# General Practice
# The Integrative Approach

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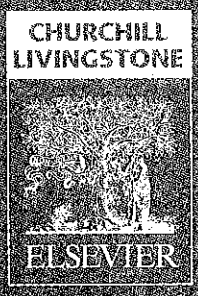


Sydney Edinburgh London New York Philadelphia St Louis Toronto

ELSEVIER

Churchill Livingstone is an imprint of Elsevier

Elsevier Australia. ACN 001 002 357
(a division of Reed International Books Australia Pty Ltd)
Tower 1, 475 Victoria Avenue, Chatswood, NSW 2067


*National Library of Australia Cataloguing-in-Publication Data*

Phelps, Kerryn.

General practice: the integrative approach / Kerryn Phelps, Craig Hassed.

9780729538046 (pbk.)

Physicians (General practice)
Family medicine

Hassed, Craig.

601

Publisher: Sophie Kaliniecki
Developmental Editor: Neli Bryant
Publishing Services Manager: Helena Klijn
Project Coordinator: Karen Griffiths
Edited by Kay Waters
Editorial coordination by Teresa McIntyre
Proofread by Tim Learner
Illustrations by TNQ
Cover and internal design by Darben Design
Index by Michael Ferreira
Typeset by Pindar NZ
Printed by C & C Offset Printing Co. Ltd.

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Based on their respective expertise, the following people have contributed content to the book and we would like to extend our gratitude to them for dedicating their time, knowledge and input to ensure the success of this project.

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# Integrative medicine and the law*

## INTRODUCTION

Integrative medicine is a major development within the healthcare systems of the Western world, including the United States, the United Kingdom, Canada and Europe. All doctors need to understand the legal implications of the practice of integrative medicine. Doctors need to be aware, for example, of the requirements for informed decision-making, and know how complementary medicines (CMs) and complementary practitioners (CPs) are regulated. While this chapter focuses on the Australian legal context, doctors in other jurisdictions will find the general discussion helpful.

Integrative medicine involves the blending of conventional and complementary and alternative medicine (CAM) 'with the aim of using the most appropriate of either or both modalities to care for the patient as a whole'.[1] There have been many attempts at defining CAM and a frequently cited definition 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.[1]

CAM includes a diverse group of healing practices such as traditional Chinese medicine, ayurvedic medicine, Western herbal medicine and naturopathy. Different taxonomies of CAM have been proposed and one frequently cited is that of the National Center for Complementary and Alternative Medicine.[2] This taxonomy divides CAM into five categories:

- alternative medical systems, such as traditional Chinese medicine and Ayurveda
- mind–body interventions, such as meditation
- biologically based therapies, such as herbs
- manipulative and body-based methods, such as osteopathy
- energy therapies—modalities that involve the use of energy fields.

The term 'CAM' has traditionally described the 'relationship between unconventional healthcare disciplines and conventional care' but is now more of 'a collective label for the disciplines themselves'.[3a] CAM brings different approaches to diagnosis and treatment, and a central focus is prevention and wellness, which complements biomedicine.[4]

While historically CAM has been on the margins of healthcare, developments in the past decade that have accorded it greater legitimacy within mainstream healthcare include a massive investment in CAM research, particularly in the United States, increasing evidence of its safety and efficacy, acknowledgement of a role for evidence-based CAM in mainstream healthcare by professional medical bodies, and a number of high-level government and institutional inquiries around the world into the role of CAM.[ii] These inquiries have focused on the regulatory interventions necessary for a planned and systematic integration of CAM into mainstream healthcare. Although a wide-ranging inquiry has not been held in Australia, there have been three recent inquiries with a narrower focus on CMs, CPs and health services.[iii] The implementation of recommendations from these inquiries is assisting, or when implemented will assist, with the promotion of integration in Australia.

Significantly, it is the ad hoc integration occurring at the level of the consumer and the health practitioner, including the general practitioner (GP), that has been driving these developments at the state and national policy level. The most recent and comprehensive data show that nearly 70% of Australians use CAM.[5] It means that Australians have one of the highest rates of CAM

* As at 28 February 2009.

usage among Western nations.[5] In the 12 months prior to the 2005 survey by Xue and colleagues, more than 44% had consulted a CP, resulting in an estimated 69.2 million visits to CPs.[5] This figure approximates the number of visits to medical practitioners during the same period.[5]

There is evidence that consumers use CAM because of a desire for holistic and natural treatment, to fill gaps in medical care, such as the management of chronic illness, and the perceived effectiveness of CAM.[6–8] It is also clear from prevalence studies that consumers use CAM as part of self-care, and in combination with biomedicine, to achieve their own type of integration. CAM users like to pragmatically pick and mix biomedical and CAM options to address their healthcare needs.[5,9,10] One difficulty with this trend is that a high proportion of patients use CAM and biomedicine concurrently, and do not inform their doctor about the CAM use and, in addition, many doctors fail to ask patients about CAM use.[5,10–16]

Doctors, and particularly GPs, have been responding to consumer demand and integrating CAM treatments into treatment plans. In 2000, 20% of GPs in Victoria and 38% of GPs in Perth, Western Australia, had practised one or more CAM modalities. Eighty-two per cent of the Victorian GPs had referred patients for a complementary therapy, and nearly 68% of Perth GPs were in favour of referring patients to CPs as part of their medical care.[17,18] A national survey of Australian GPs in 2000 (published in 2005) found that CAM, non-medicinal therapies, such as acupuncture, massage, meditation, yoga, hypnosis and chiropractic, 'are widely accepted and can be considered mainstream in Australian general practice'.[13a] At the same time, the Victorian study showed that herbal medicine, naturopathy, vitamin and mineral therapy, osteopathy and homeopathy were 'accepted by a sizable minority of doctors'.[17a] In a 2008 survey of Australian GPs, one-third reported practising integrative medicine and about 90% had recommended at least one CM in the past 12 months.[16]

