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DOCTORAL THESIS

A new model for the regulation of complementary and alternative medicine in Australia

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Chapter 1

What is complementary and alternative medicine?

Introduction

This chapter provides a definition of CAM and OM and deals with the fundamental criteria at the basis of the CAM healing philosophy. The current usage of CAM and its philosophy sets the scene for the conflicts with OM discussed in later chapters.

Definition of Western Medicine

For the purpose of the analysis in this thesis CAM needs to be defined. This task requires an understanding of the parameters of OM. As OM is so dominant in most western countries CAM is often, and arguably inappropriately, defined by its relationship to OM. OM, sometimes called western modern medicine, has been defined as ‘medical interventions which are widely taught in modern western medical schools or are generally available at U.S. hospitals, and that which is used by the majority of medical physicians in modern western industrialized countries.’³

Its critics sometimes characterize OM as ‘allopathy.’ Allopathy is a system of healing that counteracts disease by using remedies that produce opposite results from those produced by

³ Andries Kleynhans, ‘The Alternative and Complementary Health Care Perspective’ in Russell G Smith (ed), *Health Care, Crime and Regulatory Control* (1998) 97.

the disease.⁴ ‘Allopathic medicine by definition combats, counteracts, and aggressively opposes specified disease entities.’⁵ This is a term deemed derisory by OM as it does not reflect the modern complexity and sophistication of OM⁶ and it is claimed may demonstrate bias by those that use this term.⁷ The emphasis upon the role of allopathy as the fundamental approach of orthodox medicine is less prominent in modern times.

Orthodox medicine today designates itself as ‘scientific medicine’ to differentiate itself from CAM as well as justifying its predominance in society and in state medicine. At the beginning of the twentieth century the allopathic philosophy was the fundamental differentiation to homoeopathy, the most influential of CAM modalities in that period. Homeopathy relies on the opposed doctrine of similars that suggests that a healing response will occur if minute doses of a remedy are given containing a substance that will produce the same symptoms as the disease.⁸

CAM - Definition

There are many terms used to describe the practice of medicine outside of the scope of western or orthodox medicine. Terms used to describe these modalities include ‘complementary and alternative medicine’, ‘holistic medicine,’ ‘complementary medicine,’ ‘natural medicine,’ ‘traditional medicine,’ ‘holistic medicine,’ ‘natural therapies’ and ‘unorthodox medicine.’ It is difficult to categorize the varied practices and modalities of CAM under any particular term as they vary greatly in emphasis, philosophy, origin and

4 J F Drane (ed), *Encyclopedia of Bioethics* vol 1-5 (1997) 135.

5 Ibid 136.

6 Paul Starr, *The Social Transformation of American Medicine* (1982) 98.

7 J Crellin and F Ania, *Professionalism and Ethics in Complementary and Alternative Medicine* (2001) 11.

8 Encyclopedia, above n 4, 136.

therapeutic outlook.⁹ OM by comparison is much more homogeneous in outlook and underlying principles though OM exhibits differences in emphasis in sub-disciplines such as psychiatry and surgery. This homogeneity derives from its emphasis on the scientific practice of medicine. What is alternative or complementary from an OM perspective may be ‘traditional’ or ‘mainstream’ for some ethno-cultural groups such as the use of traditional Chinese medicine by the Chinese community. A therapy may be complementary in one context, for example the use of acupuncture to deal with pain in conjunction with analgesic, and alternative in another, where acupuncture is used instead of physiotherapy for muscular pain.¹⁰

In this thesis the term ‘complementary and alternative medicine’ (CAM) will be used. This is used as a general term for discussion and analysis. The term CAM is used in an attempt to incorporate the widest possible scope for the various modalities although it is acknowledged it perpetuates the tendency to define these therapies or models of healing from the perspective of orthodox medicine.¹¹ Rather than positively identifying this group of therapies they are defined negatively as against their integration or otherwise with the dominant force in the health sector.¹²

9 British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (1993) 7; Andrew Vickers, ‘Research Paradigms in Mainstream and Complementary Medicine’ in E. Ernst (ed), *Complementary Medicine: An Objective Appraisal* (1996) 7; K M Boozang, ‘Is the Alternative Medicine? Managed Care Apparently Thinks So’ (2000) 32 *Connecticut Law Review* 567, 574; Kleyhans, above n 3, 96-101.

10 York University Centre for Health Studies, *Complementary and Alternative Health Practices and Therapies – A Canadian Overview – Conceptual Package* (1999) 1.

11 Norman Gevitz, ‘Three Perspectives on Unorthodox Medicine’ in *Other Healers: Unorthodox Medicine in America* (1988) 2. Boozang above n 9, 572; Michael H Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (1998), (viii); Crellin and Ania, above n 7, 10.

12 Canadian Overview, above n 10, 13.

CAM has been defined as therapies not taught in US medical schools.¹³ The British Medical Association defined non-conventional therapies as ‘those forms of treatment which are not widely used by orthodox health-care professions, and the skills of which are not taught as part of the undergraduate curriculum of orthodox and paramedical health-care courses.’¹⁴ This definition is potentially very problematic for OM practitioners who might seek to integrate CAM into their practice. This type of definition could suggest that this practice is a deviation from conventional standards of care, making them potentially liable for negligence or professional disciplinary action.¹⁵

This negative definition of CAM is increasingly less valid as many medical schools in Australia and overseas now incorporate CAM into their curriculum. This integration is easily overstated as CAM is most often not addressed as a separate compulsory subject but as a topic within a compulsory subject or in an elective.¹⁶ In one survey sixty four percent of USA medical schools surveyed offered 1 or more courses in CAM or these topics were covered in required courses. Twenty-eight of the medical schools surveyed (37%) offered 2 or more courses.¹⁷ A Working Party of the Australian Medical Council Accreditation Committee in 1998 ascertained that all twelve medical schools in Australia and New Zealand provide at least some training in CAM as part of their degree. One medical school sought advice of an

13 Marc S Micozzi, ‘Characteristics of Complementary and Alternative Medicine’ in Marc S Micozzi (ed), *Fundamentals of Complementary and Alternative Medicine* (1996) 5; David M Eisenberg, ‘Advising Patients Who Seek Alternative Medical Therapies’ (1997) 127 *Annals of Internal Medicine* 61, 61.

14 British Medical Association, above n 9, 7-8; WB Jonas, ‘Alternative Medicine-Learning from the Past, Examining the Present, Advancing to the Future’ (1998) 280 *Journal of the American Medical Association* 1616, 1616; Kleyhans, above n 3, 98-101.

15 Michael H Cohen, *Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution* (2000) 25.

16 Canadian Overview, above n 10, 12; Australian Medical Council, AMC Discussion Paper: *Undergraduate Medical Education and Unorthodox Medical Practice* attachment 1.

17 M.S. Wetzel, D.M Eisenberg and TJ Kaptchuk, ‘Courses Involving Complementary and Alternative Medicine at U.S. Medical Schools’ (1998) 280 *Journal of the American Medical Association* 784,787; Boozang, above n 9, 572-573.

alternative medicine organization and one half planned to increase course offerings in this area.¹⁸

The level of medical education in CAM is generally perfunctory and below the standard of many lay practitioners of CAM. This education is primarily aimed at a general understanding of CAM to assist students to appreciate what patients might be receiving from CAM practitioners, the indications and contraindications for these therapies, and how they might interact with OM.¹⁹ Despite the limited sophistication of OM education in CAM the increased interest in CAM by medical doctors is reflected in the expansion of publications and online resources on the scientific basis for CAM.²⁰

CAM is often called ‘alternative medicine’. This may aptly describe the clinical approach of some practitioners of modalities such as traditional Chinese medicine or homoeopathy. These modalities seek to provide an alternative to orthodox medicine as complete systems of healing not limited to a part of the body or a limited set of treatment options.²¹ The term ‘alternative medicine’ may appear to marginalize CAM as necessarily existing outside the mainstream health care sector.²² This term may also concern some regulators who might consider this term promotes the rejection of OM as an appropriate adjunct or treatment option for some maladies. Some registered modalities such as chiropractic, that is supported by substantial scientific evidence, may object to the label ‘alternative medicine’ or

18 Australian Medical Council, above n 16 attachment 2.

19 S Fulder, *The Handbook of Alternative and Complementary Medicine* (3rd ed, 1996) 18; Michael H Cohen, ‘Holistic Health Care: Including Alternative and Complementary Medicine In Insurance and Regulatory Schemes’ (1996) 38 *Arizona Law Review* 83, 105.

20 John Weeks, ‘Major Trends in the Integration of Complementary and Alternative Medicine,’ in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 5 eg The Integrator www.onemedicine.com; Alternative Medicine Alert www.ahcpub.com/ahc_root_html/products/newletters/ama.html ; Alternative Therapies in Health and Medicine; American Journal of Acupuncture.

21 British Medical Association, above n 9, 7

‘complementary medicine’. These practitioners may perceive their profession as part of orthodox medicine.²³

In the current political and social context the use of the term ‘alternative medicine’ does not reflect the views or approaches of all modalities or practitioners. Many practitioners would both accept the significant role of OM and acknowledge its dominance of the health sector. There is evidence to suggest that most people use CAM alongside OM.²⁴ Alternative medicine may also not be an entirely satisfactory description as it merely describes a modality that is not orthodox medicine. In that sense that term does not perform a function.²⁵

The title given to CAM remains a political issue from the perspective of orthodox medicine as is demonstrated by the comments in the Australian Medical Council Discussion Paper on Undergraduate Medical Education and Unorthodox Medical Practice.²⁶ In a footnote to the paper after defining orthodox, conventional or scientific medicine the paper states it intends to use the term ‘unorthodox medicine’ because the more commonly used collective terms ‘alternative’ and ‘complementary’ are unsatisfactory.

Their plain meanings are irreconcilable with one another since a therapy cannot both be complementary and alternative at the same time. Moreover, these terms can be construed as endorsing such practices as equivalent (alternative) to scientific medicine or compatible (complementary) to it.²⁷

22 Richard A. Haigh, ‘Reconstructing Paradise: Canada’s Health Care System, Alternative Medicine and the Charter of Rights,’ (1999) 7 *Health Law Journal* 141, footnote 1, 142.

23 John W Spencer, ‘Essential Issues in Complementary and Alternative Medicine’ in John W Spencer and JJ Jacobs (eds), *Complementary/Alternative Medicine An Evidence Based Approach* (1999) 5; Boozbank, above n 9, 575.

24 Wayne B Jonas and Jeffrey S Levin, ‘Introduction: Models of Medicine and Healing’ in W B Jonas and JS Levin (eds), *Essentials of Complementary and Alternative Medicine* (1999) 4.

25 Bridgit Dimond, *The Legal Aspects of Complementary Therapy Practice: A Guide for Health Care Professionals* (1998) 7.

26 Above n 15.

27 Ibid footnote 1.

The term 'complementary medicine' suggests a modality may work in conjunction with or alongside orthodox medicine. This term would be apposite especially for modalities such as therapeutic massage that could readily be applied in conjunction with orthodox medical treatment. Some would view this label as inappropriate for homeopathy as its therapeutic philosophy is radically opposed to the allopathic approach to medicine and thereby in no way complementary.²⁸ In recent years fears that medically qualified homoeopaths may limit the practice of homoeopathy for non-medically trained persons has led in the U.K. to a softening of this view and an acceptance of a complementary role for homoeopaths.²⁹

Other terms such as 'natural medicine' or 'natural therapies' may be appropriate terms in some contexts but some therapies such as herbal medicine involve the ingestion of herbs which may not be considered entirely natural. The term 'natural therapies' is commonly used by medical doctors with emphasis on the word 'therapies' to avoid any implications these modalities offer any broad based approach to medicine. This tendency is particularly marked when nurses discuss the use of CAM and confirms the subjugation of this profession to OM only now being addressed.³⁰ The term 'unorthodox medicine' is a term that ignores the extent to which CAM is incorporated into orthodox medicine.³¹

For modalities that originated many centuries ago such as Ayurvedic medicine, acupuncture and TCM the term 'traditional medicine' may be apt. This will not apply to most modalities.

28 Haigh, above n 22, 142.

29 Sarah Cant and Ursula Sharma, 'Professionalization of complementary medicine in the United States' (1996) 4 *Complementary Therapies in Medicine*, 166-67; Sarah Cant and Ursula Sharma, 'The Reluctant Profession - Homoeopathy and the search of legitimacy' (1995) 9 *Work Employment and Society* 743, 755.

30 Pauline McCabe, 'Current and Potential Nursing Roles in Complementary Health Care' in *Complementary Therapies in Nursing From Vision to Practice* (2001) 3.

31 Walter Wardwell, 'Alternative Medicine in United States' (1994) 38 *Social Science and Medicine* 1061, 1061.

These traditional medicine modalities can comfortably fit within the term CAM in the modern context.

The term 'holistic medicine' has been used to describe CAM. This description identifies the attempts by these modalities to deal with the healing process beyond the physical level. Most CAM practitioners will deal with spiritual, emotional and lifestyle issues in their dealings with a client. The term may not be apt to describe all modalities that may rely at least in part upon a biomedical approach and a 'body as machine' model.³²

It should be understood that the definition of CAM is fluid as society, legal structures and orthodox medicine develops and good quality scientific evidence of efficacy becomes available. This may lead to CAM becoming more integrated into the health sector whether as part of the therapies offered by medical doctors or by non-medically trained practitioners. What was alternative, complementary or unacceptable practice at one time may fit into another category at a later date.³³ In recent times the medical profession has, from an evidence based perspective, stated that it disagrees with the designations OM and CAM as there are in fact only 2 forms of medicine – proven and unproven.³⁴ If CAM is backed by good scientific evidence it is proven and acceptable practice for a medical doctor. As scientific evidence for CAM develops this statement may reflect reality, but currently the history of suspicion between CAM and OM makes it difficult for this approach to apply in practice.

O'Connor suggests that it is difficult to properly categorize CAM as the category chosen tends to go beyond identification to suggest the validity or quality of the category compared

³² Joan Matthews and Julie Stone, *Complementary Medicine and the Law* (1996) 9-10.

to orthodox or western medicine.³⁵ This jaundiced view of categories of CAM creates an environment that does not permit a value free evaluation of CAM.³⁶ This militates against successful integration and negotiation between OM and CAM.³⁷

Categorization of CAM

Although the general term CAM is being employed it would be an error to suggest that CAM is a homogeneous whole. Modalities incorporate very different approaches to healing.³⁸ The term CAM defines the therapies by their position outside of OM rather than by common philosophy.³⁹ There are frequent attempts to categorize CAM using various criteria. This is a worthwhile exercise to illuminate both the connectedness and disparity of approaches by different CAM modalities.

Cant and Sharma have identified five categories of CAM delineated by the historical periods during which they developed.⁴⁰

- Modalities that developed prior to or at same time as modern biomedicine such as homoeopathy or western herbal medicine.
- Modalities that originated in the period of medical individualism in the late nineteenth century such as osteopathy and chiropractic.

33 Spencer, above n 23, 5.

34 Australian Medical Council, above n 16, 3.

35 Bonnie Blair O'Connor, *Healing Traditions: Alternative Medicine and the Health Professions* (1995) 3.

36 Ibid 4.

37 Ibid.

38 F Davidoff, 'Weighing the Alternatives: Lessons from the Paradoxes of Alternative Medicine' (1998) 129 *Annals of Internal Medicine* 1068, 1070.

39 House of Lords Science and Technology Committee, Sixth Report Session 1999-2000 *Complementary and Alternative Medicine Select Committee Report* (21 November 2000) 2.13.

40 Sarah Cant and Ursula Sharma, *A New Medical Pluralism?: Alternative Medicine, doctors, patients and the state* (1999) 5-7.

- Modalities derived from the health movements of central Europe in the nineteenth century such as naturopathy.
- Modalities imported or introduced to the West primarily in the early 1970's such as acupuncture or traditional Chinese Medicine.
- Modalities that entered the West with immigrant groups such as Ayurveda medicine.

The introduction of these modalities at different periods of history impacted on how OM responded to them. Each CAM modality challenged OM in different ways and at different stages of its development.

