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

This submission is in response to the questions for consideration in the above public consultation paper from the Medical Board of Australia. Closing date 30th June 2019. Who

Who are we?

Bio Balance Health Ltd is a not for profit charity of 20 years standing, started by parents of children who were not getting satisfactory resolution of their children's mental health issues. We are now a Company Ltd managed by a Board of Directors, the majority of which are medical doctors.

Our primary role is to educate medical doctors, only, on the biochemical imbalances and nutritional deficiencies commonly associated with mental health conditions. The second role is to support, nurture and facilitate original research at quality recognised institutions. This research is aimed at bringing to light the biochemical mechanisms underlying various mental health conditions, and develop scientific and verifiable pathology testing.

Word of mouth of the successful outcomes for patient's health, when their biochemistry is close to optimal, means we have doctors with long waiting lists and the annual doctor training is fully subscribed. Many of the doctors who have done our training have prior degrees, often in Biochemistry and Pharmacy. Many are specialists. They come to Bio Balance Health when they need more tools to manage complex cases to their satisfaction.

If we did not get successful outcomes, we would not continue our work.

Our doctors' work closely with appropriately trained quality Compounding Pharmacists as this complex issue must be managed with patience and finesse.

Our main aim is to eventually be unnecessary once this knowledge is standard inclusion in medical doctor training.

Doctors who have trained at Bio Balance Health are all actively practicing Integrative Medicine.

We draw the Medical Board of Australia (MBA) attention to all the Integrative Medicine Organisations' submissions. We also bring to your attention the Medisca Submission and submissions from Compounding Pharmacists. Our patients have responded with vigor to the threat to their doctor's practice parameters. Bio Balance Health doctors have helped tens of thousands of patients where other medical care has not.

Our Response

Our main concern is the way Integrative Medicine is defined within the consult paper.

The title of the consult paper is “complementary and unconventional, and emerging treatments” yet in the body of the paper the definition of Integrative Medicine (IM) and Alternative Medicine (AM) are included, with the premise that these methods of practice also fall within the scope of complementary and unconventional and emerging treatments. This a false, poorly executed, premise.

Summary

We fundamentally disagree with the need for a separate set of guidelines. We believe that this will set up a two-tiered system (we agree with the description in other submissions of it being a form of medical apartheid) so we will not be offering guidance or specific comments on amending the proposed guidelines.

We call on the MBA to abide by the COAG principles which demand that appropriate expert, stakeholder and community consultation take place BEFORE new guidelines are developed for public consultation.

We call on the Medical Board of Australia (MBA) to institute good Corporate Governance and look at the risks they have created for themselves through failure to manage conflicts of interest on the MBA, and in writing a document which may be challenged under Australian Consumer Law, and National Law.

Further, we call on the Medical Board of Australia (MBA) to review their processes as the distress caused by this paper to IM doctors, practicing good medicine, and their patients has been unacceptable. A more inclusive process and a paper which is well informed and clear in what it is aiming to achieve would be a more professional handling of issues of concern to the MBA. We all want to stop harmful medical practices but not by punishing many doctors who provide excellent health care, and not by stopping innovation.

We call on the MBA to withdraw the proposed guidelines, and start this process properly from the beginning. This means that the MBA seek guidance within a specific area of medicine from clinicians and experts who are actually practicing, and from *ALL* the stakeholders.

In order to progress, the Medical Board needs to change how it manages its processes, by:

1. Presenting clear and convincing evidence that separate guidelines are necessary
2. Clearly articulating and describing *ALL* terms and definitions. It is not acceptable to define something by its opposite. Be precise in the terms that they use, specifically to define what they mean by ‘conventional practice’, ‘complementary medicine’, ’emerging practices’ and ‘unconventional medicine’. Without robust definitions, these proposed guidelines are able to be applied to any group of doctors and specialists and therefore impede innovation and increases doctor stress.
3. Clarifying the terms and definitions in a satisfactory manner, they should only be written after robust stakeholder consultation.
4. By seeking input and guidance from relevant engaged stakeholders as a matter of course in any issue relating to what might be thought of as “complementary and unconventional and

emerging medicine". Integrative Medical organisations are very strong advocates for medical practice which improves health and does not harm, and should therefore be asked for advice in the case of alleged malpractice or suspicious activity within its realm.