Doctors may be motivated by a number of factors to integrate CAM, including the desire to address consumer preferences in healthcare, an interest in working with safer remedies, and the need to contain costs. It is also reasonable to assume that integrative doctors believe that CAM complements biomedical care, and can also be the primary treatment for patients suffering from chronic conditions who are unresponsive to conventional treatment.[3,13,19]

## LEGAL OBLIGATIONS IN THE PRACTICE OF INTEGRATIVE MEDICINE

It is not possible to outline all the legal obligations that may be relevant to this context, or how those obligations impinge on integrative medical practice. The ethical and legal obligations relevant to medical practice are, of course, also relevant to the practice of integrative medicine, including professional codes of conduct, the criminal law, and obligations related to confidentiality and privacy. There are texts providing information about these obligations that are written specifically for medical practice.[iv] It is a matter of applying the relevant laws to the integrative context.

Because doctors who practise integrative medicine are firstly biomedical practitioners, obligations stemming from statutory registration are of particular importance. The doctor's duty to exercise reasonable care and skill in the care of the patient is also central, as it affects every area of practice including the provision of information and advice to the patient to enable the patient to make an informed decision. There are also laws that are particularly important in the integrative context, and these include the regulation of CMs and CPs.

There is little legal authority relevant to integrative medicine, as the medico-legal issues are, for the most part, yet to be tested in the courts in Australia, the United Kingdom and the United States. This chapter therefore addresses general legal considerations and refers to tools that may assist doctors to manage the risks and generally navigate this new terrain. The chapter focuses primarily on the doctor's duty of care, and the regulation of CMs, CPs and healthcare services.

## THE DOCTOR'S DUTY OF CARE TO THE PATIENT

Through the law of negligence, the law imposes on a doctor an obligation to exercise reasonable care and skill in examination, diagnosis, treatment, and provision of information and advice, that duty being a 'single comprehensive duty'.[v] The relevant law has been affected by reforms arising from the Review of the Law of Negligence (Ipp Review) initiated by the Australian Government in 2002 in response to an insurance crisis.[20] Although it was originally intended that a model statute be developed to implement the reforms recommended by the Ipp Review in all Australian states and territories, this did not eventuate. As a result, there are a number of differences in the legislative provisions enacted in the states and territories.

There is currently little guidance from the courts on the meaning of the new statutory provisions and how they affect the common law, which applied across Australia prior to the Ipp Review reforms. What follows therefore is a discussion of elements of the law that doctors need to bear in mind in their daily practice. It is, of necessity, a broad brush approach, as it is not

possible to provide specific guidance in relation to each state or territory.

A doctor owes a duty of care to each patient to take reasonable care to avoid acts and omissions that a reasonable doctor would foresee as likely to cause harm. It is an obligation to take reasonable steps to avoid foreseeable risks of harm that are 'not insignificant'. In ascertaining what, if any, precautions a reasonable doctor would take in response to a foreseeable risk, consideration needs to be given to:

- the probability of the harm occurring
- the likely seriousness of the harm
- the expense, difficulty and inconvenience of taking precautionary action
- any other conflicting responsibilities you may have, and
- the social utility of the activity.[vi]

The greater the probability of a risk and the greater the magnitude of the harm, the greater the need to take steps to minimise that risk, particularly where the cost of doing so is reasonable.

Although CAM therapies are not without their risks, generally speaking CAM as a whole does have a lower risk profile than biomedicine. Adverse events do occur in CAM but are much less common than in biomedicine.[vii] And there are fewer complaints and claims against CPs. A US study found that claims against complementary practitioners 'occurred less frequently and typically involved less severe injury than did those against conventional practitioners in the same period'.[21a]

Doctors need to become familiar with the risks of integrative practice. The major risks include harm stemming from:

- the failure to provide safe and efficacious biomedical treatment
- a missed or delayed diagnosis of a biomedical condition, and
- complications arising from the combined use of pharmaceuticals and CMs.

Reasonable responses to these risks would generally include:

- undertaking a biomedical differential diagnosis before embarking on a treatment plan
- ensuring that patients are offered safe and efficacious biomedical treatment, and
- asking patients about CM use and taking this into account when prescribing pharmaceuticals.

These matters are all considered further below.

## THE SCOPE OF THE DOCTOR'S DUTY

At this time the scope of a doctor's duty of care extends to the provision of biomedicine only. However, according to the Australian Medical Association's (AMA) position statement on CM, a doctor appears to have an ethical obligation to at least ask a patient about CAM use in medical consultations.[22] Although the ethical obligation to engage with patients about CAM is unlikely to be enforced by the AMA, it may increasingly be recognised and enforced in other forums, such as professional disciplinary hearings and in medical litigation, because of the risks stemming from patients combining CAM and biomedicine. A doctor may also have a legal obligation to provide information and advice to some patients about evidence-based CAM treatment options, and this is discussed below (see 'Informed decision-making in integrative practice').

At present, a doctor has no positive duty, ethically or legally, to integrate CAM therapies into medical practice. At the same time, it is ethical and lawful for a doctor to provide evidence-based CAM treatments to a patient, or to refer a patient to receive such healthcare.[viii] However, once a doctor chooses to integrate CAM into conventional medical practice, the scope of the doctor's duty of care expands to include integrative practice.

## MEETING THE REQUIRED STANDARD OF CARE

The standard of reasonable care and skill required of a medical practitioner under the common law is 'that of the ordinary skilled person exercising and professing to have that special skill'.[ix] In the case of a GP, the standard of reasonable care and skill is that of a doctor who specialises in general practice.