There are many modalities that could claim the description of CAM. One source identified 60 modalities under this designation.⁴¹ One author proposed seven categories of CAM therapies based on their fundamental style of therapy:⁴²

- therapies that are spiritually or philosophically grounded (this could include acupuncture; ayurvedic medicine; TCM; homoeopathy and naturopathy.) Most of these modalities could arguably be considered part of the next or other categories. Practitioners would likely argue that the healing effect of these therapies are more than spiritually or philosophically based but based upon a direct impact on the physical body.
- Dietary and herbal remedies. This category incorporates dietary supplements; herbal medicine; Bach flower remedies; macrobiotics; aspects of naturopathy; TCM and ayurvedic medicine.
- Mind body control such as biofeedback; hypnosis and meditation.

41 Ibid 52.

42 Kathleen Boozang, 'Is the Alternative Medicine? Managed Care Apparently Thinks so' (2000) 32 *Connecticut Law Review* 567, 574.

- Alternative biological treatments including chelation therapy; colon detoxification therapies and oxygen therapies.
- Bodywork or manual manipulation including acupuncture; Alexander technique; chiropractic; osteopathy; therapeutic massage including Swedish massage; Kahuna massage; Chinese massage; reflexology; rolfing; tai chi and yoga.
- Enhancing well being through the senses. Examples of these therapies are aromatherapy; dance therapy; music therapy and sound therapy.
- External energy forces such as faith healing; prayer; spirituality; shamanism; crystal healing.

Pietroni has identified 5 categories of CAM based on their therapeutic function and completeness:⁴³

- complete systems of healing such as TCM; osteopathy; chiropractic; homoeopathy and naturopathy. These modalities exhibit features such as a coherent explanation of disease and have diagnostic, investigative and therapeutic understanding which show some similarities with orthodox medicine.⁴⁴ The British Medical Association has some problems with this characterization preferring to designate them as discrete clinical disciplines. The BMA acknowledges that these modalities may have more established foundations of training; criteria of competence and professional standards while exhibiting the greatest potential for harm.⁴⁵ This may have important implications for regulatory issues relevant to these modalities. This category will be one primary focus of this thesis.
- diagnostic methods such as iridology; kinesiology and aura diagnosis. Practitioners of complete systems of healing often use these techniques. Naturopaths commonly use

⁴³ Patrick Pietroni, *The Greening of Medicine* (1990) 180.

iridology while some chiropractors use kinesiology to detect disease or imbalance in the body.

- therapeutic methods such as therapeutic massage; reflexology and aromatherapy. The primary focus of these methods is upon the therapeutic benefits of the practice with little emphasis on diagnosis of disease or pathology. Although not creating great risk to a client these methods require an clear understanding of contraindications and the necessity for referral to a medical practitioner or other professional in appropriate cases.
- self-help measures such as relaxation; yoga and tai chi.

CAM – Common Features

Although these modalities are defined here as CAM they exhibit very different approaches to healing. Some argue categorizing the common features of CAM may caricature both OM and CAM while obscuring the extraordinary diversity of these approaches.⁴⁶ OM sources sometimes consider CAM therapies exhibit no common principle.⁴⁷ There are a number of features that could broadly be considered common to most CAM modalities. These features provide a basis of comparison with orthodox medicine.

*A belief in the interconnectedness of the mind and body*⁴⁸

The cartesian view of the human body at the basis of OM by contrast supports a disconnection between the body mind and spirit.⁴⁹ A CAM practitioner is more likely to pay

44 Ibid.

45 British Medical Association above n 9, 62.

46 Canadian Overview, above n 10, 4.

47 British Medical Association, above n 9, 7.

48 Canadian overview, above n 10, 14; Fulder, above n 19, 5.

attention to emotional; attitudinal and lifestyle issues in treating a patient in a way not common for OM. Attention to emotional; psychological and behavioural issues is fundamental to diagnosis in particular for homoeopathy and TCM.

*Individuality*⁵⁰

For CAM the patient being treated is not viewed simply as an organism with a defined illness or disease but as a person with a special set of circumstances and factors at play.⁵¹ For example, if five patients complain of asthma a CAM practitioner may discern varying causes for this manifestation in that client. This may result in five different treatments for what may appear to be the same complaint.⁵² Based upon a purely biomedical diagnosis a medical doctor might suggest very similar treatment for those clients. This tendency will vary with the modality under consideration. In western herbal medicine the individual constitution may matter less while it might be a major factor in homoeopathy or TCM.

*A partnership or self-healing model*⁵³

Orthodox medicine has a decidedly authoritarian expert/ layperson therapeutic model. Thus the medical practitioner ‘does something to’ the client who is more or less an inert participant in the process. Patient autonomy is not the primary focus in the therapeutic relationship. Most CAM practitioners emphasize an active role for the patient in the therapeutic relationship.⁵⁴ CAM practitioners will often use the term ‘client’ rather than ‘patient’ to indicate the more egalitarian therapeutic relationship that is encouraged. This tendency is especially marked in

49 Stone and Matthews, above n 32, 7; A Mitchell and M Cormack, *The Therapeutic Relationship in Complementary Health Care* (1998) 5, 10-12.

50 Stone and Matthews, *ibid* 13.

51 *Ibid*.

52 *Ibid* 13.

53 Canadian Overview, above n 10, 15

54 Heidi M Rian, ‘An Alternative Approach to Alternative Health Care’ (1983) 44 *Ohio State Law Journal* 185, 186.

the modalities that rely upon exercise regimes, changes in lifestyle and dietary requirements such as naturopathy, Feldenkrais or the Alexander Technique. For these modalities ‘respect for autonomy is not merely an abstract principle, but a therapeutic prerequisite.’⁵⁵ CAM practitioners perceive that they are ‘facilitators of patient self healing in contrast with conventional medicine’s strongly physician-centered sense of responsibility, for both therapeutic success and failure.’⁵⁶ This can engender a sense of self-control in the client and can mean that the patient not the practitioner will be assigned some blame if there is not a positive outcome from CAM treatment.

*Only nature heals*⁵⁷

To an extent that varies between modalities CAM relies on the idea that the role of a therapist is to encourage the individual’s self-healing properties and the harmonization of the energy flows in the body to promote healing and health.⁵⁸ This approach is seen in the attempts to harmonize ‘chi’ in TCM and in attempts to stimulate the body’s inherent self-healing capability in naturopathy.⁵⁹ Simon Mills described this approach as seeing illness as more ‘soil than seed’.⁶⁰ Kaptchuk and Eisenberg comment ‘Alternative medical therapies provide patients with the generous rhetorical embrace of a benevolent “nature”.’⁶¹ This return to nature is at the heart of many modalities and supports the naturopathic emphasis on natural food and the preference for botanical medicine as against its pharmaceutical equivalent. It should be stated that the malevolent effects of natural products such as herbal poisons and bacteria is not emphasised.⁶²

55 Matthews and Stone, above n 32, 6

56 Davidoff, above n 38, 1068.

57 TJ Kaptchuk and DM Eisenberg, ‘The Persuasive Appeal of Alternative Medicine’ (1998) 129 *Annals of Internal Medicine* 1061-1065; Canadian Overview above n 10, 14.

58 Mitchell and Cormack, above n 49, 5.

59 Matthews and Stone, above n 32, 12.

60 Simon Mills, *The Essential Book of Herbal Medicine* (1991) 8.

61 Kaptchuk and Eisenberg, above n 57, 1061.

62 Ibid 1062.

Brief Description of Modalities

A brief description of the history and fundamental features of the modalities the focus of this thesis will assist in understanding their role in health care.

Chiropractic

This modality originated in the late 18th century and emphasizes manipulation of the human spine to produce health outcomes. A full discussion of the principles at the basis of this modality is found in chapter 3.

Osteopathy

This is a healing system that derives from a similar historical period as chiropractic. Osteopathy has from its beginnings maintained it is a complete system of healing in direct competition with orthodox medicine.⁶³ The founder of osteopathy was Andrew Still (1828-1917) who claimed to have had medical training. He practiced in an orthodox fashion until 1864 when three of his daughters died of spinal meningitis. Drawing from a number of unorthodox medical theories⁶⁴ that were common in the mid 1800's such as bone setting; magnetic healing; the health movement and apparently divine revelation; he developed a theory of health that relied on the idea of reestablishing the flow of energy throughout the body. Still considered that displacement of bones and obstruction of blood supply was the cause of disease.⁶⁵ Restoring health was to be achieved by adjustment of osteopathic

63 EC Webb, *Report of the Committee of Inquiry into Chiropractic, Osteopathy, Homoeopathy and Naturopathy* (April 1977) 26.

64 Ibid 25.

65 Ibid.

lesions.⁶⁶ By manipulating and relieving these lesions proper flow of energy could be restored. Still was not an adherent of the germ theory of disease and maintained that osteopathic lesions were the primary cause of disease.

In Australia osteopaths have registered status in all jurisdictions. Osteopaths have the opportunity to obtain a degree from 5 years of university training through Macquarie University. Osteopathy is a smaller profession than chiropractic in Australia with approximately 300 practitioners. Osteopathy in Australia shares chiropractic's exclusion from the mainstream health sector. They generally are not employed in hospitals with most in private practice.

In the USA the progress of osteopathy has been markedly different. In response to resistance from the medical profession osteopaths have tended to conform to orthodox medicine's philosophy in return for acceptance.⁶⁷ This has meant a de-emphasis on unorthodox aspects of osteopathic principles and an emphasis on the biomedical approach to health care. This has allowed many doctors trained in osteopathy to be incorporated into the mainstream medical system though at the cost of traditional osteopathic principles.⁶⁸

Naturopathy

This modality is based upon the concept of the 'nature cure.' Naturopathy emphasises a holistic approach to treatment that deals with the physical, mental, emotional and spiritual

66 Norman Gevitz, 'Osteopathic Medicine: From Deviance to Difference' in Norman Gevitz (ed), *Other Healers: Unorthodox Medicine in America* (1988) 124-131.

67 Walter Wardwell, 'Alternative Medicine in the United States' (1994) 38 *Social Science and Medicine* 1060, 1065.

68 Gevitz, above n 66, 155.

aspects of a person.⁶⁹ The term naturopathy can encompass many different therapies based upon the principle of augmenting and supporting the bodies' ability to heal itself. This modality developed from the 19 th century belief 'that the body can be maintained in a state of health by wholesome 'natural' foods, the extensive use of water, fresh air and sunlight, together with periods of fasting.'⁷⁰ Although the existence of disease states is acknowledged the object of a naturopath is as much to maintain good health and to prevent illness, as it is to treat illness.⁷¹ A significant aspect of naturopathy is an emphasis on the role of the practitioner as a teacher who assists a client to understand how he or she can contribute to their own health by following naturopathic principles.⁷²

In Australia most naturopaths are sole practitioners in private practice. Naturopaths employ a combination of therapies such as dietary advice, vitamins and mineral supplements, herbs; homoeopathic remedies; therapeutic massage and acupuncture.⁷³ One commonly used diagnostic procedure is iridology. Iridology involves an analysis of features of the iris of the eye that is said to permit a diagnosis of disease states in the body. Owing to its eclectic nature some whose primary focus is upon another modality such as chiropractic, osteopathy or acupuncture may practice naturopathy. Currently there is no provision for the statutory registration of naturopathy in Australia. Some states of the USA and British Columbia, Canada have established statutory regulation for naturopathy.

Acupuncture

69 Carlo Calabrese, 'Assessing the Effectiveness of Naturopathic Medicine' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 680.

70 Ted J Kaptchuk, 'Historical Context of the concept of Vitalism in Complementary and Alternative medicine' in Marc S Micozzi (ed), *Fundamentals of Complementary and Alternative Medicine* (1996) 41.

71 Webb report, above n 63, 71.

72 Carlo Calabrese, above n 69, 680.

73 EH Gort and D Coburn 'Naturopathy in Canada: Changing Relationships to Medicine, Chiropractic and the State' (1998) 26 *Social Science and Medicine* 1061, 1061.

Acupuncture has a history probably dating back 2000 years. Acupuncture was known in Europe in the 17th century and early 19th century especially in France.⁷⁴ Acupuncture was little used in modern times in the West until the early 1970's when there was a broadening of contact with China. This allowed its reintroduction to the West. Acupuncture involves stimulation manually or by needles at various significant points in the body to treat disease and alleviate pain.⁷⁵ Acupuncture has been extensively researched in China using empirical research methods.⁷⁶ This does not provide influential evidence in the West. High quality scientific research into acupuncture is available but further evidence is required.⁷⁷

Acupuncture is based on the belief that the body is pervaded by energy channels or meridians through which vital energy or chi circulates.⁷⁸ The dysfunction of the flow of chi is thought to contribute to disease.⁷⁹ The insertion of acupuncture needles at appropriate points on the body is designed to regularize the circulation of the chi and thereby to restore health.

Acupuncture includes treatment called moxibustion that involves the burning of a herb *artemisia vulgaris* on the head of a needle or near the surface of the skin. Other forms of acupuncture are acupressure, which involves manual stimulation of acupuncture points and Japanese acupuncture.

74 M S Patel, 'Problems in the Evaluation of Alternative Medicine' (1987) 25 *Social Science and Medicine* 669, 671; Stephanie Downey, 'Acupuncture' in Denise F Rankin Box (ed), *The Nurses Handbook of Complementary Therapies* (1995) 43.

75 Wei Ru-Shu, 'Acupuncture and Moxibustion' in Robert H Bannermann, John Burton and Ch'en Wen-Chieh (eds), in *Traditional Medicine and Health Care Coverage* (1983) 76.

76 Downey, above n 74, 45.

77 Alan Bensoussan and Stephen P Myers, Victorian Department of Human Services, New South Wales Department of Health and Queensland Department of Health, *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia* (1996) 300.

78 Wei Ru-Shu, above n 75, 76.

79 Downey, above n 74, 43.

OM usually argues that acupuncture should only be provided by a medical doctor. Acupuncture is used extensively by medical doctors and other allied professionals.⁸⁰ This OM usage may reflect that this modality can be practiced based upon traditional Chinese principles or theory or in accordance with Western style diagnosis and pathology.⁸¹ Victoria has recently enacted protection of title legislation through the *Chinese Medicine Registration Act 2000* (Vic) for acupuncturists; Chinese medicine practitioners and Chinese herbal dispensers. This is the only state in which registered status is afforded to this modality though New South Wales is considering similar legislation.

Traditional Chinese Medicine (TCM)

TCM is a diverse set of modalities including acupuncture that is based upon a complex formulation of concepts that places emphasis on empirical observation and pattern identification. It has been described as ‘a holistic system in which health is understood as the cooperative functioning of parts within a context.’⁸² TCM views the patient as a whole and illness as representing an imbalance in the fundamental polarities of Yin and Yang.⁸³ The Yin is said to reflect the contractive downward flowing influence while the Yang reflects the flowing upward or outward influence.⁸⁴ On an energy level TCM relies upon a concept of vital energy or chi that is said to flow through the body. Sub-classifications of the chi are the five phases namely wood; fire; earth; metal and water sometimes referred to as the Five elements.⁸⁵ The practitioner’s role is to assist in the process of harmonizing these elements in the body to restore balance using a wide variety of treatments. The basic premise of TCM is

80 Medicare Benefits Review Committee, *Second Report*, (1986) 110; George Lewith (Editorial) ‘Complementary and Alternative medicine: an educational, attitudinal and research challenge’ (2000) 172 *Medical Journal of Australia* 102; G Easthope, GF Gill, JJ Bielby and BK Tranter, ‘Acupuncture in Australian General Practice: Patient Characteristics’ (1999) 170 *Medical Journal of Australia* 259-262.

81 Wei Ru-Shu, above n 75, 76.

82 Effie Poy Yew Chow, ‘Traditional Chinese Medicine: a holistic system’ in J Warren Salmon (ed), *Alternative Medicines: Popular and Policy Perspectives* (1984) 115.

83 Bensoussan and Myers above n 77, 20.

84 Chow, above n 82, 116.

that when the Yin-Yang balance is disrupted there is illness and where there is harmony health is restored.⁸⁶ TCM practitioners use a complex system of diagnosis involving attention to bodily functions and conditions in relation to the tongue; color; odor, temperature and pulses.

The types of techniques used in TCM include⁸⁷:

- Herbal medicine.
- Acupuncture.
- Chinese massage.
- Dietary advice.
- Moxibustion.
- Breathing exercises; movement and meditation.
- Manipulation and surgery.

TCM is practiced as a traditional form of medicine in South East Asia and within the Chinese community of Australia but is increasingly resorted to by a broader cross section of the community.