5. The MBA has a role to protect the public but not to limit a style of medical practice to which the public is turning to more frequently.

Bio Balance Health provide the following responses to the specific questions raised in the consult paper.

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?

***NO**.*

We do not agree with the term 'complementary and unconventional medicine and emerging treatments'.

The three terms are completely disparate.

The term that should be used is medical practice which is "**outside the code of good medical practice**".

Correctly written, this should cover all doctors who fall into the area of concern to the MBA by their utilisation of treatments which may fall in the definition of doing harm. As is clearly stated in *Good Medical Practice, A Code of Conduct for Doctors in Australia, section 3.5*, any doctor who engages in "practice" is required to provide informed consent, discuss possible benefits and risks, as well as any costs involved.

The three terms are not synonymous. They should not be grouped together

What does the MBA see as emerging treatment?

What is being taught now at medical schools, in postgraduate training programs and being written about in CME journals, may very quickly (days, weeks, months, years) become regarded as outdated, irrelevant or dangerous. E.g. Pharmaceutical medications – Vioxx, Zyban, Cisapride, Mefloquine, OTC Codeine preparations. The MBA should be more proactive in assessing risks as they arise, and do so in a consultative, cooperative manner.

Similarly, practices which were not regarded as conventional previously, which may have been seen as complementary, unconventional or emerging, can and do become part of conventional medical practice. The jurisdiction of the Medical Board of Australia is to protect the public, not decide on the details of medical practice. This is best left to the specialist colleges and the experts in the specific area of practice. These organisations can actively assist the MBA in defining practice which is outside the scope of good patient care, and how best to manage poor medical practice.

Question 1. Part two : If not, what term should be used and how should it be defined?

The Discussion paper does not provide enough evidence in the paper of incidences of harm or risk which require increased regulation. All examples used to illustrate were adequately dealt within the current medical system. These individual examples are examples of certain practices where they

fall outside of *the Code of Good Medical Practice.* They were dealt with effectively, which does not give strength to the argument that further restrictions are required. There is also no evidence presented here that illustrated these issues are a common risk. These examples do not fit in within the Integrative Medicine (IM) framework. All IM training ensures doctors comply with the Code of Good Medical Practice and hold their practitioners to the highest standard. As knowledge is growing exponentially in the IM area, IM doctors need to actively engage in education to keep abreast.

In order to receive true and valid feedback from relevant stakeholders, the Medical Board of Australia (MBA) must explain with clarity, specific examples of the concerns "requiring" further regulation. It is insufficient to state: *"Feedback has been received from stakeholders."*

A true consultation would have seen the MBA sit at a round table with the representatives of the IM community and say, *"We have these concerns. How do you see they can be best managed?"* We are all aware there are doctors who push boundaries too quickly and there is a need to identify how these doctors are approached as they move into these new areas, what are the motivation for them to commence utilising different therapies, and therefore understand how to put in checks and balances to protect the public. Proactive, rather than reactive, is a safer method of action to protect the public.

The production of this document does not fit in with the bill of accountability, transparency and non-bias that is the regulated aim of the MBA.

Question 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.

We don't agree with the proposed definition.

Again, it cannot be defined due to the inherent problems as answered in Bio Balance Health's response to Question 1.

The issue remains that "conventional medicine" is not sufficiently defined and all medical practice in Australia is already subject to the Code of Good Medical Practice.

The MBA use the term "usually considered part of conventional medicine". The MBA first needs to answer to the public and the profession: Who is doing the considering, and what are the usual circumstances under which this consideration is taking place? Failure to consult with a broad range of stakeholders in preparing the consultation paper does not make the medical community feel secure about the transparency and hence the drivers behind the MBA processes.

The behavior of the MBA can be interpreted as regulatory bullying as they have failed to illustrate adequate examples and have produced a document which is so broad and ill-defined as to make it unworkable.

However, at the same time, the guidelines can easily be able to be manipulated to frighten the general populace of doctors from being comfortable broadening their offering to their chronic and difficult patients who do not respond adequately to non-integrative medical practice.