Following the 1992 High Court decision of *Rogers v Whitaker*, the court became the final arbiter of whether or not the standard of care had been met (although medical evidence has always been influential in the view formed by the court), but this has now been modified in most jurisdictions as a result of recommendations arising from the Ipp Review. The means by which any liability in negligence will ultimately be determined is now set out in most jurisdictions in statutory provisions, such as s. 59 of the *Wrongs Act 1958* (Vic). Under s. 59 a doctor will not be negligent if he or she acts in a way that at the time is 'widely accepted in Australia by a significant number of respected practitioners in the field (the peer professional opinion) as competent professional practice in the circumstances' (*the peer professional opinion test*). The fact that there are differing opinions that are widely accepted 'does not prevent any one or more (or all) of those opinions being relied on'. Further, the peer professional opinion does not have to be universally accepted in order to be widely accepted. However, where the court determines that the peer professional opinion is unreasonable, it cannot be relied on.

The peer professional opinion test appears to create a type of defence in medical litigation.[x] This means that if

a doctor is able to provide probative evidence that his or her conduct or opinion is widely accepted as competent professional practice in the circumstances, he or she will not be negligent (provided the court considers that the opinion is reasonable).

The peer professional opinion test is similar in other states, although the widely accepted practices and opinions are not limited to Australian ones, in Queensland and Western Australia.[xi] In those states a doctor could draw on widely accepted practices in integrative medicine outside Australia, to establish that he or she had acted within the standard of care.

There is little authority on the meaning of the peer professional opinion test, but it has been suggested that:

- 'widely accepted' may require that the practice be accepted by various groups across the nation, rather than limited, for example, to a group within one region
- 'a significant number of practitioners' may mean that a large portion of those practising the medical speciality accept the conduct, although not necessarily 50% or more as there is clearly room for different schools of thought
- expert medical evidence in medical litigation should come from respected practitioners and must support the conduct of the doctor as competent.[23]

There have been no decisions where the courts have determined that peer professional opinion is irrational or unreasonable, and it is likely that this will occur only in very exceptional circumstances.[20]

## PROFESSIONAL STANDARDS AND THE PEER DEFENCE

The need to meet the standard of reasonable care and skill, and the availability of the peer defence, point to the importance of professional standards and guidelines on the practice of integrative medicine, integrative medical texts, peer-reviewed journals on evidence-based CAM, and educational programs. These professional resources will provide important guidance on what is expected.

Medical boards are the primary regulator of doctors and have ultimate responsibility for those who are integrating CAM into conventional practice.[22] Guidance on professional standards is found in the codes and guidelines published by the medical boards.[xii] Although the codes and guidelines are recommendations of the medical boards and are not legally binding, they are authoritative and an important guide to professional standards and what is expected of medical practice and performance. They are potentially enforceable through disciplinary processes in relation to allegations of unprofessional conduct and unsatisfactory professional performance. The codes and guidelines need to be applied to the integrative context. They are not comprehensive and do not cover every possibility, and it is expected that doctors will apply general principles to different circumstances as they arise.

Most medical boards have a specific policy statement on CAM and doctors should be familiar with the relevant policy and its application to practice.[xiii] However, there are a number of differences in the policies, raising questions about what the appropriate professional standards are in this area. The establishment of the National Registration and Accreditation Scheme for the health professions, including medical practitioners, in 2010 will provide the opportunity for the development of a national integrative medicine policy.[xiv]

A number of jurisdictions in the United States have passed legislation intended to protect doctors from being inappropriately targeted and disciplined for the practice of CAM.[24] Inappropriate targeting would involve findings related to the use of CAM as substandard, on the basis that a CAM treatment is different from a biomedical treatment.[25] The Medical Council of New Zealand has made provision for a similar protective clause within its policy statement on CAM.[26]

There are no similar legislative or policy provisions within Australia, but the process for dealing with CAM-related complaints by medical boards may have a similar effect. The Western Australia Medical Board, for example, makes it clear that any investigation into a complaint will involve an assessment of the overall competence of the practitioner, some assurance that integrating CAM will not in itself result in a finding of unprofessional conduct.[27] However, where CAM use forms a part of the complaint, there will be specific inquiries into matters such as the risk/benefit ratio of the treatment and whether it is greater or less than that of other treatments.[27] It is likely that this will be the approach across all Australian jurisdictions. Doctors should therefore be prepared to produce evidence of the reasoning process that led to the decision-making, as well as the informed decision-making of the patient.

There is a need for consistent guidelines in relation to CAM, and national and integrative medicine bodies, such as the Royal Australian College of General Practitioners (RACGP) and the Australian Integrative Medicine Association (AIMA), are taking a lead in this respect.

AIMA, established in 1992, is the peak body for integrative medicine in Australia. The members of AIMA are doctors who are interested or involved in integrating natural and holistic approaches into conventional care. AIMA provides a vehicle for peer support for integrative doctors, provides educational programs and resources (including a journal) and acts as an advocate of integrative medicine with government and professional bodies.[28]

The RACGP sets standards for general practice in Australia. The RACGP seeks to ensure that the general practice training curriculum reflects 'both the fundamental nature of Australian general practice and the evolution of ... [the] discipline in response to community needs and advances in science and technology'.[29a] The RACGP has a major role to play in standard setting in integrative medicine, as most doctors integrating CAM are GPs. Hence the college collaborates with AIMA through a joint working party to provide guidance to practitioners on good medical practice in the evolving field of integrative medicine.