Homoeopathy

Homoeopathy was developed by a German physician Dr Samuel Hahnemann 1755-1843.

During its peak at the end of the 1800's and early 1900's homoeopathy was a major competitor to OM in many countries with one in seven physicians in the USA being

homoeopaths.⁸⁸ The name homoeopathy is derived from the greek words *homoios pathos*

85 Ibid 117.

86 Ibid 120.

87 Bensoussan above n 77, 19.

88 Encyclopedia of Bioethics, above n 4, 139.

which means ‘similar sickness.’⁸⁹ The fundamental principle of homeopathy is the principle of similars. This principle postulates that to create a healing response it is necessary to introduce into the body a very weak dilution of a substance that will create symptoms similar to the symptoms complained of.⁹⁰ A full discussion of this modality is found in chapter 3.

Therapeutic Massage

Therapeutic massage is not a complete system of healing but may be used on its own right or in conjunction with another modality such as chiropractic or naturopathy. Massage takes many forms including Swedish massage; kahuna massage; deep tissue massage; Chinese massage; shiatsu and reflexology. Massage can be used for general improvement in circulation, relaxation, for specific therapeutic purposes such as the treatment of injuries; for psychological release through Rolfing or for broader health reasons. Massage may be used by OM or allied therapies such as physiotherapy. The principles of massage involve attention to techniques such as efflurage ie long manual massage strokes; kneading; cupping; mobilization and manipulation using the hands and elbow.⁹¹ Currently in Australia therapeutic massage does not enjoy registered status.

Herbal Medicine

Herbal medicine in some form has been used for thousands of years as it involves using the plants, herbs and substances that are readily available.⁹² Hippocrates 460-360 BC established a school of healing which incorporated use of herbal remedies. In 1653 the influential text *English Physician ‘A compleat Method or Practice of Physic’* was published by Nicholas

89 Harris L Coulter, ‘Homoeopathy’ in J.Warren Salmon (ed), *Alternative Medicines: Popular and Policy Perspectives* (1984) 58.

90 PA Nicholls, *Homeopathy and the Medical Profession* (1988) 3.

91 Carol Horrigan, ‘Massage’ in Denise F.Rankin Box (ed), *The Nurses’ Handbook of Complementary Therapies* (1995) 127.

Culpepper which contained a description of thousands of herbs and their medicinal uses.⁹³

Herbal medicine theory considers disease is caused by a weakness in the body. A herbalist attempts to bring the body into balance to allow it to withstand illness.

Herbal medicine has been prominent in important botanical medicine movements over the centuries including Thomsonism in the early 1800's and the Eclectics in the mid 1800's.⁹⁴

Many medicines used by orthodox medicine such as aspirin (from willowbark) and quinine derive from herbal medicine sources.⁹⁵ This means that the effect of many herbal substances is well known and accepted by science for treatment of a number of conditions.⁹⁶ Herbalists are not registered health professionals in Australia other than practitioners who might qualify under the TCM legislation in Victoria.

Level of Use of CAM in Australia

The high utilization rate for CAM by members of the public supports the urgency to determine the appropriate model for the regulation for CAM. Consumer demand to access CAM has been instrumental in creating pressure for the enhanced availability of CAM and its integration into OM.⁹⁷ Studies in three countries indicate a rapid growth in demand for CAM.⁹⁸ This trend is promoted by concerns about aspects of OM as well as an attraction to

92 Helen Busby, 'Herbal Medicine' in Denise F. Rankin Box (ed), *The Nurses' Handbook of Complementary Therapies* (1995) 92.

93 Barbara Griggs, *Green Pharmacy: A History of Herbal Medicine* (1981) 97.

94 Ibid 161-171, 231-239.

95 Dimond, above n 25, 315.

96 Bushby, above n 92, 93; Edzard Ernst, 'The Risk- Benefit Profile of Commonly Used Herbal Therapies: Ginkgo, St John's Wort, Gingseng, Echinacea; Saw Palmetto, and Kava' (2002) 136 *Annals of Internal Medicine* 42.

97 Weeks, above n 20, 4.

98 R.C. Kessler et al, 'Long Term Trends in the Use of CAM Therapies in the USA' (2001) 35 *Annals of Internal Medicine* 262, 266.

features of CAM.⁹⁹ Some see the success of CAM as a case of ‘cultural sedimentation. Like a residue of the past, the remedies of learned traditions filter down to the lower classes, where they remain even after the learned have abandoned them.’¹⁰⁰ This somewhat elitist view does not explain the substantial use of CAM by OM nor the fact that many consumers of CAM are high income well educated people.

There is clear evidence in Australia and overseas that a high percentage of the public use CAM and that many medical doctors are now incorporating these modalities in their practice. Eisenberg’s 1990 study showed nearly 36% of adult persons in the USA had used an alternative therapy in the previous 12 months while 20% had seen an alternative therapist.¹⁰¹ When a similar study was done in 1997 these figures had increased to 47.6% and 30.1% respectively.¹⁰² This study has been criticized as including therapies, such as exercise, that may be considered mainstream.¹⁰³ Consumer spending on CAM in the USA may have increased by 69% since 1989 with the market currently increasing at a rate of 30% annually.¹⁰⁴ One Canadian study suggested that in 1996 20% of Canadians sought the services of a CAM practitioner.¹⁰⁵ There is evidence of widespread use throughout Europe.¹⁰⁶ Similar levels of usage have been found in Great Britain where one survey suggested that one

99 Fulder, above n 19, 14; LJ Schneidermann, ‘Medical Ethics and Alternative Medicine’ (1998) 2 *Scientific Review of Alternative Medicine* 66.

100 Starr, above n 6, 47.

101 DM Eisenberg, RC Kessler, C Foster, ‘Unconventional Medicine in the United States’ (1993) 328 *New England Journal of Medicine* 246-252.

102 DM Eisenberg, RB Davis, SL Ettner, S Appel, S. Wilkey, M Van Rompay and R.C. Kessler, ‘Trends in Alternative Medicine Use in the United States 1990-1997’ (1998) 280 *Journal of American Medical Association* 1569 –1575.

103 Edzard Ernst, ‘The Rise and Fall of Complementary Medicine’ (1998) 91 *Journal of the Royal Society of Medicine* 235; House of Lords Report, above n 39, 1.16.

104 Studdert DM, DM Eisenberg, FH Miller, DA Curto, TJ Kaptchuk and TA Brennan, ‘Medical Malpractice Implications of Alternative Medicine’ (1998) 280 *Journal of American Medical Association* 1610.

105 Statistics Canada, *National Population Health Survey Overview (1994-1995)* (1995) quoted in Richard A Haigh, above n 22, 141, 142.

106 Spencer, above n 23, 13; Paul A Komesaroff, ‘Use of Complementary Medicines: scientific and ethical medicines’ (1998) 169 *Medical Journal of Australia* 180-181.

in 10 people consult a CAM practitioner each year.¹⁰⁷ To put this substantial use in perspective the OM segment of the health care system in the USA is worth 1 trillion dollars and the CAM market is 1.5% of the total market for health care.

In Australia in 1996 it was estimated that one in 5 persons used at least one form of CAM while one half of the South Australian population has used alternative medicine.¹⁰⁸ A 1992-3 study estimated that Australians spent \$621 million dollars on alternative medicines and \$309 million on services provided by CAM therapists.¹⁰⁹ In a recent update of that survey it was found that in the year 2000 over fifty percent of people surveyed used at least one non physician prescribed alternative medicine in that year while over a quarter used two alternative medicines.¹¹⁰ This survey indicated that in the year 2000 23.3% of those surveyed had visited a CAM practitioner.¹¹¹ The survey indicated that total Australian expenditure on CM was \$1671 million dollars with \$616 million dollars spent on CAM practitioners.¹¹² Some measure of the size of the market for CAM services and CM is revealed by the fact that in the year ending 31 December 2001 the Commonwealth Government spent \$688 million dollars on patient contributions for pharmaceuticals. This is less than half that spent on CM by Australians in the year 2000.¹¹³ This indicates the very substantial growth in expenditure on CAM during the past decade. These figures indicate that CAM is a large and increasing proportion of the total amount spent on health care in Australia and other western countries.

107 British News Item (1996) 311 *British Medical Journal* 131-133.

108 A Mac Lennan, D Wilson and A Taylor 'Prevalence and Cost of Alternative Medicine in Australia' (1996) 347 *Lancet* 569-573; Bensoussan and Myers, above n 77, 22.

109 Ibid, MacLennan 150.

110 A Mac Lennan, D Wilson and A Taylor, 'The Escalating Cost and Prevalence of Alternative Medicine' (2002) 35 *Preventative Medicine* 166, 167.

111 Ibid 168.

112 Ibid 169.

113 Ibid 170.

Despite ethical doubts about the use of CAM by medical practitioners it appears that many GP's either refer to CAM practitioners or use it themselves in their practice.¹¹⁴ At least 15% of the 800 Victorian GP's in one survey indicated that they practice acupuncture.¹¹⁵ Nearly 20% of GP's surveyed in Victoria had used acupuncture; meditation or hypnosis and almost one half had considered practicing these therapies. Five percent of the surveyed GP'S had used therapies such as osteopathy, homeopathy, aromatherapy and spiritual healing. Eighty two percent of the doctors surveyed had referred at least a few patients every year to a CAM practitioner.¹¹⁶

There are some commentators who suggest that the use of CAM is a passing fad that will fade in time.¹¹⁷ Recent survey evidence from the USA disputes this view as CAM is seen as having strong support across a number of age groups and especially in the post 'baby boomer' cohort.¹¹⁸ The debate about the appropriate role for CAM in the health sector is on one view a struggle between supporting consumer choice, patient autonomy and science based medicine.¹¹⁹ The increasing use of CAM represents a change in behaviour but probably just as significantly a change in the health needs and values of society. This is significant in terms of appropriate model for the regulation of CAM.¹²⁰

Why the increase in use of CAM may continue.

114 Marie Pirotta, Marc M Cohen, Vicki Kotsirilos and Stephen Farish, 'Complementary Therapies: have they become accepted in general practice?'(2000) 172 *Medical Journal of Australia* 105-109; Richard Wharton and George Lewith, 'Complementary Medicine and the general practitioner' (1986) 292 *British Medical Journal* 498-500.

115 Paul A Komersaroff, above n 106, 180-181.

116 Pirotta, above n 114, 107.

117 Ernst, above n 103, 235.

118 Kessler, above n 98, 266.

119 Boozang, above n 9, 569

120 David P.S. Dickinson, 'The Growth of Complementary Therapy: A consumer led boom' in E. Ernst (ed), *Complementary Medicine: An Objective Appraisal* (1996) 150-161.

It seems likely that the popularity of CAM will continue to be a significant factor in the health sector because of the following factors:

- The higher cost of OM may suggest the need to apply less technological means to the provision of health services.
- Projections for the production of CAM practitioners is for a rapid increase in students and practitioners thus providing a large pool of expertise to service and promote CAM therapies.
- Baby boomers will age and need treatment for a wide variety of chronic illnesses, which is CAM's forte. This group and post baby boomers are currently high users of CAM.¹²¹ The numbers of Asian/Australians is likely to increase thereby increasing demand for CAM therapies derived from eastern traditions.
- The inability of science to provide a cure for all ills may accelerate if changes such as antibiotic resistant germs become commonplace.
- The increasing availability of health insurance coverage for CAM will reduce the relative cost of these services.¹²²

Conclusion

The resort to negative definitions of CAM reflects orthodox medicine's reluctance to place CAM practice within the broad definition of healing services. This difficulty is reflected in the fact that CAM is generally not regulated. The level of usage of CAM and the significant issue of public interest that this use creates suggests the need for a reconsideration of the appropriate place for CAM in the regulatory structure. The differences in therapeutic approach between OM and CAM are fundamental. These differences provide both an

¹²¹ Kessler, above n 98, 266.

attraction to those patients that are aligned to the CAM philosophy and an opportunity for OM to argue for the limited recognition of CAM. This thesis argues the public interest is supported by more protection for consumers who choose CAM for their therapeutic needs.

Chapter 2

The health care sector – the current structure

Introduction

The regulatory structure of the health care sector in Australia reflects the hegemony of orthodox medicine¹²³ and reinforces the important influence OM has in society generally. OM defines the role, status and characteristics of other health professionals based upon their relationship to it. A key factor in the legitimacy and status of any health profession is its acceptance, endorsement or dismissal by OM.¹²⁴

Features of OM Dominance

Willis suggests OM dominance of the health sector is reflected in three ways¹²⁵:

Autonomy

Medical practitioners are not subject to direction or control by other health professionals.¹²⁶

In this way medical practitioners enjoy in practice a monopoly on certain medical procedures such as surgery (subject to certain rights vested in dentists¹²⁷ and chiropodists); prescription

123 O'Connor, above n 35, 5.

124 Walter I Wardwell, 'Chiropractors: Challengers of the Medical Domination' in J.A. Roth (ed), *Research into the Sociology of Health Care* (1981) 209.

125 Willis, above n 129, 2-3.

126 Wardwell, above n 124, 208.

127 Eg *Dental Act 1939 (WA)* s 50; *Dental Practitioners Act 2001 (Tas)* s 64.

of drugs (exceptions for Dentists and Veterinarians¹²⁸) and employment in certain positions.¹²⁹ It is common for medical practice acts to limit the appointment to government medical positions to registered medical practitioners.¹³⁰

OM autonomy is also reflected in the status of most medical doctors as private independent practitioners and not as employees. A significant recent trend in Australia is the growth in employment of doctors by large medical service companies. It is estimated that 2500 or 10% of medical doctors in practice now work in practices owned by medical corporations.¹³¹

Concern has been expressed about the impact this trend may have on medical autonomy.¹³² It is feared the employment of doctors in medical corporations may create pressures to promote profitable diagnostic tests for the financial benefit of vertically integrated pathology and radiology services. It is feared doctors may be pressured to market products or services in pursuit of corporate goals rather than acting solely for the benefit of the patient. The discrepancy in information available to health consumers and health professionals can create the potential for unethical conduct if the practitioner is pressured to make decisions on commercial rather than therapeutic grounds.¹³³

New South Wales has reacted to these concerns by amendments to the *Medical Practice Act 2000* (NSW). This legislation prescribes fines or disqualification for directors of

128 *The Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) schedule 3.

129 E Willis, *Medical Dominance: The Division of Labour in Australian health care* (1983) 2, 29.

130 An example is *Health Act 1937* (Qld) s 37 that requires the chief medical officer to be a registered medical practitioner.

131 Barry R Catchlove, 'The Why and the Wherefore' (2001) 175 *Medical Journal of Australia* 68 -70; Kathy Mott, 'The Consumer Perspective' (2001) 175 *Medical Journal of Australia* 75 -76; Arn Sprogis, 'The Divisional Alternative' (2001) 175 *Medical Journal of Australia* 70-72.

132 PD Fitzgerald, 'The Ethics of doctors and big business' (2001) 175 *Medical Journal of Australia* 73 -75 Willis, above n 129, 76; M K Outterson, 'GP Corporatisation : Lessons to be learned' (2001) 175 *Medical Journal of Australia* 426 - 427.

133 Fitzgerald, *ibid* 74.

corporations providing medical services if they are a party to professional misconduct by medical practitioners.¹³⁴ Another provision prohibits doctors and medical corporations and their directors and managers offering or accepting pecuniary benefits for patient referrals.¹³⁵ In the USA legislation attempts to limit financial arrangements between medical doctors and medical corporations.¹³⁶ The protection of autonomy also explains the long expressed discomfort felt by the medical profession with the publicly funded Medicare system that requires doctors to obtain payment from the government at the rate specified by the Medicare system.¹³⁷

OM autonomy is based upon an acceptance by government and society generally that MD's have primary access to esoteric knowledge relating to healing. State patronage has contributed to the mystic that surrounds the scientist/doctor who dispenses health services drawn from the wisdom that science has provided.¹³⁸ OM enjoys statutory endorsement by the state through medical practice acts in all jurisdictions. These statutes place OM at the center of medical care and the massive infrastructure that provides health services. Through the patronage of powerful elites in society OM has been supported financially and this has assisted in driving off competition.¹³⁹

Authority

The dominance of OM extends to its control and supervision of the work of other health professions. Medical doctors actively supervise the work of health professionals such as

134 s 116 A.

135 s 112 A and s 112 B.

136 *Ethics in Patient Referrals Act*, H.R. 939 USC (1989); *The Stark II Law* (42 USC 1395 nn).

