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

The following feedback is provided to the Medical Board of Australia (MBA) by Cancer Information & Support Society (CISS), an independent not-for-profit charity registered as a company in 1982 and an Incorporated Association registered in NSW in 1996. This feedback is provided independently of any other stakeholder organisation. The constitutional aims for which CISS was established are listed below, and those numbered (2), (4), (8), (9), and (13) are particularly pertinent to this MBA consultation. As has been found for chronic disease patients in general and cancer patients in particular, the majority of our CISS membership make use of various combinations of 'mainstream' and 'complementary and alternative' modalities. Our CISS membership therefore forms an interested stakeholder group in the outcomes of this consultation.

(1) To promote and obtain through public education the legal release of humane and effective treatment for people with cancer.

(2) To secure for the physician the right to use non-toxic, beneficial therapies for all people with cancer.

(3) To give comfort, solace, information and release from fear to those with cancer. To give hope to the lay-person that measures to restore normal body chemistry, withdrawal of all known carcinogens, and use of non-toxic materials which restrain and reduce tumour growth, coupled with non-radical surgical procedures, will provide new patterns of treatment based on new research findings.

(4) To restore constitutional right to life and free choice of treatment and doctor of those with cancer and their families.

(5) To teach and otherwise disseminate information concerning the systemic, metabolic and endocrine nature of cancer.

(6) To educate the public concerning cancer-causing factors in environment, food and drink.

(7) To institute an educational cancer-prevention program for farmers, food processors, food handlers, homemakers, physicians, industrialists, etc.

(8) To foster freedom of medical and/or health research and education. To promote acquisition of new knowledge and also the correction of errors in cancerology. To further the application of research findings in the clinical treatment of cancer.

(9) To contribute to the development of and to obtain legal release of laboratory tests which can detect body chemistry alterations which indicate the presence of cancer, or which precede the malignant state.

(10) To clarify and evaluate the current methods of treatment of cancer.

(11) To teach, lecture, and otherwise disseminate information concerning the layperson's status with regard to cancer and his/her legal rights.

(12) To write, publish and disseminate literature on all aspects of the cancer problem.

(13) To encourage a freedom of medical practice so that the physician may freely choose the treatment or modality which his/her training, research, and experience lead him/her to believe most effective.

(14) To encourage, assist and arrange for medical practitioners, scientists and others to come to Australia or to travel abroad or to travel within Australia for the purposes of research, training and the dissemination of information concerning cancer.

(15) To encourage, arrange for, promote, establish and support hospitals, clinics, infirmaries, special dispensary facilities and other institutions for the care, treatment and convalescence of people with cancer and for the assistance of the families of those with cancer.

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

No. The amalgamation of these three terms for the purposes of this MBA consultation does not form a readily recognisable construct such as could be defined in any meaningful way.

Neither do the illustrative examples provided in the discussion document form any kind of homogeneous categorisation or subtype of medical practice that could be readily defined through apparent commonalities. Instead, the examples are an oddly disparate collection, some of which may be considered questionable examples of "conventional", "unconventional" "complementary", or "emerging" medical practice or simply "bad practice" depending on the context. While each individual example is apparently considered as potentially indicating a need for further MBA regulation, when artificially grouped together for this purpose they appear to share no other commonalities. Most examples of patient dissatisfaction that come to the attention of the MBA however, probably do share in common a fundamental lack of patient-centred care, including evidence-based participatory medical decision-making, without which there can be, at best, only inadequately informed consent processes.

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

What term should be used depends on the purpose of the consultation, which at present remains unclear.

Given that the MBA does not regulate all AHPRA-regulated practitioners of Complementary and Alternative Medicine (CAM), it is assumed that the consultation aims to help ensure the future safety and effectiveness of any use of 'complementary' or of 'integrative' medical practice by those registered medical professionals who are regulated by AHPRA through the MBA, as well as further regulating their use of 'emerging treatments'.

CISS has defined Complementary or Alternative Medicine (CAM) as

"a wide variety of therapies sharing the concept of a wholistic paradigm of health with an established history of use for health promotion or the prevention, management or treatment of ill-health..." (etc)

Our full definition (Page 21) reflects the political relativity of any definition of CAM, as does the definition used by the Cochrane Collaboration, who note; *"Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed."* (1)

The term 'integrative medicine' is increasingly recognised and employed to describe the integration of some complementary medicine into mainstream medicine(2,3). Of the three proposed MBA consultation terms, 'integrative medicine' could therefore replace the term 'complementary medicine' but the meaning of this term would not adequately replace that of the other two terms (especially in a regulatory sense). Clarification would also need to be provided by the MBA regarding the regulatory purpose and scope of the consultation, because CISS does not believe that the MBA have presented a case in the discussion paper for singling out integrative medical practitioners for further regulation.

The position paper on complementary medicine published by the Royal Australian College of General Practitioners - Australasian Integrative Medicine Association (RACGP-AIMA) defines the term 'Integrative Medicine' as;

"*the blending of conventional and natural/complementary medicines and/or therapies with the aim of using the most appropriate of either or both modalities to care for the patient as a whole*".(4)

Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'?

No. CISS maintains that evidence-based, patient-centred medical care is the hallmark of 'good practice', whereas this proposed consultation definition implies that conventional orthodoxy is the practice standard against which all medical decision-making and practice should be judged and regulated.

The MBA proposed consultation definition is similar to that originally used by the U.S. National Centre for Complementary and Alternative Medicine (NCCAM), who used to define Complementary and Alternative Medicine as "a group of diverse medical and health care systems, practices and products that are not generally considered part of conventional medicine."(5) This definition however was quickly abandoned, and has for many years been unavailable on the NCCAM portal.

Clarity of communication is indispensable in the context of medical regulation, and the phrase **'not usually considered to be part of conventional medicine'** as used for this MBA consultation definition is therefore potentially highly problematic. From a legal position, the MBA has, in essence, proposed defining the practice of 'integrative medicine' as that which is 'not conventional medicine'. In the absence of an agreed definition of 'conventional medicine' it would be assumed for legal purposes that 'conventional medicine' could be defined as that which is 'not integrative medicine'. The term 'conventional medicine' therefore needs to be clearly defined by the MBA if this term is to be used to define integrative approaches to medical practice by differentiating these with 'conventional medicine' for regulatory purposes. What does the MBA consider to be a suitable definition of the term "conventional medicine" for regulatory purposes?

By defining "*complementary and unconventional medicine and emerging treatments*" according to what these terms are assumed not to be, - (i.e. 'not conventional medicine') - the MBA has also, by default, essentially defined 'conventional medicine' as 'a form of medicine that does not include any "complementary and unconventional medicine and emerging treatments'. This can readily be demonstrated not to accurately reflect the way that safe and effective evidence-based patient choice within Australian mainstream medicine is actually being practiced. [see **points 2-6 below**]

in the absence of a definition for the term "conventional medicine", this is also left open to subjective interpretation by various responding stakeholder groups according to our own perceptions of what conventional medicine is generally understood to be. CISS, for example, therefore suggests that a conceptualisation of "conventional medicine" that includes no "*complementary and unconventional medicine and emerging treatments*" may perhaps be usually understood as an unrealistically standardised practice of medicine when restricted according to:

- curriculum and syllabus content as taught during practitioners original medical training and approved continuing medical education;
- practice guidelines used for clinical decision-making in the treatment of specific discrete medical conditions ("guideline-directed medical therapy");
- traditionally established hospital procedures and practices;
- the use of TGA regulated biomedical products and medical devices largely researched, developed, trialled and promoted by pharmaceutical and medical-equipment manufacturers; - and -
- commonly accepted medical practices, products and procedures widely adopted by colleagues & peers and therefore currently considered "best practice", irrespective of the quality of their actual evidence base. [1]

[1] Examples include the once commonly accepted practice of subjecting many Australian children to unnecessary tonsillectomies, later condemned in the British context as a "dangerous fad"; Dwyer-Hemmings L. 'A Wicked Operation'? Tonsillectomy in Twentieth-Century Britain. *Med Hist*. 2018;62(2):217–241. doi:10.1017/mdh.2018.5

If the Medical Board is conceptualising the term "conventional medicine" in a different way to this understanding for regulatory purposes, it would be helpful for that definition to be clarified and made available for all medical practitioners, stakeholder groups and the public so that a meaningful discussion can begin. If a definition unique to "conventional medicine" cannot be formulated that is sufficiently uncontroversial and clearly delineated for the MBA's regulatory purposes, then it is suggested that 'integrative medicine' be defined in terms of what it actually is, rather than in terms of what it is not (ie. 'not conventional medicine).

The phrase 'not usually considered to be part of conventional medicine' as used for this MBA consultation definition, is problematic for at least six further reasons:

1. The MBA proposed consultation definition implies that conventional orthodoxy is the practice standard against which all medical decision-making and practice should be judged and regulated, whereas CISS maintains that evidence-based, patient-centred medical care is the hallmark of 'good practice'.

2. The juxtaposing of "conventional medicine" against all less mainstream forms of medicine implies that these practices are mutually exclusive (rather than relative) and that the definition of these terms is uncontroversial and clearly understood. Instead, any MBA guidelines using the proposed definition would be left widely open to subjective interpretation for other than justifiable regulatory purposes in the future.

3. The proposed definition assumes a clear demarcation between the practice of all "complementary medicine" and the practice of all "conventional medicine". The overstated dichotomy this reinforces is unhelpful to patients in general and cancer patients in particular.

4. An implied conceptualisation of "conventional medicine" as standard orthodoxy against which all medical practice should be regulated is inconsistent with the practitioner's need for professional autonomy in individualising all clinical decision-making so as to ensure evidence informed patient choice, (i.e. evidence-based medicine as originally envisaged). It potentially "de-professionalises" and "dehumanises" the relationship between medical practitioners and patients as individuals such that clinical judgement could hypothetically soon be replaced by artificial intelligence.

5. The proposed definition potentially reinforces a non-evidence based view of good conventional practice that inadvertently ratifies some problematic aspects of conventional medicine, including the widespread practice of overdiagnosis, overtreatment and defensive medicine as "status quo".

6. The proposed MBA definition seems to assume that the best practice of conventional medicine does not already include some "emerging treatments".