The RACGP/AIMA Joint Working Party (JWP) was established in 2005 and the terms of reference include establishing how complementary medicine can be incorporated into high-quality clinical practice.[xv] A *Joint Position Statement on Complementary Medicine* was released in 2005 and the primary position of the JWP is that 'evidence based aspects of complementary medicine are part of the repertoire of patient care in mainstream medical practice'.[30a]

More recently the RACGP has established a Chapter of Integrative Medicine within the college and there are plans to introduce a Fellowship of Integrative Medicine and standards for integrative practice.[xvi] An integrative medicine curriculum was published in 2007.[xvii] This incorporates the skills and knowledge needed by GPs in integrative medicine across five domains of general practice. The curriculum, Chapter and proposed Fellowship are key developments, as they direct, or will direct, doctors to the skills that they need to acquire to achieve competent practice in this area. It is clear that the RACGP is committed to addressing the integrative medicine educational needs of GPs and providing guidance in relation to the standard of care expected. When fully implemented these developments will play a highly significant role in carving out what amounts to widely accepted, competent professional practice for integrative medicine in Australia, particularly in general practice.

Other integrative medical bodies, such as the Australian Medical Acupuncture College, and the Australian College of Nutritional and Environmental Medicine, are currently playing, and will continue to play, a role in defining standards in these more specific aspects of integrative medicine—that is, acupuncture, and nutritional and environmental medicine.

Membership in the RACGP and integrative medical bodies will assist doctors to keep in touch with relevant standards and widely accepted practice in this rapidly developing area of medical practice. Such membership will also provide access to resources and peer networks for resolving the integrative medicine and medico-legal issues that will inevitably arise.

The remainder of this section considers the doctor's duty in the therapeutic encounter, with particular reference to examination, diagnosis, treatment, referral, and the provision of information and advice.

## EXAMINATION, DIAGNOSIS AND TREATMENT IN INTEGRATIVE PRACTICE

For doctors, integrative medicine involves integrating CAM into conventional medical practice. This is clear from the entire legal context. It is also apparent from guidelines, such as the Western Australia policy statement on complementary, alternative and unconventional medicine, which refers to the doctor's obligation to undertake a proper assessment, arrive at a diagnosis according to biomedical principles, devise a treatment plan, and provide information in relation to any conventional treatment, and its risks and benefits.[28]

As is illustrated in a number of chapters in this integrative medicine text, the doctor will need to make a differential biomedical diagnosis according to the usual methods of history taking, examination and diagnostic testing. And, as is standard practice within general practice, it will be necessary to exclude particular diseases, such as cancer, as a cause of symptoms (see, for example, Ch 51, Breast disease). CAM diagnostic testing may be appropriate if it will provide further information to assist in the care of the patient (see, for example, alternative testing methods in Ch 21, Allergies).

In the treatment phase, it is a matter of ascertaining treatments for the patient's condition, including any appropriate CAM options, and working with the patient to devise a treatment plan. An integrative approach may be appropriate for some conditions but not others (see, for example, Ch 42, Skin).

It is clear from existing professional guidelines that evidence-based CAM is relevant to the practice of integrative medicine.[22,30] The RACGP-AIMA position statement on complementary medicine states that:

> evidence based medicine should be the basis of evaluating complementary medicine and/or therapies and their use by the medical profession. It should also be the basis of any collaborative relationship between general practitioners and complementary therapists.[30b]

The RACGP-AIMA statement adopts the Sackett et al definition of evidence-based medicine as:

> the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice.[30c,31]

The RACGP policy on evidence-based medicine is also relevant to decision-making about CAM treatments. This policy refers to the evidence-based approach incorporating three components: the best evidence available, the biopsychosocial circumstances of the patient, and the clinical skills and judgment of the doctor.[32] Evidence-based medicine therefore involves more than the highest levels of scientific validation. It is an assessment that considers all treatments, conventional and complementary, across a multidimensional spectrum that takes into account safety and efficacy, and 'practicality, availability, utility and cost effectiveness as well as other dimensions'.[33a] And adopting an evidence-based approach to CAM is not so much about having specific knowledge as it is about acquiring evidence-based medicine problem-solving skills, and having access to texts, databases, peer networks and CAM prescribing software.[34a]

Bearing in mind the legal obligation to act reasonably and take reasonable steps to avoid foreseeable risks that are 'not insignificant', the level of evidence required will depend on the circumstances. Where treatments are potentially toxic, or where the treatment is being proposed as an alternative to biomedicine, higher levels of evidence will be necessary. With low-risk therapies, or where there is no biomedical treatment available for the condition and the CAM treatment is known to be safe, lower levels of evidence are more likely to be acceptable. Of course, doctors should ensure that the patient has realistic expectations about what can be achieved by the CAM therapy, particularly where the evidence available is equivocal.[35a]

Cohen and Eisenberg have devised a decision-making grid based on an analysis of the evidence available for safety and efficacy.[36] The grid is a useful risk management tool and provides guidelines on when CAM could be recommended, when it should be avoided, and when it could be implemented with close monitoring.

## REFERRAL IN INTEGRATIVE PRACTICE

In referral, as with the other aspects of the doctor's duty, reliance must be placed on the general principles of the law of negligence and relevant professional guidelines.

Doctors may be concerned about the potential for legal liability, such as vicarious liability (liability for the negligent conduct of another), arising from referral to CPs. Whether a referral from a doctor to a CP gives rise to the potential for vicarious liability will depend on the nature of the relationship. Where the CP is someone with whom the doctor has a pre-existing legal relationship—employee, independent contractor, business partner or licensee—there may be the potential for such liability. Doctors making referrals to such CPs should seek legal advice.

Where there is no pre-existing legal relationship, it is unlikely that the doctor will be found responsible for any negligent conduct of the CP to whom a patient is referred. However, the doctor may be liable for making a negligent referral because, for example, the CAM modality was inappropriate for the patient's condition, or the CP was not appropriately qualified to provide the healthcare. The 2002 decision of the New South Wales Court of Appeal, *McGroder v Maguire,* illustrates the difference well, because in that case the doctor was liable for a negligent referral to a chiropractor, but not for the negligence of the chiropractor to whom the referral had been made.[xviii]

To avoid a negligent referral, there appear to be two primary considerations—choosing a modality that is appropriate for the patient's condition, and referring the patient to a suitably qualified health practitioner, whether that be another doctor or a CP. Other considerations relate to the need to establish reasonable communication with the health practitioner, and an appropriate level of biomedical review of the patient's condition.

