorts are warranted in future.

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Infection-triggered disease onset, chronic immune activation and autonomic dysregulation in CFS point to an autoimmune disease directed against neurotransmitter receptors. Autoantibodies against G-protein coupled receptors were shown to play a pathogenic role in several autoimmune diseases. Here, serum samples from a patient cohort from Berlin (n=268) and from Bergen with pre- and post-treatment samples from 25 patients treated within the KTS-2 rituximab trial were analysed for IgG against human α and β adrenergic, muscarinic (M) 1–5 acetylcholine, dopamine, serotonin, angiotensin, and endothelin receptors by ELISA and compared to a healthy control cohort (n=108). Antibodies against β2, M3 and M4 receptors were significantly elevated in CFS patients compared to controls. In contrast, levels of antibodies against α adrenergic, dopamine, serotonin, angiotensin, and endothelin receptors were not different between patients and controls. A high correlation was found between levels of autoantibodies and elevated IgG1–3 subclasses, but not with IgG4. Further

patients with high β2 antibodies had significantly more frequently activated HLA-DR+ T cells and more frequently thyreoperoxidase and anti-nuclear antibodies. In patients receiving rituximab maintenance treatment achieving prolonged B-cell depletion, elevated β2 and M4 receptor autoantibodies significantly declined in clinical responder, but not in non-responder. We provide evidence that 29.5% of patients with CFS had elevated antibodies against one or more M acetylcholine and β adrenergic receptors which are potential biomarkers for response to B-cell depleting therapy. The association of autoantibodies with immune markers suggests that they activate B and T cells expressing β adrenergic and M acetylcholine receptors. Dysregulation of acetylcholine and adrenergic signalling could also explain various clinical symptoms of CFS.

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> It is established that chronic spirochetal infection can cause slowly progressive dementia, brain atrophy and amyloid deposition in late neurosyphilis. Recently it has been suggested that various types of spirochetes, in an analogous way to Treponema pallidum, could cause dementia and may be involved in the pathogenesis of Alzheimer's disease (AD). Here, we review all data available in the literature on the detection of spirochetes in AD and critically analyze the association and causal relationship between spirochetes and AD following established criteria of Koch and Hill. The results show a statistically significant association between spirochetes and AD (P = 1.5 × 10-17, OR = 20, 95% CI = 8-60, N = 247). When neutral techniques recognizing all types of spirochetes were used, or the highly prevalent periodontal pathogen Treponemas were analyzed, spirochetes were observed in the brain in more than 90% of AD cases. Borrelia burgdorferi was detected in the brain in 25.3% of AD cases analyzed and was 13 times more frequent in AD compared to controls. Periodontal pathogen Treponemas (T. pectinovorum, T. amylovorum, T. lecithinolyticum, T. maltophilum, T. medium, T. socranskii) and Borrelia burgdorferi were detected using species specific PCR and antibodies. Importantly, co-infection with several spirochetes occurs in AD. The pathological and biological hallmarks of AD were reproduced in vitro by exposure of mammalian cells to spirochetes. The analysis of reviewed data following Koch's and Hill's postulates shows a probable causal relationship between neurospirochetosis and AD. Persisting inflammation and amyloid deposition initiated and sustained by chronic spirochetal infection form together with the various hypotheses suggested to play a role in the pathogenesis of AD a comprehensive entity. As suggested by Hill, once the probability of a causal relationship is established prompt action is needed. Support and attention should be given to this field of AD research. Spirochetal infection occurs years or decades before the manifestation of dementia. As adequate antibiotic and anti-inflammatory therapies are available, as in syphilis, one might prevent and eradicate dementia.

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> The lack of robust treatment options available for neurodegenerative diseases, stroke, and central nervous system (CNS) trauma, all of which often involve both inflammation and apoptotic cell death, has led to an explosion of studies to reexamine the potential of established drugs for treatment of these conditions. Minocycline is a second-generation

tetracycline derivative with a proven, safe clinical track record as an antibiotic and anti-inflammatory drug for treating acne and arthritis. Minocycline effectively crosses the blood-brain barrier and has demonstrated neuroprotective qualities in experimental models of CNS trauma, stroke, spinal cord injury, and neurodegenerative diseases including amyotrophic lateral sclerosis, Huntington disease, Parkinson disease, and multiple sclerosis. Thus, it is not surprising that several off-label minocycline clinical trials are under way for a variety of CNS diseases. The emerging success of some of these trials raises optimism that minocycline treatment may soon be translated into clinical practice for CNS diseases, whereas others (eg, in amyotrophic lateral sclerosis) have raised red flags. A thorough understanding of minocycline's modes of action and the targeted cellular mechanisms is warranted, as are guidelines on safe and effective doses, routes of administration, and establishment of a therapeutic window. Although several lines of evidence point to a convergent action of minocycline in suppression of both apoptosis and CNS inflammation by preventing neural cell death and by inhibiting microglial activation, the exact molecular targets of minocycline have yet to be identified and characterized. This review provides an overview of the established mechanisms of action by which minocycline exerts its neuroprotective effects, summarizes results of animal studies in experimental models of neurological diseases, and discusses results of clinical trials.

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Rajeevan, M. S., et al. (2015). "Pathway-focused genetic evaluation of immune and inflammation related genes with chronic fatigue syndrome." Human Immunology **76**(8): 553-560.

Recent evidence suggests immune and inflammatory alterations are important in chronic fatigue syndrome (CFS). This study was done to explore the association of functionally important genetic variants in inflammation and immune pathways with CFS. Peripheral blood DNA was isolated from 50 CFS and 121 non-fatigued (NF) control participants in a population-based study. Genotyping was performed with the Affymetrix Immune and Inflammation Chip that covers 11K single nucleotide polymorphisms (SNPs) following the manufacturer’s protocol. Genotyping accuracy for specific genes was validated by pyrosequencing. Golden Helix SVS software was used for genetic analysis. SNP functional annotation was done using SPOT and GenomePipe programs. CFS was associated with 32 functionally important SNPs: 11 missense variants, 4 synonymous variants, 11 untranslated regulatory region (UTR) variants and 6 intronic variants. Some of these SNPs were in genes within pathways related to complement cascade (SERPINA5, CFB, CFH, MASP1 and C6), chemokines (CXCL16, CCR4, CCL27), cytokine signaling (IL18, IL17B, IL2RB), and toll-like receptor signaling (TIRAP, IRAK4). Of particular interest is association of CFS with two missense variants in genes of complement activation, rs4151667 (L9H) in CFB and rs1061170 (Y402H) in CFH. A 5′ UTR polymorphism (rs11214105) in IL18 also associated with physical fatigue, body pain and score for CFS case defining symptoms. This study identified new associations of CFS with genetic variants in pathways including complement activation providing additional support for altered innate immune response in CFS. Additional studies are needed to validate the findings of this exploratory study.

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Lyme borreliosis is a multisystem disorder with a diverse spectrum of clinical manifestations, caused by spirochaetes of the Borrelia burgdorferi sensu lato complex. It is an infectious disease that can be successfully cured by antibiotic therapy in the early stages; however, the possibility of the appearance of persistent signs and symptoms of disease following antibiotic treatment is recognized. It is known that Lyme borreliosis mimics multiple diseases that were never proven to have a spirochaete aetiology. Using complete modified Kelly–Pettenkofer medium we succeeded in cultivating live B. burgdorferi sensu lato spirochaetes from samples taken from people who suffered from undefined disorders, had symptoms not typical for Lyme borreliosis, but who had undergone antibiotic treatment due to a suspicion of having Lyme disease even though they were seronegative. We report the first recovery of live B. burgdorferi sensu stricto from residents of southeastern USA and the first successful cultivation of live Borrelia bissettii-like strain from residents of North America. Our results support the fact that B. bissettii is responsible for human Lyme borreliosis worldwide along with B. burgdorferi s.s. The involvement of new spirochaete species in Lyme borreliosis changes the understanding and recognition of clinical manifestations of this disease.

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Sotzny, F., et al. (2018). "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome – Evidence for an autoimmune disease." Autoimmunity reviews **17**(6): 601-609.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a frequent and severe chronic disease drastically impairing life quality. The underlying pathomechanism is incompletely understood yet but there is convincing evidence that in at least a subset of patients ME/CFS has an autoimmune etiology. In this review, we will discuss current autoimmune aspects for ME/CFS. Immune dysregulation in ME/CFS has been frequently described including changes in cytokine profiles and immunoglobulin levels, T- and B-cell phenotype and a decrease of natural killer cell cytotoxicity. Moreover, autoantibodies against various antigens including neurotransmitter receptors have been recently identified in ME/CFS individuals by several groups. Consistently, clinical trials from Norway have shown that B-cell depletion with rituximab results in clinical benefits in about half of ME/CFS patients. Furthermore, recent studies have provided evidence for severe metabolic disturbances presumably mediated by serum autoantibodies in ME/CFS. Therefore, further efforts are required to delineate the role of autoantibodies in the onset and pathomechanisms of ME/CFS in order to better understand and properly treat this disease.

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The etiology of myalgic encephalomyelitis also known as chronic fatigue syndrome or ME/CFS has not been established. Controversies exist over whether it is an organic disease or a psychological disorder and even the existence of ME/CFS as a disease entity is sometimes denied. Suggested causal hypotheses have included psychosomatic disorders, infectious agents, immune dysfunctions, autoimmunity, metabolic disturbances, toxins and

inherited genetic factors. Clinical, immunological and epidemiological evidence supports the hypothesis that: ME/CFS is an infectious disease; the causal pathogen persists in patients; the pathogen can be transmitted by casual contact; host factors determine susceptibility to the illness; and there is a population of healthy carriers, who may be able to shed the pathogen. ME/CFS is endemic globally as sporadic cases and occasional cluster outbreaks (epidemics). Cluster outbreaks imply an infectious agent. An abrupt flu-like onset resembling an infectious illness occurs in outbreak patients and many sporadic patients. Immune responses in sporadic patients resemble immune responses in other infectious diseases. Contagion is shown by finding secondary cases in outbreaks, and suggested by a higher prevalence of ME/CFS in sporadic patients' genetically unrelated close contacts (spouses/partners) than the community. Abortive cases, sub-clinical cases, and carrier state individuals were found in outbreaks. The chronic phase of ME/CFS does not appear to be particularly infective. Some healthy patient-contacts show immune responses similar to patients' immune responses, suggesting exposure to the same antigen (a pathogen). The chronicity of symptoms and of immune system changes and the occurrence of secondary cases suggest persistence of a causal pathogen. Risk factors which predispose to developing ME/CFS are: a close family member with ME/CFS; inherited genetic factors; female gender; age; rest/activity; previous exposure to stress or toxins; various infectious diseases preceding the onset of ME/CFS; and occupational exposure of health care professionals. The hypothesis implies that ME/CFS patients should not donate blood or tissue and usual precautions should be taken when handling patients' blood and tissue. No known pathogen has been shown to cause ME/CFS. Confirmation of the hypothesis requires identification of a causal pathogen. Research should focus on a search for unknown and known pathogens. Finding a causal pathogen could assist with diagnosis; help find a biomarker; enable the development of anti-microbial treatments; suggest preventive measures; explain pathophysiological findings; and reassure patients about the validity of their symptoms.

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Evidence for locally acquired Lyme like illness in Australia

Case studies of Lyme have been published over many years in Australia. The main argument against locally acquired Lyme disease in Australia stems from the 1994 study by Russel et al Lyme Disease a search for a causative agent in ticks in South Eastern Australia (Epidemiol Infect 1994 112 375-384). This study examined 11000 ticks looking specifically for the American strain of Lyme Borrelia Burgdorferi through culture, PCR, microscopy and antibody testing. No Borrelia Burgdorferi were found however spirochaete like objects were identified in the gastric contents of 92 ticks raising the possibility of the existence of a different species of Burgdorferi (the Asian and European strains are distinct (Borrelia Afezelii and Garinii). Furthermore these strains of Borrelia which also cause Lyme disease have been demonstrated in migratory birds that fly around the Pacific Rim from Lyme endemic areas in Asia such as Japan (see Prevalence of Lyme Disease Borrelia spp in Ticks from migratory birds on the Japanese Mainland. Ishiguro et al Applied and Environmental Microbiology March 2000). Just as the current influenza strains carried by birds from Asian migratory birds did not exist in Australia over 20 years ago it is highly probable that these birds may have introduced infected ticks in the interim which may have potentially transmitted Lyme to local hosts.

There are numerous papers documenting the existence of Lyme in Australia including most recently in 2014 diagnosis of Lyme by positive PCR from a rash biopsy around a bite with tick still in-situ identified by photo and after removal by university entomologists at as Ixodes Holocylus (the common east coast tick) at three different Australian universities. See: Evidence for Ixodes Holocylus as a vector for human Lyme Borreliosis in Australia (Journal of Insect Science December 2014).

Other papers examining Lyme in Australia include: Emerging Incidence of Lyme Borreliosis, Babesiosis, Bartonellosis and Granulocytic Ehrlichiosis in Australia. (Mayne P International Journal of General Medicine December 2011) and Evaluating the need for a Specialist service on Lyme disease in Australia (Janakiraman and Wan Australasian Journal of Psychiatry November 2014).
The Chief Medical Officer of the Commonwealth Government who has been supervising an investigation in to the existence of Lyme in Australia has stated that we should be open to the possibility of a locally acquired Lyme like illness in Australia. Most recently a Murdoch University study identified numerous tick borne pathogens including Bartonella, Anaplasma and Borrelia Relapsing Fever like species in Australian human biting ticks. Borrelia relapsing fever is known to also cause chronic neurological disease similar to Lyme. Murdoch University researchers demonstrated a novel Borrelia species sharing features of both Lyme causing Borrelia species and Relapsing fever causing Borrelia. This species has been found in both human biting ticks and in 40% of ticks on Echidna suggesting it is widespread. The clinical syndrome seen in patients in Australia complaining of locally acquired Lyme like illness has overlapping features of Borrelia relapsing fever including febrile crises at times triggered as herxheimer reactions with associated delirium and a peripheral neuromuscular disorder often mistaken as pseudo seizures or seizures. See Relapsing Fever on CDC website for description of this condition. This clinical picture correlates with the genetics of this novel hybrid Australian species.

Evidence for persistent active Lyme disease and long term antibiotic treatment

Traditional guidelines for lyme disease only involve short courses of antibiotics. These are based on limited evidence from a small number of randomised controlled trials of very restricted protocols of courses of antibiotics longer than the 3-4 week standard courses which were underpowered.

There is however a large body of evidence demonstrating failure of short courses of antibiotics in between 24 and 50% of patients (Johnson and Stricker 2004). Many of these patients symptoms are explained as being the result of post lyme syndrome with little explanation of how or why this occurs. There are numerous published studies providing evidence for persistent of Borrelia Burgdorferi infection despite what would otherwise have been considered adequate treatment (Johnson and Stricker 2004). There are likely a variety of mechanisms contributing to the persistence of lyme disease in vivo including the ability of lyme disease to suppress the immune system, the ability of lyme disease to migrate inside cells where it may evade both immune mechanisms and antibiotics, in vitro studies have shown that lyme is resistant to antibiotics in the presence of endothelial cells (Miklossy, Kasas et al. 2008) (Liang, Brown et al. 2004). Furthermore borrelia is known to transform to cystic forms in response to antibiotics which are resistant to these standard antibiotics but sensitive to metronidazole (Brorson and Brorson 1998) (Kersten, Poitschek et al. 1995) Finally there is evidence that lyme disease may form biofilm which is resistant to standard antibiotic treatment (Stricker and Johnson 2011, Sapi, Bastian et al. 2012). There is a variety of evidence to suggest that antibiotics may suppress but not eradicate Borrelia Burgdorferi infection (Johnson and Stricker 2004). The end point of most standard treatment course studies for cure is that patients are culture negative at the end of treatment in spite of often persistent symptoms. However animal studies have demonstrated that mice treated for 1 month although culture negative still demonstrated persistence of borrelia as detected by PCR and could infect other mice via tick vectors and consequently had active infection (Hodzic, Feng et al. 2008)

There are numerous published studies showing that results of treatment with antibiotics for lyme disease in chronic lyme improve with longer durations of treatment and with retreatment with antibiotics (Johnson and Stricker 2004). Although most of these papers are case studies it still constitutes evidence in the absence of any prolonged trials of adequate duration. Furthermore the double blinded studies which have been cited as evidence for not to treat for prolonged periods of

time did actually demonstrate clinically meaningful benefit in numerous factors including cognition function, pain physical functioning and overall physical function as has been reported in various analyses of these trials (Stricker 2007, A. Fallon 2012, DeLong, Blossom et al. 2012, Klempner, Baker et al. 2013).

A. Fallon, B. (2012). "A Reappraisal of the U.S. Clinical Trials of Post-Treatment Lyme Disease Syndrome." The Open Neurology Journal **6**(1): 79-87.

Brorson, O. and S. H. Brorson (1998). "In vitro conversion of Borrelia burgdorferi to cystic forms in spinal fluid, and transformation to mobile spirochetes by incubation in BSK-H medium." Infection **26**(3): 144-150.

> The purpose of this study was to examine the structural alterations of Borrelia burgdorferi when exposed to spinal fluid. Normal, mobile spirochetes were inoculated into spinal fluid, and the spirochetes were converted to cysts (spheroplast L-forms) after 1-24 h. When these cystic forms were transferred to a rich BSK-H medium, the cysts were converted back to normal, mobile spirochetes after incubation for 9 to 17 days. The cultures were examined by dark field microscopy (DFM), interference contrast microscopy (ICM) and transmission electron microscopy (TEM). When neuroborreliosis is suspected, it is necessary to realize that B, burgdorferi can be present in a cystic form, and these cysts have to be recognized by microscopy. This study may also explain why cultivation of spinal fluid often is negative with respect to B. burgdorferi.

DeLong, A. K., et al. (2012). "Antibiotic retreatment of Lyme disease in patients with persistent symptoms: A biostatistical review of randomized, placebo-controlled, clinical trials." Contemporary Clinical Trials **33**(6): 1132-1142.

> Introduction Lyme disease (Lyme borreliosis) is caused by the tick-borne spirochete Borrelia burgdorferi. Long-term persistent illness following antibiotic treatment is not uncommon, particularly when treatment is delayed. Current treatment guidelines for persistent disease primarily rely on findings from four randomized, controlled trials (RCTs), strongly advising against retreatment. Methods We performed a biostatistical review of all published RCTs evaluating antibiotic retreatment, focusing on trial design, analysis and conclusions. Results Four RCTs met the inclusion criteria; all examined the efficacy of intravenous ceftriaxone versus placebo at approximately 3 or 6 months. Design assumptions for the primary outcomes in the two Klempner trials and two outcomes in the Krupp trial were unrealistic and the trials were likely underpowered to detect clinically meaningful treatment effects. The Klempner trials were analyzed using inefficient statistical methods. The Krupp RCT was well-designed and analyzed for fatigue, finding statistically significant and clinically meaningful improvement. Fallon corroborated this finding. Fallon also found improvement in cognitive functioning, a primary outcome, at 12 weeks which was not sustained at 24 weeks; improvements in physical functioning and pain were demonstrated at week 24 as an interaction effect between treatment and baseline symptom severity with the drug effect increasing with higher baseline impairment. Discussion This biostatistical review reveals that retreatment can be beneficial. Primary outcomes originally reported as statistically insignificant were likely underpowered. The positive treatment effects of ceftriaxone are encouraging and consistent with continued infection, a hypothesis deserving additional study. Additional studies of persistent infection and antibiotic treatment are warranted.

Hodzic, E., et al. (2008). "Persistence of Borrelia burgdorferi following Antibiotic Treatment in Mice." Antimicrobial Agents and Chemotherapy **52**(5): 1728.

Johnson, L. and R. B. Stricker (2004). "Treatment of Lyme disease: a medicolegal assessment." Expert Review of Anti-Infective Therapy **2**(4): 533-557.

Lyme disease is the most common tick-borne disease in the world today. Despite extensive research into the complex nature of Borrelia burgdorferi, the spirochetal agent of Lyme disease, controversy continues over the diagnosis and treatment of this protean illness. This report will focus on two aspects of the treatment of Lyme disase. First, the medical basis for diagnostic and therapeutic uncertainty in Lyme disease, including variability in clinical presentation, shortcomings in laboratory testing procedures, and design defects in therapeutic trials. Second, the standard of care and legal issues that have resulted from the clinical uncertainty of Lyme disease diagnosis and treatment. Specifically, the divergent therapeutic standards for Lyme disease are addressed, and the difficult process of creating treatment guidelines for this complex infection is explored. Consideration by healthcare providers of the medicolegal issues outlined in this review will support a more rational approach to the diagnosis and treatment of Lyme disease and related tick-borne illnesses.

Kersten, A., et al. (1995). "Effects of penicillin, ceftriaxone, and doxycycline on morphology of Borrelia burgdorferi." Antimicrob. Agents Chemother. **39**(5): 1127-1133

Klempner, M. S., et al. (2013). Treatment trials for post-lyme disease symptoms revisited. **126:** 665-669.

The authors of 4 National Institutes of Health-sponsored antibiotic treatment trials of patients with persistent unexplained symptoms despite previous antibiotic treatment of Lyme disease determined that retreatment provides little if any benefit and carries significant risk. Two groups recently provided an independent reassessment of these trials and concluded that prolonged courses of antibiotics are likely to be helpful. We have carefully considered the points raised by these groups, along with our own critical review of the treatment trials. On the basis of this analysis, the conclusion that there is a meaningful clinical benefit to be gained from retreatment of such patients with parenteral antibiotic therapy cannot be justified. © 2013 Elsevier Inc. All rights reserved.

Liang, F. T., et al. (2004). "Protective niche for Borrelia burgdorferi to evade humoral immunity." Am. J. Pathol. **165**(3): 977-985.

The Lyme disease spirochete, Borrelia burgdorferi, is an extracellular microbe that causes persistent infection despite the development of strong immune responses against the bacterium. B. burgdorferi expresses several ligand-binding lipoproteins, including the decorin-binding proteins (Dbps) A and B, which may mediate attachment to decorin, a major component of the host extracellular matrix during murine infection. We show that B. burgdorferi was better protected in the joints and skin, two tissues with a higher decorin expression, than in the urinary bladder and heart, two tissues with a lower decorin expression, during chronic infection of wild-type mice. Targeted disruption of decorin alone completely abolished the protective niche in chronically infected decorin-deficient mice but did not affect the spirochete burden during early infection. The nature of protection appeared to be specific because the spirochetes with higher outer surface protein C expression were not protected while the protective niche seemed to favor the spirochetes with a higher dbpA expression during chronic infection. These data suggest that spirochetal DbpA may interact with host decorin during infection and such interactions could be a mechanism that B. burgdorferi uses to evade humoral immunity and establish chronic infection.

Miklossy, J., et al. (2008). "Persisting atypical and cystic forms of Borrelia burgdorferi and local inflammation in Lyme neuroborreliosis." J. Neuroinflamm. **5**.

Background: The long latent stage seen in syphilis, followed by chronic central nervous system infection and inflammation, can be explained by the persistence of atypical cystic and granular forms of Treponema pallidum. We investigated whether a similar situation may occur

in Lyme neuroborreliosis. Method: Atypical forms of Borrelia burgdorferi spirochetes were induced exposing cultures of Borrelia burgdorferi (strains B31 and ADBI) to such unfavorable conditions as osmotic and heat shock, and exposure to the binding agents Thioflavin S and Congo red. We also analyzed whether these forms may be induced in vitro, following infection of primary chicken and rat neurons, as well as rat and human astrocytes. We further analyzed whether atypical forms similar to those induced in vitro may also occur in vivo, in brains of three patients with Lyme neuroborreliosis. We used immunohistochemical methods to detect evidence of neuroinflammation in the form of reactive microglia and astrocytes. Results: Under these conditions we observed atypical cystic, rolled and granular forms of these spirochetes. We characterized these abnormal forms by histochemical, immunohistochemical, dark field and atomic force microscopy (AFM) methods. The atypical and cystic forms found in the brains of three patients with neuropathologically confirmed Lyme neuroborreliosis were identical to those induced in vitro. We also observed nuclear fragmentation of the infected astrocytes using the TUNEL method. Abundant HLA-DR positive microglia and GFAP positive reactive astrocytes were present in the cerebral cortex. Conclusion: The results indicate that atypical extra- and intracellular pleomorphic and cystic forms of Borrelia burgdorferi and local neuroinflammation occur in the brain in chronic Lyme neuroborreliosis. The persistence of these more resistant spirochete forms, and their intracellular location in neurons and glial cells, may explain the long latent stage and persistence of Borrelia infection. The results also suggest that Borrelia burgdorferi may induce cellular dysfunction and apoptosis. The detection and recognition of atypical, cystic and granular forms in infected tissues is essential for the diagnosis and the treatment as they can occur in the absence of the typical spiral Borrelia form.

Sapi, E., et al. (2012). "Characterization of Biofilm Formation by Borrelia burgdorferi In Vitro." PLoS One **7**(10).

Borrelia burgdorferi, the causative agent of Lyme disease, has long been known to be capable of forming aggregates and colonies. It was recently demonstrated that Borrelia burgdorferi aggregate formation dramatically changes the in vitro response to hostile environments by this pathogen. In this study, we investigated the hypothesis that these aggregates are indeed biofilms, structures whose resistance to unfavorable conditions are well documented. We studied Borrelia burgdorferi for several known hallmark features of biofilm, including structural rearrangements in the aggregates, variations in development on various substrate matrices and secretion of a protective extracellular polymeric substance (EPS) matrix using several modes of microscopic, cell and molecular biology techniques. The atomic force microscopic results provided evidence that multilevel rearrangements take place at different stages of aggregate development, producing a complex, continuously rearranging structure. Our results also demonstrated that Borrelia burgdorferi is capable of developing aggregates on different abiotic and biotic substrates, and is also capable of forming floating aggregates. Analyzing the extracellular substance of the aggregates for potential exopolysaccharides revealed the existence of both sulfated and non-sulfated/carboxylated substrates, predominately composed of an alginate with calcium and extracellular DNA present. In summary, we have found substantial evidence that Borrelia burgdorferi is capable of forming biofilm in vitro. Biofilm formation by Borrelia species might play an important role in their survival in diverse environmental conditions by providing refuge to individual cells.