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points

1. No. (CISS does not agree with the proposed definition).
The MBA proposed consultation definition implies that conventional orthodoxy is the practice standard against which all medical decision-making and practice should be judged and regulated, whereas CISS maintains that evidence-based, patient-centred medical care is the hallmark of 'good practice'.

Evidence based medicine" (EBM) was described by David Sackett et. al. as – "*the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."*(6) It had originally been conceived by Dr Archie Cochrane, on whom the Cochrane Collaboration was founded in 1992, and included, as a critical step, the application of the latest evidence to the particular patient's situation, values and preferences. (7). David Eddy, influenced by the work of Archie Cochrane, later coined the term Evidence Based Medicine (EBM) and helped to develop the 5 stages of the process of which the fourth was application of the best evidence in a clinical setting, ie taking account of the individual's particular situation, values and preferences (8).

The term was originally used to describe an approach to teaching the practice of medicine and improving decisions by individual physicians about treatment options that could be ethically offered to individual patients (9). In other words EBM needs to be individualised. Dr Archie Cochrane was actually a scientist motivated by ethical concerns regarding accepted practices within conventional medicine at the time, and EBM's founders did not envisage it as a means to promote any particular medical paradigm, product or practice with a rubber stamp of conventional orthodoxy. Rather, it was intended by the scientists involved in its development, simply as a measure of the comparative averaged effectiveness of particular interventions (initially restricted to drug comparisons), in order to increase the scientific validity of population based evidence that could then help inform individualised decision-making. EBM has contributed greatly to improving the internal validity of clinical trials, with randomised double-blind placebo-controlled clinical trials still generally considered the "gold standard" study design wherever applicable. Despite two decades of broad acceptance of the need for EBM and randomised controlled trials (RCTs) however, the quality of the evidence base underpinning accepted conventional medical practices remains highly variable,(10,11) for reasons somewhat beyond the scope of this current submission.
(For interested readers, please refer to selected chronologically arranged background reading; 12-20 These key commentaries have been selected to illustrate an unfolding history of problems in the application of EBM over the past 15+ years within conventional medicine (not EBM itself) and the effect this has had on the quality of the evidence base for too many conventional medical practices.)

Unlike the relatively small and under-funded but exponentially increasing research base for much "complementary medicine"[2] and many "emerging treatments"[3], most potentially profitable conventional medicine has generated an enormous industry-sponsored research base. The sheer quantity of evidence seemingly supporting any medical practice however, does not, of course, necessarily reflect the quality of that evidence,(21) with "complementary and alternative medical interventions" sometimes showing higher quality of reporting(22) and trial design(23). Furthermore, even high quality evidence supporting much conventional medicine is frequently not supportive of the outcomes most valued by the actual patients for whom a treatment is intended. For example, while most MTD[4] cytotoxic chemotherapies result in temporary tumour shrinkage (which may be enormously encouraging in the short term for all concerned),

[2] Expanded commentary page 26
[3] Expanded commentary as applicable to emerging treatments in cancer research, page 18
[4] Maximum Tolerated Dose

this often eventuates as "false hope" because too few show evidence of benefit on patients' overall survival and quality of life when these outcomes has been measured.(24,25)

In fact, this has been a repeated theme in conclusions reached throughout reviews of the evidence base for much conventional cancer medicine. While the majority of published pharmaceutical-sponsored cancer clinical trials put a positive spin on their results, most independent analyses for most solid cancers conclude that only a minority show meaningful improvement in median overall survival or report an improvement in patients' quality of life when this has been measured.(26) This situation is so dire for cancer patients that an increasing chorus of voices amongst international researchers are calling for a whole "re-think" of (translational) cancer research.(27) Unfortunately, without independence from pharmaceutical interests, conclusions reached are less ultimately likely to meaningfully benefit patients.

Patient valued outcomes regarding quality of life (QOL) usually require qualitative research to determine on a population level and always require shared decision-making to determine on an individual level.

Summary statement for point 1.
In 2019 Australia, and for the purposes of this consultation, CISS is of the opinion that the available evidence simply does not support the notion that "conventional medicine" is an evidence-based orthodox standard against which either "complementary and unconventional medicine and emerging treatments" or "integrative medicine" should be further regulated. Rather, any medical practice (whether described as "conventional", "complementary", "unconventional" or "emerging"), should be evaluated from the viewpoint of it's likely individual outcome as determined both by outcome-oriented research and by consultation with the individual patient. Therefore, the ideal regulatory practice standard should be that of highly individualised 'patient-centred' medicine with treatment options provided which are based upon the best available quality of evidence for safety and effectiveness (i.e. evidence of patient-valued outcomes from RCTs whenever applicable). This is evidence-based medicine when practiced as originally intended, because; *"Evidence-based medicine and patient centred medicine are not contradictory but complementary movements. It is not possible to practice patient-centred medicine that is not based on evidence, nor is it possible to practice evidence-based medicine at a distance from the individual patient."* (28)

> ***In 2019 Australia, and for the purposes of this consultation, CISS is of the opinion that the available evidence simply does not support the notion that "conventional medicine" is an evidence-based orthodox standard against which either "complementary and unconventional medicine and emerging treatments" or "integrative medicine" should be further regulated.***
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> ***CISS therefore requests that the MBA not attempt to single out integrative medical practitioners for tightened regulation without providing evidence based justification for doing so, because this would be at odds with Australia's pressing need to promote genuinely evidence-informed patient-participatory clinical decision-making (i.e. "Evidence-Based Medicine" as it was originally conceived).***

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points (Page 4, - point 2 cont'd)

2. No. The juxtaposing of "complementary and unconventional medicine and emerging treatments" against "conventional medicine" implies that these are understood as mutually

exclusive opposites. Instead, any MBA guidelines using the proposed definition would be left widely open to subjective interpretation for other than justifiable regulatory purposes."

CISS is concerned that proposed MBA guidelines for the further regulation of "complementary and unconventional medicine and emerging treatments" could be misused to lend an assumed orthodoxy to lobby groups with financial or ideological investment in questionable "business as usual" at the expense of evidence-based patient centred care.

The proposed definition's implied assumption of a legitimised conservative orthodoxy of "conventional medicine" that excludes all "complementary and unconventional medicine and emerging treatments" would leave the MBA proposed guidelines widely open to subjective interpretation for other than justifiable regulatory purposes. This could include the suppression of evidence-based integrative practice, (ie. the practice of integrative medicine by those registered medical professionals who are regulated by the MBA), as well as the suppression of evidence-based but not yet mainstreamed "emerging treatments" which have potential benefit for both public health and individual patients but are not able to be commercialised.(29,30)

The phrase **"not usually considered to be part of conventional medicine"** therefore begs the question,

- "**by whom**?"; (31)

As particular CAM products, practices or emerging treatments become increasingly well researched and included in integrative and conventional medical practice, **who** gets to decide in the future which of these should be considered to be part of conventional medicine for regulatory purposes? What steps would the MBA implement to ensure that these decisions were less likely to be influenced by industry agendas to the detriment of patients and our public health interests? What transparency measures are planned in relation to the current consultation? A recent Australian observational study of financial disclosure by pharmaceutical companies concluded:

"Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector."(32)

While Australian law wisely still prohibits direct-to-consumer advertising of pharmaceuticals and medical devices, industry influence on decisions with potential implications for public health is nevertheless well entrenched and ubiquitous. Furthermore, although widely recognised by many independent stakeholder groups, this influence frequently operates indirectly.(33)

Australian and international examples include significant potential for the influence of pharmaceutical interests on:

- **the public health research agenda (34)**
- **medical research (35)**
- **"evidence based medicine" (36-37)**
- **systematic reviews (38)**
- **academia per se' (39-40)**
- **Australian medical education (41)**
- **editors of medical journals (42)**
- **research publication about dietary supplements (43)**
- **media coverage of herbal remedy clinical trials (44)**
- **oncologists' treatment decision making (45)**
- **clinical practice guidelines (46-48)**

- **"key opinion leaders" (49)**
- **Australian medical organisations (50) and**
- **Continuing Medical Education (CME). (51)**

There have been many good ideas and valiant attempts to challenge this situation, spanning the past decade or more,(52,53) but no amount of regulatory reform or better reporting guidelines will change the fact that the commercial agenda (to sell product for shareholder profit), while not ethically bankrupt in and of itself, is cleverly promoted in ways which are usually not apparent; -

"the pervasive reach of industry in education, research, and practice yields a subtle yet cumulatively powerful influence on how doctors learn and think about drugs and devices. Industry employs the brightest minds in marketing. It spends many billions of dollars each year—including funding CME—to convince doctors to use its products. In this light, it is unwise to believe that even the best-intentioned regulations and reviewers can fully eliminate commercial influence and bias in CME." (51)

Genuinely evidence-informed medical decision making cannot fully operate independently inside this 'echo chamber'.[5] Conventional medical decision-making is hamstrung by the fact that the corporate agenda is simply incompatible with patients' needs to choose evidence-based treatments that fit with their values, preferences and health-related goals. Many effective treatments can never be patented, such as exercise, sleep and nutritional interventions for depression. These each now have an established independently researched evidence base in the treatment of depression, but shared-decision-making interventions that also inform general practitioners (GPs) about this evidence base, are needed to help implement these as "mainstream" treatment options that Australian GPs feel comfortable recommending for some patients.[6]

Likewise, neither can a myriad of phytochemicals, polyphenols and "nutraceuticals" from traditional botanical sources or medicinal foods be patented. Many of these have repeatedly demonstrated anticancer potential (in in-vitro and animal studies), but are still awaiting further research with RCTs which are unlikely to be properly funded in the foreseeable future. One solution that has been suggested is that a proportion of the revenue raised from all pharmaceutical profits be required to be invested to fund genuinely independent research solely in the public health agenda's interest.[7]

Arguably, those with the most legitimate and representative interests in the outcomes of this MBA consultation are health consumers and our "coal face" medical practitioners, in terms of treatment options that can be included in the context of shared decision-making. (It is worth noting though, that even Australian health consumer groups not infrequently receive corporate sponsorship (54) and may consequently be incentivised or inadvertently influenced to lobby the PBA for inclusion of expensive pharmaceuticals or new medical devices on the PBS without sufficient evidence of safety and efficacy, and to the detriment of the timely uptake of safer more cost effective options). (55)

CISS considers that the value judgements of independent, evidence-informed health consumer groups (such as citizens' juries and the Consumers' Health Forum), in addition to government regulatory agencies, are crucial in ensuring impartiality in deciding which higher risk 'conventional' or 'integrative' medical practices might or might not need further regulation, irrespective of how these practices are categorised in terms of conventional orthodoxy

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[5] "**echo chamber** is a metaphorical description of a situation in which beliefs are amplified or reinforced by communication and repetition inside a closed system. By visiting an "echo chamber", people are able to seek out information which reinforces their existing views…" - Wikipedia

[6] These options are starting to be more widely recommended by Australian medical practitioners using a patient decision aid to assist shared decision making with patients suffering from a major depressive disorder. This can expand patients evidence-based treatment options and help prevent the unnecessary prescription of antidepressant medication.