The RACGP-AIMA joint position statement refers to the need for referral to be based on evidence-based medicine. This means that the evidence-based considerations outlined above in relation to treatment also apply to decision-making about referral.[30b]

The referral from a doctor to a CP may be viewed as similar to a referral to an allied health practitioner, such as a physiotherapist, particularly where the CP is regulated by statute—that is, osteopaths and chiropractors in all Australian jurisdictions, and traditional Chinese medicine practitioners in Victoria. Where a CP is regulated by statute, the task of referral is simplified, as it is reasonable for a doctor to rely on statutory registration as indicating an acceptable level of knowledge and competence, in the absence of evidence to the contrary. However, there are many CPs within Australia who are not regulated by statute. Instead, most CPs are self-regulated through professional associations, although there may be some CPs who are not regulated at all, as membership of professional associations is voluntary.

The La Trobe University School of Public Health review of the regulation of naturopathy and Western herbal medicine severely criticised the self-regulation of these two CAM modalities.[6] Among the factors criticised were: the proliferation of education providers in the CAM field, which had resulted in a lack of appropriately qualified teaching staff (most are sessional); a limited research environment; inconsistent arrangements for clinical training; and lack of standardisation of educational requirements or significant movement to align curricula so that practitioners using the same title,

such as 'naturopath', have the same knowledge base.[6] Given this recent evidence, a CP's membership in one or more of the numerous self-regulating professional associations may not be a sufficient basis for decisions in relation to referral. The reasonable doctor may need to take further steps to ensure that the CP is qualified to provide the necessary healthcare to the patient.

General practitioners surveyed in 2000 were noted to be more concerned about CPs (such as practitioners of chiropractic, Chinese herbal medicine, herbal medicine, naturopathy and homeopathy) acting as primary carers, including in relation to serious illness, without recourse to GPs, and the potential for delayed and missed diagnosis, than the risk posed by the actual CAM therapies.[13] Therefore, setting aside formal considerations, such as qualifications, there are other matters that a doctor may also want to be reasonably confident about when making a referral. For example, does the CP regularly assess the progress of a patient and cease treatment when the condition is alleviated or the treatment is shown to be ineffective? Does the CP know when and how to refer the patient on for medical management?[35,37]

It may also be prudent to provide a written referral to the CP. A written referral provides contemporaneous documentary evidence of the nature of the referral and the expectations of the doctor. This will become relevant in the event of an adverse outcome and any subsequent legal or complaints processes. Relevant referral information may include the medical history, the clinical examination and findings, the biomedical diagnosis and treatments, and the goals of treatment.[35] It is reasonable to suggest that the more serious the condition, the greater the need for comprehensive information. In some circumstances it may also be appropriate for the doctor to ask the CP to assess the patient and provide advice about whether the practitioner and the CAM modality could assist in the care of the patient's medical condition.

There is a great deal that needs to occur at the state and national policy level to facilitate appropriate referrals between doctors and CPs, including the regulation of CPs. Traditional Chinese medicine practitioners will be regulated under the National Registration and Accreditation Scheme for the healthcare professions from 1 July 2012.[xix] There are no current plans for naturopaths and Western herbal medicine practitioners to be included in the national scheme although there have been recommendations that these healthcare professions be regulated by statute.[6,38]

There is a need for detailed guidelines and protocols for doctors in relation to referral, and no doubt these will be forthcoming from bodies such as the RACGP and AIMA in the near future. In the meantime, enquiries to professional bodies will assist in establishing relevant standards and widely accepted practice in the area of referral. For example, do GPs interview CPs and seek reference checks from peers who have worked with a CP before making a referral?[35]

## INFORMED DECISION-MAKING IN INTEGRATIVE PRACTICE

A doctor has an ethical and legal obligation to provide information and advice to enable a patient to make an informed decision, and increasingly this includes evidence-based CAM options for healthcare.

The doctor's *ethical* obligation to provide information and advice is set out in the *General Guidelines for Medical Practitioners on Providing Information to Patients*.[39,xx] The guidelines are not mandatory standards but they reflect good medical practice and may be relevant evidence in disciplinary proceedings or medical litigation. The professional obligation includes not only information about risks, such as the possibility and probability of complications and side effects, but also the benefits and likely outcomes of treatment, and alternative treatment options.

In the 1992 decision of *Rogers v Whitaker*, the Australian High Court held that a doctor has a duty to provide information and advice about the material risks of any planned procedure. A risk is material:

> if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it [the proactive limb of the test] or if the medical practitioner is or should be reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it [the reactive limb of the test] *(the test of materiality)*.[xxi]

While in *Rogers v Whitaker* the court was focused on material risks (the case was concerned with the risks of eye surgery), the doctor's legal obligation to provide information and advice also includes other types of information, such as benefits and alternative treatment options, to enable a patient to make a meaningful decision.

If the proactive limb of the test of materiality is operating, a doctor has to turn his or her mind to what the reasonable person in the position of the patient would want to know. On the other hand, if the patient asks questions, the reactive limb of the test is engaged and the specific concerns of the patient must be addressed, no matter how unreasonable those concerns may be.[xxii] And the reactive limb will operate not only where the doctor knows of the specific concerns of the patient, but also where the doctor should have known of those concerns. If, for example, the patient does not expressly ask about CAM options but the doctor is aware from the patient's history that the patient regularly uses CAM, then it is likely that the doctor should have known that

the patient would find information about CAM options material.

The peer professional opinion test pertaining to the doctor's duty in relation to examination, diagnosis, treatment and referral is not applicable to the provision of information and advice. Instead of medical opinion, it is the court that is the final arbiter as to whether the doctor acted reasonably in providing information and advice, given the application of the patient-centred test of materiality outlined above.