Stricker, R. B. (2007). "Counterpoint: Long-Term Antibiotic Therapy Improves Persistent Symptoms Associated with Lyme Disease." Clinical Infectious Diseases **45**(2): 149-157.

Background. Controversy exists regarding the diagnosis and treatment of Lyme disease. Patients with persistent symptoms after standard (2–4-week) antibiotic therapy for this tickborne illness have been denied further antibiotic treatment as a result of the perception that long-term infection with the Lyme spirochete, Borrelia burgdorferi, and associated tickborne pathogens is rare or nonexistent.Methods. I review the pathophysiology of B. burgdorferi infection and the peer-reviewed literature on diagnostic Lyme disease testing, standard treatment results, and coinfection with tickborne agents, such as Babesia, Anaplasma, Ehrlichia, and Bartonella species. I also examine uncontrolled and controlled trials of prolonged antibiotic therapy in patients with persistent symptoms of Lyme

disease.Results. The complex “stealth” pathology of B. burgdorferi allows the spirochete to invade diverse tissues, elude the immune response, and establish long-term infection. Commercial testing for Lyme disease is highly specific but relatively insensitive, especially during the later stages of disease. Numerous studies have documented the failure of standard antibiotic therapy in patients with Lyme disease. Previous uncontrolled trials and recent placebo-controlled trials suggest that prolonged antibiotic therapy (duration, <4 weeks) may be beneficial for patients with persistent Lyme disease symptoms. Tickborne coinfections may increase the severity and duration of infection with B. burgdorferi.Conclusions. Prolonged antibiotic therapy may be useful and justifiable in patients with persistent symptoms of Lyme disease and coinfection with tickborne agents.

Stricker, R. B. and L. Johnson (2011). "Lyme disease: The next decade." Infection and Drug Resistance **4**(1): 1-9.

References for persistent Borrelia Burgdorferi infection

Breier etal. Following treatment with four courses of ceftriaxone with or without methylprednisolone for up to 20 days, Borrelia burgdorferi was isolated from cultures obtained from enlarging skin lesions

Breier F, Khanakah G, Stanek G et al. Isolation and polymerase chain reaction typing of Borrelia afzelii from a skin lesion in a seronegative patient with generalized ulcerating bullous lichen sclerosus et atrophicus. Br. J. Dermatol. 144(2), 387–392 (2001).

Horowitz 80 patients treated with multiple courses of antibiotics for an average of 13 months who continued to have persistent symptoms were PCR-positive

Horowitz R. Chronic persistent Lyme borreliosis: PCR evidence of chronic infection despite extended antibiotic therapy – a retrospective review. 13th International Scientific Conference on Lyme Disease and Other Tick-Borne Disorders. CT, USA 24–26 March 2000

Oksi et al. 40% (13 out of 32 clinical relapses) were confirmed by PCR or culture

Oksi J, Marjamaki M, Nikoskelainen J, Viljanen MK. Borrelia burgdorferi detected by culture and PCR in clinical relapse of disseminated Lyme borreliosis. Ann. Med. 31(3), 225–232 (1999

Bayer et al. 97 patients with symptoms of chronic Lyme disease were PCR-positive despite having been treated with antibiotics for extended periods of time

Bayer ME, Zhang L, Bayer MH. Borrelia burgdorferi DNA in the urine of treated patients with chronic Lyme disease symptoms. A PCR study of 97 cases. Infection 24(5), 347–353 (1996).

Preac Mursic et al. Isolation of Borrelia burgdorferi by culture in five patients, four of whom had tested antibody-negative on previous occasions

Preac Mursic V, Marget W, Busch U, Pleterski Rigler D, Hagl S. Kill kinetics of Borrelia burgdorferi and bacterial findings in relation to the treatment of Lyme borreliosis. Infection 24(1), 9–16 (1996).

Burrascano Patient treated with amoxicillin for 7 months, intravenous cefotaxime for 26 weeks, then cefuroxime for 5 months. Became pregnant at start of cefotaxime. At birth, the placenta tested positive for Borrelia burgdorferi

Burrascano J. Failure of aggressive antibiotic therapy to protect the placenta from invasion by B burgdorferi in a pregnant patient with Lyme Borreliosis. 6th Annual International Science Conference on Lyme Disease and other Tick-borne Diseases. (1993) (Abstract).

Battafarano et al. A patient had chronic septic Lyme arthritis of the knee for 7 years, despite multiple antibiotic trials and multiple arthroscopic and open synovectomies. Borreliaburgdorferi was documented in synovium and synovial fluid

Battafarano DF, Combs JA, Enzenauer RJ, Fitzpatrick JE. Chronic septic arthritis caused by Borrelia burgdorferi. Clin. Orthop. 297, 238–241 (1993).

Haupl et al. After repeated antibiotic treatment, Borrelia burgdorferi was cultured from a ligament sample

Haupl T, Hahn G, Rittig M et al. Persistence of Borrelia burgdorferi in ligamentous tissue from a patient with chronic Lyme borreliosis. Arthritis Rheum. 36(11), 1621–1626 (1993).

Preac-Mursic et al. Patient with blurred vision treated with two separate month-long cycles of tetracycline had symptoms that persisted for several years. Borrelia burgdorferi was cultured from iris biopsy

Preac-Mursic V, Pfister HW, Spiegel H et al. First isolation of Borrelia burgdorferi from an iris biopsy. J. Clin. Neuroophthalmol. 13(3), 155–161 (1993).

Liegner et al. After treatment with cefotaxime and minocycline, T-cell stimulation test with Borrelia burgdorferi antigens were strongly positive. A year later, paired serum and CSF samples were also strongly positive

Liegner KB. Culture confirmed treatment failure of cefotaxime and minocycline in a case of Lyme meningoencephalomyelitis. In: Program and abstracts of the Fifth International Conference on Lyme Borreliosis. Arlington, VA, USA (1992).

Pfister et al. Borrelia burgdorferi cultured from the CSF of a patient 7.5 months after treatment

Pfister HW, Preac-Mursic V, Wilske B, Schielke E, Sorgel F, Einhaupl KM. Randomized comparison of ceftriaxone and cefotaxime in Lyme neuroborreliosis. J. Infect. Dis. 163(2), 311–318 (1991).

Preac-Mursic et al. Borrelia burgdorferi cultured from the CSF of three patients and from the skin of three others after treatment

Preac-Mursic V, Weber K, Pfister HW et al. Survival of Borrelia burgdorferi in antibiotically treated patients with Lyme borreliosis. Infection 17(6), 355–359 (1989).

Evid**ence that antibiotics may suppress but not eradicate Borrelia burgdorferi infection.**

Breier et al. Despite treatment with four courses of ceftriaxone with or without methylprednisolone for up to 20 days, a patient with lichen sclerosus et atrophicus had regression of skin lesions for up to 1year. She repeatedly relapsed despite initially successful antibiotic treatment; these relapses were treated successfully with a course of the same antibiotics as previously used

See above reference

Petrovic et al. Despite repeated intravenous and oral treatment, symptoms improved only temporarily shortly after treatment, but re-emerged within weeks or months

Petrovic M, Vogelaers D, Van Renterghem L, Carton D, De Reuck J, Afschrift M. Lyme borreliosis – a review of the late stages and treatment of four cases. Acta. Clin. Belg. 53(3), 178–183 (1998).

Bayer et al. 97 patients with symptoms of chronic Lyme disease, confirmed by polymerase chain reaction. Most of the patients had been treated with antibiotics for extended periods of time: ‘It seems to be characteristic for most of the patients in our study that, after antibiotic-free periods of a few months, they had again become increasingly ill with neurological and arthritic symptoms, so that treatment had to be resumed’

See above reference

Ferris et al. Despite seven short-term antibiotic treatments received during a 2-year period, the patient's condition greatly deteriorated. 12 months of intravenous followed by 11 months of oral antibiotics improved the quality of life greatly. Antibiotics expected to be continued in the long-term, until cure or to delay progression of the disease

Ferris Tortajada J, Lopez Andreu JA, Salcede Vivo J, Sala Lizarraga JV. Lyme Borreliosis (Letter). Lancet 345(8962), 1436–1437 (1995).

Lopez et al. With long-term antibiotics (intravenous and oral), patient's general condition improved, but each antibiotic course was followed by a relapse

Lopez-Andreu JA, Ferris J, Canosa CA, Sala-Lizarraga JV. Treatment of late Lyme disease: a challenge to accept. J. Clin. Microbiol. 32(5), 1415–1416 (1994).

Haupl et al. The patient had relapsing Lyme borreliosis with choroiditis, arthritis, carditis, and tendonitis. Repeated antibiotic treatment stopped progression of disease but did not completely eliminate Borrelia burgdorferi. Borrelia burgdorferi cultured from ligament sample

Haupl T, Hahn G, Rittig M et al. Persistence of Borrelia burgdorferi in ligamentous tissue from a patient with chronic Lyme borreliosis. Arthritis Rheum. 36(11), 1621–1626 (1993

Ozone Therapy Evidence Base

(Bocci 2004)

(Bocci, Borrelli et al. 2009)

(Di Mauro, Cantarella et al. 2019)

(Di Paolo, Bocci et al. 2005)

(Domb 2014)

(Kushmakov, Gandhi et al. 2018)

(Mallok, Vaillant et al. 2015)

(Manoto, Maepa et al. 2018)

(Martínez-Sánchez, Al-Dalain et al. 2005)

(Megele, Riemenschneider et al. 2018)

(Nogales, Ferrari et al. 2008)

(Ouf, Moussa et al. 2016)

(Raeissadat, Rayegani et al. 2018)

(Ragab, Shreef et al. 2009)

(Ripamonti, Maniezzo et al. 2012)

(Rowen 2018)

(Rowen 2018)

(Seyam, Smith et al. 2018)

(Smith, Wilson et al. 2017)

(Song, Zeng et al. 2018)

(Xiao, Tang et al. 2017)

(Yamanel, Kaldirim et al. 2011)

Bachs, L., et al. (1992). "Effects of long-term rifampicin administration in primary biliary cirrhosis." Gastroenterology **102**(6): 2077-2080.

Berk, M., et al. (2011). "The efficacy of N-acetylcysteine as an adjunctive treatment in bipolar depression: an open label trial." Journal of affective disorders **135**(1): 389-394.

Bocci, V. (2004). "Ozone as Janus: this controversial gas can be either toxic or medically useful." Mediators of inflammation **13**(1): 3-11.

> Ozone is an intrinsically toxic gas and its hazardous employment has led to a poor consideration of ozone therapy. The aim of this review is to indicate that a wrong dogma and several misconceptions thwart progress: in reality, properly performed ozone therapy, carried out by expert physicians, can be very useful when orthodox medicine appears inadequate. The unbelievable versatility of ozone therapy is due to the cascade of ozone-derived compounds able to act on several targets leading to a multifactorial correction of a pathological state. During the past decade, contrary to all expectations, it has been demonstrated that the judicious application of ozone in chronic infectious diseases, vasculopathies, orthopedics and even dentistry has yielded such striking results that it is deplorable that the medical establishment continues to ignore ozone therapy.

Bocci, V., et al. (2009). "The ozone paradox: ozone is a strong oxidant as well as a medical drug." Medicinal research reviews **29**(4): 646-682.

Borody, T., et al. (2007). "Anti-mycobacterial therapy in Crohn's disease heals mucosa with longitudinal scars." Digestive and liver disease **39**(5): 438-444.

Borody, T., et al. (2002). "Treatment of severe Crohn's disease using antimycobacterial triple therapy—approaching a cure?" Digestive and liver disease **34**(1): 29-38.

Cook, D. B., et al. (2017). "Neural consequences of post-exertion malaise in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome." Brain, Behavior, and Immunity **62**: 87-99.

> Post exertion malaise is one of the most debilitating aspects of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, yet the neurobiological consequences are largely unexplored. The objective of the study was to determine the neural consequences of acute exercise using functional brain imaging. Fifteen female Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients and 15 healthy female controls

completed 30min of submaximal exercise (70% of peak heart rate) on a cycle ergometer. Symptom assessments (e.g. fatigue, pain, mood) and brain imaging data were collected one week prior to and 24h following exercise. Functional brain images were obtained during performance of: 1) a fatiguing cognitive task – the Paced Auditory Serial Addition Task, 2) a non-fatiguing cognitive task – simple number recognition, and 3) a non-fatiguing motor task – finger tapping. Symptom and exercise data were analyzed using independent samples t-tests. Cognitive performance data were analyzed using mixed-model analysis of variance with repeated measures. Brain responses to fatiguing and non-fatiguing tasks were analyzed using linear mixed effects with cluster-wise (101-voxels) alpha of 0.05. Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients reported large symptom changes compared to controls (effect size ≥0.8, $p<0.05$). Patients and controls had similar physiological responses to exercise ($p>0.05$). However, patients exercised at significantly lower Watts and reported greater exertion and leg muscle pain ($p<0.05$). For cognitive performance, a significant Group by Time interaction ($p<0.05$), demonstrated pre- to post-exercise improvements for controls and worsening for patients. Brain responses to finger tapping did not differ between groups at either time point. During number recognition, controls exhibited greater brain activity ($p<0.05$) in the posterior cingulate cortex, but only for the pre-exercise scan. For the Paced Serial Auditory Addition Task, there was a significant Group by Time interaction ($p<0.05$) with patients exhibiting increased brain activity from pre- to post-exercise compared to controls bilaterally for inferior and superior parietal and cingulate cortices. Changes in brain activity were significantly related to symptoms for patients ($p<0.05$). Acute exercise exacerbated symptoms, impaired cognitive performance and affected brain function in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome patients. These converging results, linking symptom exacerbation with brain function, provide objective evidence of the detrimental neurophysiological effects of post-exertion malaise.

Cudkowicz, M. E., et al. (2014). "Safety and efficacy of ceftriaxone for amyotrophic lateral sclerosis: a multi-stage, randomised, double-blind, placebo-controlled trial." The Lancet Neurology **13**(11): 1083-1091.

Cunningham, A., et al. (1998). "Chronic Chlamydia pneumoniae infection and asthma exacerbations in children." European Respiratory Journal **11**(2): 345-349.

Di Mauro, R., et al. (2019). "The Biochemical and Pharmacological Properties of Ozone: The Smell of Protection in Acute and Chronic Diseases." International journal of molecular sciences **20**(3): 634.

Ozone therapy has been widely used in everyday clinical practice over the last few years, leading to significant clinical results in the treatment of herniated discs and pain management. Nevertheless, further studies have demonstrated its potential efficacy and safety under other clinical and experimental conditions. However, some of these studies showed controversial results regarding the safety and efficacy of ozone therapy, thus mining its potential use in an everyday clinical practice. To this regard, it should be considered that extensive literature review reported the use of ozone in a significant different dose range and with different delivery systems. The aim of the present review is to describe the various pharmacological effects of ozone in different organs and clinical conditions and to provide possible biochemical and molecular insights for ozone biological properties, thus providing a possible explanation for various controversial clinical outcomes described in the scientific literature.

Di Paolo, N., et al. (2005). "Extracorporeal blood oxygenation and ozonation (EBOO): a controlled trial in patients with peripheral artery disease." The International journal of artificial organs **28**(10): 1039-1050.

Dinicola, S., et al. (2018). "Natural products–alpha-lipoic acid and acetyl-L-carnitine–in the treatment of chemotherapy-induced peripheral neuropathy." European review for medical and pharmacological sciences **22**(14): 4739-4754.

Domb, W. C. (2014). "Ozone therapy in dentistry. A brief review for physicians." Interventional neuroradiology : journal of peritherapeutic neuroradiology, surgical procedures and related neurosciences **20**(5): 632-636.

> The 21(st) century dental practice is quite dynamic. New treatment protocols and new materials are being developed at a rapid pace. Ozone dental therapy falls into the category of new treatment protocols in dentistry, yet ozone is not new at all. Ozone therapy is already a major treatment modality in Europe, South America and a number of other countries. What is provided here will not be an exhaustive scientific treatise so much as a brief general introduction into what dentists are now doing with ozone therapies and the numerous oral/systemic links that make this subject so important for physicians so that, ultimately, they may serve their patients more effectively and productively.

Endresen, G. K. (2003). "Mycoplasma blood infection in chronic fatigue and fibromyalgia syndromes." Rheumatology international **23**(5): 211-215.

Finkelmeyer, A., et al. (2018). "Grey and white matter differences in Chronic Fatigue Syndrome – A voxel-based morphometry study." NeuroImage: Clinical **17**: 24-30.

> Objective Investigate global and regional grey and white matter volumes in patients with Chronic Fatigue Syndrome (CFS) using magnetic resonance imaging (MRI) and recent voxel-based morphometry (VBM) methods. Methods Forty-two patients with CFS and thirty healthy volunteers were scanned on a 3-Tesla MRI scanner. Anatomical MRI scans were segmented, normalized and submitted to a VBM analysis using randomisation methods. Group differences were identified in overall segment volumes and voxel-wise in spatially normalized grey matter (GM) and white matter (WM) segments. Results Accounting for total intracranial volume, patients had larger GM volume and lower WM volume. The voxel-wise analysis showed increased GM volume in several structures including the amygdala and insula in the patient group. Reductions in WM volume in the patient group were seen primarily in the midbrain, pons and right temporal lobe. Conclusion Elevated GM volume in CFS is seen in areas related to processing of interoceptive signals and stress. Reduced WM volume in the patient group partially supports earlier findings of WM abnormalities in regions of the midbrain and brainstem.

Galeshkalami, N. S., et al. (2019). "Alpha-lipoic acid and coenzyme Q10 combination ameliorates experimental diabetic neuropathy by modulating oxidative stress and apoptosis." Life sciences **216**: 101-110.

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Background: Adverse drug reactions (ADRs) are an important public health problem, representing a major cause of morbidity and mortality. However, several countries have no recent studies available. Since 2014, a prospective active pharmacovigilance project, aimed to improve ADRs monitoring in hospital wards (FORWARD) was performed in Sicily. This study, as part of FORWARD project, was aimed to describe ADRs occurred during the hospital stay in Internal Medicine wards. ADRs related to hospital admission, characteristics and preventability of ADRs were also evaluated. Methods: Demographic, clinical, and pharmacological data on patients admitted to six wards of Internal Medicine, from 2014 to 2015, were collected by trained, qualified monitors, who screened all medical records. The rate of ADRs occurred during hospital stay and those leading to hospitalization were analyzed. A descriptive analysis of the reactions, suspected drugs, and associated factors was performed according to the setting analyzed. Results: During the study period, 4,802 admissions were recorded; in 3.2% of them ADRs occurred during hospital stay while in 6.2%, admission was due to ADRs. The duration of hospital stay was longer in patients who experienced ADRs during hospitalization, compared to patients without ADRs [median days 12 (Q1-Q3: 8-17) vs. 9 (6-13)]; $p < 0.001$). Females [OR1.39 (95% CI 1.03-1.93)] and patients taking >/= 4 drugs [OR1.46 (95% CI 1.06-2.03)] were more likely to experience ADRs during hospital stay, as well as to be admitted because of ADRs [female: OR1.75 (95% CI 1.37-2.24); >/= 4 drugs: OR2.14 (95% CI 1.67-2.74)]. The most frequent ADRs occurred during hospital stay were cutaneous (26.8%), general (13.4%), vascular (13.4%), and cardiac (11.5%) disorders and the drug classes mainly involved were anti-bacterials (38.2%) and antithrombotic agents (21.7%). ADRs were serious in 44.6% and probably preventable in 69.4%. Gastrointestinal (27.7%), hematological (26.5%), metabolic (18.1%), and nervous (16.1%) disorders were the main ADRs cause of hospitalization, primarily due to antithrombotic agents (39.0%) RAS-inhibitors (13.9%), NSAIDs (11.9%), and diuretics (9.0%). Only 12.9% of them was not preventable. Conclusion: Adverse drug reactions occurred during hospitalization or contributing to admission to Internal Medicine wards were considerable and most of them were preventable. Females and patients taking many medications were more likely to present ADRs both during hospital stay or as cause of admission.

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Kushmakov, R., et al. (2018). "Ozone therapy for diabetic foot." Medical gas research **8**(3): 111-115.

Diabetic foot ulcers (DFU) are a burden to the diabetic community. With increasing medical bills, to unsuccessful treatment, those suffering from DFUs can use alternative therapeutics. First seen in the mid-1800s, ozone (O(3)) is thought to be unstable, due to inherent molecular nature. With the help of pharmaceutical science, various O(3) treatments have flourished in the medical community to help those suffering from DFUs. Promising results are seen through numerous studies. Usually, a mixture of both O(2) and O(3) is seen in

pressurized machines as administered to the foot ulcer. Foot ulcers, specifically DFUs, need to be assessed, cleaned, and treated as fast as possible for the fastest results. Results such as amputation can be seen if the foot is not attended to as soon as possible. With fast growing clinical trials in O(3) therapy and quick administration of the O(3), O(3) therapy may be on the rise to be at the forefront of treating DFUs. Compelling evidence is seen in clinical trials, but more must be done to fully understand the role of O(3) in DFUs.

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Landi, A., et al. (2016). "Reductions in circulating levels of IL-16, IL-7 and VEGF-A in myalgic encephalomyelitis/chronic fatigue syndrome." Cytokine **78**: 27-36.

Recently, differences in the levels of various chemokines and cytokines were reported in patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) as compared with controls. Moreover, the analyte profile differed between chronic ME/CFS patients of long duration versus patients with disease of less than 3years. In the current study, we measured the plasma levels of 34 cytokines, chemokines and growth factors in 100 chronic ME/CFS patients of long duration and in 79 gender and age-matched controls. We observed highly significant reductions in the concentration of circulating interleukin (IL)-16, IL-7, and Vascular Endothelial Growth Factor A (VEGF-A) in ME/CFS patients. All three biomarkers were significantly correlated in a multivariate cluster analysis. In addition, we identified significant reductions in the concentrations of fractalkine (CX3CL1) and monokine-induced-by-IFN-γ (MIG; CXCL9) along with increases in the concentrations of eotaxin 2 (CCL24) in ME/CFS patients. Our data recapitulates previous data from another USA ME/CFS cohort in which circulating levels of IL-7 were reduced. Also, a reduced level of VEGF-A was reported previously in sera of patients with Gulf War Illness as well as in cerebral spinal fluid samples from a different cohort of USA ME/CFS patients. To our knowledge, we are the first to test for levels of IL-16 in ME/CFS patients. In combination with previous data, our work suggests that the clustered reduction of IL-7, IL-16 and VEGF-A may have physiological relevance to ME/CFS disease. This profile is ME/CFS-specific since measurement of the same analytes present in chronic infectious and autoimmune liver diseases, where persistent fatigue is also a major symptom, failed to demonstrate the same changes. Further studies of other ME/CFS and overlapping disease cohorts are warranted in future.

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Lerner, A. M., et al. (2007). "Valacyclovir treatment in Epstein-Barr virus subset chronic fatigue syndrome: thirty-six months follow-up." in vivo **21**(5): 707-713.

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Infection-triggered disease onset, chronic immune activation and autonomic dysregulation in CFS point to an autoimmune disease directed against neurotransmitter receptors. Autoantibodies against G-protein coupled receptors were shown to play a pathogenic role in several autoimmune diseases. Here, serum samples from a patient cohort from Berlin (n=268) and from Bergen with pre- and post-treatment samples from 25 patients treated within the KTS-2 rituximab trial were analysed for IgG against human α and β adrenergic, muscarinic (M) 1–5 acetylcholine, dopamine, serotonin, angiotensin, and endothelin receptors by ELISA and compared to a healthy control cohort (n=108). Antibodies against β2, M3 and M4 receptors were significantly elevated in CFS patients compared to controls. In contrast, levels of antibodies against α adrenergic, dopamine, serotonin, angiotensin, and endothelin receptors were not different between patients and controls. A high correlation was found between levels of autoantibodies and elevated IgG1–3 subclasses, but not with IgG4. Further patients with high β2 antibodies had significantly more frequently activated HLA-DR+ T cells and more frequently thyreoperoxidase and anti-nuclear antibodies. In patients receiving rituximab maintenance treatment achieving prolonged B-cell depletion, elevated β2 and M4 receptor autoantibodies significantly declined in clinical responder, but not in non-responder. We provide evidence that 29.5% of patients with CFS had elevated antibodies against one or more M acetylcholine and β adrenergic receptors which are potential biomarkers for response to B-cell depleting therapy. The association of autoantibodies with immune markers suggests that they activate B and T cells expressing β adrenergic and M acetylcholine receptors. Dysregulation of acetylcholine and adrenergic signalling could also explain various clinical symptoms of CFS.

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BACKGROUND: The aim of this study was to estimate the incidence, main causes, and risk factors of iatrogenic disease occurring in a department of internal medicine. METHODS: Over a 1-year period, physicians systematically filled out a 2-page questionnaire for all patients admitted to the ward. A database was created and the data were statistically analyzed. Patients undergoing immunosuppressive, chemo-, or radiation therapy were excluded. Missing data were completed by reviewing the patients' charts. The patients were then divided into two groups: those with and those without iatrogenic disease. The groups were compared using several parameters including gender, age, social features, days of hospitalization, associated illness, functional status, medical impression, prognosis, associated renal or liver function impairment, drugs taken daily, and outcome. In the group with iatrogenic disease, the type, severity, and predictability were also analyzed. RESULTS: Of the 879 patients admitted to the ward, 445 completed questionnaires and were included in the study. A total of 102 patients (22.9%) developed 121 iatrogenic events. Forty-four patients (43.1%) were admitted for iatrogenic illness, 10 (9.8%) developed life-threatening events, and in 3 (6.8%) it was the cause of death. Fifty-eight patients (56.8%) registered 77 episodes of iatrogenic disease during their hospital stay, 20 (19.6%) developed life-threatening events, and 9 (11.7%) died, 4 (5.2%) of an iatrogenic cause (nosocomial infections). Significant differences were found in 20 out of 26 parameters studied (p<0.005

for all cases; 95% confidence interval). Eighteen percent of all iatrogenic disease was severe, 61.9% predictable, 54.5% avoidable, and 59% drug-related, 80% of which was due to side effects or adverse reactions. Infection and metabolic and electrolyte disorders were the most frequent effects. CONCLUSIONS: It is possible to identify risk factors for iatrogenic events. Chronically ill elderly inpatients are the main target of iatrogenic events.