137 For a brief history of Medibank and the strident opposition of OM to this scheme refer to Richard B Scotton, 'Medibank : From conception to delivery and beyond' (2000) 173 *Medical Journal of Australia* 9-11.

138; Willis, above n 129, 10; P Boreham, A Pemberton and P. Wilson, ' Introduction' in P Boreham, Alec Pemberton and P Wilson (eds), *The Professions in Australia* (1976) 8.

139 Ibid Willis 10.

nurses. The relationship with other health professionals is characterised by referral for specified tasks as in the case of referral to physiotherapists for specified therapy.¹⁴⁰ In recent years physiotherapists have claimed the entitlement to obtain clientele directly without medical referral. Nurses in New South Wales are now able to claim nurse practitioner status with an entitlement to apply specified therapies under the *Nurses Act 1991*(NSW).¹⁴¹ Authority may also be exercised indirectly through the apparent need to elicit the support of the medical profession before obtaining registered status.¹⁴²

Sovereignty

The medical profession is seen as ‘the’ expert on all health matters in dealings with members of the general public or government.¹⁴³ This reflects partly the model of statutory regulation derived from the *Medical Act 1858* (UK) which was the first major modern English statute that dealt with the regulation of OM. A proposal to use this statute to define OM and to thereby specify and outlaw ‘unorthodox medicine’ was rejected. This resulted in a statutory scheme where medical doctors are not limited to the types of techniques they could employ.¹⁴⁴ This is reflected in modern medical practice statutes in Australia and results in an ill-defined scope of practice for medical doctors that has the potential to proscribe CAM practitioners in their ordinary activities.¹⁴⁵

This thesis will argue that the health care sector regulatory structure has been created to reflect the values of OM and not necessarily the public interest. This regulatory structure effects how health care is funded, who can provide particular services, how research is

140 Ibid 2.

141 s 19A; Refer also to *Nurses Amendment Act 2000* (Vic) - not yet in force.

142 Willis, above n 129, 3.

143 Ibid 3-4; M H Kottow, ‘Classical Medicine v Alternative Medical Practices’ (1992) *Journal of Medical Ethics* 18, 18-22.

144 Webb report above n 63, 127.

funded and how health care and illegal conduct is defined. The inroads made into this structure by particular CAM modalities like chiropractic and osteopathy have been hard won and limited in scope.

Health Professions Categories

Wardwell has classified health-related professions (not medical doctors) into 4 categories reflecting a OM perspective common to many studies of health care. Despite its inherently OM orientation this categorisation provides some valuable insights into how the health care sector is constituted and the influence of OM on this structure.¹⁴⁶

Wardwell suggested four categories of:

- ancillary professions.
- limited medical professions.
- marginal professions.
- parallel and quasi professions.

Ancillary professions

Most ancillary professions have registered status and will often function under the direct supervision of a medical practitioner. These practitioners will usually not question the clinical judgement of a medical practitioner and do not normally become involved in diagnosis or treatment planning. Examples of ancillary professions are nursing, pharmacy and

145 Refer to Chapter 4 above.

146 Wardwell, above n 124, 209-211.

physiotherapy.¹⁴⁷ The role of a nurse practitioner and the practice of physiotherapists in taking clients without medical referral may bring this category into question in all cases.

Limited medical professions

These are registered health professionals such as dentists, podiatrists, optometrists and physiotherapists when accepting patients without medical referral. These professions are entitled to primary care status and accordingly do not rely upon referral from an MD. These groups generally share OM's focus on the scientific basis of health care. Because they provide a limited threat of competition for clientele they have obtained acceptance on the basis they confine their practice to certain parts of the body and specified techniques and procedures.¹⁴⁸

Marginal professions

Marginal professions 'characterise health professions that challenge the validity of orthodox conceptions of illness and therapy and base their practice on a fundamentally different theory.'¹⁴⁹ These professions will often promote a mono-causal theory of illness and suggest their ability to treat a wide variety of illness and injury. Examples of this category are chiropractors; osteopaths; naturopaths, acupuncturists and TCM practitioners. Some of these marginal professions namely chiropractic; osteopathy and TCM practitioners and acupuncturists (in Victoria) have registered status. Owing to the status and success of chiropractors it may be argued they are no longer marginal but limited medical professionals.¹⁵⁰

147 Ibid 210.

148 Eg *Dental Practice Act 2001* (NSW) – s 10AF (not yet commenced); *Dentists Act 1984* (SA) s 38.

149 Wardwell, above n 124, 210.

Because of their broader therapeutic aims these professions are perceived as providing a threat to OM. For this reason and based upon what is seen as the heretical nature of their philosophical background the relationship between marginal professions and OM has been marked by bitter divides, criticism and overt and covert campaigns to discredit one another. Any attempt to obtain registered status is met by vehement medical opposition.¹⁵¹

The struggle by CAM for full acceptance within the health sector has spawned differing strategic approaches based upon both the approach of the CAM modality and the policy of OM towards that modality.¹⁵² In Australia, chiropractors and osteopaths have relied upon their hard fought registered status to secure their position, if not within orthodox medicine, then within the broader health sector. Despite their registered status, chiropractors remain outsiders to OM. They are denied access to hospital training, hospital practice, funding under Medicare and full acceptance by OM. Gort and Coburn argue in regard to naturopathy in Canada that ‘naturopathy itself has been shaped by its status as a marginal profession and has assumed oppositional postures irrelevant to its core doctrine and that has contributed to its marginal status.’¹⁵³

150 D Coburn and CL Biggs, ‘Limits to Medical Dominance: The Case of Chiropractic’ (1986) 22 *Social Sciences and Medicine* 1035, 1036.

151 Report of the Commission of Inquiry, *Chiropractic in New Zealand* (1979) 19; Department of Human Services *Traditional Chinese Medicine: Report on Options for Regulation of Practitioners* Victorian Ministerial Advisory Committee (1998) 18 - Victorian AMA opposed registration for TCM practitioners and acupuncturists.

152 Richard Haigh, ‘Alternative Medicine and the Doctrine of Patient Disclosure’ (2000) 8 *Journal of Law and Medicine* 197, 200.

153 EH Gort and D Coburn, ‘Naturopathy in Canada: Changing Relationships to Medicine, Chiropractic and the State’ (1988) 29 *Social Sciences and Medicine* 1061, 1062.

In the USA chiropractors have statutory registered status in all states and have been more successful in achieving their professional aims. In recent years chiropractors have gained access to positions in some hospitals.¹⁵⁴

Quasi professions

These professions are described as unscientific or non-scientific groups. This category might include some practitioners that OM would deem to be ‘quacks’ such as faith healers and shamans. These groups rely upon more spiritual and esoteric therapeutic means to achieve their clinical objectives. OM might seek to place chiropractic and in Australia osteopaths into this category.¹⁵⁵ The limited role for these practitioners means they are generally not seen as a substantial threat to OM. Paradoxically, the ephemeral nature of these practices means these professions are treated more liberally by the common law and will often escape the net of legislative provisions that may catch marginal professions.¹⁵⁶

A non-OM focussed categorisation of the health professions would be 4 categories namely:

- the medical profession.
- allied professions such as physiotherapy and podiatry.
- registered CAM practitioners such as chiropractors, osteopaths and TCM practitioners and acupuncturists in Victoria; and
- non-registered CAM practitioners.

154 Keith Simpson, *The Influence of Political Medicine in the Development of the Chiropractic Profession in Australia* (Phd Thesis, University of Queensland, 2002) 340.

155 NZ report above n 151, 28; Coburn and Biggs, above n 150, 1037.

156 *Mayo v Harris* [1945] SASR 151.

Registration Status

The status of a profession within the health sector is substantially affected by whether they have registered status or not and the role that registration accords that profession.¹⁵⁷

Registration status has been granted for the following health professions in Australia¹⁵⁸:

Medical Doctors.

Physiotherapists.

Podiatrists (formerly called chiropodists) (all jurisdictions except NT).

Optometrists.

Dentists.

Chiropractors.

Osteopaths.

Traditional Chinese Medicine Practitioners (Victoria only).

Chinese Herbal Medicine dispensers (Victoria only).

Acupuncturists (Victoria only).

Speech therapists (in Queensland only).

Occupational Therapists (Qld, SA, NT and WA).

Nurses.

Opticians (NSW, SA, Tas and WA).

Aboriginal Health Workers (NT).

Psychologists.

Radiographers (NT, Tasmania and Victoria).

157 AK Cobb, 'Pluralistic Legitimization of an Alternative Therapy System: The Case of Chiropractic' (1997) 1 *Medical Anthropology* 1, 5.

158 Meg Wallace, *Health Care and the Law* (3rd ed, 2001) 418-420.

Registration status typically involves the enactment of a registration statute that follows a consistent pattern based upon the model derived from the *Medical Act 1858* (UK).¹⁵⁹

These statutes normally exhibit a number of common features:

- The establishment of a professional board comprised of members of the profession involved and in some cases lay people.
- Many statutes define a scope of practice. This was not done in the case of the *Medical Act 1858* (UK) but it is a feature of health profession regulation in many jurisdictions. Scope of practice provisions define those activities to which the registered professional is given 'exclusive' entitlement. Criminal sanction is normally applied to persons breaching the scope of practice provisions. There may be exemptions for related practices that the legislation does not intend to control. Scope of practice provisions are the subject of debate and variation and reflect the conflict over claims for therapeutic territory considered fundamental to a profession's autonomy and authority. As Bucher and Strauss argue, 'formal occupational territories are established by legislation; and the boundaries of these are produced and reproduced in political struggle with occupations attempting to defend or extend their relative position.'¹⁶⁰
- Provision for protected titles that only registered practitioners are entitled to use, for example, only a physiotherapist can use the term 'physiotherapist' and only a chiropractor can use the term 'chiropractor'. Even where the legislation does not incorporate a scope of practice provision there is normally a 'holding out' provision that punishes the use of prohibited titles by a non-registrant.¹⁶¹

¹⁵⁹ Saks M, *Professions and the Public Interest* (1995) 200.

- Provision for disciplinary proceedings by the professional board based upon what is defined as ‘unprofessional conduct’ or ‘improper behaviour.’ These proceedings may involve a hearing of a disciplinary committee or other disciplinary body that may lead to disciplinary measures against a registered practitioner.¹⁶² Disciplinary measures could include warnings; fines; suspension; practice supervision and deregistration.
- Establishment of a register of practitioners deemed to have satisfied the educational and practical training requirements of the legislation. A public servant normally called a Registrar administers this register.

Benefits of Professional Registration

Registration status provides the following benefits to the health profession:

- It limits entry into the profession.
- The establishment of standards of professionally accepted practices and procedures through by-laws; policies and codes of ethics promulgated and enforced by registration boards.
- Professional ethics enforcement by the professional board.
- The ability to restrict the use of specified professional titles by unregistered professionals enforced by criminal or quasi-criminal proceedings.
- The ability to parse an exclusive or semi exclusive part of the health sector or specified techniques using scope of practice provisions.
- Encouragement of referral of patients between different registered professions.
- Greater status within the health sector and the society generally based on the implicit government endorsement of the practice.

¹⁶⁰ Willis, above n 129, 4.

Registration Status – Reflection of hegemony

The very significant role played by professional registration statutes in Australia in parsing particular roles for health professionals is demonstrative of the hegemony of the medical profession. In no jurisdiction in Australia are medical doctors subject to a prescribed statutory scope of practice. The legislative assumption appears to be that medical doctors can perform any health service even if they are not specifically trained for such a procedure.¹⁶³ For example, in all states where the chiropractors and osteopaths registration legislation defines a scope of practice incorporating spinal manipulation there is an exemption for medical doctors.¹⁶⁴ Generally medical doctors receive little training in this technique. Doctors may be subject to control on practices that might constitute unprofessional conduct such as where they fail to provide proper support such as another practitioner to assist or proper equipment for a procedure.¹⁶⁵

In South Australia only medical doctors only can deal with specified diseases.¹⁶⁶

In all jurisdictions except Queensland or Victoria only medical doctors can ‘practice medicine’ or provide ‘medical treatment.’ Those terms are not adequately defined other than as ‘includes surgery.’¹⁶⁷

161 *Physiotherapists Act 1998 (Vic)* s 57.

162 *Health Practitioners (Professional Standards) Act 1999 (Qld)* s 122.

163 Willis, above n 129, 3.

164 *Chiropractors and Osteopaths Registration Act 1997 (Tas)* s 56; *Chiropractors Act 1964 (WA)* s 6.

165 *Ex parte Meehan; Re Medical Practitioners Act* [1965] NSW 30; *Medical Board of Queensland v Bayliss* (Unreported 6th and 8th February 1995 Queensland Medical Assessment Tribunal no 10 of 1995).

166 Regulation 7 *Medical Practice Regulations 1992 (SA)*.

167 Refer to detailed discussion Chapter 4.

Other registered professions have their professional role parsed from the therapeutic whole constituted by medical practice. For example, in Western Australia chiropractors are entitled to apply ‘a system of palpating and adjusting the articulations of the human spinal column by hand only, for the purpose of determining and correcting without the use of drugs or operative surgery, interference with normal nerve transmission and expression.’¹⁶⁸

Physiotherapists are given a scope of practice that generally involves procedures such as the external application to the human body of massage, manipulation, passive movements, remedial exercises, heat, light and sound for curing or alleviating or preventing any abnormal condition of the human body.¹⁶⁹ In all these statutory examples there is an exemption for the medical doctors who are assumed to have the ability to perform all these functions.¹⁷⁰

This approach confirms the hegemony of medical practice and the subsidiary role of all other registered professions in the health sector. The status of registration is generally not given without that profession clearly defining and limiting its scope of practice to a defined area. This statutory scope of practice will permit only registered practitioners and medical doctors to perform activities within that statutory scope of practice. This serves OM by limiting competition to specified techniques or areas of the body. Recent review of health practitioner legislation under the Competition Code¹⁷¹ has reduced the emphasis on statutory scope of practice provisions but there are a number of states where these types of provisions remain.¹⁷²

168 *Chiropractors Act 1961 (WA)* s 4.

169 For example *Physiotherapists Registration Act 1991 (SA)* s 4.

170 For example *Chiropractors and Osteopaths Registration Act 1997 (Tas)* s 58 (2); *Chiropractors Act 1964 (WA)* s 6.

171 *The Report of the Independent Committee of Inquiry into National Competition Policy* (1993) recommended economic reform to encourage economic efficiency by removing anti-competitive statutory provisions. This is legislatively based on *Competition Policy Reform Act 1995 (Cth)* with state equivalents for example *Competition Policy Reform (NSW) Act 1995 (NSW)*. An aspect of this reform was a review of health practitioner legislation to delete provisions that restrict competition without a balancing public benefit.

Unregistered Health Professions

Those health professions that do not enjoy the status of registration include most CAM practitioners. Their practice is nevertheless regulated by:

- The common law (including civil law) liability in negligence and criminal law.
- The scope of practice provisions of registered professions.
- General consumer legislation and other generalist legislation.
- Health complaints legislation.
- *Therapeutic Goods Act (Cth)* and state equivalents.

The details of the controls on unregistered CAM practitioners will be canvassed in chapter 4. Although there is a lack of specific regulation of these professions, professional associations provide a measure of professional control. There are many professional associations for CAM practitioners in Australia. All professional associations have a code of ethics that attempt to impose ethical standards on practitioners. The success of this regulation is discussed in chapter 6.

Funding for Health Care

As access to adequate healthcare is seen as essential to a humane society the increasing complexity of OM and its reliance upon technology has caused massive increases in the cost of health care. This ‘has resulted in widespread social intervention to secure this access for all, regardless of capacity to pay.’¹⁷³

172 Refer to Chapter 4 above.

These developments have resulted in ‘a progressive increase in the “transfer burden”—the cost of health-care provided to the non-wealthy sick which has to be met by others—if the equity, and indeed public health goals of the society are to be met.’¹⁷⁴ In many developed countries such as the UK, Germany and Canada a universal publicly funded national health insurance scheme was implemented. Medibank was the Australian equivalent.¹⁷⁵

Medibank to Medicare – National Health Insurance

History

The forces that lead to a universal health scheme had their origin after World War Two as health services structures relying on charity, self help and public subsidisation proved inadequate to deal with the transfer burden as the welfare state was developed. The Whitlam Labor Government introduced Medibank on July 1 1975 against vehement AMA opposition. The opposition has been seen by some as based on the threat to medical dominance and autonomy.¹⁷⁶ The system was reformed and partially dismantled by the Fraser Liberal Government after 1975 but was reintroduced as Medicare by the Hawke Labor Government in 1984 reflecting substantially the model provided by Medibank.¹⁷⁷ Medicare and the principle of a universal health scheme is now settled government policy that enjoys the support, sometimes grudgingly, of both all major political parties in Australia.