[7] See final recommendations

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points (Page 4, - point 3 cont'd)

3. No. The proposed definition assumes a clear demarcation between the practice of all "complementary medicine" and the practice of all "conventional medicine". The overstated dichotomy this reinforces is unhelpful to patients in general and cancer patients in particular.

"…the traditional rhetorical dualism between biomedicine and CAM is a social construct rather than a fact." *(56)*

Over time, across western cultures, people have been incorporating more practitioner-based CAM into their healthcare management,(57) and increasingly expect their "conventional" health providers to work collaboratively with their CAM practitioners.(58) Although CAM cannot necessarily be considered as a unified paradigm (any more so than can "conventional medicine"), what does tend to unify the CAM field, is the commonality of a philosophy of "first and foremost do no harm", and a biopsychosocial (or 'whole person'/holistic/wholistic) understanding of health and ill-health.(59) An 'alternate', wholistic understanding of health and diseases dates all the way back in time.

"The greatest mistake in the treatment of diseases is that there are physicians for the body and physicians for the soul, although the two cannot be separated." ~Plato

Traditionally, in contrast, the relatively short history of biomedicine has had a strong and often unquestioned adherence to a concept of "mind-body dualism" and a reductionist linear causality of heath and ill-health.(60) Interestingly the "cutting edge" emerging science of complexity theory from recent advances in quantum physics dovetails perfectly with CAM, as highlighted by the following excerpt from a European editorial;(61)

"…'scientific' has indeed a much deeper meaning than that which is often used as an armament against new insights. Scientific means 'cutting edge' and the papers collected here show that complex interventions, such as CAM interventions, and according theories are indeed cutting edge, because they can only really be understood, modelled, and tested fruitfully by using complexity theory. And such is the state at the forefront of science. So, kiss Descartes goodbye, at last and finally. Welcome Complexity!"

Oversimplified then, while 'conventional medicine' is aimed at the restoration of health through the treatment of either acute injury or of illness in particular body systems or organs, 'integrative medicine' has a greater emphasis on the prevention or management of chronic disease through the promotion of "whole person" health. Oversimplified still further, 'conventional medicine' treats disease to restore the person to health, while 'integrative medicine' treats the person and promotes health to prevent or manage disease. As such, the aims of these two paradigms are clearly both overlapping and complementary (rather than mutually exclusive).(62)

This wholistic understanding of health and ill-health, while having ancient roots within traditional cultures, is rapidly gaining recognition of scientific plausibility through developments in diverse sciences that investigate complex whole system interactions, including evolutionary developmental biology, epigenetics, and even quantum physics. For example, the looming "epidemic" of many (if not all) chronic diseases, can be viewed through the lens of unresolved ongoing and cumulative environmental, nutritional, metabolic and psychological (etc) stressors on the body that produce self-reinforcing feedback loops ("vicious circles") of chronic, systemic inflammatory signalling and consequent chronic immune dysregulation.(63,64)

An wholistic understanding of health and disease however, can still sit uncomfortably within a predominantly reductionist biomedical paradigm.(65) Our Australian specialists, including surgeons, endocrinologists, cardiologists and oncologists tend to be relatively siloed off from each other and, similarly, diseases are usually defined by the organ or system in which they present diagnosable symptoms. They are then treated accordingly, with symptoms less often perceived as possible evidence of systemic dysregulation requiring combination treatments and collaborative, well-coordinated, multidisciplinary care to restore "whole of person" health.

Over half the Australian population believe they derive benefit from some form of complementary medicine, with the most frequent form of regular usage remaining dietary supplementation (66,67) as is consistent with earlier reviews. Both internationally and in Australia, the level of CAM usage has been consistently reported as proportionately higher amongst women, people with higher educational levels and health consumers following the diagnosis of a chronic condition, including cancer (68-70). In Australia, relative to the general population, CAM use is also highly prevalent (valued) amongst some other sub-populations with particular health needs, including indigenous Australians,(71) women during pregnancy as part of maternity care,(72) and cancer survivors.(73-75)

There has been surprisingly little attempt to understand the prevalence of the personal use and professional recommendation of complementary medicine amongst Australian medical practitioners. A report of one large US survey however found that; *"Health care workers are more likely than the general population to use CAM. Among health care workers, health care providers are more likely to use CAM than other occupations."*(76) and another survey concluded that; *"Physicians and nurses are as likely as members of the general public to use dietary supplements, as shown by comparing the results of this survey with data from national health and nutrition surveys. Also, most physicians and nurses recommend supplements to their patients, whether or not the clinicians use dietary supplements themselves."*(77) Similar conclusions were reached regarding the use and recommendation of dietary supplements by cardiologists, dermatologists and orthopaedic specialists who tend to recommend dietary supplements to patients for reasons related to their specialty.(78)

If these results can be extrapolated to the Australian context, then it is reasonable to assume that most Australian medical practitioners would support "Option 1" of the MBA's proposed options, because it would seem they are already quietly, safely and effectively managing to integrate CAM into their practices to the extent that their knowledge of safety and efficacy supports, and without the need for further regulation. (Or, in colloquial terms, - "If it ain't broke don't fix it!")

This quiet integration of complementary medicines and therapies into Australian general practice has been proceeding uneventfully for at least two decades, without any apparent need for further regulation. (79,80) and, more recently, there has also been integration of CAM programs into other mainstream Australian healthcare services.(81) Increasing integration of CAM into mainstream medicine over time is also apparent internationally across diverse cultures, including the US.(82) Other international examples include evidence of greater knowledge and acceptance by mainstream Japanese Doctors of CAM over time that has been apparent through same-survey comparisons,(83) while in Italy, -

"Traditional and non-conventional medicines are slowly gaining ground in Italy despite the opposition of mainstream medicare. With regionalisation of public health, the mingling of cultures each with its own medical tradition, and a general shift by an internet-proficient public towards greater freedom to choose a personal style of therapy, Italy finds itself in line with a worldwide trend encapsulated in the 2008 Beijing Declaration." (84)

As in Australia, increasing integration of CAM may pose ongoing challenges for medical regulatory bodies internationally.(85-88) This has also long been a challenge for conventional medicine to respond to within the UK NHS,(1) and, more recently within developing countries, such as Uganda.(89) In accord with WHO (2000) recommendations, most countries, including Australia, have implemented regulation of CAM

products. In Australia, this function is carried out by the TGA.(90) Most countries also support the establishment of CAM practitioner(non-biomedically trained) self-regulatory bodies to help ensure CAM quality control for the public, as does Australia.(91)

No other country however, seems to have proposed separately further regulating registered medical practitioners who practice any form of integrative medicine. If the MBA proceeds with "Option Two" as preferred by the Board, it would therefore be going against international consensus concerning the WHO recommendations without any international precedent and without any readily apparent reason for setting this precedent.

In the Australian medical context, positioning toward CAM may range from extremes of uncritical zealous enthusiasm to a kind of strident, uninformed defensive tribalism, but only a minority of Australian GPs actually seem to hold sharply polarised views on CAM. Most integrative practitioners probably exercise a common-sense, cautious, but open-minded investigative stance toward CAM, with a recent content analysis of free-text survey responses from Australian GPs concluding that most were forming nuanced and evolving views regarding individual complementary medicines and modalities for specific clinical indications.(92) Most specialists, likewise, can be expected to proceed with open-minded caution toward selective integration for the sake of their patients.(93) Neither is the stereotyping of integrative medical practitioners as representing the "fringes" of the medical community supported by Australian survey evidence.(94) Meanwhile, stigmatisation of CAM use and controversies that continue to fester between extreme positions can indirectly affect patients and damage patients' trust in their conventional medical practitioners.

Qualitative studies have repeatedly found a consistent theme regarding tensions created by a territorial lack of medical pluralism that seems to contribute to patients' frequent non-disclosure of complementary medicine use to their conventional medical practitioners.(95) This theme is also consistent with Australian survey data.(96) Specifically, patient perceptions of negativity toward their usage of CAM, may preclude their disclosure of CAM use in any future consultations.(97) A consequent lack of co-ordinated or "integrated" care can be especially problematic for patients with chronic diseases.(98-99).

Cancer patients in particular, seem well aware of the tension between biomedicine and CAM practice, and frequently will not disclose CAM use due to anticipation of their doctor's cynicism or disapproval.(100-101) Although there is some evidence that cancer survivors are more likely to disclose CAM use than non-cancer patients using CAM, non-disclosure remains common.(102) A perceived blanket opposition from biomedicine toward complementary therapies experienced in the form of a kind of authoritarian confrontation is experienced as distressing for some cancer patients(103-104) and occasionally, the polarisation between biomedicine and CAM will cause cancer patients to abandon hope altogether in whatever conventional medicine can offer them.(105) Evidence-informed shared decision-making within conventional medicine clearly cannot operate in this context.