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Maier, K., et al. (2007). "Multiple neuroprotective mechanisms of minocycline in autoimmune CNS inflammation." Neurobiology of disease **25**(3): 514-525.

Mallok, A., et al. (2015). "Ozone protective effects against PTZ-induced generalized seizures are mediated by reestablishment of cellular redox balance and A1 adenosine receptors." Neurological research **37**(3): 204-210.

Manoto, S. L., et al. (2018). "Medical ozone therapy as a potential treatment modality for regeneration of damaged articular cartilage in osteoarthritis." Saudi journal of biological sciences **25**(4): 672-679.

Osteoarthritis (OA) is the most common degenerative joint disease and a growing health problem affecting more than half of the population over the age of 65. It is characterized by inflammation in the cartilage and synovium, resulting in the loss of joint structure and progressive damage to the cartilage. Many pro-inflammatory mediators are elevated in OA, including reactive oxygen species (ROS) such as nitric oxide (NO) and hydrogen peroxide (H(2)O(2)). Damaged articular cartilage remains a challenge to treat due to the limited self-healing capacity of the tissue and unsuccessful biological interventions. This highlights the need for better therapeutic strategies to heal damaged articular cartilage. Ozone (O(3)) therapy has been shown to have positive results in the treatment of OA; however the use of O(3) therapy as a therapeutic agent is controversial. There is a perception that O(3) is always toxic, whereas evidence indicates that when it is applied following a specified method, O(3) can be effective in the treatment of degenerative diseases. The mechanism of action of O(3) therapy in OA is not fully understood and this review summarizes the use of O(3) therapy in the treatment of damaged articular cartilage in OA.

Maric, D., et al. (2014). "Multivitamin mineral supplementation in patients with chronic fatigue syndrome." Medical science monitor: international medical journal of experimental and clinical research **20**: 47.

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McCaddon, A., et al. (2002). "Functional vitamin B12 deficiency and Alzheimer disease." Neurology **58**(9): 1395-1399.

Megele, R., et al. (2018). "Intra-tumoral treatment with oxygen-ozone in glioblastoma: A systematic literature search and results of a case series." Oncology letters **16**(5): 5813-5822.

Despite progress in surgery and radiochemotherapy, the prognosis of glioblastoma (GB) remains poor. GB cells exhibit a preference for hypoxia to maintain their tumor-forming capacity. Treatment strategies utilizing oxygen (O(2)) or ozone (O3) and generating reactive oxygen species induce cell growth inhibition and apoptosis. The anti-tumorigenic properties of O2-O3 are accompanied by a key role in regulating immunogenicity. The present study reported a case series of an intra-tumoral O2-O3 application in recurrent GB. Following surgery in combination with standard radiochemotherapy, O2-O3 (5 ml at 40 µg/ml) was applied every four weeks into the tumor vicinity. The patients received a median of 27 (range, 3-44) O2-O3 applications. In addition, a systematic literature search was performed in order to evaluate the role of O3 in the treatment of malignancies. The median overall survival rate was 40 (range, 16-53) months. The median survival rate following the first recurrence or the initiation of the O2-O3 treatment, respectively, was 34 (range, 12-53) months. In one patient, a local infection and in another, hemorrhage occurred, necessitating in both the temporary removal of the reservoir. The data from the present study support the potential benefit of an intra-tumoral O2-O3 application in recurrent GB. The scientific literature revealed by the bibliographic search suggests that O3 may be considered a viable adjuvant therapy in oncological patients. The present study may serve as a starting point for

further observational and clinical studies elucidating the cellular and systemic effects of O2 and/or O3 and demonstrating their efficacy and safety in larger patient samples.

Mikirova, N. and R. Hunninghake (2014). "Effect of high dose vitamin C on Epstein-Barr viral infection." Medical science monitor : international medical journal of experimental and clinical research **20**: 725-732.

Background Many natural compounds were tested for the ability to suppress viral replication. The present manuscript details an analysis of high dose vitamin C therapy on patients with EBV infection. Material and Methods The data were obtained from the patient history database at the Riordan Clinic. Among people in our database who were treated with intravenous vitamin C (7.5 g to 50 g infusions) between 1997 and 2006, 178 patients showed elevated levels of EBV EA IgG (range 25 to 211 AU) and 40 showed elevated levels of EBV VCA IgM (range 25 to 140 AU). Most of these patients had a diagnosis of chronic fatigue syndrome, with the rest being diagnosed as having mononucleosis, fatigue, or EBV infection. Results Our data provide evidence that high dose intravenous vitamin C therapy has a positive effect on disease duration and reduction of viral antibody levels. Plasma levels of ascorbic acid and vitamin D were correlated with levels of antibodies to EBV. We found an inverse correlation between EBV VCA IgM and vitamin C in plasma in patients with mononucleosis and CFS meaning that patients with high levels of vitamin C tended to have lower levels of antigens in the acute state of disease. In addition, a relation was found between vitamin D levels and EBV EA IgG with lower levels of EBV early antigen IgG for higher levels of vitamin D. Conclusions The clinical study of ascorbic acid and EBV infection showed the reduction in EBV EA IgG and EBV VCA IgM antibody levels over time during IVC therapy that is consistent with observations from the literature that millimolar levels of ascorbate hinder viral infection and replication in vitro.

Miklossy, J. (2011). "Alzheimer's disease - a neurospirochetosis. Analysis of the evidence following Koch's and Hill's criteria." Journal of neuroinflammation **8**(1): 90.

It is established that chronic spirochetal infection can cause slowly progressive dementia, brain atrophy and amyloid deposition in late neurosyphilis. Recently it has been suggested that various types of spirochetes, in an analogous way to Treponema pallidum, could cause dementia and may be involved in the pathogenesis of Alzheimer's disease (AD). Here, we review all data available in the literature on the detection of spirochetes in AD and critically analyze the association and causal relationship between spirochetes and AD following established criteria of Koch and Hill. The results show a statistically significant association between spirochetes and AD (P = 1.5 × 10-17, OR = 20, 95% CI = 8-60, N = 247). When neutral techniques recognizing all types of spirochetes were used, or the highly prevalent periodontal pathogen Treponemas were analyzed, spirochetes were observed in the brain in more than 90% of AD cases. Borrelia burgdorferi was detected in the brain in 25.3% of AD cases analyzed and was 13 times more frequent in AD compared to controls. Periodontal pathogen Treponemas (T. pectinovorum, T. amylovorum, T. lecithinolyticum, T. maltophilum, T. medium, T. socranskii) and Borrelia burgdorferi were detected using species specific PCR and antibodies. Importantly, co-infection with several spirochetes occurs in AD. The pathological and biological hallmarks of AD were reproduced in vitro by exposure of mammalian cells to spirochetes. The analysis of reviewed data following Koch's and Hill's postulates shows a probable causal relationship between neurospirochetosis and AD. Persisting inflammation and amyloid deposition initiated and sustained by chronic spirochetal infection form together with the various hypotheses suggested to play a role in the pathogenesis of AD a comprehensive entity. As suggested by Hill, once the probability of

a causal relationship is established prompt action is needed. Support and attention should be given to this field of AD research. Spirochetal infection occurs years or decades before the manifestation of dementia. As adequate antibiotic and anti-inflammatory therapies are available, as in syphilis, one might prevent and eradicate dementia.

Millea, P. J. (2009). "N-acetylcysteine: multiple clinical applications." American family physician **80**(3): 265-269.

Miyazaki, E., et al. (2008). "Minocycline for the treatment of sarcoidosis: is the mechanism of action immunomodulating or antimicrobial effect?" Clinical rheumatology **27**(9): 1195-1197.

Morris, G., et al. (2014). "The glutathione system: a new drug target in neuroimmune disorders." Molecular neurobiology **50**(3): 1059-1084.

Nguyen, N. and J. K. Takemoto (2018). "A Case for Alpha-Lipoic Acid as an Alternative Treatment for Diabetic Polyneuropathy." Journal of Pharmacy & Pharmaceutical Sciences **21**(1s): 192-199s.

Nicolson, G., et al. (2003). "Multiple co-infections (Mycoplasma, Chlamydia, human herpes virus-6) in blood of chronic fatigue syndrome patients: association with signs and symptoms." Apmis **111**(5): 557-566.

Nicolson, G. L. and R. Ellithorpe (2006). "Lipid replacement and antioxidant nutritional therapy for restoring mitochondrial function and reducing fatigue in chronic fatigue syndrome and other fatiguing illnesses." Journal of Chronic Fatigue Syndrome **13**(1): 57-68.

Nogales, C. G., et al. (2008). "Ozone therapy in medicine and dentistry." J Contemp Dent Pract **9**(4): 75-84.

Ouf, S. A., et al. (2016). "Anti-fungal potential of ozone against some dermatophytes." Brazilian journal of microbiology : [publication of the Brazilian Society for Microbiology] **47**(3): 697-702.

Dermatophytes are classified in three genera, Epidermophyton, Microsporum and Trichophyton. They have the capacity to invade keratinized tissue to produce a cutaneous infection known as dermatophytoses. This investigation was performed to study the effect of gaseous ozone and ozonized oil on three specific properties of six different dermatophytes. These properties included sporulation, mycelia leakage of sugar and nutrients and the activity of their hydrolytic enzymes. Generally, ozonized oil was found to be more efficacious than gaseous ozone. Microsporum gypseum and Microsporum canis were the most susceptible, while Trichophyton interdigitale and T. mentagrophytes were relatively resistant. The study revealed a steady decline in spore production of M. gypseum and M. canis on application of ozonated oil. An increase in leakage of electrolytes and sugar was noticed after treatment with ozonized oil in the case of M. gypseum, M. canis, T. interdigitale, T. mentagrophytes and T. rubrum. The results also revealed loss in urease, amylase, alkaline phosphatase, lipase and keratinase enzyme producing capacity of the investigated fungi.

Pandya, C. D., et al. (2013). "Antioxidants as potential therapeutics for neuropsychiatric disorders." Progress in Neuro-Psychopharmacology and Biological Psychiatry **46**: 214-223.

Plane, J. M., et al. (2010). "Prospects for Minocycline NeuroprotectionProspects for Minocycline Neuroprotection." JAMA Neurology **67**(12): 1442-1448.

The lack of robust treatment options available for neurodegenerative diseases, stroke, and central nervous system (CNS) trauma, all of which often involve both inflammation and apoptotic cell death, has led to an explosion of studies to reexamine the potential of established drugs for treatment of these conditions. Minocycline is a second-generation tetracycline derivative with a proven, safe clinical track record as an antibiotic and anti-inflammatory drug for treating acne and arthritis. Minocycline effectively crosses the blood-brain barrier and has demonstrated neuroprotective qualities in experimental models of CNS trauma, stroke, spinal cord injury, and neurodegenerative diseases including amyotrophic lateral sclerosis, Huntington disease, Parkinson disease, and multiple sclerosis. Thus, it is not surprising that several off-label minocycline clinical trials are under way for a variety of CNS diseases. The emerging success of some of these trials raises optimism that minocycline treatment may soon be translated into clinical practice for CNS diseases, whereas others (eg, in amyotrophic lateral sclerosis) have raised red flags. A thorough understanding of minocycline's modes of action and the targeted cellular mechanisms is warranted, as are guidelines on safe and effective doses, routes of administration, and establishment of a therapeutic window. Although several lines of evidence point to a convergent action of minocycline in suppression of both apoptosis and CNS inflammation by preventing neural cell death and by inhibiting microglial activation, the exact molecular targets of minocycline have yet to be identified and characterized. This review provides an overview of the established mechanisms of action by which minocycline exerts its neuroprotective effects, summarizes results of animal studies in experimental models of neurological diseases, and discusses results of clinical trials.

Porter, N. S., et al. (2010). "Alternative medical interventions used in the treatment and management of myalgic encephalomyelitis/chronic fatigue syndrome and fibromyalgia." The Journal of Alternative and Complementary Medicine **16**(3): 235-249.

Raeissadat, S. A., et al. (2018). "Intra-articular ozone or hyaluronic acid injection: Which one is superior in patients with knee osteoarthritis? A 6-month randomized clinical trial." Journal of pain research **11**: 111-117.

PURPOSE: Knee osteoarthritis (OA) is a common disease, imposing a great burden through pain and decreased function. There are many therapeutic modalities including non-pharmacologic choices and oral, topical, and intra-articular medications. New studies have shown promising results for ozone application in knee OA. Our aim was to compare the effects of ozone therapy versus hyaluronic acid (HA) intra-articular injection in knee OA patients. METHODS: In this randomized clinical trial, a total of 174 patients with more than 3 months of chronic pain or swelling in the knee joints along with consistent imaging findings were enrolled and randomly allocated into two groups of HA and ozone, which were planned to undergo 3 weekly injections of HA (Hyalgan®) and 10 mL of a 30 µg/mL ozone solution, respectively. Patients were evaluated at baseline and 6 months after the last injection for pain, stiffness, and function using the visual analog scale (VAS) and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire. RESULTS: No major adverse events were detected in this study. Total WOMAC score decreased from

40.8±9.8 to 20.4±4.9 (p<0.01) in the ozone group and from 38.5±7.9 to 17.1±4.2 (p<0.01) in the HA group. A similar trend was observed in pain improvement according to VAS. Pain, stiffness, and function significantly improved in both the groups, but no between-group difference was found. CONCLUSION: Although both ozone and HA can be effectively used for improving function and reducing pain in selected knee OA patients, neither of the two showed any superiority at 6-month follow-up.

Ragab, A., et al. (2009). "Randomised, double-blinded, placebo-controlled, clinical trial of ozone therapy as treatment of sudden sensorineural hearing loss." The Journal of Laryngology & Otology **123**(01): 54-60.

Rajeevan, M. S., et al. (2015). "Pathway-focused genetic evaluation of immune and inflammation related genes with chronic fatigue syndrome." Human Immunology **76**(8): 553-560.

Recent evidence suggests immune and inflammatory alterations are important in chronic fatigue syndrome (CFS). This study was done to explore the association of functionally important genetic variants in inflammation and immune pathways with CFS. Peripheral blood DNA was isolated from 50 CFS and 121 non-fatigued (NF) control participants in a population-based study. Genotyping was performed with the Affymetrix Immune and Inflammation Chip that covers 11K single nucleotide polymorphisms (SNPs) following the manufacturer's protocol. Genotyping accuracy for specific genes was validated by pyrosequencing. Golden Helix SVS software was used for genetic analysis. SNP functional annotation was done using SPOT and GenomePipe programs. CFS was associated with 32 functionally important SNPs: 11 missense variants, 4 synonymous variants, 11 untranslated regulatory region (UTR) variants and 6 intronic variants. Some of these SNPs were in genes within pathways related to complement cascade (SERPINA5, CFB, CFH, MASP1 and C6), chemokines (CXCL16, CCR4, CCL27), cytokine signaling (IL18, IL17B, IL2RB), and toll-like receptor signaling (TIRAP, IRAK4). Of particular interest is association of CFS with two missense variants in genes of complement activation, rs4151667 (L9H) in CFB and rs1061170 (Y402H) in CFH. A 5′ UTR polymorphism (rs11214105) in IL18 also associated with physical fatigue, body pain and score for CFS case defining symptoms. This study identified new associations of CFS with genetic variants in pathways including complement activation providing additional support for altered innate immune response in CFS. Additional studies are needed to validate the findings of this exploratory study.

Ramesh, G., et al. (2015). "Anti-inflammatory effects of dexamethasone and meloxicam on Borrelia burgdorferi-induced inflammation in neuronal cultures of dorsal root ganglia and myelinating cells of the peripheral nervous system." Journal of neuroinflammation **12**(1): 1.

Reid, M. B., et al. (1994). "N-acetylcysteine inhibits muscle fatigue in humans." Journal of Clinical Investigation **94**(6): 2468.

Ripamonti, C. I., et al. (2012). "Efficacy and tolerability of medical ozone gas insufflations in patients with osteonecrosis of the jaw treated with bisphosphonates-Preliminary data: Medical ozone gas insufflation in treating ONJ lesions." Journal of bone oncology **1**(3): 81-87.

Osteonecrosis of the Jaw (ONJ) is an adverse event reported especially in patients receiving cancer treatments regimen, bisphosphonates (BPs), and denosumab. We performed an open-label, prospective study in patients treated with zoledronic acid who developed ONJ

lesions >2.5 cm, and had no benefit after the treatment with the standard therapy, to evaluate the efficacy and tolerability of medical ozone (O3) treatment delivered as gas insufflations on each ONJ lesions. Twenty-four patients (mean age 62.5, range 41-80; 12 female) with bone metastases due to breast (11), prostate (4)and lung (4)cancers, myeloma (2), or osteoporosis (3), previously treated with zoledronic acid and not underwent dental preventive measures and with ONJ lesions >2.5 cm, were observed and treated with topical O3 gas insufflation every third day for a minimum of 10 for each pathological area or till necrotic bone sequestrum or surgery. We used a special insufflation bell-shaped device adjusted to the specific characteristics of the patient, capable of eliminating any residue of O3 diffusion by degrading it and releasing O2 into the air. Azithromicin 500 mg/day was administered for 10 days in all patients before the first three gas insufflation although they had previously received various cycles of antibiotics. Ten patients required more than 10 O3 gas insufflations due to multiple lesions and/or purulent sovrainfections; one patient received two further O3 insufflations while waiting the day of surgery. Six of 24 patients interrupted the O3 gas therapy for oncological disease progression (five patients) and for fear of an experimental therapy (one patient). Six patients had the sequestrum and complete or partial (one patient) spontaneous expulsion of the necrotic bone followed by oral mucosa re-epithelization after a range of 4-27 of O3 gas insufflations. No patient reported adverse events. In 12 patients with the largest and deeper ONJ lesions, O3 gas therapy produced the sequestrum of the necrotic bone after 10 to 38 insufflations; surgery was necessary to remove it (11 patients). Of interest, removal was possible without the resection of healthy mandible edge because of the presence of bone sequestrum. All together the response rate was 75.0% (95% CI, 53.3-90.2%) in ITT analysis and 100% (95% CI, 81.5-100%) in the PP analysis. In all patients treated with O3 gas ± surgery, no ONJ relapse appeared (follow-up mean 18 months, range 1-3 years). Medical O3 gas insufflations is an effective and safe treatment for patients treated with BPs who developed ONJ lesions >2.5 cm. Short abstract: ONJ is an adverse event reported in patients receiving cancer treatments regimen, bisphosphonates and denosumab. We performed an open-label, prospective study in 24 patients with solid tumours, myeloma or osteoporosis due to hormonal therapy, treated with zoledronic acid without previuos preventive dental screening, who developed ONJ lesions >2.5 cm, and had no benefit after standard therapy, to evaluate the efficacy and tolerability of medical ozone (O3) treatment delivered as gas insufflations on each ONJ lesions. The patients were treated with O3 every third day for a minimum of 10 for each pathological area or till necrotic bone sequestrum or surgery. Eleven patients required more than ten O3 gas insufflations. Six of 24 patients interrupted the therapy for oncological disease progression. Six patients had the sequestrum and complete or partial (one patient) spontaneous expulsion of the necrotic bone followed by oral mucosa re-epithelization after a range of 4 to 27 of O3 gas insufflations. No patient reported adverse events. In 12 patients with the largest and deeper ONJ lesions, O3 gas therapy produced the sequestrum of the necrotic bone after 10 to 38 insufflations; surgery was necessary to remove it (11 patients). Of interest, removal was possible without the resection of healthy mandible edge because of the presence of bone sequestrum. All together the response rate was 75.0% (95% CI, 53.3-90.2%) in ITT analysis and 100% (95% CI, 81.5-100%) in he PP analysis. In all patients treated with O3 gas ± surgery, no ONJ relapse appeared (follow-up mean 18 months, range 1-3 years).

Rowen, R. J. (2018). "Ozone therapy as a primary and sole treatment for acute bacterial infection: case report." Medical gas research **8**(3): 121-124.

The world is facing a crisis of antibiotic resistance, which impacts every treating physician on the planet. Thousands of patients die yearly in the USA from infections that have failed to

respond to anti-infectives. Alarms have been ringing about bacterial infection fatality resurgence, the end of the antibiotic era, a calamity in progress. Ozone therapy has been used in medicine since World War I. However, it is not patentable and has suffered from lack of private source funding for research sufficient to have it accepted by the mainstream. Basic science, both in vivo and in vitro, research has found it to have several effects including modulating the immune system, enhancing circulation, destroying microorganisms including bacteria and viruses, and enhancing oxygen delivery and consumption by the body. This report presents background basic ozone science and a case report of acute bacterial infection - tick bite cellulitis, which immediately responded to ozone therapy as the sole treatment, and which fully resolved within 24-48 hours. Ozone therapy could be considered as an adjunctive or alternative therapy for bacterial infection.

Rowen, R. J. (2018). "Ozone therapy in conjunction with oral antibiotics as a successful primary and sole treatment for chronic septic prosthetic joint: review and case report." Medical gas research **8**(2): 67-71.

The world is facing crisis in management of infectious diseases. The mainstay of treatment has been chemical anti-infectives. These drugs are failing, as superbugs emerge and medicine becomes more sophisticated with treatments such as prosthetic devices, which can harbor bacteria protected by biofilm. This case report describes a 68-year-old woman who received bilateral artificial hips on October 27, 2015. The right hip prosthesis subsequently became septic by June 2016. Three orthopedic surgeons offered her a several month program, which included removal of the prosthesis, implantation of an antibiotic impregnated "spacer" and months of intravenous antibiotics. Instead, she sought and received intravenous ozone therapy, local joint ozone gas injection, and nutritional supplements. She quickly improved. Subsequently, she was given oral Augmentin (875 mg three times daily) beginning at September 19, 2016 for 1 month, when a third culture returned positive for two oral organisms. She experienced even more rapid improvement. By October 12, she reported total resolution of symptoms. A subsequent MRI on November 30, 2016 showed total clearance of infection. This is the first report of a septic prosthetic joint infection completely resolving without some form of surgical intervention, debridement at the least. It is also the first to report such cure without the use of any parenteral antibiotics. This case and world literature suggest that ozone therapy could be considered as a useful adjunctive treatment for hard to treat infection and biofilm.

Rudenko, N., et al. (2016). "Isolation of live Borrelia burgdorferi sensu lato spirochaetes from patients with undefined disorders and symptoms not typical for Lyme borreliosis." Clinical Microbiology and Infection **22**(3): 267.e269-267.e215.

Lyme borreliosis is a multisystem disorder with a diverse spectrum of clinical manifestations, caused by spirochaetes of the Borrelia burgdorferi sensu lato complex. It is an infectious disease that can be successfully cured by antibiotic therapy in the early stages; however, the possibility of the appearance of persistent signs and symptoms of disease following antibiotic treatment is recognized. It is known that Lyme borreliosis mimics multiple diseases that were never proven to have a spirochaete aetiology. Using complete modified Kelly–Pettenkofer medium we succeeded in cultivating live B. burgdorferi sensu lato spirochaetes from samples taken from people who suffered from undefined disorders, had symptoms not typical for Lyme borreliosis, but who had undergone antibiotic treatment due to a suspicion of having Lyme disease even though they were seronegative. We report the first recovery of live B. burgdorferi sensu stricto from residents of southeastern USA and the first successful cultivation of live Borrelia bissettii-like strain from residents of North America. Our results

support the fact that B. bissettii is responsible for human Lyme borreliosis worldwide along with B. burgdorferi s.s. The involvement of new spirochaete species in Lyme borreliosis changes the understanding and recognition of clinical manifestations of this disease.

Schencking, M., et al. (2012). "Intravenous vitamin C in the treatment of shingles: results of a multicenter prospective cohort study." Medical science monitor: international medical journal of experimental and clinical research **18**(4): CR215.

Seyam, O., et al. (2018). "Clinical utility of ozone therapy for musculoskeletal disorders." Medical gas research **8**(3): 103-110.

Oxygen-ozone (O(3)) therapy serves as an alternative medical technique that increases the oxygen in the body along with the introduction of O(3). O(3) therapy has finally reached a level where the biological mechanisms of action have been understood, showing that they are in the domain of physiology, biochemistry, and pharmacology. Few clinical applications have been reviewed here as well as exemplifying that O(3) therapy is particularly useful in musculoskeletal disorders. In the therapeutic range, O(3) can be used as a more effective and safe substitute of standard medications. O(3) therapy has been used for many years for its ability to inactivate various viruses, cancer, and acquired immune deficiency syndrome but is now making strides in the treatment of musculoskeletal disorders such as rheumatoid arthritis, lumbar facet joint syndrome, subacromial bursitis, carpal tunnel syndrome, osteoarthritis, hip bursitis, shoulder adhesive capsulitis, herniated disc, and temporomandibular joint disorder.

Shoemaker, R. (2002). Use of pioglitazone to prevent intensification of persistent symptoms following cholestyramine treatment of patients with post-Lyme syndrome. Diabetes, AMER DIABETES ASSOC 1660 DUKE ST, ALEXANDRIA, VA 22314 USA.

Shungu, D. C., et al. (2012). "Increased ventricular lactate in chronic fatigue syndrome. III. Relationships to cortical glutathione and clinical symptoms implicate oxidative stress in disorder pathophysiology." NMR in Biomedicine **25**(9): 1073-1087.