A doctor's role, surely, is to be constantly considering and reconsidering all aspects of their practice, thereby refining and expanding their practice based on best available evidence, clinical experience and patient preference? This is certainly a major requirement of the Continuing Professional Development (CPD) requirements for registration.

The proposed definition appears to assume that patients always fall into clear cut, singular diagnoses that should be treated using a linear pathway. In contrast, most medical practice occurs in the grey zones of differential diagnoses, multifactorial etiologies and psychosocial contexts, with very real financial and ethical constraints. Seeking answers requires doctors to think laterally. We submit that doctors should be encouraged, rather than discouraged, to think more broadly and comprehensively, and not be made fearful of innovation.

As to what term should be used, this will depend on "the nature and extent of the issues identified in relation to medical practitioners who provide "such" treatments?"

Question 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.

We do agree that the Medical Board of Australia has the legal and moral responsibility to protect the public from medical practice which does harm, puts patients at risk, and preys on vulnerability.

The issues of containing harm and risk to patients are applicable across the WHOLE of medicine, and not limited to those doctors who might find themselves included in "*complementary and unconventional medicine and emerging treatments".* It certainly does not apply as a separate issue to IM doctors.

There is no data in the consult paper which provides information on the extent to which there is a problem of treatments which put patients at risk. There is no research cited, and no statistics which are relevant. There is nothing which supports the MBA case of having to create a separate set of guidelines to cover an ill-defined risk.

The MBA stated "*feedback has been received from stakeholders*" but no IM organisations were consulted. The Integrative Medicine community works together so we know none were consulted at any stage prior to the publication of this paper. How can you create a definition if you don't talk to the people who know?

To manage risk, the hazard first must clearly be identified.

It is relevant to guide how medicine is practiced across all realms, however we would argue that the Code of Good Medical Practice provides sufficient cover.

Compared to the staggering rates of iatrogenic complications within mainstream medicine, the small sample of cases cited in the paper actually speaks positively about the relative safety of Integrative Medicine.

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

YES.

We have no concerns in the practice of Integrative Medicine. We are concerned with the definition presented in the consultation paper of complementary and unconventional and emerging medicine as it is an inappropriate segregation as concerns of at-risk practice applies to all doctors, i.e.:

- Failure to consider differential diagnoses
- Unproven therapies
- Entrepreneurial medicine
- Progressive practice

The MBA has not defined the above terms.

An opposite concern is that not enough doctors consider the possibility of evidence-based environmental and nutritional medicine, which patients are actively seeking, especially when their needs are not being met through a conventional approach.

The MBA could do more to work towards finding common ground between all stakeholders, for the good of the patient. The language in this consultation paper is negative and derogatory to doctors who wish to extend their skills to better resolve the issues presented in their clinics.

Active encouragement for research, not regulation, is needed to evaluate the evidence of outcomes for patients utilising practitioners who, in addition to their regular medical skills, utilise holistic or non-pharmaceutical approaches to treat chronic conditions. Research funding in this area is very difficult to find as the benefit is to the public purse, not to a profit line of industry.

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

Yes, as they are for *ALL* of medicine but not necessarily more so. No evidence has been provided by the MBA for an assertion that additional safeguards are needed, compared to those that are already in place

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

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

The Medical Board of Australia's decision-making process in creating this consult paper focuses on perceived harm from a segregated area of medicine. Failure to consider the comparative harm from current common medical practice biases the document.

Evidence-Based Medicine (EBM) is the triad of best available evidence, clinician acumen and patient preference.

*"The conscientious, explicit and judicious use of current **best** evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic*

*research. Evidence-based medicine does **not** mean "cook-book" medicine, or the unthinking use of guidelines. It **does** imply that evidence should be reasonably readily available in an easily understood and useable form."*
https://www.cebma.org/wp-content/uploads/Sackett-Evidence-Based- Medicine.pdf

The Medical Board of Australia needs to be cognisant of the data that is available relating to the risks and costs of the medical community at large when conventional medicine continues unfettered.

For example:

- Missing or ineffectual discharge summaries from hospitals to GPs.
- Iatrogenic mortality due to "conventional" medical practices.
- Hyper polypharmacy.

We agree with the common aim of the Integrative Medicine Community:
For better outcomes in public health, our community needs Integrative Medicine to continue to work under the Code of Good Medical Practice, according to Evidence-Based Medicine.