While the AMA left it to the individual doctor to decide whether to adopt direct use of CAM therapies, it clearly saw the need for doctors to have at least a basic understanding of CAM, to enable advice to be provided to patients about CAM.[22] The RACGP-AIMA position statement on complementary medicine also notes that GPs 'should be sufficiently well informed about complementary medicines and/or therapies to be able to provide advice to patients when appropriate'.[30d]

I have argued elsewhere that a doctor may have a legal obligation to advise a patient about evidence-based CAM treatment options where those options are reasonably available, and where that information would be significant to the particular patient or the reasonable person in the position of the patient.[40] Since the publication of that argument there have been a number of changes that put the argument on a stronger footing. Not changes in the law but, rather, the increasing evidence of safe and efficacious CAM, and evidence that nearly 70% of the population now have an interest in CAM healthcare options (it was previously thought that 52% of the population were CAM users).[5,12]

Of course, in the integrative context it is important to remember that patients should also be advised about standard biomedical treatments. And if a patient refuses to accept biomedical treatment after being informed and advised, trying to persuade the patient to submit to biomedical treatment may not be helpful or necessary from a legal point of view. Instead, through discussion and negotiation, a 'wise agreement' can be developed in relation to a treatment plan which may include the trialling of CAM options with an appropriate level of monitoring.[41a] A doctor can also enhance, rather than jeopardise, the therapeutic relationship by engaging in a dialogue with the patient. It is necessary for the doctor to remain open to the patient's use of CAM and explore the patient's concerns, health goals and reasons for using CAM.[7,42] It is also important from a professional and a legal point of view that the treatment plan and the patient's informed decision be documented. This documentation will assist in the event of an adverse outcome, if the matter becomes the subject of disciplinary proceedings, a coronial inquiry or medical litigation.

## REGULATION OF COMPLEMENTARY MEDICINES

It is essential for doctors to have a good working knowledge of how CMs are regulated. Without this information, practitioners are not in a position to advise consumers and prescribe such treatments competently.

Complementary medicines include vitamins, minerals, herbs and nutritional supplements, homeopathic medicines and some aromatherapy products. Complementary medicines are given different labels in other countries. In Canada, for example, they are referred to as 'natural health products'. The regulation of CMs also varies greatly internationally. There is minimal regulation in some countries, such as New Zealand, where there is no pre-market scrutiny of safety and quality.[43] In other jurisdictions, CMs are heavily regulated. In Germany and France, for example, herbal medicines at least are regulated like pharmaceuticals, with pre-market approval of safety, quality and efficacy.[44] Australia's regulatory scheme for CMs is robust but the regulatory approach is based on the low-risk profile of CMs. A brief introduction to the regulatory scheme is provided here. For more details, you are referred to other resources.[xxiii]

Complementary medicines are regulated under the Therapeutic Goods Act 1989 (Cth) (TG Act) and Therapeutic Goods Regulations 1990 (Cth) (TG Regs).[xxiv] The regulatory scheme is administered by the Therapeutic Goods Administration (TGA). The Office of Complementary Medicines (OCM) is a discrete, administrative group within the TGA established to focus exclusively on the regulation of CMs. The Complementary Medicines Evaluation Committee (CMEC) is an expert committee that evaluates CMs and provides scientific and policy advice to the TGA.

All therapeutic goods (including CMs) must be registered with the Australian Register of Therapeutic Goods (ARTG) established under the TG Act. Most CMs are 'listed' goods and prescription medicines are 'registered' goods under the ARTG. The distinction is important, as registered goods are subject to efficacy requirements prior to marketing, but listed goods are not.[xxv]

The Australian regulatory approach aims to achieve a balance between the four regulatory objectives (safety, efficacy, quality and timely availability) through the licensing of manufacturers, good manufacturing requirements, a pre-market safety evaluation of therapeutic substances to be included in CMs, and post-market surveillance, including a system for reporting adverse events.[xxvi]

Pharmaceuticals have a narrow therapeutic window, and apart from over-the-counter medication, access is restricted via prescription according to requirements

under drugs and poisons legislation.[xxvii] Many complementary medicines, on the other hand, have a wide therapeutic window, and are widely available without prescription through outlets such as pharmacies, health food stores and supermarkets.

Listed CMs are not evaluated for safety, although the therapeutic ingredients that are incorporated into listed CMs are evaluated. Listed CMs are also not evaluated for efficacy in the same way as prescription medicines, and this enables the products to be marketed fairly quickly. At the same time, the claims that can be made for listed CMs are limited to general and medium-level claims. For example, a medium-level claim based on traditional use of the medicine could state that: 'this traditional Chinese medicine has been used for the relief of the symptoms of eczema. If symptoms persist, consult your healthcare practitioner'.[45a] Sponsors of the CM must hold evidence related to the level of the claim that is made prior to marketing.[xxviii]

The Australian regulatory scheme was evaluated in 2003 and considered appropriate for CMs, but doctors should be aware of current gaps in the regulation of CMs. First, there are risks that arise as a result of the lack of regulation of raw herbs, including misidentification, heavy metal and toxin contamination, inadvertent or deliberate substitution, and adulteration with Western pharmaceutical products.[6] While these matters are being addressed by the regulator it may be necessary to inform a patient about such risks. Second, there is no regulation requiring the standardisation of herbal ingredients in CMs. Without regulation to define the standardisation of herbal ingredients, and what is necessary to meet that definition, there is no consistent approach between manufacturers. This can lead to potential variations in dosages within and between brands, even resulting in sub-potent and super-potent dosages, compromising herbal treatment.[6] These matters may need to be considered when informing a patient about the risks of some treatments and when prescribing CMs.