Smith, N. L., et al. (2017). "Ozone therapy: an overview of pharmacodynamics, current research, and clinical utility." Medical gas research **7**(3): 212-219.

The use of ozone (O(3)) gas as a therapy in alternative medicine has attracted skepticism due to its unstable molecular structure. However, copious volumes of research have provided evidence that O(3)'s dynamic resonance structures facilitate physiological interactions useful in treating a myriad of pathologies. Specifically, O(3) therapy induces moderate oxidative stress when interacting with lipids. This interaction increases endogenous production of antioxidants, local perfusion, and oxygen delivery, as well as enhances immune responses. We have conducted a comprehensive review of O(3) therapy, investigating its contraindications, routes and concentrations of administration, mechanisms of action, disinfectant properties in various microorganisms, and its medicinal use in different pathologies. We explore the therapeutic value of O(3) in pathologies of the cardiovascular system, gastrointestinal tract, genitourinary system, central nervous system, head and neck, musculoskeletal, subcutaneous tissue, and peripheral vascular disease. Despite compelling evidence, further studies are essential to mark it as a viable and quintessential treatment option in medicine.

Song, M., et al. (2018). "The antibacterial effect of topical ozone on the treatment of MRSA skin infection." Molecular medicine reports **17**(2): 2449-2455.

> Skin can be infected by many types of microorganisms, most commonly by gram‐positive strains of Staphylococcus and Streptococcus spp. Treatment of Staphylococcus aureus (S. aureus) infections, particularly that of methicillin resistant Staphylococcus aureus (MRSA), is a challenge in clinical practice. Ozone therapy has proven to be one of the strongest antiseptics against the majority of microorganisms involved in skin infections. The purpose of the present study was to evaluate the microbicidal effects of topical ozone therapy on S. aureus and MRSA, and determine the clinical efficacy of ozone therapy on patients with MRSA skin infection. Microbicidal effects of ozonated oil and ozonated water were determined by plating and Kirby Bauer methods. Clinical efficacy and safety of topical ozone were evaluated in two cases with skin MRSA infection. The killing rates of ozonated oil for S. aureus and MRSA were greater when compared with the control oil group. Almost 100% of S. aureus were eliminated by ozonated oil following 5 min. Almost 100% MRSA were eliminated by ozonated oil following 15 min. In addition, 100% S. aureus and 100% MRSA were eliminated by ozonated water in 1 min. The inhibition zone diameters of ozonated oil for S. aureus and MRSA were 17 and 13 mm, respectively, which were significantly larger than the control group. Both cases of skin MRSA infection were completely healed with ozone therapy. In conclusion, ozone therapy is a potential treatment for S. aureus and MRSA skin infection as it has great efficacy, few side effects and low‐costs.

Sotzny, F., et al. (2018). "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome – Evidence for an autoimmune disease." Autoimmunity reviews **17**(6): 601-609.

> Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a frequent and severe chronic disease drastically impairing life quality. The underlying pathomechanism is incompletely understood yet but there is convincing evidence that in at least a subset of patients ME/CFS has an autoimmune etiology. In this review, we will discuss current autoimmune aspects for ME/CFS. Immune dysregulation in ME/CFS has been frequently described including changes in cytokine profiles and immunoglobulin levels, T- and B-cell phenotype and a decrease of natural killer cell cytotoxicity. Moreover, autoantibodies against various antigens including neurotransmitter receptors have been recently identified in ME/CFS individuals by several groups. Consistently, clinical trials from Norway have shown that B-cell depletion with rituximab results in clinical benefits in about half of ME/CFS patients. Furthermore, recent studies have provided evidence for severe metabolic disturbances presumably mediated by serum autoantibodies in ME/CFS. Therefore, further efforts are required to delineate the role of autoantibodies in the onset and pathomechanisms of ME/CFS in order to better understand and properly treat this disease.

Stein, D. G. (2001). "Brain damage, sex hormones and recovery: a new role for progesterone and estrogen?" Trends in neurosciences **24**(7): 386-391.

Stevens, M. J., et al. (2000). "Effects of DL-alpha-lipoic acid on peripheral nerve conduction, blood flow, energy metabolism, and oxidative stress in experimental diabetic neuropathy." Diabetes **49**(6): 1006-1015.

SUN, Y., et al. (2005). "Effectiveness of vitamin B12 on diabetic neuropathy: systematic review of clinical controlled trials." Acta Neurologica Taiwanica **14**(2): 48-54.

Talaei, A., et al. (2009). "Vitamin B12 may be more effective than nortriptyline in improving painful diabetic neuropathy." International journal of food sciences and nutrition **60**(sup5): 71-76.

Teitelbaum, J. E., et al. (2000). "Effective treatment of chronic fatigue syndrome and fibromyalgia—a randomized, double-blind, placebo-controlled, intent-to-treat study." Journal of Chronic Fatigue Syndrome **8**(2): 3-15.

Tilley, B. C., et al. (1995). "Minocycline in rheumatoid arthritis: a 48-week, double-blind, placebo-controlled trial." Annals of internal medicine **122**(2): 81-89.

Traber, M. G., et al. (2018). "The relationship between vitamin C status, the gut-liver axis, and metabolic syndrome." Redox biology **21**: 101091-101091.

Metabolic syndrome (MetS) is a constellation of cardiometabolic risk factors, which together predict increased risk of more serious chronic diseases. We propose that one consequence of dietary overnutrition is increased abundance of Gram-negative bacteria in the gut that cause increased inflammation, impaired gut function, and endotoxemia that further dysregulate the already compromised antioxidant vitamin status in MetS. This discussion is timely because "healthy" individuals are no longer the societal norm and specialized dietary requirements are needed for the growing prevalence of MetS. Further, these lines of evidence provide the foundational basis for investigation that poor vitamin C status promotes endotoxemia, leading to metabolic dysfunction that impairs vitamin E trafficking through a mechanism involving the gut-liver axis. This report will establish a critical need for translational research aimed at validating therapeutic approaches to manage endotoxemia-an early, but inflammation-inducing phenomenon, which not only occurs in MetS, but is also prognostic of more advanced metabolic disorders including type 2 diabetes mellitus, as well as the increasing severity of nonalcoholic fatty liver diseases.

Underhill, R. A. (2015). "Myalgic encephalomyelitis, chronic fatigue syndrome: An infectious disease." Medical Hypotheses **85**(6): 765-773.

The etiology of myalgic encephalomyelitis also known as chronic fatigue syndrome or ME/CFS has not been established. Controversies exist over whether it is an organic disease or a psychological disorder and even the existence of ME/CFS as a disease entity is sometimes denied. Suggested causal hypotheses have included psychosomatic disorders, infectious agents, immune dysfunctions, autoimmunity, metabolic disturbances, toxins and inherited genetic factors. Clinical, immunological and epidemiological evidence supports the hypothesis that: ME/CFS is an infectious disease; the causal pathogen persists in patients; the pathogen can be transmitted by casual contact; host factors determine susceptibility to the illness; and there is a population of healthy carriers, who may be able to shed the pathogen. ME/CFS is endemic globally as sporadic cases and occasional cluster outbreaks (epidemics). Cluster outbreaks imply an infectious agent. An abrupt flu-like onset resembling an infectious illness occurs in outbreak patients and many sporadic patients. Immune responses in sporadic patients resemble immune responses in other infectious diseases. Contagion is shown by finding secondary cases in outbreaks, and suggested by a higher prevalence of ME/CFS in sporadic patients' genetically unrelated close contacts (spouses/partners) than the community. Abortive cases, sub-clinical cases, and carrier state individuals were found in outbreaks. The chronic phase of ME/CFS does not appear to be particularly infective. Some healthy patient-contacts show immune responses similar to

patients' immune responses, suggesting exposure to the same antigen (a pathogen). The chronicity of symptoms and of immune system changes and the occurrence of secondary cases suggest persistence of a causal pathogen. Risk factors which predispose to developing ME/CFS are: a close family member with ME/CFS; inherited genetic factors; female gender; age; rest/activity; previous exposure to stress or toxins; various infectious diseases preceding the onset of ME/CFS; and occupational exposure of health care professionals. The hypothesis implies that ME/CFS patients should not donate blood or tissue and usual precautions should be taken when handling patients' blood and tissue. No known pathogen has been shown to cause ME/CFS. Confirmation of the hypothesis requires identification of a causal pathogen. Research should focus on a search for unknown and known pathogens. Finding a causal pathogen could assist with diagnosis; help find a biomarker; enable the development of anti-microbial treatments; suggest preventive measures; explain pathophysiological findings; and reassure patients about the validity of their symptoms.

Walker, J. G., et al. (2012). "Oral folic acid and vitamin B-12 supplementation to prevent cognitive decline in community-dwelling older adults with depressive symptoms—the Beyond Ageing Project: a randomized controlled trial." The American Journal of Clinical Nutrition **95**(1): 194-203.

Background: Evidence remains unclear as to whether folic acid (FA) and vitamin B-12 supplementation is effective in reducing depressive symptoms.Objectives: The objective was to determine whether oral FA + vitamin B-12 supplementation prevented cognitive decline in a cohort of community-dwelling older adults with elevated psychological distress.Design: A randomized controlled trial (RCT) with a completely crossed 2 × 2 × 2 factorial design comprising daily oral 400 μg FA + 100 μg vitamin B-12 supplementation (compared with placebo), physical activity promotion, and depression literacy with comparator control interventions for reducing depressive symptoms was conducted in 900 adults aged 60–74 y with elevated psychological distress (Kessler Distress 10–Scale; scores >15). The 2-y intervention was delivered in 10 modules via mail with concurrent telephone tracking calls. Main outcome measures examined change in cognitive functioning at 12 and 24 mo by using the Telephone Interview for Cognitive Status–Modified (TICS-M) and the Brief Test of Adult Cognition by Telephone (processing speed); the Informant Questionnaire on Cognitive Decline in the Elderly was administered at 24 mo.Results: FA + vitamin B-12 improved the TICS-M total (P = 0.032; effect size d = 0.17), TICS-M immediate (P = 0.046; d = 0.15), and TICS-M delayed recall (P = 0.013; effect size d = 0.18) scores at 24 mo in comparison with placebo. No significant changes were evident in orientation, attention, semantic memory, processing speed, or informant reports.Conclusion: Long-term supplementation of daily oral 400 μg FA + 100 μg vitamin B-12 promotes improvement in cognitive functioning after 24 mo, particularly in immediate and delayed memory performance. This trial was registered at clinicaltrials.gov as NCT00214682.

Watanabe, T., et al. (1994). "Ultra-high dose methylcobalamin promotes nerve regeneration in experimental acrylamide neuropathy." Journal of the neurological sciences **122**(2): 140-143.

Werbach, M. R. (2000). "Nutritional strategies for treating chronic fatigue syndrome." Alternative Medicine Review **5**(2): 93-108.

Xiao, G., et al. (2008). "Improved outcomes from the administration of progesterone for patients with acute severe traumatic brain injury: a randomized controlled trial." Critical Care **12**(2): 1.

Xiao, W., et al. (2017). "Ozone oil promotes wound healing by increasing the migration of fibroblasts via PI3K/Akt/mTOR signaling pathway." Bioscience reports **37**(6): BSR20170658.

Skin injury affects millions of people via the uncontrolled inflammation and infection. Many cellular components including fibroblasts and signaling pathways such as transforming growth factor-β (TGF-β) were activated to facilitate the wound healing to repair injured tissues. C57BL/6 female mice were divided into control and ozone oil treated groups. Excisional wounds were made on the dorsal skin and the fibroblasts were isolated from granulation tissues. The skin injured mouse model revealed that ozone oil could significantly decrease the wound area and accelerate wound healing compared with control group. QPCR and Western blotting assays showed that ozone oil up-regulated collagen I, α-SMA, and TGF-β1 mRNA and protein levels in fibroblasts. Wound healing assay demonstrated that ozone oil could increase the migration of fibroblasts. Western blotting assay demonstrated that ozone oil increased the epithelial-mesenchymal transition (EMT) process in fibroblasts via up-regulating fibronectin, vimentin, N-cadherin, MMP-2, MMP-9, insulin-like growth factor binding protein (IGFBP)-3, IGFBP5, and IGFBP6, and decreasing epithelial protein E-cadherin and cellular senescence marker p16 expression. Mechanistically, Western blotting assay revealed that ozone oil increased the phosphorylation of PI3K, Akt, and mTOR to regulate the EMT process, while inhibition of PI3K reversed this effect of ozone oil. At last, the results from Cytometric Bead Array (CBA) demonstrated ozone oil significantly decreased the inflammation in fibroblasts. Our results demonstrated that ozone oil facilitated the wound healing via increasing fibroblast migration and EMT process via PI3K/Akt/mTOR signaling pathway in vivo and in vitro The cellular and molecular mechanisms we found here may provide new therapeutic targets for the treatment of skin injury.

Yamanel, L., et al. (2011). "Ozone therapy and hyperbaric oxygen treatment in lung injury in septic rats." International journal of medical sciences **8**(1): 48-55.

Various therapeutic protocols were used for the management of sepsis including hyperbaric oxygen (HBO) therapy. It has been shown that ozone therapy (OT) reduced inflammation in several entities and exhibits some similarity with HBO in regard to mechanisms of action. We designed a study to evaluate the efficacy of OT in an experimental rat model of sepsis to compare with HBO. Male Wistar rats were divided into sham, sepsis+cefepime, sepsis+cefepime+HBO, and sepsis+cefepime+OT groups. Sepsis was induced by an intraperitoneal injection of Escherichia coli; HBO was administered twice daily; OT was set as intraperitoneal injections once a day. The treatments were continued for 5 days after the induction of sepsis. At the end of experiment, the lung tissues and blood samples were harvested for biochemical and histological analysis. Myeloperoxidase activities and oxidative stress parameters, and serum proinflammatory cytokine levels, IL-1β and TNF-α, were found to be ameliorated by the adjuvant use of HBO and OT in the lung tissue when compared with the antibiotherapy only group. Histologic evaluation of the lung tissue samples confirmed the biochemical outcome. Our data presented that both HBO and OT reduced inflammation and injury in the septic rats' lungs; a greater benefit was obtained for OT. The current study demonstrated that the administration of OT as well as HBO as adjuvant therapy may support antibiotherapy in protecting the lung against septic injury. HBO and OT reduced tissue oxidative stress, regulated the systemic inflammatory response, and abated cellular infiltration to the lung demonstrated by findings of MPO activity and histopathologic examination. These findings indicated that OT tended to be more effective than HBO, in particular regarding serum IL-1β, lung GSH-Px and histologic outcome.

Yong, V. W., et al. (2004). "The promise of minocycline in neurology." The Lancet Neurology **3**(12): 744-751.

Ziegler, D., et al. (2006). "Oral treatment with α-lipoic acid improves symptomatic diabetic polyneuropathy: the SYDNEY 2 trial." Diabetes care **29**(11): 2365-2370.

Ziegler, D., et al. (2016). "Predictors of improvement and progression of diabetic polyneuropathy following treatment with α-lipoic acid for 4 years in the NATHAN 1 trial." Journal of Diabetes and its Complications **30**(2): 350-356.

Ziegler, D., et al. (2004). "Treatment of symptomatic diabetic polyneuropathy with the antioxidant α-lipoic acid: a meta-analysis." Diabetic Medicine **21**(2): 114-121.

Options

6. **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

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

   No This approach is unethical and will impair patients right to acquire the health care consistent with the holistic WHO model of health, will discriminate against other cultures and traditions/ conventions of health care will result in further over scrutiny of evidence based complementary health practitioners resulted in restricted patient access to the doctors who are trained from a scientific model who we want patients to be assessing evidence based information from driving them to those with lesser levels of training outside our profession.

8. **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?**

   These draft guidelines should be rejected in their entirety and replaced by formalisation of establishing bodies of trained professionals in complementary health care who oversee the approach of complementary health practitioners. We need colleges of Integrative and complementary healthcare who can be referred to to scrutinise care in their respective domains and that can also serve to fill the education gap in Medical Schools and post graduate training to ensure adequate training in integrative health care and an elimination of bias and ignorance.

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

   Only the biases of following medical convention without question and the need to ensure practice remains up to date

10. **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.

      Possibly

    - 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*.:**ABSOLUTELY NOT**

    - **Other Option 3 Preferred Option**

    - **– Formation of AHPRA acknowledged colleges of Integrative medicine and complementary health care who can educate both undergraduate and post graduate health professionals to a high scientific and ethical standard and scrutinise the safety, ethics and validity of practice within their domain.**

From: Keith Ready [redacted]
Sent: Friday, 5 April 2019 8:50 AM
To: medboardconsultation
Subject: Proposed changes to regulation by the Medical Board of Australia - Public consultation paper

Importance: High

Dear Sir or Madam

I wish to advise that I support Option 2 in the Public consultation paper to 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.

Best wishes

Keith Ready

M: [redacted]
E: [redacted]

From: Leonie Regan [redacted]
Sent: Wednesday, 26 June 2019 11:36 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

I strongly object to the proposal which will prevent doctors from practicing safe and effective Integrative Medicine. To limit this is to limit my choices as a patient.

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 focused on the health and safety of ALL Australians. There should be only ONE set of good practice guidelines that ALL doctors should follow.

Kind regards,

Leonie Regan

From: [redacted]
Sent: Wednesday, 10 April 2019 7:49 AM
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

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
Nichole Reid
10-4-2019

From: [redacted]
To: medboardconsultation
Cc: [redacted]
Subject: 'Public consultation on complementary and unconventional medicine and emerging treatments'
Date: Saturday, 4 May 2019 8:55:08 PM

To Whom It May Concern;

Thank you for this guideline, which I certainly think is needed.

I do have issue, however with the word "complementary". This implies that the therapy is question is indeed complementary and usually there is no evidence for this, or in fact evidence to the contrary!

One of my main areas of practice is reproductive medicine and patients often take active substances which may interfere with standard medications, or have the potential to cause teratogenesis to their developing embryo. The belief seems to be that "herbs" are natural and therefore complement a healthy pregnancy. Given studies outlining the association between significant murine embryotoxicity (limb defects) and some of the Chinese herbs; I strongly feel that "complementary" is a dangerous title.

I would prefer "alternative" or "off-label" or "non-evidenced based herbs". I'm not convinced the word medicine should really be in there either...
Or simply leave the title as "Unconventional therapies and emerging treatments".

Thanks for your consideration,
Dr Sally Reid
O&G, [redacted]

From: Claire Martin Reyes [redacted]
Sent: Sunday, 30 June 2019 9:44 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

>
> I choose Option 1.
> 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.
> Members of my family have been let down and disappointed by
> conventional medical treatment. and Positive outcomes were achieved
> after seeking out Integrative Medical Doctors.
> I prefer non-drug approaches for managing my family's and my own
> health or illnesses.
> My family and I are happy with seeing a GP for simple treatments
> within brief consultations, but want to go further with prevention and
> a deeper understanding of what we can do for our health. Our
> integrative medicine doctor provides us the time and knowledge to do
> that.
> We want and need more from our doctor. More time. More understanding
> of causes of illness. More power to understand the ways in which we
> can improve our health to reduce my need for drugs, surgery and
> medical appointments. Our Integrative Medicine doctor provides these
> for us 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.

Kind Regards,

Claire Martin Reyes

Submission to MBA Consultation document on complementary and unconventional medicine and emerging treatments.

Executive Officer, Medical, AHPRA,

The Medical Board of Australia proposal to impose greater regulation around the use of integrative, complementary and alternative medicines (CAMs), is misguided and unnecessary.

No more control or regulation is required. If all registered and appropriately qualified practitioners abide by the regulations as they currently exist, there will be no problems. Mind you, there will always be a very small number of practitioners that bend the rules, that is human nature.

Option 2, if implemented, will significantly limit patients' treatment options for many conditions for which so-called "conventional" medicine has no solution, save a "let's try this drug or that drug and see what happens".

The MBA has no right to deny patients access to alternative treatment options when they provide improvement in health and wellbeing.

There is no doubt that increasing numbers of people are embracing alternative and complementary therapies to provide their healthcare solutions. This is borne out by the consumer expenditure in this area. Does the growing size of complementary pie have anything to do with the requirement for further regulation?

The alternative and complementary therapies are under attack from many quarters.
The 2015 Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance is a case in point, whereby the scope, period of review and English language limitation of the Strategic Review produced an extremely biased outcome, the end result of which was a further erosion of people's access to valid and evidence based healthcare options.

Now we have the MBA Proposal to further "regulate" integrative, complementary and alternative medicines. There seems to be a pattern developing here.

The claim that:- "The available information indicates that patients are being offered treatments for which the safety and efficacy are not known and they may be having treatments which may be unnecessary or may result in delayed access to more effective treatment options." can just as easily be levelled at conventional medicine.

Consider polypharmacy and the problems that can occur with patients often taking 5 or more medications concurrently. Double blind "clinical trials" do not protect patients from adverse drug reactions, which are also under reported. There is no evidence base here because the clinical trial looks at only one drug in isolation. Hardly a real world scenario.

I urge the Medical Board of Australia to think long and hard about this proposal and the wider implications for access to healthcare in Australia. Patients have a right to be fully informed about all the available options for their healthcare, not just those considered "conventional". Let's not forget conventional medicine has a huge pool of vested interests also.

This submission wholly supports **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,

P A Reynolds

From: Pamela Reynolds [redacted]
Sent: Thursday, 4 April 2019 2:06 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To Whom it May Concern

I have read the Public Consultation Paper dated February 2019 regarding clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

As a user of many types of complementary and "unconventional" medicine under the care of both my registered General Practitioner and other therapists I am extremely concerned about the potential impact the Medical Board of Australia is proposing regarding Option 2 of this paper.

Self-serving interests and protectionist regulations have no place in modern Australian society.

I strongly support Option 1 to "Retain the Status Quo".

Sincerely
Pamela Reynolds

From: kylie rhodes [redacted]
Sent: Tuesday, 26 March 2019 12:12 AM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

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

Kylie Rhodes

25 March 2019

From: [redacted]
To: medboardconsultation
Subject: submission re guidelines for... 'complementary and unconventional...'
Date: Wednesday, 26 June 2019 10:45:39 PM

I favour Option 1: keeping the status quo. I have personally benefited for many years from integrative medicine in particular, as well as complementary treatments for lifelong disabling chronic conditions. That they weren't available to me for much of my life, however, has been a misfortune. I find the alternative to Option 1 inadequate.

INTRODUCTION
I agree wholeheartedly with the aims of the second proposal: safeguards against the risk of harm to patients. However, alongside the potential for delayed access to more effective treatment, there is another that too easily gets overlooked:

poverty of access to a wide range of treatments.

Without acknowledging this as a priority, the proposal loses balance. Moreover, the second proposal segregates doctors into those whose regulation is unchanged and those who get extra regulation. The criteria for this categorisation are hazy and incoherent so that however we focus on semantic minutiae, the concepts behind them evade being pinned down.

THE RISK OF PASSIVITY IN PROVIDING TREATMENT
Poverty of access to a wide range of treatments comes about when doctors are afraid. Uncertainty breeds insecurity and timid people hold their help back. The stakes are high: If doctors can't take pride in their work, who can?

I recently had a striking experience. I was with a friend having a specialist consultation for a prospective procedure with a surgeon who worked at a teaching hospital. A few years ago I had myself seen a younger specialist about this. He had recommended against the procedure because it often had unwanted results and often didn't work. Now with a more eminent practitioner advocating it to my friend, I couldn't resist recalling that.

My friend's elderly specialist was indignant. Who had said that? He denied it. For the remaining ten minutes of the consultation he got more and more anxious, finally oozing us out the door in a startling panic.

It's not just that a doctor fears a penalty. Even one exonerated has paid a price, where someone who would denounce her pays none. Just being challenged can make her a victim of bullying.

To give an analogy outside medicine, I once knew a personal care worker who was accused of "assaulting clients by over-vigorous brushing of teeth." We can laugh, but in accordance with strict guidelines he was suspended on reduced pay for nine months, during an investigation that culminated in the immanency of a charge. In a letter he finally took the initiative in defending himself and was reinstated with no penalty. Unfortunately, he was then stigmatised by coworkers as a whistle blower and suffered further for years.

What went wrong here? Although the workplace was a reputable government department, through cost cutting the formal management structure had been weakened. The woman making the accusation had been misled by a powerful personality but she herself had integrity. The accused man had been esteemed by his colleagues but refused to join in victimising a client and opposed a consensus to get a dog for the place, which could not even care properly for people's oral health.

A challenge to one's professionalism can be vexatious or, as here, even political, but that's actually besides the point. Guidelines are a mere tool. In practice, they depend on the functioning of an authority that may itself be timid or diffident about using discretion. Our scenario then shows how they may be exploited to bully with impunity, and also that confidence in exoneration is not enough. When denunciation is too easy, stark realism trumps in the professionalism of survivors. They don't stick their necks out. I don't want my doctor in this position.

In medicine, there are even more ready sources for baseless challenges. Angry people who can't attack the actual menace can perversely target those who care most for them instead. The clerk is castigated at the office and comes home to berate his wife, who criticises the child, who punishes the dog. A distraught friend of a patient can take it out, not on fate, but on the trusted professional.

I've experienced this motivation myself, once toward a doctor but also in another setting. I've also been the victim of it in helping someone even after he was exonerated of guilt for a crime. It takes an effort of self-awareness not to act on such a motivation.

Timidity nudges a doctor towards providing only the "safest" options (as she sees them or suspects that others may see them). But we have still more qualms. How could it happen that a doctor should fear anything if she's done nothing wrong? Here we get down to the nitty-gritty: the nature of having special guidelines for special doctors.

SOURCES OF UNCERTAINTY

The proposed guidelines are a tool, but to regulate what? In a professional search for reassurance, let's look at the nature of the criteria for complementary and unconventional medicine and emerging treatments (or whatever form of words we might substitute). What would the concept cover?