Conversely, non-judgemental, patient-centred communication has been demonstrated to facilitate disclosure of CAM to physicians.(106-108) Another study of facilitators of CAM discussions in oncology visits found that these are mostly patient initiated, and that *"CAM discussions do not occur at random; they take place in visits characterized by patient-centred communication and are associated with higher visit satisfaction."* (109)

In summary then, CAM is:

- united by a 'wholistic' paradigm of health and ill-health aimed at "whole person" care
- focussed more on preventative health and "lifestyle medicine"
- growing in popularity and here to stay
- already integrated smoothly into some general practices – as sometimes termed "integrative medicine" (although non-disclosure rates remain high in others)
- potentially complementary to mainstream medicine

"(Mainstream medicine) is not going to wither away, whatever the strength of the critique or the unsustainable cost. But it clearly does need integrating with other cheaper, more holistic, more person-centred expertise. Integrative Medicine (IM) fills this gap. It works with the mainstream, supplementing its deficiencies, bearing some of the brunt, redressing the emphases."(110)

The common juxtaposing of conventional medicine against CAM (as if mutually exclusive), although just an (often) unquestioned social construct, matters in terms of the future of collaborative evidence-based patient-centred care for Australian cancer patients, and so is worth considering further;

Although a difficult concept to communicate non-visually, rather than being juxtaposed as though opposites, the relationship between "standardised-only conventional medicine" (as defined above), and different forms of "complementary and unconventional medicine and emerging treatments" in actual clinical practice should be conceptualised as clustering toward the two poles of a continuum of "conservative orthodoxy". While some consensus regarding exclusivity would likely be reached toward either end point, (about what is 'complementary' and what is 'conventional') there remains much overlap and room for disagreement in the centre; - Much overlap certainly applies to Australian integrative general practice and includes 'integrative' practices such as nutritional interventions & the prescription of exercise & dietary supplements. For instance, does the incorporation of a combination of natural products, pharmaceutical drugs, self-care and digital/mobile health technologies into molecular-behavioural combination therapies for chronic diseases best exemplify "conventional medicine" or "complementary and unconventional medicine and emerging treatments" or just simply "good medical practice"? (111)[8]

This concept of a continuum of conservative orthodoxy between "conventional" and "unconventional" medicine is reflected within the RACGP-AIMA definition of "Integrative Medicine"(3), which is arguably applicable to all good medical practice. The quality of the evidence base underpinning various medical practices also forms a continuum, but one which can be pictured as intersecting with that of a continuum of relative conventionality (or "conservative orthodoxy") concerning the acceptance of different practices within medicine. In other words, some longstanding conventional medical practices have a low quality evidence base while some not-yet-conventional medical practices have a higher quality evidence base and vice versa. – And so it has always been, throughout the history of science and medicine.(112) In this context, evidence-based shared decision-making can help bridge the conceptual divide between more polarised factions within these paradigms that will encourage better pluralism in time.(113)

> ***CISS respectfully urges the MBA to re-think it's juxtaposing of CAM against conventional medicine for regulatory purposes, and instead draft a definition of either 'conventional medicine' or 'integrative medicine' that is consistent with the need to help promote safe and effective patient choice in healthcare that is evidence-based and well-coordinated for all Australians, - including cancer survivors.***

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points (Page 4, - point 4 cont'd)

4. No. An implied definition of "conventional medicine" as standard orthodoxy against which all medical practice should be regulated is inconsistent with practitioners' need to exercise professional autonomy in order to individualise clinical decision-making; particularly to ensure evidence-informed patient choice and shared decision making with patients who have chronic diseases (including cancer) and multiple comorbidities. A rigid conceptualisation of conventional medicine potentially both "de-professionalises"

[8] *(Please note that in our opinion, the authors' assumption that chronic care patients are always better off taking their prescribed medications is often not evidence based,- particularly in the context of the practice of "polypharmacy".)*

and “dehumanises” all Australian medical practitioners such that clinical judgement could hypothetically soon be replaced by artificial intelligence (AI). (114)

The reflection of a dehumanising trend in modern conventional medical practice

Conventional medicine does not cover all aspects of individual health - nor should it be expected to do so in the context of the changing demographic in which people are often able to assume significant self-responsibility for the prevention and management of chronic diseases. The ideal practice of conventional medicine however is patient-centred in actuality – not merely rhetorically with tokenistic inclusion. As such, comprehensive healthcare does ideally incorporate all aspects important to an individual patient where there is an unmet health-related need, including mental health care needs. Yet even in the context of the very human issues involved in general practice mental health care, patient values, treatment preferences and psychosocial goals are too often inconsequential and patient-reported outcomes seldom measured. This is not due to any lack of humanity on the part of the GP, -far from it. It is that very capacity for empathy that motivates the GP to try to help their patient in the only way in which their medical training has provided a rubber stamp of standardised conventional orthodoxy (and therefore with unquestioned assumptions of safety and efficacy) -i.e. the prescription of antidepressant medication.(115)

Within an unquestioned medical culture, there are many ubiquitous conventional, attitudes, behaviours and practices that unintentionally dehumanise patients. Virtually from the moment the person is diagnosed and assigned a new identity as a “patient” they tend to be considered as somehow less capable of thinking for themselves, making well-reasoned decisions or assuming ultimate responsibility for their health; - as many doctors who have themselves become patients have learned the hard way, - from the other side of the physician’s desk. If the person decides to forego radical surgery that offers little likelihood of long-term potential benefit and substantial risk, they have “refused treatment” and are often treated accordingly.[9] If a cancer patient decides to undergo chemotherapy and the cancer does not respond or quickly recurs, they have “failed chemotherapy” -(chemo’ is never said to have “failed the patient”). In extreme cases, patients can feel coerced or manipulated into “compliance” completely against their better judgement.

A decline in the capacity for empathy toward patients has been noted during medical training, (116) although this does appear to be preventable.(117,118) Dehumanisation has been described as endemic to the cultural paradigm underlying the practice of conventional western biomedicine world-wide.(119) Medical practitioners’ chronic stress as shown by the high level of ‘doctor burn-out’(120) explains part, but only part, of this phenomena which is especially apparent in the high stress areas of acute care and oncology.(121)

While there are of course many conventional practitioners who manage to combine their objectivity with their humanity throughout their training and career, organisational trends toward a depersonalising of the physician’s work has been recognised for some time internationally within medical organisations and their regulation.(122) Furthermore, at the same time as we have entered an era of ambitious expectations for ‘personalised’ medicine, an objectification of the patient to fit within the molecular biomedical paradigm has also been noted.(123,124) A little ironically, the term ‘personalised medicine’ does not mean what health consumers would reasonably assume it to mean. Rather than describing person-centred healthcare,(125) ‘personalised medicine’, has been defined as an emerging approach to treatment that -

> *“ …seeks to improve stratification and timing of health care by utilizing biological information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics.”*(126)

Within the paradigm of standardised conventional medicine, treatment decision-making could therefore arguably be best “personalised” according to individual biomedical variables by a sophisticated AI

[9] This can be especially problematic for those unfortunate patients who have may well have had more time to research their particular condition and may have acquired a higher level of health literacy than their medical provider regarding their particular situation. A good dose of egalitarian humanity and a willingness to communicate medical uncertainty is sometimes required.

algorithm. This may be predictable for the near future, with some claiming that AI could soon personalise then replicate the science of RCT-evidence-based treatment decision-making, without needing to incorporate the very human relationship art of clinical practice.

The reason this will not happen anytime soon is that the future of work is essentially human. Human skills of lateral thinking, reflective listening, empathic understanding, intuition, and genuine kindness and compassion cannot ever be replicated by AI.

Patients know this, as do their medical practitioners. The currency of the doctor patient relationship is trust which is earned not merely through professional competence and sound clinical judgement but also through these very human abilities and skills. Essentially, -*"healthcare … is not a grand machine, a complex of physical facilities, advanced pharmaceuticals, surgical techniques, or an administrative system, however wonderfully conceived. It is instead an essentially human activity, undertaken and given meaning by people in relationships with one another and their communities, both public and professional."* (127)

It is precisely when this relationship goes wrong for patients that complaints can be anticipated by the MBA.(128)

A poor doctor-patient relationship within conventional medicine is one (although only one) of the many factors reported as motivating patients to use CAM, (129) including sometimes for a minority of cancer patients, as an alternative rather than as a complement to conventional medicine.(130)

A de-professionalising trend …

A "de-skilling" or "de-professionalising" trend as reflected in the MBA definition has potential implications for the clinical autonomy of all medical practitioners. AI is well suited to the above definition of "standardised conventional medicine",[pg14] provided the algorithms entered are based on the highest (and unbiased) quality evidence of safety as well as evidence of efficacy from RCTs. By this definition however, while conventional medicine may meet the medical needs of more "standardised" conventional patients it would not comfortably accommodate complex case-specific or situationally-dependent clinical reasoning, which is widely recognised as vital for patients with chronic complex conditions,(131) who usually present with challenges requiring variations from guidelines developed as though for "standardised patients". Without clinical reasoning therefore, (and sometimes a good deal of lateral thinking and creativity) evidence-based medicine can remain academic.(133,134)

Therefore a rigid standardisation of conventional medicine would leave no room for the clinical decision making autonomy of the medical practitioner, nor the need to respect patent autonomy,(135) let alone the ideal of adjusting the treatment decision-making process according to the degree of participation wanted by the patient with awareness of the effect of the power differential(136). It would not in fact require the physician to actually interact with the patient as an individual in order to accommodate patient variability. Neither physical, health-related variability (including comorbidities) nor the patient's health-related goals, values or preferences would need to be accommodated. The practice of 'conventional medicine' could then indeed be replicated by a relatively unsophisticated artificial intelligence algorithm, and it could be argued that, if left devoid of more patient-centred, individualised and "integrative" practice, AI will be the future of medicine.(114)

In reality of course, few GPs or specialists would restrict their clinical decision-making autonomy to the practice of conventional medicine if defined so narrowly [as on pg 3], as this would predict poor outcomes for the many patients who require human interaction with a GP who is qualified and skilled in the "art" as well as the "science" behind sound medical decision making. (137,138) The realities of actual clinical practice mean that GPs often find themselves confronted with patients for whom the limitations of conventional products and procedures require the application of divergent thought to clinical judgement in complex decision-making situations. Treatment options often need to include more "unconventional" possibilities, (such as well researched drug re-positioning), - especially for the growing proportion of

patients who have chronic diseases (including cancer) with multiple comorbidities for whom the standard options are inadequate or even potentially dangerous.(139)

Therefore, even with the most stringent adherence to the first three principles of evidence-based medicine, this understanding of conventional medicine may predict poor patient outcomes overall when applied to the challenges of "real world" general practice; - (and especially so for patients with chronic complex conditions). It would also predict low patient satisfaction and a high rate of justifiable patient-initiated complaints to regulatory authorities such as AHPRA.