Public Funding for Medicare

The public sources of funding for health care is dominated in Australia by the Medicare scheme under the *Commonwealth Medicare Benefits Schedule (CMBS)* administered under

173 Scotton, above n 137, 9.

174 Ibid.

175 Ibid.

176 Marj Milburn, *Informed Choice of Medical Services: Is the Law Just?* (2001) 64.

the *Health Insurance Act 1973* (Cth) and regulations. Medicare derives its funding in part directly from the compulsory Medicare levy under the *Medicare Levy Act 1986* (Cth) based upon a fixed percentage (1.5%) of taxable income and from indirect funding from the revenue of the States, Territories and Commonwealth. In 1999-2000 \$53.7 billion dollars was spent on health services in Australia.¹⁷⁸ This figure constitutes 8.5 % of Australia's GDP.¹⁷⁹

From October 1997 high-income individuals without private medical insurance were obliged to pay a further levy of 1% of taxable income to total 2.5% of income.¹⁸⁰ Funding of health services is provided partially by Commonwealth payments to states under the Five yearly Commonwealth-State Health Funding Agreements and through payments by private patients. In 1999-2000 the Commonwealth provided 48.1% of funding for public hospitals.¹⁸¹ The Commonwealth through Medicare makes payments to individual doctors for medical services provided outside of hospitals based upon the CMBS. The Commonwealth also provides Health Program grants to government and non-government service providers to achieve specific health policy objectives.¹⁸²

Medical Services Funded by Medicare

Medicare, administered by the Health Insurance Commission, covers a minimum level of provider reimbursement for the cost of professional services provided to the consumer.

Professional services are defined in *Health Insurance Act 1973* (Cth) by section 3 to include those services that are clinically relevant services provided by a medical doctor. Clinically relevant treatment is defined in section 3 as treatment generally accepted in the medical,

177 Scotton, above n 137, 11.

178 AIHW, *Australia's Health 2002: The Eighth Biennial Health Report of the Australian Institute of Health and Welfare* (2002) 243.

179 Ibid 243, 248.

180 Ibid 244.

181 Ibid 248.

optometrist and dental profession as being necessary for the appropriate treatment of the patient.

Medical services including professional fees, pathology and diagnostic imaging technology fund services by medical doctors primarily but in some cases for dentists and optometrists and in limited circumstances for diagnostic imaging services for chiropractors.¹⁸³ Other than this provision there is no reimbursement of CAM therapies by CAM practitioners from Medicare.¹⁸⁴ The Webb Report in 1977 recommended that chiropractic and osteopathy be included in Medicare services if physiotherapy was included.¹⁸⁵ The fact that physiotherapy has never been included in the Medicare scheme and the increasing economic burden of Medicare has meant this has not occurred nor is it likely to occur in the foreseeable future. The Commonwealth Pharmaceutical Benefits Scheme provides a subsidy for the cost of the provision of a broad range of prescription drugs.¹⁸⁶

Role of Public Hospitals

Public hospitals provide free health care to public inpatients. Outpatients and casualty services in public hospitals are provided as part of the Medicare system.¹⁸⁷ The states fund other public patient treatment ie day surgery services in public hospitals.¹⁸⁸ Australia has a very high hospital bed utilisation rate by world standards.¹⁸⁹ This adds to the costs of the

182 Australian Bureau of Statistics, *Year Book Australia* (2001) 353.

183 Kleynhans, above n 3, 105.

184 G Easthorpe, 'The Response of Orthodox Medicine to the Challenge of Alternative Medicine in Australia' (1993) 29 *Australian and New Zealand Journal of Sociology* 289, 298.

185 Webb Report, above n 63, Xii and 221.

186 A Hood, 'Anti-Competitive Detriment and Public Benefit in the Australian Health Care Industry: A Progress Report' (2000) 28 *Australian Business Law Review* 293, 296.

187 Ibid 297.

188 F C Cunningham, 'Medicare: Diagnosis and Prognosis' (2000) 173 *Medical Journal of Australia* 52, 53.

189 Ibid.

structure. The public hospital structure is also characterised by long waiting lists for non-urgent cases.¹⁹⁰

Private Health Sector

The private sector provides substantial input into health services in Australia through for profit and not for profit organizations including private hospitals and private health funds. Privately owned nursing homes provide the majority of long-term aged care beds.¹⁹¹ The private sector includes self-employed doctors and paramedical staff providing services such as diagnostic services, pathology and physiotherapy.

Effect of National Health Scheme

A national health insurance program tends to lock in place the features of the existing health care system that is based on a fee for service financing for medical services.¹⁹² This system creates inflexibility in pricing which does not deal well with the rapid pace of technological developments and costs of medical services.¹⁹³ This inflexibility has fostered an approach by medical doctors that deals with falling real incomes by focusing on short patient visits and higher patient throughput. That process is supported by the therapeutic approach favoured by OM. The Medicare system does not accord clear priority to preventative health programs that may deliver future costs savings.¹⁹⁴

190 Rosemary Odgers and Tanya Moore, 'Surgery queue grows for sick', *The Courier Mail* (Brisbane, Australia), 10 February 2003, 1, 5.

191 Ibid.

192 Cunningham above n 188, 52.

193 Ibid.

194 Ibid.

Private Health Care Funds

There are in Australia 44 registered private health care funds under the *National Health Act 1953* (Cth).¹⁹⁵ In 1998-1999 approximately 9.5% of total health expenditure was funded through private health insurance.¹⁹⁶ Registered health benefit organizations provide patients with the ability to insure against the cost of medical care not covered by the Medicare scheme. This coverage can include a portion of fees for hospital theatre, accommodation costs and medical costs provided to patients in private and public hospitals.¹⁹⁷ The largest funds such as the Medical Benefits Fund and Medibank Private are represented in all states and territories while other funds are limited to one or a number of states.

The initial estimates of the cost of Medicare assumed that approximately 40% of consumers would retain private medical insurance. In the years before Medicare in 1983 private insurance cover was about 60%. In subsequent years the percentage of the population with private health care declined substantially to 31% at June 1999.¹⁹⁸ The Commonwealth government sought to reverse this trend by:

- introducing a 30% tax rebate for payment of premiums for private health insurance.¹⁹⁹
- introducing an additional medicare levy for those without private health insurance hospital cover.²⁰⁰
- removing the community rating principle allowing lower premium rates for younger and healthier participants.

195 Year Book, above n 182, 358.

196 Australia's Health 2002, above n 178, 262.

197 Ibid.

198 Cunningham above n 188, 54 - from Private Health Insurance Administration Council, *Quarterly Statistics March 2000* (2000) www.phiac.org.au.

199 This rebate cost the Commonwealth \$1.6 billion in 1999-2000 - AIHW *Health Expenditure Bulletin (1999-2000)*.

200 Australia's Health 2002, above n 178, 265.

- Provision of no-gap insurance products to avoid the gap payment between insurance payouts and hospital related fees.

This has been successful in increasing the percentage of the population with private health coverage to 44.9% in June 2002 down from a peak of 45.8% in September 2000.²⁰¹

The professional fees for most OM professions ie MD's (where fees not covered by Medicare), optometry, physiotherapy, podiatry and dentistry, are covered by these funds.

Each private health fund takes a different approach to coverage of CAM services. Most funds refund a proportion of professional fees incurred for chiropractic and osteopathy, while professional fees for acupuncture, naturopathy, homoeopathy and remedial massage are covered by many funds.

Some modalities such as kinesiology, iridology and Alexander technique are covered by only a few health funds.²⁰² The trend towards private health funding for CAM trend is also reflected in the USA.²⁰³ This trend has been criticised as responding only to consumer demand without appropriate evidence of efficacy and safety while sending a message to consumers that CAM is an accepted and respectable form of treatment.²⁰⁴ The access to private health fund refunds creates an incentive to use the professional services of CAM practitioners. With little direct or indirect government funding CAM is often a more expensive option than government subsidised OM.

201 Australia's Health 2002, above n 178, 263.

202 Editor, 'Health Funds Update' (2002) 8 *Journal of the Australian Traditional Medicine Society* 45.

203 DM Eisenberg, 'Advising Patients Who Seek Alternative Medical Therapies' (1997) 127 *Annals of Internal Medicine* 61, 61.

204 Boozang, above n 42, 571.

Indirect Government funding for Health

Federal and State governments supply substantial indirect funding for OM in all its forms through the funding of university medical and allied medical education throughout Australia.²⁰⁵ In addition, some students receive direct funding for living expenses under the Austudy scheme. This applies to all university students. This funding includes provision of clinical training in hospitals for medical and allied medical students. Student derived HECS fees provide a proportion of the cost of this university training privately.

CAM education obtains indirect funding for the education of students through diploma, degree and masters level university training in a number of universities namely:

University of Western Sydney – Osteopathy.

RMIT – Chiropractic, Osteopathy, Acupuncture and TCM.

University of New England – Naturopathy.

Macquarie University – Chiropractic and Osteopathy.

Southern Cross University – Naturopathy.

Victoria University of Technology – Osteopathy and Natural Medicine and Chinese Medicine.

University of Technology Sydney – Acupuncture.

In addition, government education funding for various CAM modalities is available in a number of TAFE establishments for diploma and certificate courses in therapeutic massage and homoeopathy. There is virtually no provision for clinical training of practitioners in

205 A.M. Kleyhans, 'The Culture of Chiropractic: an Educational Perspective' (1998) 28 *Chiropractic Journal of Australia* 49, 55.

hospitals. Clinical training relies upon in-house clinics found at these institutions. This limits access to the broad scope of maladies to which OM students may be exposed.

A large proportion of CAM students in Australia receive their education through private colleges where there is no direct funding by the Federal government. These private colleges rely primarily on private tuition fees to fund the education received.²⁰⁶ The private colleges vary widely in the quality of their offerings. Colleges provide up to a level of degree status for some courses as in the case of Australian College of Natural Medicine where a degree can be obtained in naturopathy. There are currently dozens of colleges in Australia educating thousands of students in the whole gamut of CAM, except chiropractic and osteopathy that is currently limited to University education.

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (Cth) controls the supply and manufacturing of pharmaceutical and complementary medicine products in Australia. A detailed analysis of this legislation is provided in chapter 5 below.

Health Rights legislation

In all states and Territories, other than South Australia, health rights legislation gives health service consumers the entitlement to complain about health services providers.²⁰⁷

²⁰⁶ Ibid.

²⁰⁷ *Health Care Complaints Act 1993* (NSW); *Health Services (Conciliation and Review) Act 1987* (Vic); *Health Rights Commission Act 1991* (Qld). *Health Services (Conciliation and Review) Act 1995* (W.A.); *Health*

These statutes provide an additional statutory complaint mechanism for registered health professionals augmenting the complaint mechanism under the relevant registration acts. For unregistered CAM practitioners it is the only statutory based complaint mechanism. The detail of these statutes is discussed in Chapter 4.

GST exemptions

The importance of health care is emphasised by the exempt status given both to medical services and pharmaceuticals in the GST legislation. The significant role played by CAM in the provision of health services was partially acknowledged by Section 38-10 of the *A New Tax System (Goods and Services Tax) Act 1999* (Cth). This sections confirms that the supply of health services for chiropractic, osteopathy, acupuncture; naturopathy or herbal medicine including traditional Chinese Herbal medicine are GST free if:

- the supplier is a recognized professional in relation to the supply of services of that kind; and
- the supply would generally be accepted, in the profession associated with supplying services of that kind, as being necessary for the appropriate treatment of the recipient of the supply.

A ‘recognized professional’ is defined as a person who has a permission, approval or registered status under state or territory legislation or is a member of a professional association with uniform national registration requirements in relation to the supply of services of that kind.²⁰⁸ Chiropractors and osteopaths duly registered under the applicable state legislation would satisfy this definition. In Victoria acupuncturists and TCM practitioners will now be regarded as satisfying these requirements on registration under the

Complaints Act 1995 (Tas); *Health Complaints Act 1993* (ACT); *Health and Community Services Complaints*

Chinese Medicine Registration Act 2000 (Vic). Other CAM practitioners will need to rely on membership of a professional association with uniform national registration requirements.

The necessity to satisfy these provisions to protect the GST exempt status for acupuncture, naturopathy, herbal medicine or TCM practitioners is postponed by section 21 of the *A New Tax System (Goods and Services Tax Transition) Act 1999* (Cmth). This provision states that the requirement to be a 'recognised professional' to qualify for the GST exempt status does not apply if the services are provided before 1 July 2003 and specified educational standards and membership of professional bodies or other qualifications are satisfied.

After 1 July 2003 to retain exempt status these practitioners will need to qualify as a 'recognized professional.' This has provided substantial impetus to the movement for these professions to be registered or for practitioners to obtain membership of national professional organizations that have appropriate registration requirements. In February 2002 the Commonwealth Department of Health and Aging announced that five of the major CAM professional associations would each receive a share of .5 million dollars to assist them to establish a uniform national registration system to preserve their GST exempt status. This program has been named the 'Complementary Therapies Funding Program for the Establishment of Uniform National Registration Systems for Suitably Qualified Practitioners in Acupuncture, Herbal Medicine and Naturopathy.' The Australian Taxation Office has recently now acknowledged a number of major professional associations as having a uniform national registration system thus allowing members to retain GST exempt status.²⁰⁹

Act 1998 (NT).

208 s 195 -1.

209 Editor, 'Professional Registration and the GST' (2002-2003) 2 *Diversity* 13.

The supply of goods associated with exempt professional services may also be exempt from GST for chiropractic, osteopathy and acupuncture if the supply is made at the premises at which the service is supplied, that is, the clinic.²¹⁰ This would presumably include the supply of acupuncture needles, vitamins and supplements. For herbal medicine, including TCM and naturopathy, the supply of goods such as medicine or herbs is GST free, if the supply is made in the course of supplying the services and is supplied and used or consumed at the premises.²¹¹

The GST free status does not apply to services supplied by massage therapists and homoeopaths. The non-inclusion of homoeopaths is significant. It appears that the OM view that this modality has no effect whatsoever on the body's biological processes, has influenced government policy. The reasons for this exclusion probably relate to the historical conflict that has existed between OM and homoeopathy since the late 1800's. This exclusion is an example of the impact that OM can have on government policy. This issue will be considered in Chapter 3.

Impact of Government Involvement in the Health Sector

The impact of the extensive government involvement in Australian health care is substantial. As medical services rendered in a private hospital and most standard medical services of medical doctors in private practice are covered by the CBMS there is little incentive for a consumer to look elsewhere for cheaper medical services. If services are free or almost free there is little incentive for a consumer to seek fewer services. There is no

210 *A New Tax System (Goods and Services Tax) Act 1999 (Cth)* s 38 (3).

211 *A New Tax System (Goods and Services Tax) Act 1999 (Cth)* s 38 (4).

correlation between the amount paid by an individual for the Medicare levy and the amount of services claimed.²¹²

The extensive government involvement in health care may encourage a tendency to look at health funding not in relation to its effectiveness but on the basis of a ‘more is better’ perspective.²¹³ Within this perspective little emphasis is placed upon preventative aspects of health care. Focus is primarily upon dealing with disease states as they present themselves. This focus is supported by the interventionist tendencies of OM that favours dramatic interventions once a disease state is detected.

There is no provision for the funding of CAM services (other than the x-ray services for some chiropractic services) as part of direct Commonwealth funding. The only exception is direct funding for acupuncture performed by a medical doctor for particular conditions.²¹⁴ Many doctors who perform acupuncture will do so with much less training than lay practitioners.²¹⁵ In 1996 15% of GP’S presented medicare forms for the provision of acupuncture. The number of Medicare claims for acupuncture grew by 50% in 12 years to nearly 1 million in 1996 –1997 with reimbursement increasing by \$7.7million to \$17.7 million.²¹⁶ There may be statistically a small decline in that trend as CBMS payments for acupuncture constituted \$15.2 million dollars in 2000-2001 for 719,000 acupuncture claims.²¹⁷

212 Hood, above n 186, 297.

213 Jeffrey Braithwaite, ‘Competition, Productivity and the Cult of ‘More is good’ in the Australian Health Care Sector’ (1997) 56 *Australian Journal of Public Administration* 37, 39.