We could mull over wordings. I feel that the wood rather than the trees would be to look at the concepts they're trying to identify. Rather than definitions of words, let's look for criteria for things. Proposal 2 seems to have two different kinds of these things, whose criteria are at odds.

Will we think of concepts of the medicine in question as prescriptive or descriptive? I apologise for an easy way of borrowing language terminology for thinking about concepts, but in English, "It is I" is prescriptive and "It's me" is descriptive. We're supposed to do one and we actually do the other. So what about our concepts? They're instances of prescriptive and descriptive grammar respectively.

The relevance is not academic. Aversion to prescribing opioids can be seen as prescriptive, and the convention of prescribing more in palliative care as descriptive. The proposal mentions “inappropriate prescribing” and I've come to suspect the notoriously fuzzy "inappropriate" heralds a prescription.

A PRESCRIPTIVE UNDERSTANDING

For this we need an objective criterion: e.g., the “impact on safe, effective delivery of services”. We feel confident that research can establish safety and effectiveness.

Now we get the problem that we want black and white, right or wrong for our proposal but the objectivity of research is a greyish spectrum. The unpalatable fact is, our recognitions of it may be inherently value-laden. It can be disputed. Vested interests may make for research with an exploitative agenda (fat-sugar; thalidomide). The agenda may be ideological: A distaste for anything metaphysical can motivate rejection of meditation for blood pressure, for example (Cf. Benson, The Relaxation Response on supporting evidence… but easier, maybe just to take the pills?) or even of anything mental.

Is a treatment inappropriate until evidence makes it appropriate? Don't doctors have room for some humility here? Optimal practice is great as an absolute ideal, but immutability in our notions of it, in reality, remains elusive.

In the end, I want my doctor to be safe that faith in someone else's optimal absolute will not be used to brand her as a special kind of doctor. I want to choose a doctor who has security in making up her own mind about offering me what is optimal.

A DESCRIPTIVE UNDERSTANDING

This could be something more subjective, along the lines of “…[things] not usually considered to be part of conventional medicine…” By nature, those things are a) relative to context and b) not absolute. Blood letting was normal practice in the context of certain times and places.

Moreover, what is right for one cohort of practitioners may not be for another. Psychoanalysis once dominated psychiatry. Now a rival, cognitive behaviour therapy competes. Wallowing in the past is wrong for the latter, which aims to supplant rumination with positive thinking. Distraction from the past is wrong for the former, which intensely probes it for insight.

There are analogies too from speech pathology. Not long ago and still in some countries now, the consensus on stuttering was that it resulted from something like self-consciousness. Treating it by drawing attention to each instance of it was harmful. A clinician who taught relaxation as part of the therapy, on the other hand, would not be challenged. Using relaxation as part of therapy for a voice disorder, in contrast, would have been seen as leading a patient down the garden path.

With solid evidence, Australia has pioneered new practice in treating stuttering. Nowadays child stutterers (not adult) respond magnificently through skilfully calling attention to each instance of stuttering. Relaxation doesn't help them, though, and adult stutterers might conceivably benefit from relaxation only insofar as it helps them slow their speech rate. Relaxation, on the other hand, has become a standard part (not just complementary) of treatment for voice disorders in general, of which 50% have been established to be psychic in origin and of which some authorities believe even organic ones may also have a psychological component.

What has become standard here and now, though, was not so always and is not still in some places. Our proposal alludes to “the nature and extent of the issues identified“ (p.3: unspecified in scope) and envisages “additional information separately from approved guidelines will enable the Board to update it as needed“ (also p.3: the prospect of arbitrary variation over time).

Where does this relativity leave my doctor? Can some other context of some other doctors' practice that she may not even envisage make her practice odd? Can she be branded a special kind of doctor on that basis? I want to go to her and not others, because she makes available to me the range of what she individually is capable.

CONCLUSION
Fear of the ease with which her practice can be challenged results in timid treatment for others. There is a missing link in this chain of causation: the threat of segregation. We start to have two kinds of doctors.

The right doctors get one kind of guidelines (the old ones) and suspect ones, the outsiders another. We're tempted to liken people of good or bad class background under Mao. How foolhardy is my doctor if she offers something special? How certain can she be of not slipping into the wrong category?

Even if proud of her practice, just being put in a category makes different guidelines apply. They make her practice more susceptible to a challenge, which is the point of them. She may be exonerated eventually, but only if she can defend herself under guidelines that don't apply to others.

Meanwhile she becomes vulnerable to someone exploiting that flaw in the regulation of her. That person can use them as a tool to harass her in distinction from others, perhaps even with a political agenda, as with our care worker.

Of course, we don't want snake oil salesmen but this proposal catches not just doctors who benefit by a treatment they advocate (which still may have efficacy, let's not forget). It indiscriminately catches others who don't, who aren't snake oil salesmen.

Drug companies, among other things, influence people's views, including views on what is optimal medicine. Perhaps sometimes, whereas the doctor classified as odd isn't selling a rival treatment, the proponents of the supposedly normal one are. Who then sells the snake oil?

Looking for what is optimal is great as an ideal. Doctors however who remain tentative about finding it may well be more realistic. How will they feel about suppositions of it being used to classify them?

I agree wholeheartedly with the aims of the second proposal, but to repeat, alongside the potential for delayed access to more effective treatment, there is another that too easily gets overlooked:

poverty of access to a range of treatments.

The proposal does once allude to this problem in a cursory way at the very end (p.18): "Guidelines that define good practice for complementary and unconventional medicine and emerging treatment would not reduce consumer choice". As though confessing to doubt this, though, it is prepared with the proviso, "The Board must balance its responsibilities to protect the public while facilitating access to services in accordance with the public interest." (p.17)

Wishful thinking doesn't address the problem. Without acknowledging this as a priority, the second proposal

loses balance and becomes a potential hornet's nest of other issues - the kind that makes the guidelines liable to being exploited. Tinkering with semantics won't help with this. It's inherent in having guidelines that apply to one kind of doctor and not another.

I don't want my doctor to worry about being put in a special category, where different guidelines apply to her and not others. We already have regulation that does a more than adequate job. It's a question of not throwing the baby out with the bath water. Let's stick with Option 1.

Harold Richards (senior)
BA, Dip Ed, B App Sc (speech path)
[redacted]

From: lisa richards [redacted]
Sent: Saturday, 13 April 2019 10:37 AM
To: medboardconsultation
Subject: Complementary medicine

Hi

As far as I am aware a Dr not causing harm and using evidence to provide care even if not yet mainstream advice should not have further restrictions or codes to follow. They all have to meet the good doctor code anyway.

I myself have discovered a change in diet, not through my personal GP who didn't want to know when i told them as though just not telling me to go back to a standard diet could get them in trouble. But Dr's around the world as well as scientists and journalists have put information out there about said diet. This allowed me to make a better informed decision to try. It has significantly improved my well being. I no longer suffer from brain fog and my daily pain went from a 5-7 out of 10 to 0-2 out of 10. All because of diet changes. I work in health care and have generally been skeptical of such claims but with the information i gained i decided to just try for 2 months, 9 months later I am still eating wholefoods LCHF as i do not want to feel like i did before i changed my Diet. It was thanks to Doctors who were willing to go against convention and put the evedince as they had found it out there that allowed me to feel better. Further restrictions on Dr's to be able to offer unconventional advice will make it less likely to occur.

Since Dr [redacted] has only recently had an appology and restrictions removed from his registration for reccomending the same diet I feel that further placing extra hurdles onto a doctors practice will mean less doctors providing options that could potentially be beneficial to patients because the Dr will be more concerned over if they can keep practicing, than over the best possible outcome for each patient.

Please leave it at option 1. They still have rules and regulations to follow and can be dealt with if causing harm. And shouldn't Dr's be weighing potential risk vs benefit of any intervention they do? A good Dr will discuss this with the patient as well so the patient can decide what will work best for them.

The board can always deal with actual complaints as they currently do. If the board notice a trend of people becoming unwell, injured or worsening of health over similar complementary care being provided then look further into that particular area. Don't assume because another doctor doesn't fully understand it that it is not beneficial to the patient so should be stopped or limited. Let the good Doctor and the patients they work decide what is the best option in each case, using current regulations to guide the doctor in providing care.

If you want to do anything ask or require all doctors clinics display a complaints resolution option easily visible in every clinic. Ie how to contact the head Dr of clinic (or manager) through to ombudsman, trust me i hear plenty of people regarding regular care from a standard Dr that could also benefit from knowing how to make a complaint, yet to personally here of any that want to complain about care provided (or not) from an integrated GP

Lisa Richards

From: Bob Richardson [redacted]
Sent: Thursday, 27 June 2019 1:39 AM
To: medboardconsultation
Cc: [redacted]
Subject: Public consultation on complimentary medicine etc

Dear MBA

I appreciate that you are concerned that many medical practitioners have extended their patient advice and treatment beyond the conventions of traditional medical training.
As I expect you are aware the practice of medicine has evolved over the years, decades and centuries.
With this evolution is also the awareness that many pharmaceutical remedies have been developed by use of or synthesis of natural and plant based treatments from the past.
To preserve a practice without allowing observation and evolution is to retard the development of medical science.
Even the methods of testing currently used may be replaced as more advanced methods develop.
Medicine should be patient focused. Patients should be encouraged to know more about health, as should doctors.
To inhibit patients' and doctors' use of complementary and alternative remedies has the potential to retard the progression of health improvement.
There will be errors made both by complementary and conventional practitioners in the future. That is a fact of life.
Option 2 will not improve that situation.
You are responsible to the public for the maintenance and development of a healthy society.
To increase restriction in this area would be a retrograde step.
Do not increase restrictions.

Regards
Bob Richardson

30/6/19

To AHPRA,

I have personally had both positive and negative experiences while receiving treatment by General Practitioners using complementary medicine.

I would like to see a minimum education standard for doctors prescribing complementary medicine or that the doctor work with a suitably trained herbalist, nutritionist, aromatherapist etc. From my experience, GP's that were prescribing high doses of nutrients as supplements did not know the potential adverse reactions and did not use appropriate testing to monitor either the success of the treatment or for any signs of overdosing.

I would not like to see the ability of doctors to provide individualised treatment to be diminished. I would not like doctors to be limited in their ability to refer a patient to a naturopath, nutritionist, herbalist etc. if they believed that complementary medicine treatment may offer the patient a benefit that the GP cannot provide.

I believe that integrated complementary medicine and medical medicine could ensure the safety of the patient and a very high level of care for many, especially people that medical medicine has limited options for treatment or for preventative healthcare. Integration could be used to ensure that the complementary medicine practitioner is adequately trained and registered with a professional association (with insurance and CPE etc).

Complementary medicine is widely used in Australia and it would be beneficial to the community to be able to integrate all types of healthcare.

I do not have any experience with unconventional medicine or emerging treatments. I would like to see these treatments available, with proper informed consent, to patients who may benefit, especially when current medicine has not been helpful.

Kind regards,

Gabrielle Richardson

From: Joanna Richardson [redacted]
Sent: Friday, 5 April 2019 2:40 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

I wish to register some grave concerns about the proposed changes. These include

- That the rationale groups integrative medicine with 'unconventional medicine' and 'emerging treatments'; by association, this implies that IM is 'fringe' rather than not only based on evidence but also a valid and vital adjunct within our medical practice
- That many of the terms used in the rationale, including 'unconventional medicine', 'inappropriate use' and 'emerging treatments', are not adequately defined, which by default creates ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines, which is defined as a basic human right both in Australia and by the WHO
- That there is no evidence produced in the discussion paper that quantifies risk or relative risk in practising complementary or integrative medicine vs 'conventional' medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document came out, giving us limited opportunity to inform the process
- 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 2 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' vs. 'unconventional' can be misused by people with professional differences of opinion and thereby result in vexatious complaints

Kind regards,
Joanna Richardson, PhD

From: Nola Richmond [redacted]
Sent: Sunday, 30 June 2019 11:02 AM
To: medboardconsultation
Subject: Submission to MBA

30th June, 2019
Please do NOT take away our rights as individuals, to choose the path we take to our own health and healing.

As intelligent informed human beings with free choice and self knowledge, each person has the right to choose what we feel is best for us, either Integrative Medicine or Conventional Medicine.
Therefore please do not introduce legislation that disadvantages Integrative Medicine by denying:
- it's positive practices for thousands of people
- it's positive outcomes for thousands of people
- it's future as an alternative

Positive pathway for thousands of people in nutrition lifestyle and prevention The guidelines for IM practitioners and CM practitioners must be the same.
Nola Richmond
[redacted]

From: Georgie Rist
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments
Date: Tuesday, 25 June 2019 1:41:19 PM

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: a) Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options. and b)I prefer non-drug approaches for managing my family's and my own health or illnesses. and lastly c) I want more from my doctor fro myself and my unwell mother who is often neglected by current model. 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.

Georgie Rist
Bachelor of Nutrition and Dietetics
[redacted]

From: Eileen Robbins [redacted]
Sent: Monday, 25 March 2019 7:44 PM
To: medboardconsultation
Subject: Fwd: PUBLIC CONSULTATION ON COMPLIMENTRY MEDICINE ND 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 with significant health gains 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 and insist on free choice in making decisions regarding my own personal medical treatment. In fact, ultimately it is my responsibility to do so.

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.

Yours sincerely

NAME Mrs. Eileen Robbins
DATE 25th. March 2019

From: [redacted]
Sent: Saturday, 30 March 2019 1:53 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments'

I support Option 2, but the wording should be changed to reflect reality: Strengthen current guidance for medical practitioners who provide unproven 'medical' intervention 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.
Jeff Robinson.

From: [redacted]
Sent: Sunday, 26 May 2019 7:33 PM
To: medboardconsultation
Subject: Consultation on Complementary Medicine

My various associates have probably already emailed you by now. I thought I would add my two cents:
You are a fascist organization (please look up the definition of fascist) that seeks to control others by the definitions you believe to be correct
Integrative medicine engenders les complaints than "normal" medicine
You incorrectly connect all types of complementary medicine, when this is obviously wrong – but you know this, don't you?
This Anne Tomlinson character, & one other, supports the 18th century group, Friends Of Science In Medicine, - conflict of interest & unethical behaviour!
You believe that integrative medicine doctors shouldn't sell the products that their patients might need, but are happy for pharmacists to consult patients then prescribe various medicines – what a double standard! Paid by the Pharmacy guild are we?
Big Pharma obviously is behind all this.
I believe in Option 1. If you bring in Option 2, then you take away Patients Freedom Of Choice to consult who they want to. It is NOT up to you to decide this.
If Option 2 comes in, we must start GetUp or change.org to begin the dismantling of you suppressive, leftist, fascist group. People power & populist power will prevail.
Catherine Rochester

From: Catherine Rogers [redacted]
Sent: Thursday, 27 June 2019 4:10 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments[1]

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 am writing to express my serious concerns that two different sets of rules be imposed governing 'conventional' medical practitioners with another more stringent set for those providing 'complementary and unconventional medicine and emerging treatments'.

Good medical practitioners today are employing a range of treatments from the conventional drug and surgical solution driven treatments to others ranging from acupuncture to massage and diet and other approaches. This is today's NORMAL, not some witch doctor approach.

Treatments employed in countries outside the western world have a long history of testing and successful treatment for their citizens. At what point did we determine that only the drug companies of the west understand medical treatments? New treatments are emerging and will continue to emerge and if patients are being treated by a trained person and are willing to try the treatment then it should be an option for them.

My personal experience with several of my conventionally qualified medical practitioners over many years is that they have employed other complementary treatments for me- treatments which fall under this 'complementary and unconventional medicine and emerging treatments' label-with considerable success.

I fail to see why I should no longer be given the option of being offered these treatments under the careful management of a qualified person. Nor do I see why one group in the health industry should be allowed to impose their methods and views across the board thereby preventing the development of any new or emerging treatments.

There needs to be **one** set of rules governing all our health care practitioners to provide a safety net for patients, and to ensure the fullest range of approaches and treatment options is available both for preventative and elective care as well as disease management and cure.

Kind regards

Catherine

CATHERINE ROGERS
[redacted]

From: Leyla Rogers [redacted]
Sent: Wednesday, 26 June 2019 5:04 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I'm opposed the changes to complimentary medical treatment proposed by the MBA.

Don't take away our freedom of choice.

Leyla

From: Ben Rohde [redacted]
Sent: Monday, 1 July 2019 6:14 PM
To: medboardconsultation
Subject: Re: Consultation on complementary and unconventional medicine and emerging treatments

To the medical board consultation:

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

I find it very concerning that you are even proposing these new restrictive regulations. It is unfair as it should be up to individual families and their doctors to decide what treatments are best for their health. These regulations will remove our choices in health care and burden the already struggling system. There should be much more focus on providing greater access to these kind of services to ALL families as currently the higher cost and limited practitioners is a major barrier. There should be a MUCH greater focus in our health care system on prevention and overall wellbeing to lower the rates of chronic illnesses and huge need and dependancy on drugs and surgeries. Health is not a one size fits all and many people require and would like alternative options but this is not currently easily accessible.

Further removal of the option to use Integrative and preventative medicine will not have any positive long term benefits and it's criminal that you are seeking to remove these options. 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 failed to disclose the details of why the new regulations have been proposed. There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation. Just because these services are seen as a threat to some industries does not make them unsafe and should not make them a target.

The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly that "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 VERY 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. We are sick of corrupt governments and industry lobbyists removing our rights to choose what is best for our own families, and removing the rights of our chosen health care practitioners to treat us accordingly - with such negative consequences to our health and the health care system and only serves to benefit their own agenda.

From

Ben Rohde

From: Lydia Rohde [redacted]
Sent: Sunday, 30 June 2019 11:03 AM
To: medboardconsultation
Cc: [redacted]
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To the medical board consultation:

I choose Option 1… no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine. If anything there should be LESS restriction in place for these doctors. And better access to their services for ALL Australians.

Conventional medicine provided no answers at all as to why my family was sick and we desperately needed to seek medical care with a wider range of diagnostic and treatment options which has enabled better long term health and wellbeing for all of us. Removing this option can only possibly burden the current health care system more than it already is.

Additionally many conventional medical treatments can be harmful, especially for sensitive individuals like myself and my family and alternative treatment options must be made available for those who wish to seek long term non-drug approaches for managing their health or illnesses.

We have a wonderful GP which whom I am very happy with my for simple treatments within brief consultations, and for acute illnesses but I want to go further with prevention and a deeper understanding of what I can be doing for long term wellness for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that, alongside and in consultation with my GP, paediatrician, nutritionist and chiropractor. I want more from my medical care. Health and wellbeing of myself and my family is very important to me. I expect to be spending more time with my doctor when working on long term wellness goals with someone with a deeper understanding of causes of illness. More power is important to understand the ways in which I can improve my health to reduce my need for drugs, surgery as well as preventative practices. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with my GP cannot. This preventative and long term approach to health and wellness requires more time in consultations and additional medical training that I found in my integrative medicine doctor and integrative medical team. This deeper approach is much more beneficial to my long term health than just masking or ignoring my symptoms with conventional medicine.

I find it very concerning that you are even proposing these new restrictive regulations. It is very unfair as it should be up to us to decide what care is best for our families and up to our doctors to help guide this. These regulations would only serve to further remove our choices in health care and burden the already struggling system. There should be much more focus on providing greater access to these kind of services to ALL families as currently the higher cost and limited practitioners is a major barrier. There should be a MUCH greater focus in our health care system on prevention and overall wellbeing to lower the rates of chronic illnesses and huge need and dependancy on drugs and surgeries. Health is not a one size fits all and many people require and would like alternative options but this is not currently easily accessible.

Further removal of the option to use Integrative and preventative medicine will not have any positive long term benefits and it's criminal that you are seeking to remove these options. 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 failed to disclose the details of why the new regulations have been proposed. There is no demonstrated need to regulate Complementary Medicine or

Integrative Medicine. These are safe practices that need no further regulation. Just because these services are seen as a threat to some industries does not make them unsafe and should not make them a target.

The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly that "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 VERY 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. We are sick of corrupt governments and industry lobbyists removing our rights to choose what is best for our own families, and removing the rights of our chosen health care practitioners to treat us accordingly - with such negative consequences to our health and the health care system and only serves to benefit their own agenda.

From

Lydia Rohde

June 25 2019

Dear Medical Board of Australia;

Regarding your public Consultation paper on 'Clearer Regulation of Medical Practitioners who provide Complimentary and unconventional medicine and emerging treatments" I very strongly object to you imposing ANY further restrictions on medical Doctors practising the above disciplines.

As an Australian citizen, I urge you to choose
Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medicalpractitioners who provide complementary (and unconventional) medicine (and emerging treatments) via the Board's approved code of conduct.

There is no good reason for you to change the current legislation regarding CAM.
CAM has a very strong case and works extremely well when used alongside 'conventional' medicine.

It is very wrong for you as a regulatory Board to group complementary medicine with unconventional medicine and emerging treatments.

Complementary Medicine is safe (have used it numerous times myself as have my family to excellent results).

Yours sincerely,
Shannon Rooney
[redacted]

From: Fiona Rose [redacted]
Sent: Wednesday, 6 March 2019 2:54 PM
To: medboardconsultation
Subject: Integrative Medicine Importance

Medical Board Submission
Regarding the public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

As an Australian citizen/resident I feel it's important that I have the freedom of choice in the type of medical care that I use to address my chronic health issues.
I have been suffering from:

Conventional medical doctors have not been able to successfully treat my condition(s) and bring me to a satisfactory level of health.
Pharmaceuticals and the use of conventional methods simply did not work (and in some instances also delivered unwanted side-effects in my case) and, seemed to waste Medicare funds and resources.
It was only when I saw an integrative medical doctor who included lifestyle change, diet and supplements of vitamins and minerals to address my problems that my condition began to improve.
If I cannot see an integrative doctor, or the Doctor is restricted in what he or she is able to prescribe for me, I feel that my health will deteriorate and have a continuing impact on my family, my work, and my wellbeing.
Additional notes:

Concerned,

Name: Fiona Rose

Signature: FSROSE

Date: ____6___/_____3__/_____19___

Occupation: Retired

Please submit to:

Fiona Rose

From: [redacted]
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments
Date: Thursday, 4 April 2019 9:52:54 AM

To whom it may concern,

The recent paper titled *"Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments"* 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.

This is because the regulations group "complementary and unconventional medicine and emerging therapies" into a single definition. This is unreasonable and unjustifiable within a scientific framework. Such a definition has a political motive to separate the perceived good doctors who follow conventional medicine from the bad doctors that question the boundaries of conventional medicine

I implore you to select the following option (**Option One**):

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,

Miriam Rose

[redacted]

From: Trish Rossi [redacted]
Sent: Monday, 1 July 2019 1:06 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To The Board of AHPRA,

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 am now on a completely minimal and natural regime and have completely resolved an issue that dermatologists have told me would have required a lifetime of various medications and subsequent 6 monthly liver tests. This issue has cost me tens of thousands and for the many years whilst on medications my well being was significantly compromised.

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.

Yours sincerely,
Trish Rossi

From: Mandy Rudd [redacted]
Sent: Tuesday, 30 April 2019 1:46 PM
To: medboardconsultation
Subject: Changes to code of. Conduct 2014

I have found my doctor irreplaceable because of her accompanying knowledge of vitamins and other complimentary health practices There are many world firsts stemming from new practices I trust my doctor

Mandy Rudd

From: [redacted]
Sent: Friday, 28 June 2019 10:48 AM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1...

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.

Regards
Theodora Russell

From: Giuliana Ryan [redacted]
Sent: Saturday, 27 April 2019 8:26 AM
To: medboardconsultation
Subject: Integrative Doctor [redacted]

I see Dr [redacted] - an ACNEM trained integrative GP. I do not want her to be restricted in her practice and I demand option 1.
Dr [redacted] has been an incredible asset and blessing to my medical conditions and has given me the opportunity to restore my health through a combination of traditional medicine and natural medicine.
Please give patients the opportunity to choose what best suits them.

Kind Regards
Giuliana Ryan

From: Kelly S [redacted]
Sent: Monday, 1 July 2019 9:35 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

No new regulations should be imposed on doctors practising in the area of complementary medicine and integrative medicine.

I choose to be involved in my own and families care and have chosen to use other complementary and integrative medicines regularly.
I prefer to use alternative treatments instead of the drug approach recommended by most GPs, I want to investigate further preventions and believe there is a need for a deeper understanding of what is the underlying issues. I think all Gps should be trained in integrative medicine, as an alternative to drugs.
I want more from my doctor. More time and understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce any 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.

From: Trine Salisbury [redacted]
Sent: Tuesday, 7 May 2019 11:39 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To Whom it may concern,

I strongly believe that medicine should be moving towards a much more holistic model - looking at the patient as a whole. Most of our current lifestyle diseases that cost Medicare and our hospital system so much money are related to diet and lifestyle. That being, people are unaware of proper diets and and exercising too little. Any Doctor that can help a patient to improve their diet, exercise levels and overall healthy living should have the upmost support given to them. Please don't take away their medical rights to practice - this is almost absurd.

Integrative/Functional Medicine should be being promoted as the new way forward in medicine - grab it with two hands and show the world that Australia cares about it's people and their health.

Let research be funded. Let clients speak out. I personally, as a physiotherapist have witnessed the benefits that integrative medicine holds.

I hope the directors on the medical board will see this and do their own research.

Regards,

Katrina Salisbury

From: natalie sammut [redacted]
Sent: Wednesday, 20 March 2019 9:01 AM
To: medboardconsultation
Subject: Medicine failed me .

Disappointing to see that complimentary medicine is under attack.
I found relief for many issues I had from herbal medicines and essential oils..
But I guess the issue is profit , so you want to limit people getting really well when you can keep them sick and make them keep paying more to big pharma for drugs that kill the body.

From: Tanya Saramandif [redacted]
Sent: Monday, 17 June 2019 2:39 PM
To: medboardconsultation
Subject: I am very concerned and want this to go on record

To whom it may concern,
I have been seeing an Integrative Doctor for over 12 months now and feel the consultations are more thorough than conventional GPs consultations. I would like to outline some other 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.