The MBA proposed definition implies that conventional practice is a standardised orthodoxy against which all somewhat more divergent medical practice should be judged and regulated. To equate conventional medicine with a rigid notion of standardised orthodoxy against which all patient care undertaken by medical practitioners should be regulated is inconsistent with practitioners' need for professional autonomy in individualising clinical decision-making so as to provide patient choice based on the most relevant evidence. (140)

CISS suggests that the MBA drafts a new definition of either 'conventional medicine' or 'integrative conventional medicine' that will stand the test of time, or alternatively, use the AIMA definition. The definition needs to be consistent with the realities and complexities of actual clinical decision-making with real people, particularly the need for medical practitioners to use their professional autonomy and provide evidence-informed choice with real people who are living with complex, chronic conditions and multi-morbidities, including cancer survivors.

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points (Page 4, - point 5 cont'd)

5. No. The proposed MBA definition potentially reinforces a non-evidence based view of good conventional practice that inadvertently ratifies the widespread practice of overdiagnosis and overtreatment as "status quo".

Australian GPs and specialists should not have to choose between identification with the principles of evidence based integrative medicine on ideological grounds of "do no harm", and unswerving allegiance to conventional practices of overdiagnosis and overtreatment on the grounds of medico-legal pragmatism. A conceptualisation of conventional medicine as the regulatory standard potentially imposes just such an ideological versus pragmatic choice between "doing what is right for the patient" versus "doing what is legally safest for the medical practitioner". In the context of a high rate of "burn out", this also has indirect implications for medical practitioners' mental well-being through impeding their ability to accommodate evidence informed patient choice in health-care decision-making without fear of unjustified litigation. This, in turn, would tend to encourage the continued over-investment in the practice of overdiagnosis, overtreatment and "defensive medicine" at the expense of "patient-valued-outcomes-oriented medicine".

Conventional medicine is slowly undergoing a profound paradigm shift. In essence, this can be characterised as a shift away from common assumptions that "more (conventional) medicine equals better medicine" toward a growing awareness of the individual, societal and modelled economic costs of "too much medicine"(141). For Australian GPs and specialists, the questioning of long-standing assumptions about the quality of evidence underpinning too much conventional medicine has facilitated an increasing

recognition of the widespread problem of overdiagnosis/overtreatment.(142,143) Overdiagnosis occurs when the diagnosis of a disease and subsequent treatment causes more overall harm than overall benefit for patients. On an individual level, overdiagnosis means that the standardised treatment approach to a diagnosis leaves the person ultimately worse off than if they had not been diagnosed in the first place.(144,145)

Overtreatment can also occur even with a correct diagnosis. It occurs when the best scientific evidence demonstrates that a treatment provides no benefit for the diagnosed condition.(146) This applies frequently in relation to cancer.(147)

Overdiagnosis and overtreatment both lead to waste of health resources, from a public health perspective. Economically, according to a U.S. 2012 Institute of Medicine report, wastage accounted for up to 30% of total health care expenditure, of which "unnecessary services" was the largest contributor.(148) Australian estimates also place the annual economic costs to the health budget of overdiagnosis/overtreatment at about 30%, as cited in the ABC Four Corners investigation, 'Wasted': *"We as a nation spend about $155 billion a year on health. And about a third of that, $46 billion, each year is being squandered…."*

Other sources suggest the waste is much higher. The British Medical Journal's Clinical Evidence Group estimated that only about 35% of 3,000 common medical interventions have been proven to be beneficial, including about 11% evaluated through RCTs.(149) In a societal context which has imbued within community beliefs the cultural assumption that 'more (conventional) medicine equals better medicine', the concept of overdiagnosis/overtreatment can seem counterintuitive and therefore difficult for many patients and practitioners to grasp; - especially in cancer diagnosis and treatment,(150) where newly diagnosed patients and those who care for them usually experience a sense of urgency to "Do something radical and DO IT NOW!" Research on overdiagnosis has mostly focussed on population based screening for prostate cancer (151) and breast cancer,(152) but doubts have also been raised about the value of whole population-based screening programs for skin cancer, including melanoma,(153) and for thyroid cancer,(154) lung cancer,(155) and colorectal cancer.(156)

Despite broad research-based expert consensus that routine ovarian cancer screening is not evidence-based practice, it is demonstrably recommended by a significant number of U.S. physicians.(157) Likewise, another vignette-based study found that around 40% of physicians reported offering colorectal cancer screening tests to young asymptomatic women, and 75% would offer breast cancer screening tests; - (both scenarios demonstrating non-evidence based recommendations contrary to the applicable guidelines).(158)

Why would a high proportion of conventionally-trained physicians provide their patients with non-evidence-based treatment recommendations likely to lead to more harm than good? Much of the over-enthusiasm for cancer screening leading to overdiagnosis and overtreatment can be attributed to the fact that seeming (ie. statistical-only) improvements in cancer survival due to the detection of benign lesions (miscategorised as malignancies) is commonly mistaken for real improvements in actual cancer survival (ie. deaths delayed or lives saved) and attributed to "early detection". Studies using common clinical scenarios demonstrate that learning from a closed positive feedback loop which precludes negative feedback also reinforces overdiagnosis.(159)

Furthermore, much medical diagnosis entails uncertainty which often motivates "erring on the side of caution" within the context of an overly standardised conventional medical paradigm and an increasingly litigious society. As evidence and awareness of overdiagnosis accumulates however, a "perfect storm" of litigation is likely to follow if this particular problem within the conventional medical paradigm is not able to be addressed, - as is the goal of the NHMRC-funded Wiser Healthcare initiative.

https://www.wiserhealthcare.org.au/about/

The evidence that has accumulated from routine cancer screening showing no survival benefit in a wide range of different cancers has generated considerable confusion for patients and controversies amongst

Australian experts surrounding screening/treatment decisions.(160) Hopefully this confusion will ultimately resolve in the direction of patient outcome-driven evidence-based medical practice. Again, highly individualised evidence-based shared decision making is the ultimate preventative antidote for the current preponderance of the overtreatment of patients with non-evidence-based medical practices and the concurrent undertreatment with evidence-based patient-oriented practices. This shift would potentially benefit all health consumers. Meanwhile however, there is still widespread unquestioning public acceptance of media-reinforced myths perpetuating overdiagnosis and overtreatment,(161,162) with public perceptions in turn reinforcing the preponderance of "defensive medicine".

Defensive medicine is overdiagnosis and overtreatment when motivated by the perceived need to avoid risking accusations of medical negligence and subsequent litigation. Common societal myths perpetuating the unquestioned acceptance of defensive medical practices include the belief that more cancer screening will prevent more cancer deaths, and more radical cancer surgery will prolong life.(163) So, at the same time as cultural changes have been supporting the expansion of patient-centred integrative medicine which emphasises treatment harm reduction, other trends have been encouraging the very opposite trend; i.e. the continued entrenchment of the practice of defensive medicine, - at the expense of harm reduction through "informed-patient-valued-outcomes-oriented medicine".(164) For this reason, CISS considers that the NHMRC-funded Wiser Healthcare initiative is vital, both from a public healthcare perspective and that of each of our CISS members as individual cancer survivors.

Medical practitioners are undoubtedly more likely to be sued by their patients if they do not competently practice both EBM and Shared Decision Making,(165-167) although this can be a difficult area to adequately research.(168) According to expert testimony backing a one-off US court ruling however, EBM and Shared Decision Making were not considered by consensus to be "standard of care" (i.e. "not how most physicians practice") and therefore by extension could technically be considered "unconventional medicine" in need of further regulation through the MBA.(169 *referring to* 170) This court ruling testifies to the disconnect between conventional medicine's allegiance to "evidence rhetoric" and the actual poor uptake of EBM as the 'standard of care' in too much medical decision-making, (with potential implications for all individual patients as well as public health). The irony here also testifies to the fact that non-evidence based medical practices, including overdiagnosis and overtreatment, have been increasingly incorporated into conventional medicine (as evidenced by the growing antibiotic resistance exacerbated by antibiotic over-prescription for common upper respiratory tract viral infections).

In summary, CISS is concerned that the MBA proposed definition implies that conventional practice is that against which all less common approaches should be judged. This understanding therefore does nothing to help shift common non-evidence-based practices within conventional medicine such as overdiagnosis and overtreatment. This may have unintended legal ramifications as well as indirect consequences for medical practitioners' mental well-being, by impeding their ability to prioritise evidence-informed patient choice over standardised orthodoxy in health-care decision making, without risking unwarranted litigation.

CISS maintains that highly individualised evidence-based shared decision making is the ultimate preventative antidote for the current preponderance of overtreatment of patients with non-evidence-based medical practices and the concurrent undertreatment with evidence-based patient-oriented options.

"Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments…"

Expansion of above six points (Page 5 point 6 cont'd)

6. No. The proposed MBA definition is also predicated upon an assumption that good "conventional medicine" does not already include some "emerging treatments".

Any definition used for this consultation needs to be consistent with the reality that medicine is a rapidly evolving field. The best practice of 'conventional medicine' is dynamic rather than static, as it requires frequent adjustment of medical best practice according to emerging independent research-based evidence. All medical practitioners are needing to frequently appraise those emerging treatments which have potential relevance to better meeting their patients' healthcare needs, according to the best evidence realistically available to them.

Medicine also faces a range of emerging challenges. An aging population with a high proportion of people with chronic illness and multiple medical comorbidities plus unsustainably escalating costs poses challenges that will only be met if conventional medicine increasingly incorporates the science of preventative medicine and translational public health research (including qualitative research). Conventional medicine though has historically not prioritised prevention, with still only a very small proportion of Australia's health budget dedicated to preventative programs. We therefore have a highly myopic response to the looming healthcare crisis which will only be met if future decision-makers place a higher priority on longer preventative health initiatives.

It could be argued that "standardised conventional medicine" works best when focussed upon the treatment of acute illnesses and injuries in otherwise well people(139). "Integrative medicine" will increasingly be needed to meet the emerging challenges posed by the increasing proportion of people with chronic illness and multiple medical comorbidities because of its greater emphasis on the prevention and management of chronic disease through the promotion of "whole person" health.(171) This applies in the changing Australian demographic both from a public health perspective (172,173) and from the perspective of individual patients.(174)

From our perspective as a cancer information and support service, CISS asks the MBA to re-think the potential negative effects on cancer patients of further restricting patient choice regarding evidence-informed emerging treatments. Our strongly held rationale for this stance is based on the history of emerging treatments within the field of conventional cancer research and that of the emerging science underpinning integrative oncology.