214 Refer to *Health Insurance Act 2000 (Cth) General Medical Services Table Regulations item 173 Sch 1 Group A7*.

215 Alan Bensoussan, Stephen P Myers and A Carlton, ‘Risks Associated With the Practice of Traditional Chinese Medicine’ (2000) 9 *Archives of Family Medicine* 1071, 1077.

216 PA Komesaroff, G Easthorpe, JJ Beilby, GF Gill and BK Tranter, ‘Acupuncture in Australian general practice: practitioner characteristics’ (1998) 169 *Medical Journal of Australia* 197.

217 Australia's Health 2002, above n 178, 320.

The provision of government funding for health services means that, whether in private practice or as part of public hospital care, OM is subsidised or completely covered by direct or indirect government funding. There is no direct funding for CAM services by non-medical practitioners. This means that the real cost of CAM to consumers is greater than OM. This provides a substantial financial disincentive to the use of CAM in the health care sector. Despite this disincentive the clients of CAM practitioners are still prepared to fund this treatment.²¹⁸

Integrative Medicine

Extent of Use of CAM by Medical Doctors

One recent and significant development has been the influence of CAM on the practices of many doctors especially general practitioners.²¹⁹ One survey of 145 GP's in England indicated that 38% claimed to have had training in CAM while 15% would like to arrange training.²²⁰ This study also showed most GP's impliedly endorse CAM by their practice of referring patients for CAM.²²¹

Pirrotta and Cohen estimates the percentage of GP's that use CAM in their practice varies from 16% in Canada and the UK, 30% in New Zealand, 47% in Holland (mainly homoeopathy) and up to 85% in Germany (mainly herbal medicine).²²² The Royal College of General Practitioners has indicated that from 1992 to 1996 the number of GP's who are

218 F Davidoff, 'Weighing the Alternatives: Lessons from the paradoxes of Alternative Medicine' (1998) 129 *Annals of Internal Medicine* 1068, 1069.

219 Haigh, above n 152, 199; British Medical Association, above n 9, 32.

220 R Wharton and G Lewith, 'Complementary Medicine and the General Practitioner' (1986) 292 *British Medical Journal* 1498, 1498.

221 Ibid.

222 Pirrotta, above n 114, 105.

incorporating CAM into their daily practices increased from 2000 to 4000.²²³ Prestigious medical journals now debate the merits of CAM.²²⁴

Reasons for Growth of Integrative Medicine

The reason for this process has been explained as:²²⁵

- a response to consumer demand because of the clinical success of CAM even if scientific evidence may be lacking.
- a response to market pressures that support creating greater consumer choice; increased competition and a shift in power to the consumer; and
- a return to traditional roots driven by a postmodernist perspective on society.²²⁶
- an openness to CAM amongst GP's brought about by disillusionment with aspects of OM contributed to by broader post modernist trends.

Education in Integrative Medicine

This trend is supported by educational opportunities now available to medical doctors and medical students. At Swinburne University Graduate School of Integrative Medicine, a college formed in 1998, medically trained students are able to obtain graduate certificate, diploma and masters level qualifications in nutritional and integrative medicine.

The Australasian Integrative Medicine Association (AIMA) is an association of medical students and medical practitioners formed in 1997. AIMA perceives its role is:²²⁷

223 Swinburne University Graduate School of Integrative Medicine Website swin.edu.au/gsim/frames/main-frame.htm 3/2/2001.

224 Haigh, above n 152, 199, Heather Eastwood, 'Complementary Therapies: the appeal to general practitioners' (2000) 173 *Medical Journal of Australia* 95, 98.

225 Eastwood, *ibid* 95.

‘to act as a peak medical body that promotes the integration of holistic and complementary medicine with current mainstream practice.’

The Australian College of Nutritional and Environmental Medicine (ACNEM) permits membership by medical doctors and other health professionals. ACNEM has a mission: ‘to transform the health and well being for all people, by encouraging the practice of nutritional and environmental medicine as a rational means for the prevention and treatment of disease.’²²⁸

In Australia and other countries the development of integrative medicine reflects in various university centers of research exemplified by:

The Arizona Centre for Health and Healing Services (University of Arizona School of Medicine.

The Harvard University Medical School Mind/Body Institute at Deaconess Teaching Hospital.

Columbia University The Richard and Hilda Rosenthal Centre of Complementary and Alternative Medicine.²²⁹

UCLA Centre for East- West Medicine.²³⁰

University of Arizona School of Medicine: The Arizona Center for Health and Healing.

The Chinese Medicine Research Group – Royal Melbourne Institute of Technology.

The University of Sydney – Herbal Medicine Research and Education Centre.

226 JJ Chan and JE Chan, ‘Medicine for the Millenium: The Challenge of Postmodernism’ (2000) 172 *Medical Journal of Australia* 332, 332.

227 [http:// www.aima.net.au](http://www.aima.net.au) (18th November 2002).

228 <http://www.acnem.org/>.

229 [http://www. cpmcnet. Columbia.edu/dept/rosenthal/](http://www.cpmcnet.columbia.edu/dept/rosenthal/).

230 [http://www.medsch.ucla.edu/som/ medicine/cewm/othermks.asp](http://www.medsch.ucla.edu/som/medicine/cewm/othermks.asp).

Australian Centre for Complementary Medicine Education and Research (Joint Centre between University of Queensland and Southern Cross University).

Centre for Complementary Medicine (Monash University).

Centre for Advancement of Food Technology and Nutrition (University of Newcastle).

The Cellulose Valley Project (A project of Southern Cross University).

The Centre for Phytochemistry (Cellulose Valley Project – Southern Cross University).

Victorian Complementary and Alternative Medicine Research Centre Project (Monash University and The Baker Medical Research Institute).

These initiatives are reflected in medical research that incorporates consideration of lifestyle issues and greater involvement by patients in their own health care.²³¹ This trend is fostered by those MD's who are convinced by empirical evidence and what scientific evidence there is of the success of CAM. They may be convinced that hard scientific evidence will be available at a later date.²³² MD's often vary or reject the traditional explanations for CAM practice. For example, a MD may prefer to rely on biomedical explanations for the therapeutic impact of acupuncture without embracing traditional Chinese medicine explanations or philosophy.²³³

The best quality outcome for the provision of health services may be an integration of OM and CAM. To accommodate the scientific background of the more powerful influence of OM CAM must progress with an evidenced-based approach to the assessment of the efficacy of its treatments.²³⁴

231 C Cassidy, 'Social Science Theory and Methods in the Study of Alternative and Complementary Medicine' (1995) 1 *The Journal of Alternative and Complementary Medicine* 19, 21.

232 Crellin and Ania, above n 7, 21.

233 Ibid.

234 GT Lewith and Ors, 'Complementary Medicine Must be Research Led and Evidence based' (2000) 320 *British Medical Journal* 188.

Despite the trend towards integrative medicine there continues to be a lack of communication between OM and CAM resulting in tensions; suspicions and more importantly a lack of knowledge of the CAM options available to an MD. This lack of communication, pro-active referral practices or appropriate advice on CAM treatment does not promote quality outcomes in health care. The reluctance of OM to refer patients to CAM for treatment may be based on a concern for the potential liability for that referral if the patient does not receive adequate care.²³⁵ The style and type of education of CAM practitioners as compared to OM may not easily permit close cooperation.²³⁶ The provision of broader statutory regulation of CAM would assist the process of increasing communication and referral between CAM and OM.

The benefits of integrated medicine may be substantial. CAM can provide a higher satisfaction level for clients with its more egalitarian approach to therapy. CAM is likely to cause fewer adverse side effects and can promote the use of less costly remedies that rely on lifestyle, dietary and behavioural changes.²³⁷

Another major bulwark to cooperation is the view taken by OM that only medical doctors who have the broad biomedical training and skills in diagnosis to safely provide CAM treatment. This reflects the historical approach of OM to seek to colonise and control the provision of health services when the provision of those services provides a threat to the hegemony of OM.

Summary of General Position

235 Studdert and Eisenberg, above n 104, 1610.

236 Crellin and Ania, above n 7, 10-11.

237 Jonas and Levin, above n 24, 11.

While OM receives substantial funding by government and enjoys legislative and regulatory endorsement CAM has no direct funding by government; lacks broad legislative endorsement and is substantially reliant on private funding both for the education of its practitioners and the funding of professional fees.

This position may change as a number of influences discussed below begin to impact upon how health care is regulated. The purpose of chapter 3 is to analyse the various social, legal, political and scientific influences that have created the current OM hegemony. These influences provide an insight into why health care is perceived as it is today and what might be alternative models of regulating health. By appreciating the past an observer is given some perspective on the paradigm from which CAM is assessed. This paradigm provides a jaundiced view of the purpose and effectiveness of CAM to provide appropriate health outcomes. This has impacted negatively on the regulatory environment even though there has remained a solid base of public support for CAM. The rationalist reductionist scientific approach to health care has provided many benefits. By spurning the subjective, the empirical, the social, the emotional, the philosophical and cultural aspects of health care one aspect of the healing process for human beings is under-represented.

The Concept of health.

The perception of what is 'health' is of vital importance to the determination of the power structure within the health sector. The concept of health defined by OM is deeply ingrained in society and impacts on many levels. Paul Starr expressed it in the following way:²³⁸

Modern medicine is one of those extraordinary works of reason: an elaborate system of specialized knowledge, technical procedures, and rules of behaviour. By no means are these all purely rational: our conceptions of disease and responses to it unquestionably show the

238 Starr, above n 6, 1.

imprint of our particular culture, especially it's individualistic and activist therapeutic mentality.²³⁹

The OM approach to health that characterises contemporary medical culture is at odds with the approach to health prior to the 19th century when health was intricately entwined with the practice of living.²⁴⁰ The conception of health as a process rather than simply as an end result of treatment focussed attention on health practice on a daily basis.²⁴¹ This supported viewing a person as a whole. Illness was seen as an imbalance in the harmony of the body. This holistic as against mechanistic or reductionist approach to health care characterised prior concepts of health.²⁴² In this way disease can be seen to have a cultural aspect.²⁴³

OM has become our own culturally specific perspective about what is health and disease. In that sense it has become Western culture's folk medicine.²⁴⁴ This view reflects the fact that 'reality' is itself a construct. Whatever a person perceives reality to be, is taken from a specific personal, historical, cultural and political perspective. This is noted in anthropology and physics as the Heisenberg principle.²⁴⁵

If it can be shown 'some medical practices are less the result of scientific determinism than they are a manifestation of a certain cultural practice, then it is a short step to acknowledge that other alternatives deserve similar recognition.'²⁴⁶ For this reason to attempt to look outside the OM construct of illness and disease it is necessary to understand the sources of

239 Refer also to Encyclopedia of Bioethics, above n 4, 135-143, 136.

240 H.S. Berliner and J W Salmon, 'The Holistic Alternative to Scientific Medicine: History and Analysis' (1980) 10 *International Journal of Health Services* 133, 134.

241 Ibid.

242 Ibid.

243 George Engel, 'The Need for a New Medical Model: A Challenge for Biomedicine' (1977) 196 *Science* 129, 130.

244 Ibid.

245 McGraw Hill, *Dictionary of Scientific and Technical Terms* (4th ed 1989) 1993.

246 Haigh, above n 152, 201.

this construct. This involves a complex interplay of scientific, historical, economic and cultural influences that has resulted in the current regulatory structure of the health sector.²⁴⁷

If the cultural aspects of medicine are accepted then there is a prospect that OM, and how it is perceived, may be influenced by fundamental social change such as the developing postmodernist perspective. OM could be seen as modernist in outlook 'characterised by a belief in the truth; objectivity; determinacy, causality and impartial observation.'²⁴⁸ It has been described as 'a search for an underlying and unifying truth and certainty, a search for a definitive discourse that makes the world self coherent, meaningful and masterable.'²⁴⁹

The postmodernist perspective embraces concepts like:

individuality; complexity and subjectivity of personal experience. The postmodernist paradigm cannot accept that all things may be understood and mastered through science. The validity of intuition and experience is considered equal to that of traditional methods of observation, induction and experimentation.²⁵⁰

If health is viewed through the prism of postmodernist thought, the sheen that science and rationality gives to scientific medicine may be revealed as flawed.

The ability of the postmodernist perspective to dictate OM in the future will be hampered by a number of factors:

- on health issues even a post modernist thinker may prefer a remedy with more formally confirmed effectiveness.
- the inflexibility of Medicare and the health care infrastructure will slow any rapid adjustments to medical practice and approaches to health.

247 AL Glaser, 'Alternative Healing, Chiropractic and the Law' (1995) 37 *Trauma* 63-75 223-224; George L Engel, 'The Need for a New Medical Model: A challenge for Biomedicine' (1977) 196 *Science* 129, 130.

248 Chan and Chan, above n 226, 332.

249 Ibid.

- many people who use medical services ie the older members of society are not as fundamentally touched by this outlook.
- The fundamentally conservative and entrenched nature of OM will not easily accommodate such change.

Conclusion

The above analysis demonstrates the significant role that OM has had in setting the pattern for the Australian health sector. This makes the task of forging a significant role for CAM difficult. The authoritative role that OM has over the conception of what 'health' is and how treatment regimes should be designed and funded has a significant impact on the regulatory structure. As the OM perspective on health is so deeply embedded in society and its influence so integral in the health care structure, it is for many people difficult to envisage a contrary healing philosophy. The OM structure is based on a distinct philosophy that leaves little room for CAM concepts. The means by which OM achieved this paramount position will be canvassed in chapter 3.

Chapter 3

Precursors to Hegemony

Introduction

This chapter will deal with the important legal, sociological, economic and philosophical conflicts that consumed OM and CAM over the past 200 years and formed the modern regulatory structure. It is difficult to understand and analyse that structure and in turn to suggest proposals for its reform without tracing these themes and their impact. In the same way that these influences have formed the current regulatory structure, important changes in society are forging pressures to develop new ways to regulate the provision of healing in our society. As the modernist perspective gives way to postmodernist influences the health sector will change to reflect new definitions of what 'health' is and the increasing role of autonomous decisions by consumers in the process of health service delivery.

Orthodox and Complementary and Alternative Medicine – Defined by the Struggle

CAM and OM share a symbiotic relationship. As each contributes to the provision of healing they are competitors. Each has incorporated aspects of the other in their practice. One threat to the independent practice of CAM is the potential for its incorporation into OM or colonisation by OM.²⁵¹ Each to some extent define and influences the other.²⁵² CAM has survived and flourished partly because some aspects of OM do not resonate with or satisfy all

251 Crellin and Ania above n 7, 31.

252 Encyclopedia of Bioethics, above n 4, 135.

clients.²⁵³ CAM has been attributed with providing a more pronounced spirit of self-criticism within the health and social-service professions as it fosters an acknowledgment of the overly mechanistic OM approach to health services that sometimes fails to deal with the patient at a personal level.²⁵⁴

Public demand has historically provided CAM with its greatest support. The strength of CAM is its ability to deliver what the recipients consider are benefits even if the scientific evidence prized by OM is not available. Many clients think empirically ('it works for me') rather than scientifically and discount the need for scientific evidence. The question for regulators is the extent to which you respect and support this consumer empiricism in the regulatory structure. The purpose of this chapter is to review aspects of the history of OM and CAM to suggest that these historical influences should not unduly influence the modern regulatory structure unless they express aspects of the public interest.

This historical analysis is important, as often the original regulatory structures imposed on an industry will have an influence on the pattern of future regulation.²⁵⁵ An understanding of history will reveal the parallels between the influence of CAM at the beginning of the 21st century and the flourishing of CAM modalities in first half of the 20th century.²⁵⁶ This historical perspective will reveal that the hegemony of OM has been in place for only the last 100 years or so. This analysis will parse relevant themes that placed OM as the dominant arbiter of healing in western society thereby creating its modern relationship to CAM.

253 Kottow, above n 143, 18; Wayne Jonas, 'Alternative Medicine – Learning From the Past, Examining the Present, Advancing the Future' (1998) 280 *Journal of the American Medical Association* 1616, 1616.