I seriously worry about the ongoing health system and wonder if there is a 'blinkered' system in place due to pay backs from pharmaceutical kick backs. If this isn't so then the current ideology of patient being able to pick their type of doctor should continue.
Please think of all of us and not just yourselves when you go forward with this.
Kindest regards,
Tanya Saramandif

From: Mark Saul [redacted]
Sent: Thursday, 27 June 2019 11:46 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

> Dear Medical Board,

> 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,

Mark Saul.

From: Lyn-K Saunders [redacted]
Sent: Wednesday, 12 June 2019 7:01 AM
To: medboardconsultation
Subject: Integrative med threatened.

To whom it may concern,

I oppose the idea of making changes to the guidelines for 'complementary and unconventional medicine and emerging treatments'.

Having read the documentation on those changes, I share the following concerns with others;

- 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,
Lyn-K Saunders, (patient, teacher, concerned member of the public.)

[redacted]

From: Narelle Savage [redacted]
Sent: Monday, 1 July 2019 12:02 AM
To: medboardconsultation
Subject: Good Medical Practice of Complementary Medicine

Dear Medical Board of Australia,
I choose option 1, given that all doctors should follow one code of conduct and one set of guidelines for all Good Medical Practice.

I value regulation for safety and ethical practice of medicine, however, it is important from my understanding, that the regulation of complementary medicine and emerging medicine be made in full consultation with Colleges who offer appropriate training in, and/or expert oversight of, what is considered safe, and efficacious complementary medicine practice.

With kind regards,
Narelle Savage

From: Angelo [redacted]
Sent: Friday, 12 April 2019 12:41 PM
To: medboardconsultation
Subject: Complementary and Unconventional and Emerging Medicine - Petition

Importance: High

To Whom it may concern,

My name is Angelo Savino and I here by voice my strongest opposition to the proposed strict new regulation.

I am appalled by this proposal which seems purely designed to put sick people last.

I am 100% in support of the continuation of the current existing guidelines for medical practice.

The choice to visit an Integrative medicine GP should remain the right of the people and not the Medical Board of Australia who seems so out of touch with the Australian populous.

Regards,
Angelo Savino
Mob [redacted]
Email [redacted]

From: Connie Schell [redacted]
Sent: Wednesday, 10 April 2019 9:38 AM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern

Please consider this email 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 or 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
Connie Schell
10 April 2019

From: Patricia Schiavon [redacted]
Sent: Friday, 29 March 2019 3:35 PM
To: medboardconsultation
Subject: My Healthcare Right - URGENT -

I voice my opposition to further changes or additions to the existing Code of Conduct 2014

I choose to support my submission by telling my story of how satisfied I am with my current Practitioner. The benefits to my health before and after have been sensational.

The treatment was and continues to be marvellous compare to how I was before and now.
My increased ability to self manage my health; my work and my life balance has been extraordinary.

The difference it has made to me; my family; my work place together with my community as a whole and been nothing short of a miracle.

All the best.
Patricia Schiavon

From: Victoria Schnaedelbach [redacted]
Sent: Sunday, 23 June 2019 10:20 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

I choose no new regulations to be required for doctors practising in the areas of complementary medicine and integrative medicine.
I have chosen to see Integrative Medicine doctors for a variety of reasons.

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

2) Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options. Whilst I am not yet fully recovered, my quality of life has improved markedly, both physically and psychologically. I felt undermined and dehumanised by the mainstream medical care i was offered.

3)I have also been harmed by conventional medical treatment, and needed to find other options. I was prescribed antibiotics consistently and often unecessarily from the age of 8 - 30 and the OCP from age 13.
Both have resulted in long term, complex problems for me.

4)I prefer non-drug approaches for managing my own health or illnesses.
I am happy with my GP for simple treatments within briefconsultations, but I want to go further with prevention and a deeper understanding of what I can do for myself. My integrative medicine doctor provides me the time and knowledge to do that.

5) 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 furtherregulation.
I believe 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. I am not a child that needs the MBA to be my big brother!

- 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 are necessary.

I feel extremely strongly about this issue. I am very willing to provide more commentary and details of my experience in the health care sector should you wish to hear.

I have received medical training myself. M.B.B.S @ uni of melb in the 90's. I am a masters level practicing creative arts therapist. I have chosen to discontinue my career as a doctor.

Sincerely
Victoria Schnaedelbach

From: Brigitte Schneider [redacted]
Sent: Wednesday, 26 June 2019 6:25 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

It unnecessary to impose greater regulations around the use of integrative, complementary and alternative medicine.
It would be a step back to the past.
People in a democratic land should have the choice with method they are being treated with.

Prevention of disease is the first aim of complementary medicine.
Complimentary medicine is safe and in my opinion and thousands of other people is safer as using a conventional doctor which only prescribes drugs.
In most cases, except in an emergency, it is better to try complimentary medicine first.

Kinds Regards

Brigitte Schneider

[redacted]

From:	Doreen Schwegler
To:	medboardconsultation
Subject:	“Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments”
Date:	Wednesday, 3 April 2019 6:04:57 PM

I would like to provide input regarding my support for safe and effective integrative medicine practices and say that Integrative medicinal doctors combine quality conventional medicine with safe and effective complementary medicine to improve health and reduce unnecessary medical treatments.

They embrace prevention and help manage complex illness and care for patients for whom conventional medicine has not assisted.

As a recipient of such integrative medical advice, I support *Option one – That you 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.*
Regards

From: Petar Scott [redacted]
Sent: Saturday, 20 April 2019 11:42 PM
To: medboardconsultation
Subject: Submission on Proposed Policy Changes

The following points have been identified as areas of general concern:

- 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

RESOURCES AVAILABLE

We encourage you to view the following materials and podcasts to understand the implications for integrative medicine practitioners and the importance of integrative medicine as an approach to the prevention, management and treatment of chronic and complex disorders and diseases.

- Interview with Dr Penny Caldicott, President of the Australasian Integrative Medicine Association
- Interview with Professor Stephen Myers, Researcher and Academic Southern Cross University
- Integrative Medicine Freedom of Choice for Healthcare
- AIMA The Australasian Integrative Medicine Association Challenging the MBA Guidelines

From: Sophie Scott [redacted]
Sent: Thursday, 4 April 2019 1:37 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

I am shocked to see that the Medical Board is planning to squash integrative medical practitioners. I personally have had great experiences with GPs who are more wholistic in practice and look at the whole person. Other GPs I've been to have just suggested medications, when I actually didn't need them and complementary medicines were more appropriate. I feel more confident going to a GP who also prescribes natural supplements than going to a naturopath or nutritionist.

Please retract this prosposed regulation - it will only lead to the demise in health of the Australian population. Doctors practising Integrative Medicine is NOT risky for the patient.

Sophie Scott
[redacted]

From: Robyn Seelin [redacted]
Sent: Thursday, 27 June 2019 9:22 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Subject: Consultation on complementary and unconventional medicine and emerging treatments

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 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 if it is at all possible and need to be able to explore these options with my Doctor.
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.
Sincerely
Robyn Seelin

From: [redacted]
Sent: Friday, 28 June 2019 7:29 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

>
> I choose Option 1...as the choice of an Australian consumer to freely
> choose safe and effective treatments for their own health issues is
> vital.
> GP,s do a fantastic job at treating many health concerns, however time
> constraints in their practices often mean patients underlying
> pathology is not able to be fully investigated in a short
> consultation. This means that pharmaceutical treatments become the
> mainstay of practice as they are a quicker option than delving into
> lifestyle, environmental, dietary or toxicity issues.
> Australians have a great health system with access to well educated
> health professionals. Unfortunately the MBA with pressure from AHPRA
> and FSM are taking away people's freedom of choice and in many cases
> access to safe effective medicine with less side effects and proven
> results.
> Please do not stop these highly trained medical professionals from
> helping those with chronic health conditions.
> Regards
> Rob Seletto

From:	Linda D Sesta
To:	medboardconsultation
Subject:	Consultation on complementary and unconventional medicine and emerging treatments
Date:	Thursday, 4 April 2019 10:29:42 AM

To whom it may concern

I am a qualified Nutritionist and regularly refer clients to Integrative Medicine doctors for complex and/or chronic health issues.

First and foremost I am shocked that the Medical Board of Australia put out proposed regulations without any consultation with the Integrative Medicine community. To not include stakeholders in the planning and developing of regulations lacks procedural fairness and can only mean an outcome which is not in the interest of patients.

A further concern would be the restriction of consumer choice of their doctor outside “conventional” medical practice.

Furthermore the MBA has failed to identify any significant concerns about the safety of Integrative Medicine or any risk to the public.

I urge the MBA to reconsider this draconian proposed regulations and work closely with the relevant stakeholders such as the AIMA to obtain an outcome which gives the public the choice to see qualified Integrative Medical doctors.

Kind Regards,

Linda Sesta

From: [redacted]
Sent: Saturday, 6 April 2019 11:23 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatment

Dear Sir/Madam,

I have grave concerns about the proposal to limit doctors practicing complimentary medicine in Australia. This is a draconian and completely unwarranted measure. I have personally seen several integrative GPs in [redacted] over the years and my health improved tremendously from their care. They are able to prescribe preventive supplements and order tests that conventional GPs have no idea about. It is our right to choose the type of healthcare we want, especially given the consults are privately funded! Restricting doctors from practicing complimentary medicine is an attack on our freedom of choice when it comes to healthcare. Please stop this insanity.

M. Shaflender

Sent from my iPhone

From: [redacted]
Sent: Saturday, 13 April 2019 7:41 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear Sir/Madam,

I am willing to make a submission and express my opinion in regards to the subject matter in supporting the existing Complementary medicines regulation, which I understand is the option 1 of the consultation.
I believe the current complementary medicines regulation is adequate for Australia, as reasonably well harmonized with the same of other OECD countries, like Germany, UK, France, Japan, and though it has certain issues, as being too strict in regulating some herbal treatments, like a recent case with banning from sale Uva Ursi, mild diuretic herb, which is still approved for non-restricted use in all OECD countries.
As a member of general public (I am a registered Engineer) I believe that people should have full unrestricted access to all traditionally used natural treatments, like herbs and minerals, as well as vitamins, aminoacids and other naturally occurring substances, which human kind has had access for thousands of years.
Restricting access to herbs and other complementary medicines as through a doctor only will create absolutely unnecessary barriers to a very basic health care an every human is entitled to.
I don't believe a TGA has even a single case of death reported as caused by usage of herbs or vitamins, so unsure what is this consultation is all about.
It seems like it's not about public safety at all, but instead it is promoted by pharmaceutical companies, who are worried about losing markets.
I am more concerned about non-restricted use of chemically produced medications like paracetamol, ibuprofen, aspirin, freely sold in supermarkets, which create much greater risks and can cause much more severe complications than any natural treatment.

Regards
Dmitri Sharov
Ph: [redacted]

[redacted]

26 JUNE 19.

Dr Susan O'Dwyer
Queensland Board MBA

Dear Dr O'Dwyer

I am writing in connection with the proposed changes in access to complementary medicines.

Those of us who have benefitted from Homoeopathy and Naturopathy, and seen others benefit as well, we wish to continue that kind of treatment, and it is our right to do so.

I worked for [redacted]
when he was the Homeopath
to the Royal Household.
For generations they have used
Homoeopathy, and London
has the Royal London Hospital
for integrated medicine which
formerly used Homoeopathy only.
(since 1849)

I also worked in a "health farm"
in England --- this was
not a place of pampering, but
a clinic ([redacted] Naturopathic
Clinic, now closed) for people
with chronic illness who had
not been helped by allopathic
medicine. After a two
weeks fast, and a change of
diet, these patients improved

There are no side effects from these more gentle + subtle ways of treating illness.

I urge you to re-think the decision regarding proposed changes, and also, if ever you have symptoms which are not relieved by allopathic medicine, please look elsewhere — Naturopathy, Homeopathy, Chinese Medicine etc

Sincerely Judith

JUDITH HELEN SHAW

From: [redacted]
Sent: Tuesday, 26 March 2019 6:10 PM
To: medboardconsultation
Cc: [redacted]
Subject: Medical Board Submission and Concern regarding censorship of integrated medicine

To whom it may concern,

As an Australian citizen living in a democracy, I am exercising my right to my freedom of choice, when it comes to my health.

I strongly oppose the Medical Board of Australia's attempt to impose severe censorship of integrated medical treatment within Australia.

It is paramount that everyone in Australia has the freedom of choice regarding available treatments and medical care, to address their own personal health issues.

Conventional medicine or doctors have not been able to address or successfully treat my health condition or better my quality of life !!

I have a right to access IV vitamins, minerals, supplements and treatments. I have a right to consult with integrated practitioners to improve my quality of life and health! The Medical Board of Australia do not have the right to deny me that freedom of choice.

I strongly oppose the Medical Board's submission for imposing severe censorship of integrated medicine in Australia.

Please submit my expression of concern to the Medical Board submission and put a stop to this extreme form of censorship, thank you.

Regards

Paula Shaw
26.3.2019

From: [redacted]
Sent: Tuesday, 12 March 2019 6:59 PM
To: medboardconsultation
Subject: Public Consultation Paper

Consultation on complementary and unconventional medicine and emerging treatments.

I am [redacted] years old and a third generation Australian and have lived in Australia all of my life.
I believe I should have the right to choose whomever I wish, to treat me and my health conditions.

Over the years I have suffered many side effects from drugs that were prescribed for me by doctors practising conventional medicine.
It wasn't until I started going to an integrative medical doctor that I was able to get relief.
The advice I have received from integrative doctors and natural health professionals has included diet change and nutritional supplements, and I have noticed a big improvement in my health - and no side effects.

I definitely believe that we do need conventional medical practitioners but we also need practitioners who use complementary methods.

I just want to have the opportunity to make my own choices.
I am very concerned as to what will happen with my health if this choice is taken away.

Elizabeth Shelton

From: Michael Shirley [redacted]
Sent: Tuesday, 2 April 2019 2:06 PM
To: medboardconsultation
Subject: Integrative/Complimentary Medicine

Dear Executive Officer, Medical, AHPRA

In the strongest terms may I submit the following in support of my right to continue consulting my Integrative/Complimentary practitioner:

I am [redacted] years of age, live in [redacted], [redacted], [redacted].
I have been consulting my integrative/complimentary medicine practitioner for some years. I have found my health and that of my wife to have improved since I began this consultation. I do not want my access to change in any way.

I strongly value my personal right to chose who I consult. I am offended that your board wishes to intervene in my life.

My practitioner provides me with advice regarding the available therapies and drugs and I choose which route I will follow.

Yours faithfully
Michael Shirley
[redacted]

From: Alvin Siaw [redacted]
Sent: Wednesday, 3 April 2019 6:50 PM
To: medboardconsultation
Subject: Change of CAM practice and regulations

Dear sir,

I was made aware of a possible change of regulation pertaining to practice of CAM.

I am a pharmacist. Though CAM is not a primary product that we supply our patients, we do however find that there are gaps that they fill , especially when patient has no other viable treatment that their general practice provider can offer.

Therefore , I'd like to strongly recommend:

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.

With perhaps the only suggestion of potential supply of these CAMs to be supplied via pharmacies or health food shops where advice can be sought , rather than just supermarkets .

Regards,

Alvin
B.Pharm.

From: Anna Siebert [redacted]
Sent: Sunday, 30 June 2019 10:05 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

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 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. It requires seeing my children as people first and foremost not pathologies, and I have found this in our integrative medicine doctors.
• Conventional medicine provided no answers about why I was sick and no plan forward. I became bedridden and unable to work or study, and I was faced with no options. Because I couldn't get a proper diagnosis I couldn't access disability supports either. I needed medical care with a wider range of diagnostic and treatment options, which I found in my integrative medicine doctor. I was able to return to work and become a contributing member of society.
• I have been harmed by conventional medical treatment on many, many occasions, and sought other options. Many of these remedies and answers I found in my integrative medicine doctors.
• I love having access to medicines when they are needed, but if there is another option I refer non-drug approaches for managing my family's and my own health or illnesses. I love being able to gain health without the list of side effects.
• 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 am grateful to have what I feel is the best of both worlds.
• For many of my concerns, 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. Her training and extensive specialist knowledge in these areas cannot be provided by my excellent GP.

I have *serious* 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.

Integrative medicine is well established in many other developed countries. There is no need to justify an evidence based practice that does no harm. In the case of many families, reducing or restricting the treatments available to them will only cause more people to become burdens to society. People are choosing these other non-conventional options because conventional medicine is failing people. Restricting this is dangerous and contradicts the Hippocratic Oath.

No new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine.

Sincerely,

Anna Siebert

From: Ingrid Siles [redacted]
Sent: Friday, 14 June 2019 3:10 PM
To: medboardconsultation
Subject: Integrative medicine

Dear Medical Board,
I am writing to you in response to the public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments. I would like to explain why I opt for Option 1: 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 approved code of conduct. My interpretation of this is that there are no significant changes that need to be made in how this area of medicine is functioning today.
I am a scientist, graduated from the University of Melbourne, and after leaving research I have worked for 13 years in private hospitals and clinics as a medical sonographer. Over the last 25 years I have had many personal and indirect experiences with various doctors in the complementary medicine area. Along with my mother, my sons, my husband, friends and colleagues I have had extensive interactions with doctors in complementary medical practice. At all times I have felt confidant in their recommendations for treatment, tests and therapies.
It has been a life-giving opportunity to pursue other options, when allopathic medicine was unable to help. Choice is a right to all human beings. An opportunity to be informed of alternatives that can and do improve our health and well-being is absolutely necessary to our society.
I request that the board vote to allow medical practitioners who provide complementary and unconventional medicine continue to practice as they do today.

Yours Sincerely,

Ingrid Siles

From: Kylie Silvester [redacted]
Sent: Thursday, 4 April 2019 8:13 PM
To: medboardconsultation
Subject: Threat to Integrative Health and medicine

I would like to express my concerns regarding the threat to *complementary and integrative health* proposed by the Medical Board.
Below is a summary of my concerns. Integrative and complementary medicine is a rapidly growing industry in Australia and overseas. I understand that it needs guidelines, however;

- 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

Yours Sincerely,
Kylie Silvester
-

From: Sharon Simas [redacted]
Sent: Monday, 18 March 2019 4:43 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Here is my feedback on the issues and options outlined in the discussion paper.

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?

No. There should not be a line drawn here. Doctors should have access to a full toolbox of therapies that help patients.

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.’ If not, how should it be defined?

No. “Conventional medicine” keeps evolving. New cancer therapies are not a part of conventional medicine. Stomach ulcers were not understood to be caused by h. pylori. The gut and oral microbiomes are emerging as important factors in many diseases. Drawing an arbitrary line stifles innovation and prevents treatment of patients with difficult and complex diseases such as myalgic encephalomyelitis/chronic fatigue syndrome, which are underresearched and for which there is no standard of care but which can and do respond to individualized treatments due to differences in genetic and environmental factors leading to their etiology.

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. This looks like a misguided way to restrict the medical profession to the “old boys club," to the detriment of payornts and innovative practitioners

Conventional medicine does not help all patients. Patients fall through the cracks. Many are harmed, even killed, by drugs, surgeries and other medical interventions. Current treatments, in many cases, bandaid problems without ever addressing the root cause, enriching pharmaceutical companies and draining public coffers.

Sensibly questioning the status quo, testing to develop a good understanding of medical conditions and their idiosyncracies and etiology is important. Developing individualized treatment plans, customized to a patient's genetics, environmental exposures, and lifestyle factors offers the opportunity to help patients who are not being helped today.

Some patients are harmed by drugs that help others due to their genetics, allergies, or comorbidities. They need alternatives. Drugs can be repurposed to help patients for indications not currently “on label.” Modalities like platelet rich plasma, prolozone, and acupuncture offer effective alternatives to opioids.

Medicine has developed through observation, thoughtful intervention, and innovation in clinical practice. By no means does modern, western medicine have all the answers. Emerging treatments offers the opportunity to help patients for whom western medicine has failed, like patients with myalgic encephalomyelitis/chronic fatigue syndrome.

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?

That conventional medicine practitioners are myopic and not open-minded to include these tests and treatments, especially to help patients not helped by conventional medicine.

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

A reasonable explanation along with applicable research should be provided to patients. Concerns/risks should be communicated.

Boards of practioners of “Conventional and unconventional medicine and emerging treatments” should be able to evaluate risks and limit potentially dangerous treatments.

Conventional doctors should not be policing these tests and treatments.

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

Look to Washington State in the United States, which has an “Every Provider Law.” examine statistics of people harmed by conventional and unconventional medicine there. Talk with leaders at the Institute for Systems Biology, Bastyr University and the Institute for Functional Medicine to look at evidence based practice for alternatives to conventional medicine, e.g., personalized medicine.

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.

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

To the detriment of patients, yes. To limiting tests and treatments that might help, not allowing off-label or compounded medications, IV therapies, and innovative ideas in emerging medicine. If you want to be firmly entrenched in 20th century medicine and harm patients, by all means, go ahead with option 2. Australia already lacks tests and treatments available in other first world countries and needs to move forward with emerging medical strategies and not be limiting tests and treatments and be stuck in the past.

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?

Yes. The status quo is adequate. The draft guidelines are a heavy handed effort to stifle innovation, restrict enlightened development of new tests and treatments, and restrict modalities that are successful elsewhere (bioidentical hormones, platelet rich plasma, stem cells for orthopedic use) and devastate the opportunity for patients with complex and difficult diseases to have thorough diagnostic testing and treatments that can help.

For example, there is no standard of care for myalgic encephalomyelitis, yet patients with access to thorough diagnostics are being helped with treatments prescribed off-label, including IVIG, antivirals, low dose naltrexone, Rituximab, plasmapharesis, beta blockers, mast cell medications, bioidentical hormones, and IV nutrients like glutathione, NAD+, carnitine, B vitamins and minerals. Conventional treatment has offered CBT and graded exercise whoch damage these patients, based on flawed studies by UK psychiatrists which ignored the many medical abnormalities with these patients' immune, nervous, and endocrine systems, as well as mitochondrial dysfunction.

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

Leave the status quo as is and collect statistics.

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

From: Anita Simonovic [redacted]
Sent: Saturday, 6 April 2019 12:11 PM
To: medboardconsultation
Subject: Proposed changes to medical treatments

I oppose changes to the existing code of conduct 2014 . At the moment I enjoy the right to choose my form of treatment by a doctor who can give multiple options of treatment . These treatments allow me to treat the cause of the problem not just the symptom which will actually save the government money from not needing to go to the doctor repeatedly because of the problem not getting fixed. I also like to know my doctor will promote traditional medicine as well as alternative medicine to get the best of both worlds as both methods are needed. I actually wish more doctors would treat patients with integrative medicine .
A Simonovic

From: Felicity Simpson [redacted]
Sent: Wednesday, 27 February 2019 1:42 PM
To: medboardconsultation
Subject: 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.

Kind regards
Felicity

From: Denise Sims [redacted]
Sent: Thursday, 27 June 2019 6:16 PM
To: medboardconsultation
Subject: Public submissions on complementary and unconventional treatment.

I would like to support the current regulations which I feel give adequate protection for patients and doctors, that is, I support option 1. It is vital that patients are involved in their own healthcare and are able to choose treatment from complementary medicine as well as conventional medicine. I have been helped enormously by a medical practitioner who is able to prescribe complementary medicine when conventional medicines were not adequate. I cherish the right to choose complementary medicine. Please leave the status-quo. Denise Sims

From: Ellen Singleton [redacted]
Sent: Wednesday, 26 June 2019 12:47 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To the AMA:

I would like to address the current proposal to limit the breadth of services and treatments offered by innovative, modern MDs.

It is time for traditional, conservative older MDs very set in their ways and addicted to the benefits from large pharma companies to open their minds to alternatives that are very effective in overall treatment plans. Younger MDs are open to effective results and open to these alternatives when patients report improvement in their conditions. No clinical trials? We as patients aren't STUPID. We don't need a clinical trial to feel better.

This heavy handed proposal must have been written by the same people who wrote the Handmaids Tale. We, as the patient, are in control of our bodies. This means that if I choose to use homeopathic remedies, chiropractors, herbal remedies, etc., I expect my MD to support that decision and offer complimentary pharma advice to fit into my overall program. I am the captain of this ship, and my MD is only one of the people on the team.

Please stop dictating to perfectly intelligent patients and MDs who are innovative and outcomes based. This should be non-threatening to the conservative base. There is really no excuse for resorting to delisting the very MDs who we choose because they are innovative. Please stop trying to control us. You really do not have that right in a free society.

This has all the appearances of a pharma-led push to get their share of the alternative wallet back again. You can delist all the innovative practitioners, and we will still make our own choices. You are fighting Dr. Google - want to try to delist him too?

From: Gary Slee [redacted]
Sent: Friday, 28 June 2019 11:34 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear Board Members,

Despite so-called evidence-based conventional medicine, our society is getting sicker at all ages. Why is this so?

Conventional medicine is good at acute conditions but very poor at chronic conditions. Conventional medicine treats the symptoms of chronic conditions but not the causes - hence its ineffectiveness.
This is approach creates a sicker society - not protect it. Consequently conventional medicine is unsafe for chronic conditions.

Obviously, conventional medicine needs a new health model for chronic conditions. This is where integrative medicine is the next advance in health care .. to protect our society.

I choose Option 1: “no new regulations are required for doctors practicing 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 the 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 on 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 a failure to disclose the details of why the new regulations.

- There appear to be significant elements within the conventional medicine cohort who have invested in the existing orthodoxy and want to protect it. There is a significant gap between current medical scientific research (which supports the direction of integrative medicine) and conventional medical practices.

Change is required around conventional practices, informed consent and medical choice.