A brief overview of the history of emerging treatments within conventional cancer research.

Despite rapid advances in high-throughput genomic and proteomic technologies, studies identifying 'driver' genetic mutations that actually can translate into effective treatments have mostly been disappointing, serving to merely prolong the seemingly endless elusive search for a genetically targeted single-treatment 'cure' for cancer. Emerging treatments from cancer research that prove of real survival benefit to patients will probably be multitargeted combinations, including lifestyle interventions (175) and other "no harm" treatments based on epigenetic mechanisms.(176-178) and metronomic approaches consistent with our growing understanding of tumour evolutionary principles.(179-182) Genuinely pro-survival emerging cancer treatments therefore usually require "thinking outside the box".(183,184)
https://abcmedia.akamaized.net/rn/podcast/2011/06/hrt_20110620_0851.mp3

Repeated attempts to discover and apply univariate solutions to the complex ecological systems of tumour growth means that the history of cancer drug research has been dominated by a repeating cycle with three

predictable stages:- First comes a stage of well financed but hard-won progress in better understanding a previously puzzling aspect of the molecular complexities of certain cancer cell dynamics.

The second stage is one of excitement and hope inspired by in vitro studies followed by generally less promising animal studies attempting to translate these findings into new (& usually patent-able) therapeutics.

The third and final stage can be recognised as a slowly unravelling crash of disappointed hopes, as evidence accumulates from properly conducted human clinical trials revealing that the new drug, while temporarily reducing the size of certain tumours, inevitably then leads to drug resistance for most trial participants, attendant with aggressive recurrence and increased metastatic potential. This is partly due to the pro-tumour-survival adaptations of cancer stem cells(185) in the context of the tumour microenvironment.(186) Most pharmaceutical-sponsored in vivo studies designed to test new and emerging cancer drugs in clinical trials in order to demonstrate efficacy, use relative tumour shrinkage and/or surrogate endpoints as the outcome measure, rather than overall survival or even progression-free survival,(187) and have been found to often adjust (downgrade) their outcome criteria as the study progresses which can make the results appear more positive.

Furthermore, as there is generally a time lag between the idealised hope & hype generated by stage one and two, and the eventual crash of stage three, the new drug's predilection to transform tumours into more aggressive pro-metastatic phenotypes with associated systemic dysregulation may not be initially attributed to the drug - but may nevertheless shorten survival. First one and then another independent researcher eventually start to point out the inconvenient truth that the treatment does not "work" in a way that meaningfully increases survival for most of the cancer patients for whom it was intended.(188,189)

In contrast, studies underpinning emerging therapies in integrative oncology are typically both underfunded and underpowered, and the sequencing of conventional stages of drug discovery and testing tend to be reversed,(190) because traditional knowledge of clinical effects and safety often become the starting point preceding in-vitro investigation of possible anti-cancer mechanisms.(191) Neither are epigenetic anti-cancer therapies generally intended to produce a "cure" via just one modality as shown in the following hypothetical example of an integrative oncology session:

An example of the need for conventional medicine to integrate combinations of highly individualised emerging treatments.

In the near future, Mr Liu, (an hypothetical patient) consults an integrative oncologist for a third opinion regarding his treatment options for surviving esophageal cancer. He is in considerable cancer-related pain and has chemotherapy-induced neuropathy and chronic waking insomnia. He is also, predictably, profoundly depressed, but he has a supportive family network and is not yet suicidal. Prior to his cancer diagnosis several months ago, he was a little overweight, but he now has cancer cachexia having lost 20 kg. He has given up all exercise and has a very poor quality of life as measured by a standardised checklist completed with a naturopath (who had been recommended to him recently by a friend).

Mr Liu is university educated and has long been a "medical sceptic". Immediately after diagnosis he had been started on MTD cytotoxic chemotherapy (cisplatin and 5-fluorouracil) which he had completed. This had been commenced with the hope of increasing the chances that the cancerous tissue might then be considered more likely to prove resectible but this was never properly explained to him, and he'd assumed that it's intent was curative. Neither was he involved in writing an agreed Treatment Plan.

He is now seeking an independent third opinion because he'd felt pressured by his multidisciplinary team to undergo immediate radical surgery, followed by chemoradiotherapy. He had declined this in order to buy himself time to make an informed decision in view of emerging evidence that cancer surgery(etc) for his particular condition is as likely to provoke metastatic disease as it is to prevent it. As a self-funded retiree, he is also worried about the gap fee for the surgery and his likely out-of-pocket expenses for

chemotherapy (although his daughter is trying for help for him through 'crowdfunding'.) He'd also felt blamed for his cancer when he'd answered truthfully about his former smoking, and disparaged when he'd attempted to discuss with his previous oncologist some recent research studies he'd found on the internet concerning RCTs of CAM use with esophageal cancer patients, including the use of Sehydrin (Hydrazine Sulphate) for cancer cachexia. Mr Liu has brought a written list of his major priorities and questions for discussion (as all patients with chronic conditions should be encouraged to do if this helps them organise their thoughts and share in the medical decision-making):

PATIENT AGENDA FOR CONSULT' WITH DR BROWN

1. History of my disease from my angle to correct referral misinformation.

2. In your opinion, what are my chances of survival if I do have (robotic) surgery versus if I don't?

3. Requesting referral for updated MRI & monitoring of circulating tumour cells or DNA?

4. Do you think Traditional Chinese Medicine might be able to help me in some way?

5. Needing your opinion about my insomnia, pain & cachexia :
- might Cannabidiol help all three?
- What about Sehydrin?[10]
- what else might help me get my strength back to better fight the cancer?

Dr Brown is Mr Liu's new oncologist. As a recent registrar she was well trained in the art of patient-participatory medical decision-making, and as a breast cancer 'survivor' she has no problem listening to patients and letting her empathy and humanity show whenever needed. She has also completed postgraduate training in emerging treatments in integrative oncology and is relatively aware of her own decision-making biases.

Together they discuss the pros and cons of testing for circulating tumour cells both before and after minimally invasive robotic surgery (her new patient's major concerns and both examples of "emerging" techniques). Dr Brown then provides him with a link to an online Patient Decision Aid to help him clarify his evidence-based treatment options and QOL values, as well as increasing his confidence in making well-informed shared decisions in his future survival plan. She also discusses with him the possibility of enrolment in an independent clinical trial of low dose multi-targeted metronomic chemotherapy (an "emerging treatment") in conjunction with immunotherapy. He takes some written information about this trial to consider, and welcomes a referral to a nutritionally-trained exercise physiologist and a Chinese herbal medicine practitioner. Mr Liu is already on several potentially interactive medications for other chronic conditions as well as having recently added several supplements (including Graviola extract and low dose Nicotinamide Riboside).

She therefore recommends Honokiol and PEA (Palmitoylethanolamide) to help reduce his pain and HMB to help halt his cachexia (until she has had time to look into the Sehydrin trials etc.) In view of his blood test results however, she prescribes only a low dose Cox2 inhibitor, and Phenergen & slow-release melatonin before sleep. Mr Liu also welcomes a referral to a local pharmacist for a free medication x supplement

[10] Mr Liu had identified Sehydrin as a possible treatment that he'd like to try for his cachexia. He supplied Ms Brown with a printed report of a trial that seemed to show that patients with late stage esophageal cancer had experienced a beneficial response to their cachexia using Sehydrin. She told him that she was unfamiliar with this compound but undertook to investigate the evidence of its safety and effectiveness for cancer cachexia and if she thought it might help him would see if she could provide it for him.

review and the oncologist uses the last three minutes of the consultation teaching him a deep breathing exercise to use before sleep. Mr Liu leaves the consultation much less inclined to disengage entirely from whatever conventional medicine may still offer him, and makes a further appointment. That night, he has his first good sleep for many months.

Many Australian cancer patients like Mr Liu urgently need the integrative knowledge and skills demonstrated by oncologists like Dr Brown, together with well-trained CAM professionals and integrative general practitioners who will work collaboratively to optimise our care.

> ***CISS therefore respectfully urges the MBA to help ensure that those MBA registered medical practitioners who use "emerging treatments" are regulated no differently to any who do not do so, because "emerging treatments" should be considered a part of "good practice". Rather, the MBA again has the ability to help promote safe and effective evidence-based practice and patient-participatory decision-making, including in regard to emerging treatments.***

If not, how should it be defined?

Please note that CISS finds this question a little confusing, because what "it" is that the MBA are wanting to define is not actually specified.

If however the MBA wish to define "Complementary Medicine" (rather than "conventional medicine", "unconventional medicine" or "emerging treatments"), any definition used for Australian regulatory purposes needs to be formulated in consultation with relevant stakeholder groups, especially AIMA as the only stakeholder group representing MBA regulated medical practitioners whose purpose is to support safe and effective integrative practice amongst this professional group.

Our organisation's full definition of CAM is as follows:

> **Complementary or Alternative Medicine (CAM) can be defined as a wide variety of therapies sharing the concept of a wholistic paradigm of health with an established history of use for health promotion or the prevention, management or treatment of ill-health.**
>
> ***Complementary Therapies* can be defined as those that form part of this wholistic paradigm that can be *added to* conventional treatments, thus broadening their effects beyond the treatment of symptoms, often enhancing their positive effects and minimising any side effects.**
>
> ***Alternative Therapies* are those seen as being based on a different paradigm of health from the conventional one, seeing the role of the state of the mind, emotions and spirit as an essential part of the causation of ill-health, alongside that of the physical body, and therefore needing to be addressed as part of treatment.**
>
> **CAM therapies are usually used in highly individualised combinations aimed at synergistic interactions for "whole of person" effects, based on the Hippocratic oath of "first, do no harm" and promoting the concept of the individual taking control of their own health.**
>
> **The relationship between CAM and mainstream medicine is in transition in most countries, with many CAM therapies being gradually integrated into mainstream medicine as mutual understanding and the evidence base for CAM continues to expand.**

Similarly, the Cochrane Collaboration's definition of complementary medicine accurately reflects the political relativity of any definition of CAM:

"Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed."(1)

The U.S. Cochrane School of Complementary Medicine's definition of complementary medicine is likewise consistent with the WHO Year 2000 statement on CAM in emphasising a markedly less dichotomous relationship between complementary medicine and conventional medicine than that reflected in the MBA proposed definition: "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodox methods or by diversifying the conceptual framework of medicine".