254 Crellin and Ania, above n 7, 41.

255 Matthews and Stone, above n 32, 19.

256 Crellin and Ania, above n 7, 18.

Unlike the other traditional professions such as the law and the clergy that have had few competitors, OM has throughout its history been involved actively in dealing with groups of dissident healers. These groups were variously characterised by OM as ‘cults’ ‘quacks’ or ‘sects.’²⁵⁷ Although the constant competition provided by these groups did and continues to erode OM’s influence and market share it had the effect of galvanizing and uniting OM to the benefit of the profession’s prestige and legislative control over health.²⁵⁸

OM as Scientific Medicine

OM has ‘through its postulation of rational, as opposed to empirical, theories of disease aetiology’ developed into scientific medicine.²⁵⁹

Scientific medicine has been defined as:

the generic term for a specific mode of healing characterised by: (1) the assumption that all disease is materially generated by specific etiological agents such as bacteria, viruses, parasites, genetic malformations, or internal chemical imbalance; (2) a passive patient role; and (3) the use of invasive manipulation to restore/maintain the human organism at a statistically derived equilibrium point (health).²⁶⁰

Science was the primary driving force in the development of knowledge and capacity in the 20th century. This trend supported OM as it claimed the status and influence of the mantle of ‘scientific medicine.’²⁶¹

The influence of science on OM became dominant when medical education in the USA was transformed in the early years of the 20th century towards a research-based discipline where

257 Ibid 17.

258 Willis, above n 129, 55.

259 Howard S Berliner, ‘Scientific Medicine Since Flexner’ in Warren Salmon (ed), *Alternative Medicines Popular and Policy Perspectives*, (1984) 31.

260 Ibid.

261 Willis, above n 129, 62.

scientific research reliant upon laboratory research and hospital training became the norm. The growth of the hospital system in the 19th century gave more opportunity for clinical research.²⁶²

The connection with scientific research was fortuitous as the advances of the general sciences allowed OM to attach itself in the minds of the general public and policy makers to the potential of advances in medical science. Willis comments OM 'utilised the growing legitimacy of science as a means of collective upward social mobility.'²⁶³

Coalition of Science and OM

In the late 1880's and early 1900's appeals to the rationality of science as the basis of authority became an important new ideology legitimating the social order.²⁶⁴ This characterized the era of modernism that spawned the pursuit of progress through the realization of grand theories.²⁶⁵ Prior to this period the lack of successful and acceptable treatments for many of the ills of humanity threatened the legitimacy of OM.²⁶⁶ Science has been 'idealized as possessing a clarity of viewpoint and an unimpeachable rigor of method that inherently surmount cultural values and interest-group bias.'²⁶⁷ This approach suggests science is the final arbiter of what is or is not the truth suggesting that unscientific endeavour is inherently inferior and unreliable.²⁶⁸ This viewpoint was invaluable in obtaining political patronage required to secure OM's legislative protection. OM was able to forge a public

262 PA Nicholls, *Homoeopathy and the Medical Profession* (1988) 39.

263 Willis, above n 129, 81.

264 Ibid 62.

265 Mike Saks, 'Medicine and Complementary Medicine' in G Scrambler and P Higgs (eds), *Modernity, Medicine and Health Medical Sociology Towards 2000* (1998) 199.

266 Willis, above n 129, 39.

267 O'Connor, above n 35, 14.

268 Ibid.

perception that it was an exact science.²⁶⁹ This led to an acquiescence to the view that OM diagnosis and treatment was the only way to appropriately provide health services. This was allied to the principle that a single standard of care should be available to all, thus leading to pervasive OM control over the provision of health care.²⁷⁰

OM has achieved its modern status despite the fact that for most of its history science has played a small part in most therapeutic interventions. Until the early 1900's most interventions relied substantially on empiricism and experience. OM as scientific medicine is a title that can probably only be properly applied in the last 100 years. Until significant discoveries were made relative to the germ theory, the use of antiseptics, and later antibiotics the predominant approach of OM to knowledge was empirical. With the exception of smallpox (which was treated by inoculation) or diphtheria (treated with anti-toxin)²⁷¹ it was only after these scientific discoveries were actually incorporated into treatment of humans in the 1930's that real progress occurred in treatment of disease.²⁷²

How Much of OM is scientific?

Even in the modern context there is no clear consensus on the extent to which OM is based upon solid scientific evidence.²⁷³ At the extreme edge of opinion one source states that because of the poor quality of much scientific research that only about 15% of medical

²⁶⁹ Clark C Havighurst, 'The Changing Locus of Decisionmaking in the Health Care Sector' (1986) 11 *Journal of Health Politics Policy and Law* 697, 706.

²⁷⁰ Ibid.

²⁷¹ Roy Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity From Antiquity to the Present* (1997) 274-276, 438-439.

²⁷² Berliner, above n 259, 33.

²⁷³ MJ Hensley and PG Gibson, 'Complementary and Alternative Medicine: an educational, attitudinal and research challenge' (2000) 172 *Medical Journal of Australia* 102, 102-103.

interventions are supported by solid scientific evidence.²⁷⁴ A less dramatic picture is suggested by one study where it was found 53% of patients in a British hospital received primary care that had been validated in randomised controlled trials with an additional 29% receiving treatment that was well supported.²⁷⁵ Another study suggested that 81% of patients in general practice received evidence based interventions.²⁷⁶ Sixty percent of all therapeutic benefits are attributed to placebo and Hawthorn effects.²⁷⁷ There is evidence to suggest that much of what is valued by MD's in practice is empirical clinical experience.²⁷⁸

Even when scientific evidence is available the quality of some of the science relied upon by OM has been doubted on the basis:

- Few studies are properly evaluated for their scientific integrity.²⁷⁹
- Studies can quickly become dated as technology progresses.
- Trials are set in atypical settings casting doubt on their relevance to clinical practice.
- The expense of studies supports small sample sizes where it is difficult to study the impact on subgroups.
- The use of scientific evidence can downgrade emphasis on non-measurable aspects of practice such as social context and psychological issues leading to problems of communication with patients.²⁸⁰
- The use of scientific studies that rely upon the effects of a substance on a group does not necessarily relate to how a substance effects an individual.²⁸¹

274 Richard Smith, 'Where is the wisdom...? The poverty of medical evidence' (1991) 303 *British Medical Journal* 798; National Institute of Health, *Consensus Development Statement Acupuncture Revised Draft* (1997) 5; Commonwealth Department of Human Services and Health, *Review of Professional Indemnity Arrangements for Health Care Professionals Compensation and Professional Indemnity in Health Care: A Final Report* (1995) 3.

275 Ellis J Mulligan, I Rower and J Sacket, 'Inpatient medicine is evidence based' (1995) 346 *Lancet* 407-410.

276 Gill P Dowell and AC Neal, 'Evidence Based General Practice: A retrospective study of interventions in one training practice' (1996) 312 *British Medical Journal* 812-822.

277 Haigh, above n 152, 210.

278 Willis, above n 129, 20.

279 Ray Moynihan, *Too Much Medicine: The Business of Health and its Risks for you* (1988) 233.

- The bias in studies is upon the issue of effectiveness and not side effects of treatment.²⁸²
- There is a bias towards seeking scientific evidence of drugs and not procedures. Many well-known and apparently well-accepted procedures such as coronary bypass surgery were performed from the mid 1960's but not confirmed as appropriate therapy until 1977. Many antibiotic therapies are still not evidence based.²⁸³
- There appears to be a bias in favour of publishing studies of drugs that find a positive result. This creates a biased knowledge base on certain substances.²⁸⁴ This may also be reflected in CAM research, as there are very few published studies commenced by CAM investigators that are negative for CAM.²⁸⁵

The legitimacy of OM has been enhanced in recent years by the principles of evidence-based medicine. Evidence based medicine suggests that practitioners should make therapeutic decisions in accordance with the best available supporting scientific evidence.²⁸⁶

Although evidence based medicine can support honest communications between doctor and patient on the benefits, risks and doubts about a particular therapy²⁸⁷ many doctors still rely on experience (empiricism) for much of their practice and may perceive evidence based medicine as an attack on their clinical freedom.²⁸⁸

280 Ibid 236.

281 Ibid 232.

282 Ibid 220-234.

283 James E Dalen, 'Conventional and "Unconventional" Medicine: Can They be Integrated,' (1998) 158 *Archives of Internal Medicine* 2179, 2181.

284 Craig Hassed, *New Frontiers in Medicine: The Body as the Shadow of the Soul* (2000) 52.

285 K Schmidt, MH Pittler and E Ernst, 'Bias in Alternative Medicine is still rife but is diminishing' (2001) 323 *British Medical Journal* 1071; CC Commens, 'Truth in clinical research trials involving pharmaceutical sponsorship' (2001) 174 *Medical Journal of Australia* 648-649.

286 Moynihan, above n 279, 213-241; Michael J Hensley and Peter J Gibson 'Promoting Evidence Based Alternative Medicine' (1998) 169 *Medical Journal of Australia* 573-574.

287 Moynihan, above n 279, 215.

288 Milburn, above n 176, 45.

Importance of OM/ Science Connection

The relationship OM has with science is important for a number of reasons.

It has provided and continues to provide an important counterpoint to the therapeutic claims of CAM. If CAM claims to provide positive outcomes, these claims are dismissed as reliant upon unreliable and unscientific empirical data. The origin of any such claims provides an opportunity to dismiss its importance or validity.²⁸⁹

The OM/ science connection has permitted the political acceptance and influence necessary to provide the statutory endorsement that both created and supported the prestige of OM and allowed in some contexts the statutory exclusion of CAM.²⁹⁰

The mantle of scientific medicine provided the means to align OM with the interests of the ruling classes and the capitalist system. This assisted in attracting vast sums of endowments to fund treatment, educational and research infrastructure such as universities, medical schools and hospitals that favoured scientific medicine.²⁹¹ CAM, perceived as non-scientific, was excluded from this process.

One of the most instructive lessons that history teaches is that healing has always been so closely associated with political power in society that those who claim the knowledge to heal will often find themselves having to defend that right in a philosophical and political arena, and in terms that have changed hardly at all over the centuries.²⁹²

289 Dalen, above n 283, 2180; For example refer to Encyclopedia of Bioethics, above n 4, 136 and Editorial, 'Alternative Medicine - The Risks of Untested and Unregulated Remedies' (1998) 339 *The New England Journal of Medicine* 839.

290 Starr, above n 6, 4.

291 Hans A Baer, 'The Drive for Professionalization in British Osteopathy' (1984) 19 *Social Sciences and Medicine* 717, 722.

292 Matthews and Stone, above n 32, 21.

The anchoring of OM in societal power structures provides a dilemma for OM as society changes in accordance with post modernist perspectives. In a postmodernist world less importance is placed upon the certainties of science with greater emphasis on truth derived from experience, individuality and subjective experience. This context provides scientific medicine with shifting ground and a loss of important supports.²⁹³

In effect, medicine is becoming a modernist phenomenon which can neither progress nor provide the necessary service to a society which is increasingly postmodernist. In the past, there were fewer alternatives to medical practice. Nowadays the needs of society are met by allied health professionals, naturopaths and other similar therapists. Unless the practice of medicine becomes more focussed on the unique individual, with an understanding of the limitations of the modern science of medicine, our role runs the risk of becoming less relevant to people today.²⁹⁴

Progression in OM Therapy

Based upon centuries of practice, OM until the modern era was heavily influenced theories reliant upon the Hippocratic belief in the need to provide equilibrium in the humours or bodily fluids. These humours were described as yellow bile; phlegm; black bile and blood.²⁹⁵ These beliefs favoured a number of dramatic therapies until the late 1800's.²⁹⁶

These now notorious therapies involved procedures such as:

- inducing sweating.
- blood letting which is the derivation of the medical icon, the lancet, used to draw blood.²⁹⁷
- emetics for vomiting.
- laxatives for evacuating the bowels.

293 Chan and Chan, above n 226, 333.

294 Ibid.

295 Porter, above n 271, 56-58.

296 Ibid 674.

297 I Chalmers, 'Evidence of the effects of health care: a plea for a single standard across 'orthodox' and 'complementary' medicine' (1998) 6 *Complementary Therapies in Medicine* 211-213.

- plasters for the creation of blisters on the skin, and
- use of highly toxic mercury or camomel.

These dramatic therapies aptly earned the description of ‘heroic medicine’. Many clients would recover during this treatment (and probably despite it). As there was no training in ascertaining or isolating the effects of treatment this was often accepted as resulting from the therapy applied. In reality the healing was not so much a demonstration of the validity of the treatment but the self-limiting nature of many conditions that draw upon the body’s recuperative powers.²⁹⁸ In the modern era this is used to explain some of the success of CAM along with the placebo effect.²⁹⁹

The understandably negative reactions by patients to these violent, painful and probably ineffectual remedies supported movements to other more gentle therapies such as homoeopathy that offered a cure without the attendant side effects.

Orthodox Medicine – Scientific Revolution

The development of scientific medicine gathered pace as the 20th century continued.³⁰⁰ The medical profession that had previously looked backwards to techniques anchored in the medical theories of Galen, Paracelsus and Hippocrates now looked forwards to science as its arbiter.³⁰¹ This transformation involved what Kuhn would describe as a ‘scientific revolution’ that lead from one paradigm to another.

298 Berliner, above n 259, 31.

299 Wayne B Jonas, ‘Safety in Complementary Medicine’ in Edzard Ernst (ed), *Complementary Medicine: An objective appraisal* (1996) 132.

300 Porter, above n 271, 10-11; Encyclopedia of Bioethics, above n 4, 136; Berliner in Salmon, above n 259, 30-56.

301 Fulder, above n 19, 11.

Kuhn suggests science develops and progresses in stages from non-science – normal science – crisis – revolution – new normal science – new crisis. This process charts the progression of knowledge from one generation to the next. Each generation acts within the laws, rules and assumptions of the imperfect current paradigm that sets the standards of legitimate work. In the normal science stage a scientist may be uncritical of the paradigm while exploring its nature.³⁰² It is only when these investigations reveal sufficient anomalies that a crisis period is reached. Then the possibility of another revolution may arise, perhaps by the efforts of a creative thinker, who provides the basis of a new way of looking at the problem. This may lead to another normal science period.³⁰³ Vickers argues for a more absolute view of science in OM and distinguishes scientific and health care paradigms to suggest that the application of Kuhn's principles to health is inappropriate.³⁰⁴

The rise of scientific medicine has been interpreted as a revolution in medical science and the development of a new paradigm.³⁰⁵ In Kuhn's terms a 'scientific revolution' occurred involving a paradigm shift in the understanding and treatment of disease. The new paradigm has come to be called the germ theory, that is, the tracing of the cause of diseases to specific etiological agents (germs) which can be identified and treated or cured through either biological means (vaccines) or chemical means (drugs). The germ theory came to provide the theoretical underpinning of 'scientific medicine.'³⁰⁶

302 AF Chalmers, *What is this Thing called Science?* (1999) 112-117;

303 Chalmers, *ibid* 107-109; Jonas and Levin, *above n* 24, 3; Milburn, *above n* 176, 46; Cohen, *above n* 11, 1

304 Andrew Vickers, 'Research Paradigms in Mainstream and Complementary Medicine' in Edzard Ernst (ed), *Complementary Medicine: An Objective Appraisal* (1996) 11.

305 *Encyclopedia of Bioethics*, *above n* 4, 137; Willis, *above n* 129, 63; Cohen, *above n* 11, 1-2.

306 Willis *ibid* 61; Berliner, *above n* 259, 32.

Working within a paradigm makes it difficult to perceive and understand phenomenon outside that paradigm.³⁰⁷ As a result within the OM paradigm CAM is seen at best as an anomaly, of no worth or deceptive in its claims. This paradigm also causes a resistance to evidence that contradicts conventional views.³⁰⁸ CAM is perceived as unsupported by evidence of accepted veracity to warrant consideration.

The emphasis on the germ theory suggested that germs were the primary reason for disease. This diverted attention from the environmental and social causes of disease. Until recently OM lacked a focus on preventative medicine.³⁰⁹ This may be based at least partially on the difficulties in applying the principles of reductionist medicine to what is yet to occur.³¹⁰ There is now an increasing awareness amongst OM of the importance of preventative medicine.³¹¹ Preventative measures have centered on cervical smears; mammography; cholesterol and blood pressure.³¹² In 1998-1999 the Australian government spent \$880 million dollars on preventative health programs. This sum constitutes only 2% of recurrent expenditure on health services. Of this amount 21% was spent on health promotion; 20% on immunisation and 16.5% on communicable disease control.³¹³ Greater expenditure on preventative medicine could lead to large savings in medical costs as lifestyle issues cause many medical problems.³¹⁴

307 Patel, above n 74, 669.

308 Ibid.

309 Berliner and Salmon, above n 240, 140.

310 Alan D Watkins, 'Contemporary Context of Complementary and Alternative Medicine' in M S Micozzi (ed), *Fundamentals of Complementary and Alternative Medicine* (1996) 50.