Kind regards

Gary Slee
[redacted]
M: [redacted]
E: [redacted]

From: [redacted]
Sent: Friday, 3 May 2019 7:30 PM
To: medboardconsultation
Subject: 'Public consultation on complementary and unconventional medicine and emerging treatments'

To whom it may concern,
I wish to express my concern about the proposed tightening of regulations for medical practitioners who practise integrative medicine. To have access to medical practitioners who seek the underlying cause of medical problems before they become greater issues is invaluable, both to individual patients and to society as a whole. Every Australian has the right to choose this approach if they choose to do so, and to have access to the full extent of health care services. It would be a short-sighted decision and a significant backwards step to restrict integrative medical practitioners from using their invaluable knowledge, insights and tools for better health.
Thank you,
Cindy Smart

Feedback on the Medical Board of Australia's consultation on the regulation of practitioners who provide complementary and unconventional medicine and emerging treatments

John Smartt

[redacted]

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?

No.

It is a cumbersome expression, and the examples used in the documentation actually seem to draw examples and inferences from a wide range of practices, including:

1. integrative medicine;
2. new technologies not regulated by the TGA (such as stem-cell therapy);
3. the prescription of hormones for purposes for which there is not an identified deficiency; and
4. off-label prescribing (prescribing for purposes which do not have regulatory approval).

These issues appear to have nothing in common. Some of them fit very much within "usual practice". The contraceptive pill is the prescription of hormones without an identified deficiency. Off-label prescribing is actually both "very common" and "unavoidable", according to the National Prescribing Service[1].

Each of the areas under consideration or used as an example requires more analysis than this documentation suggests they have had, before any change to the regulatory situation should be considered.

Even attempting a single approach to the whole of "complementary and alternative medicine" is a challenging, and probably unhelpful, undertaking. "Much confusion exists regarding the definitions of complementary and alternative… medicine (CAM)…(which) is nothing more than a categorical label that subsumes numerous therapeutic modalities generally sharing few commonalities. Creating a unique category out of such diversity has lead to misunderstanding and skepticism. From the physician's stand-point, this can generate numerous stereotypes, prejudices, and misconceptions that may compromise the therapeutic relationship, impede compliance, and lead to treatment failure."[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.' If not, how should it be defined?

No.

The expression "usually considered to be part of conventional medicine" is highly problematic in a regulatory environment. Who is to decide what this means, and where its limits are drawn?

There are at least five important pitfalls in assuming that anything that is not currently, commonly practiced must inherently require more regulation, regardless of its demonstrated safety and effectiveness.

1) Medicine is a rapidly changing field, whereas this definition implies that it is a static, conventional body of knowledge and practice (and implementing this proposed guideline would tend to make it more static). Each *month*, there are more than 100,000 new research papers published on PubMed; most of which contain the phrase "…more research is needed…" Medicine is an exploding field of study, not a fixed

one that should be limited to unchanging "conventional" practices. Right now, an animal in a veterinary clinic may have access to more advanced medical treatment than a human. There are good reasons for this. Risks of new medicines and therapies are rightly assessed more carefully for humans than for animals, which inevitably slows the approval process down. It is a mistake, though, to think only of the risks involved in allowing doctors more autonomy in individualising their clinical judgement, without also considering the risks to patients when doctors do *not* consider some forms of "unconventional therapy", when safe and effective to do so. A balance is clearly needed; and it should be based on a careful risk/benefit determination, not on an attempt to entrench the status quo. The Medical Board's role is to protect the public, not to protect a conservative outlook or entrenched positions.

2) AHPRA is somewhat under-resourced, and there is no guarantee that those of its staff who are charged with policing guidelines and making initial notifications have either medical or research training or experience. This means that it is highly likely that preliminary enforcement actions would tend to lack nuanced understanding; it is more likely they would act on the black-and-white letter of guidelines and clarifying documentation. (Through a disciplinary process a practitioner is likely to deal with people who have more relevant education, but the experiences involved in getting to that point can be traumatic and unjustified for all involved.) A rigid understanding of what "conventional" medicine actually involves potentially stultifies progress; and particularly where people without in-depth training around the issues are the ones charged with making an initial judgement about who has to explain his or her actions within a disciplinary setting.

3) "Conventional medicine" cannot always be automatically equated with "the best practice of medicine for the individual patient". It often can. "Conventional medicine" is best-applied to the needs of "conventional patients". It is at its best when:

    a. patients clearly fit into well-researched and well-delineated categories;

    b. there are no significant co-morbidities;

    c. there is a proven pharmaceutical or surgical treatment-of-choice for the condition, which has minimal side effects or risks;

    d. the pharmaceutical solutions are not facing a future of diminishing effectiveness (as are antibiotics);

    e. a "specialised" response is appropriate (i.e. condition can be treated solely within the organ or bodily system in which it manifests, in isolation from broader interconnections throughout the body); and

    f. the goal is resolving a specific crisis rather than maximising health-related quality of life.

    Many patients do not fit these criteria. The medical profession is facing a perfect storm of: increasing anti-biotic resistance, increasing rates of non-communicable and chronic diseases, and an aging population with multiple co-morbidities. We are also seeing more and more patients where a fundamental dysregulation of immune/inflammatory processes underlies a range of conditions. At the same time, many patients are seeking more than just a diagnosis and cure for a particular symptom or condition; they are seeking better health-related quality of life. Finding answers to these challenges often requires doctors to think in less-conventional ways – to look for underlying causes, see the whole person, and consider the complex internal interconnections underlying each patient's individual health status. For example, doctors trained in integrative medicine appear to prescribe less antibiotics in the UK than doctors without this training[3]. Doctors with the commitment and courage

think holistically and innovate appropriately should be encouraged, not threatened with disciplinary action.

This is a direction that medicine as a whole increasingly needs to take. In the words of the recent UK Parliament's Inter-party Working Group looking into integrative medicine: "The future of healthcare lies in our health system recognising that physical, emotional and mental health are intrinsically linked, and that only by treating a patient as a whole person can we tackle the root cause of illness and deal with the problem of patients presenting with multiple and complex conditions."[4]

4) "Usual practice" can also not automatically be equated with "the most cost-effective practice". The report referred to immediately above was largely driven by the increasingly unaffordable cost of the British NHS, and the need for more cost-effective approaches. There is emerging evidence that approaches that look for underlying causes and deal with the whole picture of patient-health may be more cost-effective than approaches that compartmentalise thinking about aspects of human health [5] [6].

5) Unfortunately "usual practice" also cannot automatically be equated with "safe practise". It has been estimated that there at least 80,000 medication-related hospitalisations per year in Australia, and of these (depending on the method of estimation) between 32% and 69% are considered "avoidable"[7]. It has also been estimated that one in six hospital admissions results in an "adverse event", which results in disability or a longer hospital stay for the patient and was caused by health care management; 51% of the adverse events being considered preventable. In this analysis 77.1% the disability resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died[8]. Much of the time "usual practice" will be the safest alternative for patients; but this is clearly not always the case. These statistics would cause outrage, except for one thing: the assumption that there is no viable alternative. In many cases that may be correct; but it is clear that doctors should be actively encouraged to at least look for safer alternatives, rather than threatened with disciplinary action if they do.

   Consider the example of the conventional treatment of pain. Prescription opioids were identified as being involved in 794 deaths in Australia in 2016 (more than two people every day)[9], and paracetamol a further 170 (nearly one person every two days)[10]. It has not been possible to get an accurate number of annual Australia-wide deaths involving pregabalin (Lyrica), but if a recent press article is correct, it was involved in 164 deaths in Victoria alone between 2013 and 2017[11]. It has also not been possible to obtain accurate data about deaths from NSAIDs (including aspirin), but given that GI bleeding and increased risk of stroke and other cardiovascular events are known risks of these medications, the number of deaths may also not be small[12]. These numbers do not consider other adverse health outcomes, nor the economic costs of these. We also know that pain is an extremely complex phenomenon, and that nociceptive input is only one of a number of inputs determining whether and to what degree a patient experiences pain. One of the alternative treatments mentioned in the discussion document is reiki. I personally have no absolutely no idea whether reiki is an effective therapy for pain of any sort. A 2018 meta-analysis appears to lend some credibility, so, given the complex nature of pain, it just might be; at least for some patients[13]. It may be simply placebo for all I know; but placebo can be particularly powerful in some forms of pain, with neurochemical and neurophysiological mechanisms for placebo-response increasingly being identified. I do know that reiki is extremely safe. No one dies from it. It is obvious that if a patient tries it for pain, and doesn't find it helpful, he or she is unlikely to persist with it.

With that background, assume that a hypothetical doctor decides, based on her knowledge of a patient and his circumstances, to recommend a trial of reiki before a trial of medication. Assume the patient has a history of addictions and GI bleeds, some liver inflammation and a familial history of strokes. One would have thought that the suggestion of a trial of reiki was a commendable (if socially courageous) recommendation; if it doesn't help, then it doesn't help. Medication remains an option. But under the Medical Board's recommendations, because the potentially dangerous pain-killer is "usual practice", the practitioner is not in danger of being put through a disciplinary process for prescribing it; but if she makes the safer recommendation of reiki, she puts herself at risk of a disciplinary process.

Therefore "usual practice" maybe safer for doctors, while being less safe for patients. It should be the Medical Board's role to advise AHPRA about how to reverse this situation, not to re-enforce it.

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. The discussion document only identifies negative issues with non-traditional treatment; and appears to have difficulty finding appropriate examples. A single case of an iatrogenic death from an emerging treatment is reported; and this was from a case of liposuction where a consent process, pre-operative preparation and post-operative management were all inadequate. Liposuction has been in common use since at least the 1980s. There is an existing regulatory framework to deal with situations like this, and it hardly applies to what would normally be called "integrative", "nutritional", "complementary" or "alternative" medicine. It is, rather, a not-uncommon form of invasive surgery. Compared to the staggering rates of iatrogenic complications within mainstream medicine, a single case (and one that wasn't really relevant to the issues in question) actually speaks volumes about the relative safety of the sorts of approaches under consideration.

The discussion paper also lists some tribunal decisions for some medical practices that were already dealt with under existing regulations. Five of the seven cases cited were for the inappropriate use of hormone prescriptions. Hormones are commonly prescribed now; the issue in these cases was simply whether the medical justification was appropriate in these individual cases, not whether anything alternative or innovative was being offered.

In the absence of any significant hard-data about adverse events through different approaches, the paper also identifies "complaints as a source of information". It does not say how may of these complaints were raised by health consumers who were unhappy with their treatment; compared with how many were raised by people and groups who may see different ways of thinking as a competitive or territorial threat. It does not reveal how many of the complaints are from lobby groups that receive funding from pharmaceuticals. (Given media reports on this subject, however, if behind-the-scenes lobbying from the pharmaceutical industry played no part in these complaints, the discussion document should probably say so[14].) In a situation like this, complaints from the latter sources should be ignored.

These medical practices that received complaints warrant careful consideration, in terms of whether any of them justify increased scrutiny or regulation.

Issue raised in complaint	Consideration
Unconventional and unproven diagnostic techniques and equipment, e.g. thermography to detect breast cancer.	The major screening tool which is currently used, mammography, is itself highly controversial. A systematic review of systematic reviews into mammography concluded: "Differences in the conclusions of systematic reviews of the evidence for mammography have persisted for 15 years. We found no strong evidence that [study] design characteristics were associated with greater support for the benefits of mammography in routine breast cancer screening. Instead, the results suggested that the specific expertise and competing interests of the authors influenced the conclusions of systematic reviews."[15] There are certainly types of breast cancers that are ignored by mammography, giving false negatives (particularly: subtle carcinoma, masked carcinoma, multifocal carcinoma and multi-centric carcinoma[16]); and over-reliance on it may lead to ignoring other approaches that may reveal their presence. In this situation, alternative approaches should be sought out, not discouraged.
Diagnosis and subsequent treatments based on results from non-accredited laboratories.	Practitioners would obviously prefer to use an accredited laboratory over an unaccredited one, where the same tests were available. Non-accredited laboratories continue to exist precisely because they offer diagnostic procedures not available elsewhere in Australia. Those who are seeking to really understand their patients' conditions and their underlying causes are those likely to use these tests. Once again, provided there is adequate evidence of safety and value, they should be encouraged, not discouraged.
Failure to consider differential diagnoses.	This is an issue that could apply to any medical practitioner. No evidence has been presented that it is particularly an issue for those who practice outside of the norm.
Treating most or all patients for the same condition and/or providing the same treatments regardless of their presentation.	Once again, this concern could apply to any practitioner, especially if they become "burned out". A corrective to it may be more emphasis on diagnostic testing; including less commonly-used tests (which this paper seems to want to discourage).
Failure to refer patients with complex diagnoses to specialists.	This can apply to any medical practitioner. There is, however, an important point here. It could be argued that it is precisely where complex diagnosis is involved that lateral thinking and an integrative approach becomes most important; and where the emphasis of specialisation (and, increasingly, special interests within a specialisation) may prove least useful.

Issue raised in complaint	Consideration
Failure to manage co-existing medical conditions.	The argument in the point above applies here. A nurse told me recently about a patient who was admitted to her hospital with a bladder infection. The infection was treated, and the patient sent home. Two weeks later the patient died of cancer, which was missed by the hospital. A "failure to manage co-existing conditions" is much more likely to occur in a situation which has taken the idea of specialisation to an extreme, than one where the practitioner is well-trained in an integrative approach that seeks to factor in information about the whole health of the patient.
Providing alternative therapies for cancer treatment in place of conventional treatments with inadequate consent process.	"Inadequate consent" is an important issue of potential concern in any medical situation, and there are existing approaches to address this.
Treatment outside accepted treatment protocol/therapeutic guidelines, e.g. long-term antibiotics in the absence of an identified infection.	Long-term medication developed for acute conditions is a common problem that needs careful monitoring. For example, the long-term use of PPIs for gastro-intestinal reflux is common, even though guidelines discourage it. Practitioners who continue to prescribe them over the long term would probably say that they prefer not to, but that they don't have an alternative. Which is precisely the point. Once again, those looking at alternative approaches to reflux – at underlying causes and connections with other medical issues – need to be actively encouraged, not threatened with increased oversight.
Promoting indiscriminate use of health services without proven benefits, e.g. intravenous vitamins for wellbeing, hormones for performance enhancement.	The use of hormones purely for performance enhancement should probably be banned outright, if it isn't already. The MBA should, however, be very careful before attempting to eliminate all health services "without proven benefits", if "proven benefits" are defined as a "meta-analysis of RCT's only"[17]. This is essentially an "evidence-only medicine" approach, which is very different from "evidence-based medicine", and which doesn't have widespread support among clinicians anywhere[18]. Contrary to common assumptions, high-quality evidence simply hasn't been obtained yet for many of the practices that are commonly undertaken; it is virtually impossible to obtain for new surgical procedures, for example, until there is a sufficient base of patients to test. The long-term effects of poly-pharmacy, in particular, which is particularly common among the elderly, has virtually never been studied. Some things just aren't practical to clinically research, and clinical judgement has to come into the picture. More high-quality evidence needs to be obtained, and it should absolutely be followed when it is available; but its absence is not grounds for banning practices that patients find helpful, and which are both safe and plausible.

Issue raised in complaint	Consideration
Prescribing when not clinically indicated, e.g. hormones for a person without a hormone deficiency.	The Medical Board of Australia (MBA) needs to be very careful in trying to centrally regulate this. As mentioned earlier, the contraceptive pill is the prescription of hormones for people without a hormone deficiency.
Complications from inappropriate or unnecessary treatments e.g. infection from peripherally inserted central catheter (PICC) lines inserted into the venous system and remaining for a prolonged period of time to administer long term antibiotics.	Infections from catheters are not the exclusive domain of non-tradition practitioners. Nor are "unnecessary treatments". Thousands of patients underwent knee arthroscopies for many years before, finally, the evidence was collected indicating that they caused more problems than they solved. Individual clinicians will not be blamed for this, because they followed "accepted practice". In an ideal world they would have been encouraged to think through the likely results of this intervention for themselves, and to look for alternatives, rather than relying on a herd mentality for a commonly-accepted practice without either good evidence or common sense behind it.
High fees and complaints about financial exploitation.	This complaint is not limited to medical practitioners who operate outside of the mainstream[19]. The regulation of fees is a wider, more complex issue than one that should be considered within this context.

The emphasis of the paper on the negative consequences of the practices under review is simply not supported by: the paper itself, the available evidence, prevailing community attitudes or common sense. Rather, it should balance its criticism of any negatives associated with unconventional thinking, with the positive aspects of these approaches.

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. The Board could do more to address the unnecessary and unhelpful polarising reactions to different ways of thinking that serve to accentuate controversy rather than find common ground between all stakeholders. Issues that could be looked at include:

- ways to promote influence of integrative thinking in hospital settings;
- encouragement to involve qualified practitioners who will treat patients holistically in all situations and help to better coordinate care where two or more specialists are involved in the treatment (such as having "hospitalists" in hospitals);
- active encouragement to at least consider the evidence for alternative approaches in situations of chronic conditions with long-term poly-pharmacy (particularly compared to the lack of evidence supporting most forms of poly-pharmacy); and
- mandatory continuing education of doctors regarding those complementary and alternative approaches that have an increasingly solid evidence base behind them for safety and efficacy when used in specific conditions. For example, a 2018 scoping review of systematic reviews of complementary and alternative medicine (CAM) for

musculoskeletal and mental health conditions concluded that: "The evidence base for CAM varies widely. For musculoskeletal and mental health conditions, which are common in primary care, and were the focus of the authors' larger scoping study, good quality reviews were identified with moderate to good quality evidence of effectiveness for yoga, osteopathy, acupuncture, and spinal manipulation and/or mobilisation for low back pain; acupuncture for myofascial trigger point pain; tai chi and acupuncture for osteoarthritis; manual therapy, manipulation and acupuncture for neck pain; acupuncture for fibromyalgia; mindfulness and/or meditation and tai chi for depression; meditation and/or mindfulness-based stress reduction for anxiety; meditative and/or mind-body movement for sleep; and mindfulness for stress and distress."[20] A matched-pair study conducted over a decade ago demonstrated higher quality of placebo-controlled trials in Western phytotherapy (herbal medicine) than conventional medicine[21], and the intervening decade has witnessed an explosion of research in this area, partly due to the rapid development of high throughput screening technologies.

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

Yes; but most of these are already provided by the TGA. No evidence has been provided for an assertion that additional safeguards are needed, compared to those that are already in place.

It is true that patients with chronic and/or life-threatening conditions are particularly vulnerable. However, this fact needs to be balanced by the understanding that these patients, if they decide to stop relying on what the mainstream has to offer, actually have unprecedented access to accurate information. They have usually done web-searches about their condition, and they usually belong to on-line discussion groups where information is shared. They are far less vulnerable than they would have been in the past.

Safeguards for them may be best provided by an integrative GP who is well-trained in individualised risk/benefit analysis and shared decision making with individual patients.

The MBA could help to uphold safe, effective integrative practice by supporting good communication between individual patients, their GPs and integrative medicine providers. A current lack of co-ordinated care between integrative and "mainstream" medical practitioners consistently emerges through the relevant literature as a key problematic issue for patients[22] [23].

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

Yes. The Board could familiarise itself with the rapid increase of high-quality research supporting a large number of "alternative" and "complementary" therapies for specific indications, and critically analyse the ready acceptance of evidence rhetoric around existing practices. This is particularly the case in the context of expert critical appraisals of the evidence supporting much of mainstream medicine, the quality of evidence (though not the quantity) being much poorer, in general, than may be generally realised[24]. This isn't just this writer's opinion. According to an editor of The Lancet "much of the scientific literature, perhaps half, may simply be untrue"[25] When combined with the realisation that pharmaceutical companies are being selective about what they choose to publish (the British House of Commons Public Accounts Committee noted late in 2013 that drug companies, despite much negative publicity around the practice, were still only publishing around 50% of the results of clinical trials which they funded[26]), that puts the scientific basis of much of mainstream medicine onto a very shaky foundation. A former editor of the New England Journal of Medicine expressed it in these terms: "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... Most of the big drug companies have settled charges of fraud, off-label marketing, and other offences. [redacted], for example, in 2001 pleaded guilty and agreed to pay $875 million to settle criminal and civil charges brought under the federal False Claims Act over its fraudulent marketing of [redacted], a drug used for treatment of prostate cancer. In addition to [redacted], other companies that have settled charges of fraud include [redacted]. The costs, while enormous in some cases, are still dwarfed by the profits generated by these illegal activities, and are therefore not much of a deterrent."[27] According to Medical Observer, the behaviour of major corporations in using their resources to slant information in favour of their products continues to this time[28] [29]. If a company in another industry, such as food or car manufacturing, tried to underplay or completely hide safety-related information in this way there would be an enormous outcry.

It is dangerous to allow major, profit-making corporations to be the sole drivers of medical innovation. Individual doctors should be actively encouraged to think laterally and keep an open mind about what can be done for the individual patients they work with; they should not be discouraged from doing so, unless there is clear evidence or at least a reasonable expectation that this actually creates problems for patients.

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?

Based on the paucity of actual (as opposed to hypothetical) problems identified, it certainly appears to be. There is no justification for using an ill-defined notion of "usual practice" as the gold standard, against which all other interventions should be measured.

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

Only if they are far more constructive and consensus-building towards different ways of practicing medicine than the current document under discussion suggests they would be.

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?

Yes. If these guidelines are to be used, any reference to "accepted practice" or "usual practice" needs to be rethought, in order to provide more clarity about what is being talked about. "Usual practice" simply should not be held up as the ultimate in what may be helpful to patients; particularly in situations of chronic, complex conditions.

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

Yes.

The Board could put a lot more energy into finding out why consumers elect to use approaches to their health that are outside of the mainstream, before assuming that their decisions to do so are based on the fact that they must be gullible and easily led. (Most studies actually seem to indicate the opposite[30].) The discussion documents point to the extent to which consumers are voting with their feet and their wallets, in terms of unconventional approaches. Very few patients would completely abandon conventional medicine in favour of alternatives; but a large proportion elect to gain the benefits of both, as shown by the positive

correlation between the use of conventional care and complementary and alternative medicine use[31].

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. 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. Other – please specify.

Other.

The MBA should follow the example of the Therapeutic Goods Administration (TGA), in its proposed regulatory changes related to personalised and 3D-printed medical devices[32]. The TGA proposes to increase the regulation in some situations, whilst decreasing it in others, in order to enable individual doctors to be more responsive to the individual needs of individual patients. Its assessment criteria include the level of risk involved; and it recognises the risk of *not* allowing doctors to respond individually.

The followings are some statements that could, ideally, be incorporated into future guidelines for doctors.

Good medical practice involves:

- searching for the underlying causes of chronic ill health, and not just treating presenting complaints;
- viewing people holistically, and being aware of the interactions of different 'systems' and parts of the body in the aetiology and treatment of different conditions;
- being aware of published research evidence, and balancing this with your own clinical judgement about the patient before you and their individual situation;
- being judicious in the use of pharmaceutical drugs, and particularly where there is long-term, poly-pharmacy involved;
- taking care not to accept the advertising of pharmaceutical companies, nor the statements of their representatives, at face value, without assessing the evidence for yourself (regardless of what your peers appear to be doing);
- being open to alternative ways of addressing the medical conditions of your patients – both those that are innovative and those that are from other medical traditions – carefully assessing the evidence, the therapeutic rationale and the risks for each of them, rather than assuming that existing practice automatically represents the best possible thinking about human health for every condition of every patient;
- taking careful account of the risk to the patient in front of you of any proposed course of medical intervention, ensuring that the patient can make an informed decision based on those risks; and
- seeking an active, positive dialogue with other practitioners, of whatever persuasion, who are also treating your patients.

In other words, good medical practice involves practicing in an integrated manner.

Footnotes

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29 https://www.medicalobserver.com.au/views/are-safety-warnings-secret-drug-company-business

30 Note, though, that these studies may tend to conflate health literacy with multi-morbidities and higher education with socio-economic confounders. Sharp D, Lorenc A, Morris R, et al. Complementary medicine use, views, and experiences: a national survey in England. BJGP Open. 2018;2(4):bjgpopen18X101614. Published 2018 Nov 14. doi:10.3399/bjgpopen18X101614

31 Canizares M, Hogg-Johnson S, Gignac MAM, Glazier RH, Badley EM. Changes in the use of practitioner-based complementary and alternative medicine over time in Canada: Cohort and period effects. PLoS One. 2017;12(5):e0177307. Published 2017 May 11. doi:10.1371/journal.pone.0177307

32 https://www.tga.gov.au/sites/default/files/consultation-proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices.pdf

Jenny Smiley

[redacted] yo

[redacted]

To whom it may concern,

I'm `writing this note regarding some news I have just heard from my Interactive Medical practitioner.

I've been with my current Unconventional practitioner for ten years, whom I use as my Conventional practitioner as well, I am very happy with the availability from my doctor, and I very much like the fact that he offers advice from both his unconventional and conventional training and I especially like the fact that he makes himself available to discuss all my health needs whenever I need him.

Our consultation is very in depth and extremely thorough, so that he pinpoints all my issues and ailments and then sets about to help me improve and even eradicate most of my issue with a series of treatments. I value the freedom that I have and the fact that I have the best of both worlds with him which this is very important to me.

I wish that the outcome from this proposal from The Medical Board of Australia is that we stay Status quo.

And if this is not possible, that it be modified from the current proposal , to ensure that it applies to all medical practitioner 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 Medicine as well as conventional medicine, be recognised as a Specialty, in order to allow increased Medicare rebates to help cover the increased costs of fulling the new regulations

From: Ben Smith [redacted]
Sent: Monday, 25 March 2019 9:56 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Dear Sir/madam,

proposed changes to restrict the services of doctors practising complementary and integrative medicine should not be implemented. There are too many cases out there where modern medicine is unable to provide solutions, having an alternative effective path gives hope and solutions to those who have reached a dead end with their health. Our health system does not support those people to the full extent required, doctors practising complementary and integrative medicine are able to help these people and provide alternative solutions, find relief from their suffering and begin to rebuild their lives.