The regulatory scheme for CMs includes a voluntary scheme for reporting adverse events. It would be prudent to be aware of reports of adverse reactions as well as alerts and advisories provided by the TGA in relation to complementary medicines, and to take these into consideration when prescribing treatment and advising patients. Information can be received regularly via email through the *Australian Adverse Drug Reactions Bulletin*.[46]

Australia's National Medicines Policy (NMP) complements the regulation of pharmaceuticals and CMs by the TGA. It focuses on the appropriate use of medicines once they are in the market. Central to this policy is the National Strategy for Quality Use of Medicines (QUM) authored by G Moses.[47] Moses, a pharmacist, has developed guidelines based on the QUM principles—called 'complementary medicine protocols'—to assist pharmacists and other integrative health practitioners to advise consumers about CMs. The guidelines assist a practitioner to make decisions about CM use through a six-step analysis. For example, in the case of heart failure, is it appropriate to use the herb hawthorn 'before, with or after digoxin?'.[47] The protocols may be a useful tool to assist with integrating CMs into the care of a patient.

## REGULATION OF HEALTH SERVICES UNDER MEDICARE

Integrative medicine involves more than substituting CMs for pharmaceuticals. Integrative medicine also:

> aims to shift some of the basic orientations of medicine: toward healing rather than symptomatic treatment, toward a closer relationship with nature, toward a strengthened doctor–patient relationship and an emphasis on mind and spirit in addition to body.[48a]

And this broad vision is incorporated into the RACGP definition of integrative medicine.[1] The RACGP acknowledges that the integration of complementary medicines is a central aspect of integrative medicine, but also emphasises that, like general practice, integrative medicine 'embraces and encourages a holistic approach to practice incorporating patient involvement in self health care, prevention and lifestyle interventions'.[1a]

The holistic approach to the patient and relationship in integrative practice may diminish the potential for legal liability, as it is well documented that lack of good communication and failure to include the patient's perspective is responsible for most formal complaints and litigation.[49] However, working with the patient to strengthen the relationship and empower the patient to take greater responsibility for the healthcare takes time, and longer patient consultations tend to be a feature of integrative practice. As integrative practitioners often work with those with chronic and complex conditions, this care also takes time and may require greater pathology testing.[50] It is important therefore that doctors practising integrative medicine meet regulatory requirements when providing services funded by Medicare Australia.

Patient consultations, and other services such as pathology requests, provided by doctors and other health practitioners under Medicare are monitored and, where considered necessary, investigated. The regulatory task is shared by three entities: Medicare Australia, the Professional Services Review Scheme (PSRS) and the Determining Authority.[xxix]

The object of the regulation is to protect patients from the risks, and the public purse from the cost, of inappropriate practice. The regulator is concerned with

conduct, such as a high volume of rendered services, a high average number of services per patient and high levels of prescribing under the Pharmaceutical Benefits Scheme (PBS). The services of practitioners are monitored by Medicare Australia through a review process that includes the use of statistics, and in particular the use of a normal distribution or bell curve.[xxx] The focus of the monitoring is usually the outer right of the bell curve within the third standard deviation from the mean, where 2.5% of occurrences sit. For example, GPs who are the highest users of a particular Medical Benefits Schedule (MBS) item under Medicare, such as long consultations and pathology testing, have the potential to come under the scrutiny of the regulator, because their pattern of consultations will lie outside that of most GPs.

The CEO of Medicare Australia can request that the director of the PSRS review the provision of services of a practitioner. This review may result in the director taking no further action or entering into an agreement with the practitioner about future conduct. Alternatively, the director may make a referral to the Professional Services Review Committee (PSRC), who investigate and make findings about whether the practitioner has engaged in 'inappropriate practice' in connection with the rendering or initiation of services for which a Medicare benefit was payable. A GP would be engaging in inappropriate practice if his or her conduct in rendering or initiating a service was such that it could reasonably be concluded that the conduct would be unacceptable to the general body of GPs. A service provided must be clinically relevant—that is, generally accepted by the medical profession as necessary for the appropriate treatment of the patient. And the PSRC must have regard (in addition to other relevant matters) as to whether or not the practitioner kept adequate and contemporaneous records in the rendering of the services.[xxxi]

In the event of a finding of inappropriate practice, the Determining Authority decides what sanctions to impose. This will include one or more sanctions such as a reprimand, counselling or cessation of Medicare payments.

Under Medicare, eligibility for rebates is limited by strict criteria, as set out under the MBS item. When billing for long consultations (or other MBS items) it is recommended that GPs consider two questions: does the service rendered comply with the time and content requirements of the MBS item descriptor; and would the majority of my peers accept that the treatment provided during the service is clinically appropriate for this patient? If the answer is a confident yes to both questions and the GP has adequate, contemporaneous documentation of the consultation, this should place the GP in good stead in the event of an audit by the regulator.[xxxii] Where a doctor is also engaged in 'integrative medicine' tasks, they need to be accommodated in addition to the MBS criteria for the specific consultation claimed.

Doctors should ensure that pathology testing is clinically appropriate for the treatment of the patient. Sometimes it is necessary to educate patients who are anxious to have regular pathology tests that clinical outcomes are often more important than pathology tests. And there may be circumstances where it is appropriate to pass on the costs of some pathology tests to patients.[xxxiii]

A recent review of the PSRS has recommended a number of changes to the scheme. The review acknowledges the growing number of special-interest practices, such as integrative medicine, and the difficulty of identifying inappropriate practice in these areas, due to different work practices.[51] This acknowledgement provides an opening for bodies such as the RACGP and AIMA to raise concerns about Medicare and integrative practice, including the role and significance of long consultations, with the aim of bringing about appropriate regulatory change to facilitate the practice of integrative medicine. Some initial discussions have taken place between the AIMA and the PSRS.[xxxiv] In 2008 the Minister for Health, Nicola Roxon, also indicated that the Department of Health and Ageing will examine whether current general practice requires changes to Medicare items, including items for long consultations.[xxxv]

## CONCLUSION

Integrative medicine is evolving rapidly and there is an increasing obligation on the part of doctors to become familiar with evidence-based CAM and to provide information and advice to patients about CAM options, to enable patients to make informed decisions. It is critical that doctors acquire the necessary knowledge and skills and become familiar with guidelines that are indicative of the standard of care and widely accepted practice before embarking on an integrative approach. The law does not make allowances for the inexperienced.[xxxvi]

It would be prudent to check with your medical indemnity insurer to establish that the particular practices you plan to adopt are covered by the insurer. And always consult with professional and regulatory bodies, and seek legal advice about particular circumstances where necessary.