The term "Complementary and Alternative Medicine" (CAM) is used to describe a wide variety of therapies that are increasingly used by health consumers for disease prevention and health promotion. CAM may encompass at least five distinctive (while somewhat overlapping) subsets of "less-mainstream" health-related practices;

- the use of biologically based natural medicinal products, including medicinal foods, botanical therapies, phytochemical compounds and dietary nutritional supplements.
- whole systems of culturally unique traditional medicine, including Indigenous Australian "bush medicine",(176) Indian Ayurveda and Traditional Chinese Medicine.
- musculoskeletal and other manual body based therapies including osteopathy and therapeutic massage.
- "mind-body therapies" including yoga and meditation.
- "energy therapies" including reiki and acupuncture.

Some definitions include mindfulness training (177) and other common stress reduction techniques as "complementary therapies", despite the fact that these are increasingly becoming "mainstreamed".

Within each of the above subsets there is often great variability and sometimes controversy about what (and who) should be considered "in" or "out" of the category.(178,179)

As such, complementary/integrative medicine cannot necessarily be considered as a unified paradigm (any more so than can "conventional medicine"). It is unsurprising then that debate has long persisted internationally surrounding an agreed definition of complementary medicine, and the MBA is certainly not alone in grappling with this controversial issue.

Any of these definitions would be acceptable to CISS because they each acknowledge the potential overlap between CAM and "conventional medicine" (as the MBA definition does not) as well as the political relativity of what is considered to be "conventional" medicine within any country.

For example, acupuncture and herbal medicine are considered to be part of conventional medicine in most parts of China, whereas in white anglo-saxon Australia these are usually considered to be CAM choices (although increasingly considered as in the process of being integrated into supportive cancer care).
-
These above definitions of CAM therefore, (unlike the MBA definition) do not inadvertently position "conventional medicine" as that which is "not CAM".

A patient-centred view

It has been argued that patients are in the best position to individually decide what constitutes complementary, alternative, and integrative medicine according to their own situation and needs.(180) In this sense, therapy could be regarded as "Complementary" or "Alternative" whenever used by an individual to meet healthcare needs that are not otherwise fully met within the mainstream healthcare options that they personally find accessible, acceptable and effective. A mainstream practitioner can safely

assume a CAM therapy to be beneficial to their patient who experiences it to be so, provided it has been adequately researched (which can include studies based on accumulated traditional knowledge for "proof of concept") and determined as safe and effective for the purpose/s for which the person is using it (including via non-specific effects in placebo-responsive conditions such as pain, insomnia, depression and anxiety). In this patient-centric view, the term "accessible" would encompasses financial, geographic and logistic accessibility, as well as access to suitably trained practitioners with adequate professional and interpersonal skills in providing needed healthcare in a manner psychosocially beneficial or not harmful.

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. A wide range of issues is covered in the discussion document, ranging from 'liposuction' (an established invasive cosmetic surgical procedure}, to 'off-label prescribing' (which is very common in conventional medicine, particularly in paediatrics and palliative care) through to 'the prescription of hormones in the absence of a deficiency' (which could describe the contraceptive pill). These examples appear to have nothing in common.

It would be helpful if the discussion could be narrowed to a meaningful issue of concern, with appropriate examples used to illustrate the perceived issue in common that the MBA hopes to address.

In all probability however, most examples of patient dissatisfaction that come to the attention of the MBA (short of actual malpractice), fundamentally represent a lack of patient-centred care with processes in place to ensure evidence-informed patient choice and adequately informed consent processes.(181) Unfortunately, this can be a common experience for cancer patients in some settings.(182)

Although many factors besides the medical paradigm itself can contribute to the quality of clinical decision making processes (including the medical organisational culture), one of the strengths of integrative medicine is its emphasis on patient engagement and participatory decision-making. Cancer patients in particular need to be provided with evidence informed shared decision making, (including all options likely to assist our "whole of person" well-being), and this shared ideal can help bridge the gap between the different medical paradigms.(113)

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

If by "concerns" the Board means 'issues that may cause harm to patients', there do not appear to be.

The Board has not presented evidence (not even a single anecdote) to suggest that an individual patient with a challenging medical condition has been worse off by consulting a practitioner who practices in an integrative way, than they would be if they had limited themselves to a practitioner who was more 'mainstream'. On that basis, there would appear to be no requirement for any tighter regulation of practitioners who think and work in this way.

It is worth noting however that, besides the anticipation of an unhelpful response, another common reason for patients non-disclosure of CAM use is their apparently correct perception of a general lack of knowledge about CAM by their 'conventionally-only trained' medical practitioners. For example, an Irish survey that found a high prevalence of CAM use among oncology health care professionals, also found both a low level of self-rated knowledge about CAM as well as more empirically assessed knowledge of "level 1a" RCT based evidence;

"……..Health care professionals were asked to self-rate their knowledge on CAM. With regards to having adequate knowledge, 1 strongly agreed, 22 (14.4%) agreed, 40 (26.1%) undecided, 62 (40.5%) disagreed and 28 (18.3%) strongly disagreed. When asked if they were up to date with the best available evidence on CAM use, none strongly agreed, 5 agreed, 27 (17.5%) undecided, 83 (53.9%) disagreed and 39 (25.3%) strongly disagreed.

Five questions based on level 1a evidence were designed to assess health care professionals' knowledge on the evidence-based CAM practices including: the role of acupuncture in chemotherapy-induced nausea and vomiting; Chinese herbal medicine for side-effects of chemotherapy; antioxidant for the prevention of lung cancer; oral fish oil for the treatment of cancer cachexia and ginger as an effective anti-emetic remedy. The answers provided are summarised in Table Table5.5. The majority were undecided on all five questions highlighting the lack of knowledge." (183)

Although small, this study would be worthwhile and relatively easy to replicate in the context of Australian oncology centres. Ideally all Australian medical practitioners would have basic competency training in CAM during their initial as well as continuing medical education. Meanwhile, the resource "Talking with your patients about Complementary Medicine " published in 2015 by the NHMRC is a good starting point;

Talking with your patients about Complementary Medicine - a Resource for Clinicians
https://www.nhmrc.gov.au/about-us/publications/talking-your-patients-about-complementary-medicine-resource-clinicians

and reliable information is increasingly available regarding CAM safety issues relevant to particular patient cohorts, both for medical practitioners,(184) and for health consumers.(185)

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

Yes *(naturally),* - but not necessarily "further regulatory safeguards". Like all health consumers, those who seek 'complementary and unconventional medicine and emerging treatments' obviously deserve access to clear, unbiased information to inform their health and treatment decisions, as well as the right to consult well trained practitioners who are sufficiently knowledgeable about those CAM modalities most likely to be used by their patients, and who do not attempt to practice outside their particular areas of professional training, knowledge and skill.

For example, the Australian Society of Hypnosis (ASH) trains both psychologists and medical practitioners, including GPs, dentists, nurses etc, leading to a postgraduate diploma in clinical hypnosis (1yr FTE), but each graduate is expected to use this additional training only within their area of core professional training and expertise. For example, a nurse or GP could use this form of CAM training as an option for shared decision making in order to help treat his or her patients with menopausal climactic symptoms (186). Likewise, in shared decision making context, a midwife might use clinical hypnosis to help prepare a woman for labour, a dentist to treat needle phobia or an oncologist to treat paediatric pain (for instance), but none of these professionals would be considered qualified to attempt to treat patients with indications outside their professional competence using their ASH hypnosis training.

Most medical practitioners however would consider this plain common sense. In the event of any perceived malpractice, patients could initiate a complaint directly to ASH, to the MBA, AHPRA, or to the Health Care Complaints Commission, but this occurrence seems to be non-existent.

In terms of CAM practitioner regulation, an interesting European study found little inter-country consensus regarding the relative perceived risks of different CAM modalities.(187) Overall though, the three most often seen as carrying a risk high enough to warrant professional regulation were chiropractic, acupuncture and massage, which are presumably highly unlikely to be used by integrative medical practitioners regulated by the MBA.

A sound case can be made that TGA regulation of CAM products,(90) and the self-regulation of CAM practitioners who use non TGA regulated products, is generally working remarkably well within Australia,

given the apparent lack of complaints to the MBA or AHPRA attributable to the practice of integrative medicine.

As is often stressed in the literature regarding the potential for drug x CAM product interactions, "natural" does not necessarily mean "safe.(188) To state another obvious fact however, there is good reason that many CAM products (including traditionally used phytochemicals) are subjected to less rigorous TGA approval processes than pharmaceutical drugs and surgical equipment - many of the latter being potentially inherently dangerous, - and in Australia, the post-marketing surveillance is often woefully inadequate. Consider for example, the findings of the recent parliamentary inquiry concerning medical implants (entitled "Number of women in Australia who have had transvaginal mesh implants and related matters"). The report criticised the history of the safeguards that had failed Australian women from multiple angles such as the lack of transparency in research and development, lack of due diligence in regulatory approval, lack of adequately informed consent processes, lack of adverse event reporting, and lack of post-marketing surveillance.