Support for research to evaluate outcomes for patients using well trained IM doctors would create a more informed space for medical health regulatory management.

There is evidence that Integrative Medicine can be cost saving.

Integrative Medicine is increasingly being incorporated into what may previously have been regarded as conventional realms, such as oncology.

Integrative Medicine is increasingly being "mainstreamed" internationally.

What has not been addressed in these proposed regulations are the real costs and risks of what the MBA appears to be referring to as conventional medicine, which are not insignificant.

There seems to be a cultural fear that the use of unconventional treatments means ***not*** using conventional ones. Medicine is about working out the best approach, not necessarily categorising approaches. IM doctors use all their medical training as well as enhance patient outcomes by working to constantly upgrade their education. Due to their training to address a multitude of patient problems every day, GP's are best to care for complex multifactorial issues with the support of appropriate specialists as required. This is in contrast to the supposition in the consult paper that patients may have delayed treatment because they were not sent to a specialist early enough.

Data around preventive medicine, nutrition and lifestyle, have been considered complementary, emerging or unconventional in the past but are now rapidly becoming mainstream as the rate of research expands and the number of IM doctors increase.

Patient preference is changing. Word of mouth of successful outcomes after attending an IM doctor is driving long waiting lists.

Question 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.

The **Medical Board of Australia's: Good Medical Practice: A Code of Conduct for Doctors in Australia,** addresses all the issues raised.

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

NO.

The proposed guidelines create an apartheid attitude by separating practice into what can be seen as good and bad. For the MBA to achieve a better outcome, they need to act in a manner which is far more constructive and consensus-building towards different ways of practicing medicine than the current document under discussion suggests they would be. This document shows a disconnect between the MBA and doctors who work hard to increase their skills to enhance their patient outcomes.

The MBA have not used examples which illustrate the need for any expanded regulatory guidelines.

Question 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?

At this point, as we completely disagree with the need for specific guidelines, it would be disingenuous to make comment on their contents.

There are several major stakeholders in Integrative Medicine in Australia. As the consult document confuses the roles of an IM doctor with the three categories listed in the title of the consult paper, this provides an unclear outcome for IM doctors and their supporting services. We urge the MBA to approach these stakeholders to seek guidance on the development of guidelines for use within a specific area of medicine. We are all concerned with the unsafe practices which do create risk for patients, and would appreciate being able to work with the MBA to resolve the issues which they have been unable to address lucidly.

We bring your attention to all the Integrative Medicine organisations, related industries and concerned patients who have submitted submissions, and request you value their knowledge and their contribution to good patient outcomes.

In order to progress, the Medical Board of Australia needs to:

Work with all relevant stakeholders in order to create a document which targets real issues of concern, yet does not stifle innovation.

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

There are mechanisms in place to deal with other concerns as they emerge over time. The MBA has chosen to develop guidelines without adequate evidence and without stakeholder involvement in the early stages.

The MBA needs to be more conversant with the level of education, training and the range of issues resolved by IM doctors, and the high standard of practice of IM. Since 1970, pathways for integrative medicine have been available in Australia. We have concerns that the MBA has not identified any evidence on which to base the proposed new guidelines.

The MBA has not addressed the issue of evaluation of outcomes. There is a presumption that only "conventional" medical practice provides the right health outcome for the patients. As there is an increase in the use of many non-conservative doctor and non-doctor therapies, the reason why needs to be explored. Exploring the patient outcomes should illustrate what the Integrative Medicine doctor community knows. Patients are not being assisted adequately by standard practice, and following successful outcomes for themselves, and are recommending family and friends explore the options of an integrative medical treatment. Outcome evaluations are becoming standard in many overseas medical communities, so the knowledge of how to institute these is readily available.

Also, it should be highlighted that GP's are now seeing a far larger percentage of patients who have chronic health issues, as well as GP's reporting that mental health is now around 50% of their client base. This is in complete contrast to the commencement of Medicare when most GP's saw acute cases as their major workload. Training in Integrative Medicine is well supported by the medical community as a result of this shift in practice demographics. The MBA 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 since they must be gullible and easily led.

Question 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 Medical Board of Australia's (MBA) expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the MBA's approved Code of Good Medical Practice.

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