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## NOTES

i This definition appears frequently in the literature. It is variously attributed to the Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine) and the Cochrane Collaboration, but does not appear on either website. The definition appears to be in general usage.

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vi See: *Wyong Shire Council v Shirt* (1980) 146 CLR 40, 47-8 (Mason J); Wrongs Act 1958 (Vic) s. 48; Civil Liability Act 2003 (Qld) s. 9; Civil Liability Act 2002 (NSW) s. 5B; Civil Liability Act 2002 (Tas) s. 11; Civil Law (Wrongs) Act 2002 (ACT) s. 43; Civil Liability Act 2002 (WA) s. 5B(1); and Civil Liability Act 1936 (SA) s. 32.

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x See *Dobler v Kenneth Halverson* (2007) 70 NSWLR 151 (Giles, Ipp and Basten JJA).

xi See Civil Liability Act 2003 (Qld) s. 22 (not limited to Australian opinion); Civil Liability Act 2002 (NSW) s. 50 (limited to Australian opinion); Civil Liability Act 2002 (Tas) s. 22 (limited to Australian opinion); Civil Liability Act 1936 (SA) s. 41 (limited to Australian opinion); Civil Liability Act 2002 (WA) s. 5PB (not limited to Australian opinion). In these jurisdictions if the court determines that the peer professional opinion is irrational (rather than unreasonable, as in Victoria) it cannot be relied on. Ipp-related statutory reforms in the Northern Territory and the Australian Capital Territory do not include the peer professional opinion test and so the common law remains applicable. See *Rogers v Whitaker* (1992) 175 CLR 479.

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xx See also guidelines on informed decision-making provided by Medical Boards and the RACGP.

xxi *Rogers v Whitaker* (1992) 175 CLR 479, 490 (Mason CJ, Brennan J, Dawson J, Toohey J, McHugh J).

xxii *Rosenberg v Percival* (2001) 205 CLR 434, 500 (Callinan J).

xxiii See: Therapeutic Goods Administration website at http://tga.com.au; Commonwealth of Australia, *Expert Committee on Complementary Medicines in the Health System—Report to the Parliamentary Secretary to the Minister for Health and Ageing* (2003) http://www.tga.gov.au/docs/html/cmreport1.htm 24 March 2009; Hall J. Recent developments in complementary medicines regulation. In: Cohen M, ed. The art and science of holistic health; 2005:120.

xxiv Because of the Commonwealth's limited ability to regulate the entire field of therapeutic goods, and the failure of most other jurisdictions to pass complementary legislation, some 'therapeutic goods' may not be regulated. Commonwealth of Australia, Expert Committee on Complementary Medicines in the Health System – Report to the Parliamentary Secretary to the Minister for Health and Ageing, 2003, http://www.tga.gov.au/docs/html/cmreport1.htm 24 March 2009.

xxv It is possible for CMs to be registered goods provided they meet all the requirements of registration. As it is a lengthy and costly process and is not mandatory for CMs, few are actually registered goods: Commonwealth of Australia, Expert Committee on Complementary Medicines in the Health System—Report to the Parliamentary Secretary to the Minister for Health and Ageing, 2003, http://www.tga.gov.au/docs/html/cmreport1.htm 24 March 2009.

xxvi There are also labelling and advertising requirements under the TG Act, TG Regs and the Therapeutic Goods Advertising Code 2007.

xxvii See, for example, Drugs, Poisons and Controlled Substances Act 1986 (Vic) and Drugs, Poisons and Controlled Substances Regulations 2006.

xxviii The evidence can be traditional use, including evidence set out in a TGA-approved monograph, or it may be scientific evidence, including evidence such as case studies: Australian Government Therapeutic Goods Administration, Guidelines for levels and kinds of evidence to support indications and claims: for non-registrable medicines, including complementary medicines and other listable medicines, 2001, http://www.tga.gov.au/docs/pdf/tgaccevi.pdf 24 March 2009.

xxix See Health Insurance Act 1973 (Cth) Part VAA.

xxx See Bell R. Medicare regulation through professional services review—lessons learned. In: Freckleton I, ed. Regulating health practitioners; 2006:113.

xxxi Health Insurance Act 1973 (Cth) s. 82, s. 10, s. 3.

xxxii Department of Health and Ageing. Fact sheet: Correct claiming of Medicare Group A1- level C and D items, http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/AD01CA668C5E4588CA2574E40017C10D/$File/Fact_Sheet-Level_C_and_D_items.pdf 24 March 2009.

xxxiii See Woolhouse M. Feeling safe under the Medicare system. JAIMA 2009; 14(1):6–7.

xxxiv See Woolhouse M. Feeling safe under the Medicare system. JAIMA 2009; 14(1):6–7.

xxxv Department of Health and Ageing. Fact sheet: Correct claiming of Medicare Group A1- level C and D items, http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/AD01CA668C5E4588CA2574E40017C10D/$File/Fact_Sheet-Level_C_and_D_items.pdf 24 March 2009.

xxxvi *Jones v Manchester Corporation* (1952) 2 QB 852; *Imbree v McNeilly* [2008] Aust Torts Reports 81-966.