REPORT TO THE PARLIAMENTARY INQUIRY - Number of women in Australia who have had transvaginal mesh implants and related matters, 28 March 2018. Chapter 5, "Responding to the Evidence",
Chapter 5 - Responding to the evidence Commonwealth of Australia 2018
ISBN 978-1-76010-701-7

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report/c05

Moreover, an ongoing lack of transparency in pharmaceutical adverse events reporting was recently highlighted again by an expose' of refusal of FOI requests for Australian "direct health professional communications" by Torka et. al as written up as a case study titled "Secret safety warnings on medicines: A case study of information access requests.".(189) The authors concluded: *"Our experience highlights unacceptable secrecy concerning safety warnings previously sent to thousands of Australian clinicians. In the absence of explicit regulatory policy supporting disclosure, companies differed in their response. These letters warn of serious and often life-threatening harm and guide safer care; full ongoing public access is needed, ideally in searchable online databases."*

Study co-author from the University of Sydney's Charles Perkins Centre and School of Pharmacy, A.Prof Barbara Mintzes, summarised; *'Our [findings] demonstrate an unacceptable secrecy around potentially serious harmful effects of medicines, which has no place in modern medicine and should not be tolerated by regulatory agencies'*
https://www1.racgp.org.au/newsgp/clinical/commercial-sensitivity-or-patient-safety-secrecy-a

Roughead et. al., for example, writing over a decade ago, estimated that over 1.5 million Australians experienced an adverse event from medicines each year, (190) resulting in at least 400,000 visits to general practitioners and 190,000 hospital admissions.(191) Risks of adverse medication events are exponentially greater for the increasing proportion of patients with chronic diseases and multiple comorbidities who are often on "polypharmacy". Commenting, on the Torka paper, A.Prof. C Hogan states; *"In these days of information technology & GP computerisation, it is a scandal that Australia does not have a user friendly way of collecting adverse drug reactions."*

CISS maintains that it is not "patients who seek 'complementary and unconventional medicine and emerging treatments" from well-trained integrative medical practitioners who need additional regulatory safeguarding but all Australians who use conventional pharmaceuticals in the context of a lack of adverse events transparency and therefore inadequate evidence of risk versus benefit that should potentially better inform our choices (i.e. virtually all of us).

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

YES

CISS is concerned that the MBA's proposal to single out integrative medical practitioners for further regulation without justification for doing so may be based upon common misunderstandings of the nature of the evidence base underpinning CAM. We also suspect that there is a general lack of awareness within biomedical practice as to the recent exponential expansion of quality evidence for CAM, despite research underfunding in this area. Common assumptions around the evidence base for CAM have been impeding the uptake of evidence-based patient choice in Australian healthcare.

Evaluating complementary and alternative therapies

A common confusion has been noted between an insufficient research base for some CAM therapies (for certain indications), or a "lack of evidence", and assumptions of "evidence of lack of efficacy", the latter becoming increasingly important to medical decision making, the greater the inherent risk of the particular intervention.

The concept of "conventional medicine" is also sometimes mistakenly confused with the concept of "evidence based medicine" (EBM), and then contrasted with CAM (193)

CAM was actually once defined by one Australian organisation as medical practice that was "not evidence based". This was, of course a non-evidence based over-generalisation, which became an oft-repeated belief within the 'echo-chamber' informing assumptions used to reject all CAM, due to the fact that CAM has been under-studied relative to most "conventional medicine". The main reason for this has been a long standing lack of funding for the large scale evaluations of CAM interventions through high quality RCTs (wherever appropriate) and other methodologies, although this is now being better addressed. International bodies are now undertaking concerted efforts to expand upon the evidence base for CAM,(194) although Australia is lagging behind in this area.

Two of the criteria of evidence based medicine are that where possible best practice be based on the results of well-conducted randomised controlled trials (RCTs); and that the final treatment chosen be based on the individual patient's situation, values and preferences. As CAM interventions are unified by a biopsychosocial paradigm, they are usually complex interventions that make considerable use of synergistic interactions between the component parts in contributing to the "whole person" intervention. CAM interventions are therefore sometimes better assessed for effectiveness through complex system methodologies,(195) rather than through randomised controlled trials (RCTs), because RCTs normally require that only one treatment or factor can be evaluated at a time.

Methodologically sound assessment of the effectiveness of most "whole person" CAM interventions is both essential and possible however, including through a well-reasoned adaptation of the reasoning model underpinning EBM sequencing stages to include "Medicine Based Evidence",(196) such as in the integration of CAM products into cancer precision medicine, (197) or through at least one of the following:

(a) Using new methodologies devised specifically for complex systems.

(b) evaluating individual modalities using RCT methodology, then testing whether combining these individual factors might retain or enhance their individual benefits; or

(c) as has been developed for RCTs in homeopathy, formulating generic remedies by combining individual remedies developed for separate conditions such as brain, lung, esophageal and breast cancers (after observing common contributory factors in many individuals with a particular manifestation). (198)

Thus it is possible to evaluate treatments that CAM uses synergistically by using RCTs, in addition to other conventional methodologies. High quality (well controlled) RCTs provide causal inference in the evidence increasingly underpinning CAM modalities that can be lacking through other methodologies, such as the correlation between CAM use and self-ratings of improvements in health status found through whole population surveys.(199) RCTs however cannot answer questions such as; "What is conventional medicine not providing that patients are finding in the CAM approach?", which require well-funded large scale

qualitative research.(200) Neither can they answer questions such as “Do those patients whose GP has been educated in CAM tend to have lower health-related costs and live longer?”(201)

Evidence-Based Patient Choice

Australia has also been lagging behind international progress in the implementation of shared decision making interventions in healthcare,(202) and is the only westernised country not to have implemented an across-whole-country public health initiative in this area.

Investment in training medical practitioners to Increase their patients’ engagement in highly individualised evidence-based treatment decision-making has the potential to improve both the effectiveness and safety of care from a public health vantage point, but a concept of “patient engagement” as tokenistic inclusion of individual consumer health representatives in public health decision-making organisations is less likely to effect needed change.(203)

Australia’s deficit in implementing evidence based shared decision making (SDM) is a challenge that can be helpfully responded to throughout the entire spectrum of medical training, practice and regulation across Australia. The current MBA “Good Practice “ guidelines include the single statement that “Making decisions about healthcare is the shared responsibility of the doctor and the patient.”, but no further guidance is provided.

Evidence-based patient choice, (SDM) and the process of informed consent negotiations are inter-related skills that can be taught.(204)

An MBA consultation regarding the issue of “evidence-based shared medical decision-making and adequately informed consent processes in Australian healthcare” initially undertaken with a view to expanding on this single statement (and equally applicable to both “integrative” and “conventional” practice) could potentially do much to lessen instances of patient dissatisfaction (and probably litigation), prevent overdiagnosis and overtreatment, and increase patient safety across all medical practice in Australia.

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

It is more likely that these proposed guidelines, despite their intentions to protect the public, would simply serve to limit the choices available to patients who wish to utilise the best of what both conventional medicine and CAM can provide, and without scientifically based justification for limiting their choices.

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?

They should not be used at all. They read as though their purpose is to protect pharmaceutical and medical device/equipment manufacturers, and those who limit their prescribing practices and treatment options to these products, rather than to protect the public as intended.

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.

Option 1

-(or) "Other": Collaborate with health consumer groups and independent researchers to expand upon the single sentence in the MBA's "Good Practice" guidelines regarding shared decision making. This could also help lay a foundation from which a public health initiative or public policy research organisation. such as the new UOW Australian Centre for Health Engagement, Evidence and Values (ACHEEV), could help launch an Australia-wide initiative in preventing overdiagnosis and over-treatment through promoting the adoption of evidence-based patient choice in medical decision-making.

Final Summary

Integrative medicine is meeting healthcare-related needs for a great many Australian health consumers; particularly those with chronic conditions. This has public health implications for the future of Australia's looming health crisis and warrants substantial NHMR investment to help organisations such as the MBA more fully understand and more helpfully respond to the growing CAM use. In this endeavour, the voices of health consumers will be vital.

From the dual perspective of one of our CISS members who is also a CAM practitioner: *"Complementary" (medicine) offers a corrective to some over-emphases in mainstream medicine, particularly: over-fragmentation in thinking about the body, over-reliance on the advice and influence of major corporate financial interests; overly-broad categorisation of patient-presentations; over-reliance on a single medical tradition; and over-emphasis on dealing with acute presentation while under-emphasising prevention."* [11]

[11] (CAM member quoted with permission)

Recommendations for the MBA

"OPTION 1."

CISS ALSO CALLS UPON The MBA TO:

- Indicate support of our call for a proportion of the revenue raised from all pharmaceutical profits in Australia to be invested into a research fund dedicated solely to financing genuinely independent research into promising CAM treatments currently lacking RCT studies. Related suggestions for this fund include**:**
  - the prioritising of research into the unique phytochemicals contained in Australian "bush medicine"
  - (with any remaining revenue at any one time) the balancing of qualitative and quantitative research regarding CAM use in Australia more generally.
  - Approved research proposals would need to be prioritised according to the public health agenda's interest and the potential for benefit to all Australians.

- Collaborate with the Consumers' Health Forum and independent researchers in shared medical decision making (such as the Sydney University based "Centre for Medical Psychology and Evidence-Based Decision Making") to request assistance in expanding upon the single sentence in the MBA's "Good Practice" guidelines regarding shared medical decision making.

- The above recommendations could also help lay a foundation from which a public health initiative organisation or health policy research organisation, such as the new UOW based Australian Centre for Health Engagement, Evidence and Values (ACHEEV) could help launch an Australia-wide initiative in preventing overdiagnosis and overtreatment through promoting the adoption of evidence-based patient choice in medical decision-making.

- Support the training of the new generation of medical practitioners to be patient centred, critical consumers of the evidence base underpinning both "more mainstream" and "less mainstream" medicine by commissioning research into Australian medical students training needs and established practitioners CME/professional development needs regarding evidence based CAM options for patients.

- Work collaboratively with the RACGP (AIMA) branch through a "modified Delphi" consensus process for the purpose of drafting a 'consensus position paper' to expand upon agreed principles of good practice that could help optimise evidence based patient choice regarding the provision of CAM options within Australian medical practice into the future. Note:

  - These principles would be relevant and applicable to all medical practitioners and could then also be referred to by the MBA as needed.
  - The process to draft the 'consensus position paper' would need to be transparent, inclusive of consumer voices, iterative and independent of vested interests.
  - For this exercise to be useful, the evidence informing the position paper would need to be scientifically rigorous, patient-outcomes-oriented and contestable.

- Draft a definition of the term "conventional medicine".

- Support the call for mandatory reporting of all adverse events by all Australian Medical Practitioners by initiating a transparent public consultation, with a view to establishing a publicly accessible data base.[12]

[12] If inclusive of CAM products, the integrity of the data base would need to be incorruptible through possible false reporting by pharmaceutical-funded practitioners – e.g. a patient would need to provide verifiable informed consent that provides an ID number for the record of notification (that protects their privacy) but which the patient could then use to check the record in the online database.

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