Implementation of the new regulations will impact the health, quality of life and future of these people to a degree that undeniably is not understandable till one suffers the aliments that doctors practising complementary and integrative medicine provide solutions and relief for.

Kind regards
Benjamin Smith

From: Holly Smith [redacted]
Sent: Wednesday, 20 February 2019 1:10 PM
To: medboardconsultation
Subject: Integrative Medicine

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.
Warm regards,
Holly Smith

From: [redacted]
Sent: Thursday, 27 June 2019 11:06 PM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

> Dear MBA,
>
> I believe that no new regulations are required for doctors practising
> in the areas of complementary medicine and integrative medicine,
> especially regulations created by people with conflicts of interest
> and a lack of or want to understand the important role that
> integrative medicine has for thousands of people.
> 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.
> I personally have had my quality of health and life significantly
> improved with integrative and complementary medicine. Please call me
> [redacted] so I can discuss my own journey with you to illustrate how
> vital having these treatment choices are to people.
> Thanks
> Joanne Smith

From:	Samuel Smith
To:	medboardconsultation
Subject:	Consultation on complementary and unconventional medicine and emerging treatments
Date:	Thursday, 4 April 2019 5:41:58 PM
Attachments:	[redacted]

Hello,

Please find a few comments attached to the MBA's proposed policy of complementary medicine practitioners.

Questions for consideration

The Board is inviting feedback on the issues and options outlined in the discussion paper.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? YES

   If not, what term should be used and how should it be defined?

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?

   I would ask that there be further clarification re: "part of conventional medicine"- whilst the intent is clear, this board definition could be applied to a number of off-label, but still scientifically sound and supported by evidence methods of treatment.

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'?

   A possible harm that I don't think I saw mentioned is the demonization of "Western" medicine by these practitioners, and the fact that often these practitioners discourage their "patients" from seeking conventional medical therapy, or the harm done by those who discredit existing, lifesaving medical practices (e.g. vaccines).

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 masquerading by alternative health practitioners (e.g. chiropractors) using the title "Doctor" to give baseless and costly treatments legitimacy
   - Strengthening advertising regulations regarding supplements and alternative health practices
   - Better regulation of the supplement and fitness industries, which provide the public with poorly regulated products
   - More punitive measures for healthcare workers in legitimate settings (e.g. nurses, midwives, doctors) who recommend harmful alternative practices, as their position and standing gives more credance to false claims, and whether they intend it or not, represents a breach of patient's trust.

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

   Yes

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

[1] **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

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?

No

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

   It would be a start.

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?

As above

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

Higher punitive measures for practitioners working outside of these boundaries; there needs to be more done to make practitioners think twice before making false or misleading clairms, or advising vulnerable patients their medications don't work.

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.

    - 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*.

    Option 2

    - Other – please specify.

From: Peter Solomon [redacted]
Sent: Monday, 25 February 2019 6:26 PM
To: medboardconsultation
Subject: Integrative Doctors

To whom it may concern,

I have been made aware that the board is looking into limiting what integrative doctors can prescribe, and in so doing, what they can practice. I have been seeing an integrative doctor for many years and have benefited enormously from their specific knowledge and training, which goes well beyond a regular general practitioner.

I am equally concerned that the board would consider limiting my rights as an individual with respect to my health choices.

I am certain the board will reflect on this and desist.

Yours sincerely,

peter c solomon | [redacted]

From: Luisa Soussa [redacted]
Sent: Wednesday, 13 March 2019 12:43 PM
To: medboardconsultation
Subject: Consultation on complimentary and unconventional medicine and emerging treatments - OPTION 1

TO: MEDICAL BOARD AUSTRALIA

As a patient of Integrative Medicine and conventional medicine I would like to make this submission to the Medical Board regarding the Public consultation paper to regulate integrative medical practitioners further. I would like to strongly vote for **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.**

The current regulations of medical practitioners who provide complementary and unconventional medicine and emerging treatments is adequate to address the issues and protect patients.

Thank you very much for this opportunity as a patient and member of the public to have an opinion.

Regards
Luisa

From: Andrea Southern [redacted]
Sent: Monday, 15 April 2019 11:52 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Hello,

I am writing in response to the public consultation paper seeking feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

I strongly endorse Option 1 - to retain the status quo.

To further restrict Medical Practitioners to use only "conventional" medicine treatments and diagnostics is to severely limit the options for the general public who are dealing with health issues. Natural Medicine and alternative treatments focus on preventative medicine, and by restricting even further the ability for Medical Practitioners to use these alternative treatments will place a huge burden on an already strained Health system.

Despite accusations to the contrary, “Natural Medicine” is science based. My years of study to become a qualified Naturopath, Clinical Nutritionist and Western Medicine Herbalist showed this to be true. Throughout my studies, the science behind all treatments was always emphasised. There is obviously some anecdotal evidence used in practise, but Medical Practitioners use this as well – they know for example, anecdotally, which medicines appear to work better than others for their patients.

THE BOARD’S PROPOSED DEFINITION OF COMPLEMENTARY AND UNCONVENTIONAL MEDICINE

I also object to the Board's proposed definition of Complementary and unconventional medicine and emerging treatments for the following reasons.

The fact that an assessment, diagnostic technique, therapy or treatment etc. (as outlined in the proposed definition) is not currently considered to be part of conventional medicine does not mean that its development is not science based, and indeed does not mean that it cannot be used to successfully treat people for various health conditions and diseases.

There are many examples of “alternative” treatments, just one example is herbs, that in the past have not been considered as part of conventional medicine, but now are. By totally limiting the use of treatments and therapies that have been successfully used for thousands of years, but are not at the moment classed as “conventional medicine” would be unfairly restricting hundreds, if not thousands, of beneficial treatment options for the public.

Take care,

Andrea Southern
Naturopath
[redacted]

From: Maria Spencer [redacted]
Sent: Thursday, 4 April 2019 11:37 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Good morning,

I support *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.*

It is not the governments job to take away freedom of choice in relation to an individuals heath & well-being.

Kind regards,

Maria Spencer

From: Michael Stanton [redacted]
Sent: Thursday, 4 April 2019 4:44 PM
To: medboardconsultation
Subject: Public consultation paper: complementary and unconventional medicine and emerging treatments

Please register my opposition to this inappropriate consultation.

The Medical Board of Australia being allowed to demonise integrative health care in this way is unacceptable to any thinking individual. As well as those who have suffered adverse effects to drugs or medical errors in any way.

Perhaps the representatives of the MBA can better spend their time replacing the words medicine and medical, and any other terms they use to associate their area of influence to the pharmaceutical industry. Societal health is all the MBA should care about and good health is more than whatever assistance can be provided by manufactured chemicals.

A properly named Health Board of Australia would, by the power of words, realign its directors and members focus away from where it is: the pharmaceutical industry and profits, to where it should be: societal health and wellbeing.

When focused on health and wellbeing a HBA board would not only welcome integrative health care amongst its members but encourage the expansion of natural remedies and wholistic research.

Regards

Michael Stanton

From: Danielle Steedman [redacted]
Sent: Thursday, 27 June 2019 3:49 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments'

To whom it may concern,

I am writing to voice my opposition to the proposed changes the current MBA guidelines to the use of integrative, complementary and alternative medicines by medical doctors. This will significantly restrain the practice of integrative medicine and the use of these modalities.

The proposed new regulation is draconian and simply unnecessary. The MBA already has a strong code of conduct on good medical practice which sets out what is expected of all doctors registered to practise medicine in Australia.

I am requesting 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.

My own personal use and the access my family has to integrative medicine as practiced by our general practitioner is of huge value to our health. I strongly believe restrictions to this type of healthcare will jeopardize my health, the health of my husband and our two beautiful children.

We are educated people who have a right to access quality healthcare of our choice. I strongly believe preventative healthcare is a right we should be free to choose as we wish, and do not need restrictions imposed from the MBA. We also choose to treat illness with a combination of conventional and complementary medicine and would continue to do this, possibly without the guidance of our general practitioner, if we did not have access to our GP in the future.

Therefore it is very important to us, and our wider circle of family and friends to have access to quality medical treatment and consultation, rather than rely on word of mouth from unqualified sources, the questionable information on the internet and various company's with vested interest in selling products rather than educating patients. These would be our sources unfortunately, if we did not have access to our GP. I feel without the guidance of our GP our future healthcare is threatened.

Please reconsider these new regulations, and allow people the option to choose the best option for them, with teh guidance of an educated medical professional.

Kind regards,
Danielle Steedman

From: [redacted]
Sent: Sunday, 30 June 2019 10:06 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1... because a combination of traditional medicine and natural medicine provides a combination that works well for me and my family.

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, when appropriate.

Regards,
A. Stephens

From: Leroy Steven [redacted]
Sent: Tuesday, 25 June 2019 12:22 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments.

To whom it may concern,

Imposing greater regulation around the use of integrative, complementary and alternative medicines is draconian and simply unnecessary.

The MBA already has a strong code of conduct on good medical practice which sets out what is expected of all doctors registered to practise medicine in Australia.

Integrative medicine doctors combine quality conventional medicine with safe and effective complementary medicine to improve health and reduce unnecessary medical treatments.

Imposing greater regulations will significantly restrain the practice of integrative medicine and the use of these modalities.

Thank you.

Regards,
Leroy Steven
[redacted]

From: [redacted]
Sent: Sunday, 30 June 2019 8:53 PM
To: medboardconsultation
Subject: RE: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern

I am concerned about the Medical Board of Australia's consultation process into Integrative Medicine in Australia.

I do not believe that there needs to be any interference with the system that currently exists in Australia. Every Australian should have the right to choose their own doctor and how they choose to be treated.

Personally, I prefer non-drug approaches for managing my own health and I do not want to see this right taken away from me and controlled by big pharmaceutical companies.

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 should be a decision left to me.

Thank you for your consideration of my opinion.

Kind Regards

Belle Stevenson
[redacted]

Declaration of dennis-ross

My Will is that you do not now or at any time in the future, *effective immediately upon receipt of this Declaration,* introduce any changes, whether legislative or otherwise, that can or may effect, in any way, or place restrictions, conditions or other requirements upon the work or practises of doctors who have expanded their knowledge from that of the usual limited standard medical practitioner, to include in their practises, **Complimentary and Integrative Medicine,** without you **first giving:**

a. all such Practitioners, and

b. their patients, current and past, but not so that you gain access to or knowledge of any of their private patient records, and

c. the widespread public in general,

the full, written and complete disclosure and details of any and all such proposals, that are supported by your sworn Affidavit, and that **prior to any such changes being implemented**, you have received the written, clear and sworn Declarations of at least **sixty percent** (60%) of all such practitioners.

It is my further Will that you have, in plain written English, given such complete details of such proposed changes to all such Complimentary and Integrative Medical Practitioners that you can reasonably contact, at least **six (6) months prior to the date of any such changes actually being made.**

My Will as stated above is clear and is not open to interpretation.

I have had little need of help from such Practitioners because it is rare for me to seek assistance from anyone with regard to my body, to the degree that I do not have a doctor and have not visited one for some 45 years. However, I do understand the value and knowledge of Complimentary and Integrative Medicine due to my studies and have recommended and influenced hundreds of people to see such well qualified practitioners over the decades.

I find that Complimentary and Integrative Medicine Practitioners are studied and practiced in the traditional laws of health and disease. In contrast, I have learned that the normal limited medical training, and thus practitioners they train, is largely based on removing and suppressing symptoms with perilous, costly surgery, chemotherapy, radiation and drugs, **not** on understanding, preventing and correcting disease causes.

In my research and in talking with hundreds of people over some decades, I find that standard doctors do a poor job of knowing their clients medical history, weight, age, allergies, illnesses and all drugs taken and their compounding effects. Nor do they often or effectively disclose the ingredients and harmful effects of the drugs and treatments they propose for their patients, or give fully informed knowledge of, and gain consent for, many treatments they prescribe.

Is it surprising that the Chief Editor of one of the world's most respected Medical Journals said, *It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgement of trusted physicians or authoritative medical guidelines*. ***New England Journal of Medicine***: *Chief Editor M. Angell MD*.

Perhaps the record of over 200 yrs of medical disasters, which include thalidomide, mercury, Vioxx, childbed fever carnage, asbestos, DDT, lead etc. illustrates the story of what happens with quite limited and often uncaring (to only spend a few minutes with patients is unconscionable) training and practices of standard doctors.

My will is that you honourably accept your sworn role to help people to the very best of your knowledge and to cause no harm, and, if such knowledge is inadequate, to study Complimentary and Integrative Medicine.

My very best regards,

dennis-ross

[redacted]

From: Sandy [redacted]
Sent: Monday, 1 July 2019 3:00 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear Sir/Madam,
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.
Regards
Sandy Stevenson

2/6/2019

Mr Vyvyan Stott
[redacted]

Executive Medical Officer
AHPRA, Melbourne

by registered post.

Dear Sir/Madame

Regarding your notice entitled "current consultations" concerning (15.2) complementary, non-chemical healing methods; as an elector, this is my will:

How you define "clearer" regulation, "complementary + unconventional" I am unsure. However there is a perception that an illness which can be connected in any way to a cause by complementary medicine will be made into an issue to restrict such healers.

One instance was of a baby given 20-30 times too many vitamins, which generated negative publicity about vitamins.

A figure of 23,000 fatalities annually was quoted, as caused by chemical medical malpractice.

Freedom of choice is far preferable to 10 minute big-pharma style appointments.

Most complementary healers do high quality work. All medical practitioners need to be treated alike; not singling out non-corparate healers for bullying treatment.

Please do not introduce new regulations, but rather retract this "consultation" document. As public servants, please do the will of your employers, the patients.

Yours faithfully

[redacted]

P.S. Please acknowledge receipt of this letter.

From: chris strakosch
To: medboardconsultation
Subject: Unconventional treatment
Date: Tuesday, 28 May 2019 9:23:30 AM

Dear Sirs

There will always be a group of patients with often disabling symptoms who have been unable to be cured or at least relieved by usual medical treatments. Such patients do very badly and are usually dismissed as "Nutters"

If a treatment is harmless and provides benefit I can see no reason for not using it. Lets recall that placebo is one of our strongest treatments

Regards

--
Christopher R Strakosch DMed, FRACP
[redacted]
The universe and all that's in it can be explained by gravity alone. (Hawking)

[redacted]

From: melanie stratford [redacted]
Sent: Friday, 28 June 2019 11:16 AM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

Subject: Consultation on complementary and unconventional medicine and emerging treatments
Reply-To: [redacted]

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.

Bottom line is this:
Freedom of choice
Why would Australian Citizens not have a right to choose the type of healthcare they want?
No genuine reason just that the AMA is being dictated to by big pharma who have always known that real medicine that treats the cause of illness, has always been a huge threat to their big revenues.

The people cannot be deprived of fundamental human rights to choose the healthcare they want.

Melanie Stratford

From: Claire Stretch [redacted]
Sent: Monday, 29 April 2019 4:05 PM
To: medboardconsultation
Subject: Great concern the limiting of Integrative Doctors

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 the this is an abhorrent limitation on my rights to seek the appropriate medical attention.

To put those 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 respective field.

I request that no such measures are put in place so that I may continue to receive Integrative Medical treatment.

Best wishes
Claire

Claire Stretch
[redacted]

‘

Response to the Medical Board of Australia draft regulations re ‘Consultation on complementary and unconventional medicine and emerging treatments’.

By Dr. Graeme Stringer **BDSC.,MDSC,FRACDS,FACNEM(Dent),FASLM,Adv. Dip.(Ayurved. Med.)**

The document conflates “ complementary “ , integrated” medicine and ”emerging” and “ unconventional medicine” as one group whereas any reasonable reflection would clearly see the vast differences in those aspects of medicine. Each area has particular issues to address which, in my view, should be adequately covered by existing guidelines and regulations for ethical and informed practice of medicine.

The lack of consultation with the “stakeholder” groups before releasing the Discussion Paper, has resulted in a number of concerns raised by some key representative bodies such as AIMA and ACNEM. Indeed, the Australian newspaper carried a report of concerns being expressed about the Medical Board actions by both the AMA and RACGP.

Whilst the Medical Board has raised some issues of concern for the medical profession, extending the consultative period has been a positive move to enable more communication and feedback from the particular groups most directly affected by the proposed changes.

Under the existing regulations one would expect that any Health Practitioner and specifically medical practitioner would follow the guidelines to determine investigative and diagnostic procedures on a diagnostic benefit risk and costs benefits for each patient. As part of CPD each Practitioner would be expected to maintain currency with procedures. When new diagnostic procedures are developed and documented then it would be encouraged to discuss and promote these throughout the medical literature, online discussions, and at conferences.

Similarly with treatments.

As there is always a graduation of evidence from very strong to weak , it is up to practitioners to carefully evaluate emerging practices before implementing them.

This is vastly different from integrative or complementary medicine , where well documented therapies and diagnostic techniques are utilised.

Australia has a number of world leading organisation that rigorously research and review new complementary techniques and provide world leading education and certification of standards of practitioners.

The Practitioner Research and Collaboration Initiative (PRACI. Ref https.praci.com.au) is the largest national practice-based research network for complementary healthcare practitioners in the world.

Within Australia there are a growing number of Integrative medicine organisations for Medical practitioners and others including:

- AIMA- Australian Integrative Medical Association,
- ACNEM- Australasian College of Nutritional and Environmental Medicine ,
- ASLM-Australasian Society of Lifestyle Medicine.
- The National Institute of Integrative Medicine runs educational courses, as do many other groups.

- Doctors For Nutrition.
- The Cancer Council Of NSW lists 25 complementary medicine organisations on their website:
- https://www.cancercouncil.com.au/cancer-information/complementary-therapies/professional-associations/
- NICM, National Institute for Complementary Medicine based at University of Western Sydney, is very active in research and education of medical and other health practitioners
- Australian Research Centre in Complementary and Integrative Medicine (ARCCIM) based at University of Technology Sydney is very active in education and research. Indeed they were the key sponsor of the recent International Conference on Complementary Medicine Research –ICCMR2019, in Brisbane May 2019.
- The key organisation related to this International Conference is the International Society of Complementary Medicine Research (ISCMR), with an active chapter in Australia.

These act as peer groups for implementing many of the Medical Boards guidelines in educating practitioners, peer group evaluation of procedures, diagnostic tests and practical effectiveness of the cost benefits of these.

The Medical Board could convene meetings with these groups to both educate as to ethical approaches expected and to listen to concerns of each group. To improve health outcomes for the Australian population an ongoing dialogue with such groups would enable the good will and common aim of improved health outcomes for all to work together with this common goal, despite a wide range of approaches.

Within the Integrative Medicine area there are now a range of well scientifically documented procedures. The range of practitioner based organisations listed above, regularly promote to the broader medical profession. It does require medical practitioners to actively investigate these areas if they wish to learn more.

The activities of these organisations constitute additional evidence for the Medical Board to consider. The conferences organised by key groups promotes evidence based knowledge of these key areas. Indeed the fact that over 70% of presentation to Medical Practitioners relates to diseases linked to lifestyle factors that respond better to lifestyle advice, education and motivation , rather than pharmacological interventions, is a clear signal that the Practitioner community is responding to the health needs of the community at this point in time.

To summarise, the Medical profession and complementary medicine profession are self organising and self developing skills in these areas in an ethical professional way. In my view, if there are cases of practitioners acting in an unethical manner then, like the Profession at large, there are procedures to deal with any such situations under existing rules.

The emerging medical field and “non conventional” medicine field whilst different from well documented integrative and complementary medicine are also covered under existing guidelines for ethical practice.

If there is evidence of problems then that is where the Board needs to act.

Guidelines on presenting evidence to patients for ALL procedures and diagnostic tests already is covered. If the implementation of these guidelines is considered a problem, then that is the issue to be addressed.

That is assessing the problem carefully first to address the causes of the issue, if any exist, before proposing solutions without consulting the key stakeholders first.

At the undergraduate level, and or the College of General Practitioners, some presentations on ethics and approaches to complementary medicine, integrative medicine, emerging medicine and non-conventional medicine can be provided with the aim of improving awareness of the issues and ways to address any dilemmas or concerns that arise. Electronic resources can assist in educating larger numbers, and those with difficulties in attending live presentations. The Medical Board could potentially develop a greater educational role.

The issue of clinical research can also be addressed. Some guidelines on ethical approaches to this and examples of what has worked well. Links with clinical research organisations such as PRACI and NHMRC guidelines for clinical research can inform those with an interest in this area. A similar body to PRACI for medical practitioners could be developed.

In conclusion, the key concerns need to be more clearly elucidated and the suggested solutions documented as to expected benefit in addressing the specific concerns.

The issue of innovation at the clinical level is vital in this era of rapid change and large volumes of new data and clinical options. This is an area that could be developed in a positive manner , with the PRACI organisation as one potential model.

The question of rogue behaviour has been around since registration bodies were formed. The safeguards need to be effective, yet allow growth and development of new procedures. The current system has many checks and balances and the reasons and needs for proposed changes to current rules have not been documented sufficiently to my mind. It would benefit all of the Profession if the Medical Board was able to establish a regular dialogue with a number of the Practitioner representative bodies in this area. This could be in an educational format regarding ethical issues, potential conflict of interest issues or other themes that arise from discussions with Practitioner representative bodies. This level of communication and development of trust would enable any issues to be dealt with in a professional manner and at the same time increasing practitioner understanding of the Medical Board's concerns.

Finally, I support the Option 1 to maintain the status quo regarding Medical Board arrangements in this area.

From: [redacted]
Sent: Tuesday, 19 March 2019 7:28 PM
To: medboardconsultation
Subject: Fwd: Regulations regarding the use Complementary and Unconventional and Emerging Medicine

To the Executive Officer

My name is Cristina Strohschneider I live in [redacted] and I am [redacted] years old.

Over the years I have benefited from the use of complementary medicine prescribed by various medical practitioners. I have always been informed about options of treatments their relative merits and potential problems.

I value the free choice in making my own decisions over my medical treatment. I also value the fact that complementary medical treatment options are currently available.

I therefore support the continuation of the existing guidelines governing the practice of Complementary, Unconventional and Emerging Medicine.
If the Medical Board eventually decides to chose to apply greater regulation, my preference would be to modify 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 costs of fulfilling the new regulations.

Cristina Strohschneider
19 March 2019

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

To: The Medical Board of Australia

From: Chin Chin Su

Telephone: [redacted]

E-mail: [redacted]

Website:

Date: 21 June 2019

Consultation

I, Chin Chin Su, 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.

To the Medical Board

I'm writing in the strongest terms in objecting to your Board's preference to Option 2. I am alarmed by this draft paper attempting to "regulate" integrative medical practitioners.

Regarding '*Questions for Consideration'* I make the following general statements.

1. I'm not qualified to comment.
2. I'm not qualified to comment.
3. I'm not qualified to comment.
4. I'm not qualified to comment.
5. I thought there were sufficient safeguards.
6. I'm not qualified to comment.

The following comments are in relation to my experience with highly trained integrative medical practitioners and the sorts of treatment I seek out for my benefit.

I consider any concerns in relation to integrative medical practitioners, to be unfounded, in my view.

When you say the following, the four points are based on a false premiss:

"Concerns include patients being offered and/or having treatments:

- *for which the safety and efficacy are not known*
- *which may be unnecessary*
- *that expose them to serious side-effects, and*
- *that may result in delayed access to more effective treatment options"*

I totally disagree with the implications. The Board cannot be referring to vitamins here because there have been no untoward side-effects, serious or otherwise and certainly no deaths from vitamins but plenty from pharmaceutical drugs. In addition, integrative medicine is about doing no harm, something conventional medicine can no longer claim since it got captured by the pharmaceutical industry (a personal view).

Anyone with a modicum of intelligence today can find with ease on the internet a plethora of solid science from double blind randomised studies on any number of vitamins and complementary treatments showing them to be safe and effective. On these matters conventional medicine continues to ignore the evidence. Safe and effective is something the Board can't say about drugs. Your concerns are misplaced. They would be better served if targeted to conventional medicine! How many people die each year in Australia taking drugs strictly in accordance with the protocols? In the US it's over 100,000 deaths! So, from my outside perspective, it begs the question, just where do the Board's priorities lie?

To me it is an imperative that I have the ability to see doctors that practice integrative medicine and understand proven complementary medicine and look for underlying causes and treat them rather than treating symptoms which is all that most conventional doctors have time for. It is my right to have responsibility for my own heath and to seek help where I choose.

Despite the Board's assurances I have grave concerns about where it would end if Option 2 were to prevail. I suspect this whole 'consultation process' may be clandestine in its approach. I seek your assurances that it is not an attempt to close down Integrative Medical practitioners' practices and then other practitioners in Australia including compounding pharmacies and the sale of all vitamins. Without these assurances I would have grave reservations about the Board's intentions. I will be referring this to my local State and Federal MPs.

What also concerns me is how many submissions will be considered sufficient? It is only by accident that my attention was drawn to this public consultation paper. How would all those affected get to know of the paper's presence? There would be many thousands of people who have a vested interest in retaining the services of Integrative Medical practitioners. How widely publicised has this exercise been?

As a Civil Engineer I have gained the necessary skills over my professional life, to be able to read relevant literature sufficiently to make competent judgements about medical matters affecting me. That is why people like me appreciate the benefits of integrative medicine from highly trained integrative medical practitioners.

In my experience, when it comes to treating chronic disease I find conventional doctors of little use. In my view conventional doctors don't appreciate the power of correct diet and appropriate supplements, an area they have virtually no training. That's why, through experience over the years, I no longer seek conventional doctors' services in these areas.

I'm [redacted] years old and have no requirement for 'medications' because of correct diet and taking vitamins such as vitamin C in large doses when required. Those professionals of most need to me are integrative medical practitioners who see past the limitations of allopathic medicine and have training in complementary medicine.

Integrative medicine is regulated enough as it is, in my view.

I require Option 1 to be the desired result.

Denis Sullivan BE MBA
[redacted]