311 House of Lords, above n 39, 2.16; Moynihan above n 279, 243.

312 Watkins, above n 310, 50; G Easthorpe, 'The Response of Orthodox Medicine to the Challenge of Alternative Medicine in Australia' (1993) 29 *Australia and New Zealand Journal of Sociology* 289, 292; Willis, above n 129, 82; Australia's Health 2002, above n 178, 323-328.

313 Australian Institute of Health and Welfare and National Public Health, *Report (1998-1999) Health and Welfare Expenditure Series no 10* (2001) 126.

314 Australia Health 2002, above n 178, 324.

A greater interest in the social causes of disease and preventative measures may be perceived as risking undermining science as a basis of OM legitimacy as social issues are not as easily measurable at the individual level. It appears that OM is more secure when dealing with biology than sociology.³¹⁵

The attachment of OM to the germ theory provided an important connection to the capitalist class in the late 1800's as it placed responsibility for disease upon germs and not upon living and working conditions. This exculpated industry from responsibility.³¹⁶ Disease was now a process centered on the impact of germs on an individual that could be stripped of the relevant social, historical and cultural setting.³¹⁷ This downgraded the impact of social experiences in the healing process.

This stripping of disease from the social structure is based on a viewpoint that 'Historical connections and human influences are not considered part of science.'³¹⁸ Scientism 'became an important form of authority and social control, masked by the name of science, mediated through middle class professional organizations but supported and funded by upper class groups.'³¹⁹

Whatever might have been the actual impact of scientific medicine on mortality rates OM was able to claim that improvements in the control of disease in the early 1900's was as a result of the advances of science as they applied to medical knowledge. This strengthened the

315 Easthorpe, above n 312, 295.

316 Willis, above n 129, 24.

317 Baer, above n 292, 723.

318 Nancy Ehrenreich, 'The Colonization of the Womb' (1993) 43 *Duke Law Journal* 492, 532; George L Engel 'The Need for New Medical Model: A Challenge for Biomedicine (1986) 196 *Science* 129, 130.

319 Willis, above n 129, 82.

claim OM made for legitimacy and dominance in the health sector. This was significant in the political influence that permitted legislative backing for this hegemony.

Many CAM modalities also tend to ignore the broader social context. One can by massage and meditation relieve stress but that does not remove stress from life. CAM does not emphasise social change or criticise social institutions but focuses attention on the dynamics of change within the individual.³²⁰ There is little attention given to occupational and environmental hazards as it is viewed as beyond the control of the individual.³²¹

Counterpoint to CAM

One consistent historical feature of the political struggle for control of the provision of health services has been OM's attempts to control CAM or other non-mainstream health practices.³²² Exemplified by OM success in maintaining a position of dominance over optometry, physiotherapy and midwifery OM has sought to achieve a similar control over CAM.³²³ Armed with the mantle of protector of the public interest OM has attempted to deal with CAM in one of four ways:³²⁴

Exclusion

By statutory regulation in many jurisdictions CAM practitioners are positively excluded from plying their trade or limitations are placed on how practitioners can advertise or hold out their

320 Berliner and Salmon, above n 240, 144; Sharma and Cant, above n 40, 19; Alonda Oubre, 'Social Context of Complementary Medicine in Western Society' (1995) 1 *The Journal of Alternative and Complementary Medicine* 50.

321 HA Baer, 'The Holistic Health Movement in the San Francisco Bay Area: Some Preliminary Observations' (1998) 47 *Society Science and Medicine* 1495, 1499.

322 Milburn, above n 176, 64.

323 Mike Saks, 'Medicine and Complementary Medicine: Challenge and Change' in Graham Scrambler and Paul Higgs (eds), *Modernity, Medicine and Health* (1998) 202; Simpson, above n 154, 42.

ability to provide services. Gort and Coburn discuss OM attempts to eliminate or restrict naturopathy in Canada ³²⁵ while in Australia the AMA sought to exclude Medicare rebates for CAM practitioners.³²⁶

Incorporation of CAM therapies within OM

This has occurred in relation to osteopathy in the USA where osteopathy has virtually become an arm of OM with limited recourse to osteopathic principle in treatment.³²⁷ In Australia and other countries acupuncture and other CAM therapies have become part of accepted OM treatment.³²⁸ OM historically has been quick to incorporate specific CAM substances and techniques that proved effective such as vaccination, digitilis and quinine without incorporating CAM theoretical or philosophical models. It would be problematic for OM to incorporate healing techniques and philosophies that contradict its paradigm.³²⁹ OM has also incorporated practices that mimic the supposed strengths of CAM like empathetic communication with patients.

Subordination

By placing the therapy under the control of OM. This has occurred in regard to physiotherapy and midwifery. Both these professions now struggle to define their individuality.³³⁰ This is

324 Hans Baer 'Comparative View of a Heterodox Health System: Chiropractic in America and Britain' Summer (1984) *Medical Anthropology* 151, 153.

325 Gort and Coburn, above n 153, 1061-1062.

326 Easthorpe, above n 312, 290.

327 Wardwell, above n 124, 213.

328 Pirotta, above n 114,105; Jonas and Levin, above n 24, 3; Fulder above n 19, 74; AL Glaser, 'Alternative Healing, Chiropractic and the Law' (1995) 37 *Trauma* 63-75; WB Jonas 'Alternative Medicine - Learning from the Past, Examining the Present, Advancing to the Future' (1998) 280 *Journal of the American Medical Association* 1616, 1616; Easthorpe, above n 312, 295.

329 Patel, above n 74, 670; Nicholls, above n 262, 4.

330 Willis, above n 129, 92, 123; Cant and Sharma, above n 29, 162.

reflected in suggestions that CAM should only be provided by an MD or after referral by an MD.³³¹

Discrediting

OM has actively sought to discredit chiropractic and other CAM therapies considered a threat to OM.³³² In one period in the late 19th century the British Medical Association campaigned against ‘quacks’ but in its own journal accepted advertisements for the same products.³³³

This process is inevitably presented as being directed to the public interest. The impact of these measures and arguably the unstated aim is directed to the self-interest of OM. Any threat to OM’s hegemony is met by one of the above techniques to blunt the impact of the threat.

By contrast, whatever might be the strength of the scientific basis for CAM its primary support has come from the public who continue to use CAM therapies. When legal impediments were introduced the most effective responses came from consumers who lobbied to repeal or amend legislation or who sought out practitioners despite these legal impediments.

Recurrent Themes

331 Malcolm Parker, ‘Chinese Dragon or Toothless Tiger? Regulating the Professional Competence of Traditional Chinese Medicine Practitioners’ (2003) 10 *Journal of Law and Medicine* 285, 295.

332 Jonas and Levin, above n 24, 3; Nicholls, above n 90, 151; Glaser, above n 247, 219-220; Rolf E Peters and M.A. Chance, ‘Chiropractic’s First Half Century 1895-1945 Chiropractic and the Law; Prosecution, Persecution, Protection and Politics’ (1999) 29 *Chiropractic Journal of Australia* 55; Crellin and Ania, above n 7, 9; Saks, above n 265, 202.

333 Crellin and Ania, above n 7, 9.

The history of legislative initiatives in the UK, USA and Australia demonstrate familiar themes reflecting attempts to confirm the hegemony of OM. Much of the legislative intervention into the health sector reflects the influence that OM has been able to exert over government.³³⁴ The history of the process by which OM attained statutory acknowledgment reveals a number of themes:

- The importance of united action by OM professional associations in obtaining government support for legislative intervention necessary to deal with chiropractors; homoeopaths and other non-OM practitioners.
- The public stance by OM that statutory protection was required for the public benefit. Self-interest was clearly relevant to many measures to deal with unqualified practitioners and the control on the numbers of medical doctors and the quality, length and cost of medical education.³³⁵
- The importance of the connections OM had with powerful elites in society in ensuring state patronage.
- The importance of controls on medical education and entry into the profession as the means to raise the status of OM.³³⁶
- That many of the statutory reforms which gave OM its ascendancy were enacted before there was substantial evidence of the scientific effectiveness of OM (which came later) thus suggesting that the relationship to science was only part of the reason for the obtaining of state patronage.³³⁷
- The impetus towards state patronage of OM is reflected throughout the western world from the middle to the end of the 19th century. This process was partially sustained by the post feudal perception of the value of human life and individualism that placed a

334 Cohen, above n 19, 91.

335 Simpson, above n 154, 148.

336 E L Hodgson, 'Restrictions on Unorthodox Health Treatment in California: A Legal and Economic Analysis' (1997) 24 *UCLA Law Review* 647, 663.

high value on the provision of professional and effective medical treatment.³³⁸ Contra to this philosophy was the laissez - faire approach to economic activity that was influential at that era. Free competition and market forces were seen as the best method of regulation in the economy generally and in regard to medical practice.³³⁹

United Kingdom

History of Domestic/ Lay Practice

In England in the centuries before the 19th century medical pluralism pervaded the provision of medical services. The pluralism was superceded as lay practice began to be perceived as superstition in the light of the progress of scientific bio-medicine.³⁴⁰ In England there is a long history of domestic and lay healers providing services to those who could not afford the high cost of OM practitioners.³⁴¹ Deriving their knowledge from experience and oral tradition mothers usually provided domestic health care. Even today most health demands are not dealt with by professional healers but by self-diagnosis and treatment. This long tradition of lay practice supported by lay support and patronage may provide an unstated basis for the sometimes timid approach taken by some administrators to the enforcement of statutory controls specifically directed to CAM.³⁴²

Historical Status of MD's

The strength of the lay or domestic healing tradition meant there was pressure on OM practitioners to demonstrate their professional status; to justify their fees and to properly

337 Willis, above n 129, 74.

338 Ibid 46.

339 Ibid.

340 Saks, above n 265, 200.

341 Kottow, above n 143, 18-22; Mike Saks, above n 265, 200.

342 Starr, above n 6, 34; Easthorpe, above n 312, 290.

differentiate themselves. Prior to medical practice legislation in the early years of the 1800's physicians were described as:

an embattled and powerless occupational group, plying their services in competition with hosts of unqualified practitioners of varying skill levels often only barely able to make a living in a rapidly expanding economy where the easy availability of mass-produced remedies added to the pressures of professional survival.³⁴³

Socially surgeons were seen as 'craftsmen; physicians as domestic servants of the rich and apothecaries as tradesmen.'³⁴⁴ The medical profession was comprised of three types of practitioners. The physicians who practiced the profession of physic were university trained and therefore accorded higher status. Those educated at Oxford and Cambridge were eligible for the Fellowship of the College of Physicians.³⁴⁵ The surgeons were of a lower status as they were trained by apprenticeship and were associated at their inception with the barbers. Surgeons only became independent of the barbers in 1745. As their claims to therapeutic effectiveness was somewhat tenuous in this period reference to class, connections, grooming and manners and general educational status was required to create an aura of professionalism and to differentiate themselves from lay persons.³⁴⁶ The use of heroic treatments based upon esoteric and mysterious terminology provided the other means of differentiation.

Beginnings of Legislative Endorsement

The first major success of OM in obtaining statutory endorsement was the *Medical Act of 1512* (UK). This statute made it an offence to practice physic or surgery unless the practitioner was a university graduate or was licensed by the Bishop of London on the recommendation of four physicians.³⁴⁷ The policy basis for this legislation was said to be

343 Stone and Matthews above n 32, 26; Nicholls, above n 262, 50.

344 Stone and Matthews *ibid.*

345 *Ibid.*

346 Willis, above n 129, 39.

347 Griggs, above n 93, 60.

need to stop the damage inflicted by quacks, witches and sorcery.³⁴⁸ In the years after this legislation the Company of Physicians (which became the Royal College of Physicians) was established (1518) while the surgeons unionised in the Union Company of Barber-Surgeons. These developments may be part of the medieval tendency to use professional guilds to serve the professional purposes of raising barriers to entry to a profession to maintain a high fee structure.³⁴⁹

This statutory structure was not well suited to the nature of the time, as the vast majority of people could not afford the high cost of medical fees. The problems that resulted from the 1512 statute forced the passing of *The Herbalist Charter*.³⁵⁰ (known by adherents of OM as *The Quack's Charter*). This statute indicated it was designed to deal with the mischief that surgeons had been 'minding only their own lucre' and had been allowing people to 'rot and perish to death for lack of help.'³⁵¹

The Herbalist Charter exempted lay practitioners of herbal medicine from the penalties under the 1512 Act if they only charged for the supply of the herbs. This created an exemption so long as the practitioner did not charge for the advice. The reaction of the legislature, apparently supported by Henry VIII, who is said to have had an interest in herbal medicine, reflects a somewhat paternalistic regard for non-orthodox medicine.³⁵²

The policy reasons for *The Herbalist Charter* could reflect an acknowledgment that there were insufficient doctors to satisfy the demand for their services.³⁵³ It may also reflect Tudor

348 Ibid.

349 Anthony Ogus, *Regulation: Legal Form and Economic Theory* (1994) 7.

350 Griggs, above n 93, 61.

351 *Statutes of the Realm* 34-35 Hen c.8.19; Griggs, *ibid* 61-62.

352 *Ibid* Griggs 54.

353 Matthews and Stone, above n 32, 25.

regulation policy to satisfy a symbolic political purpose without being accompanied by a commitment to a specific legislative goal.³⁵⁴ *The Herbalists Charter* confirmed that lay practitioners were in demand and the important connections that some of these practitioners had to the legislature and the Crown.³⁵⁵

The Medical Act of 1858

The Medical Act 1858 (UK) (1858 Act) is significant as it demonstrates the close relationship that had developed between OM and government. This relationship and the terms of the statute provided the fulcrum for OM's prestige and influence that followed. It has been said that it was not possible to speak of a medical profession before the 1858 Act and for sometime after.³⁵⁶ The British Medical Association was formed in 1858.

The government was finally convinced of the need to distinguish between qualified and unqualified practitioners after a number of disease epidemics had once again scourged the country leading to the passing of the 1858 Act.³⁵⁷

The 1858 Act provided a blueprint for subsequent self-regulation legislation in the UK and in Australia.³⁵⁸ It incorporates a form of contract between government and the medical profession. The legislation delegates the control of the profession to the medical profession itself.

354 Ogus, above n 349, 6.

355 Griggs, above n 93, 63. There is reference to this act in Canadian case of *R v Kish* 20 W.C.B. (2d) (1993) 309.

356 Willis, above n 129, 37.

357 Matthews and Stone, above n 32, 27.

358 Saks, above n 265, 200.

It is significant that this legislation did not include specific provisions dealing with the enforcement of ethical concerns. These provisions were added later.³⁵⁹ This supports the view that at least initially the primary intention of 1858 Act was the preservation of the status and position of the medical profession and not the protection of the public. This was part of an attempt to effect social closure for OM. As the professions involve the production of services not products the only effective means to create social closure is through controlling the production of practitioners in the same way that guilds and trade unions limited access to the trades.³⁶⁰

Australia

Australia has followed a similar pattern to the UK though based upon the colonial status of Australia and its physical isolation in the 18th century events have tended to occur after and as a direct reaction to events in the UK.

Like the UK the impetus for statutory regulation came from a united and powerful medical profession using the model of the 1858 Act. This process was fostered by the need to deal with unqualified practitioners who threatened the livelihood of medical doctors. At this time an unregulated free market existed in health care with little government regulation.

Victoria

The first major piece of legislation that regulated the medical profession in this state was the *Medical Practitioners Act 1862* (Vic). This legislation is a reflection of the enhanced influence and status of OM. An important reason for the establishment of the *Australian*

³⁵⁹ Stone and Matthews, above n 32, 226.

Medical Journal in 1856 was the promotion of medical reform and the control on unqualified practice. In 1852 the Victorian Medical Society (VMS) was formed with the aim of restricting unqualified practice.³⁶¹ The VMS amalgamated with the Castlemaine Medical Association in 1855 to form the Medical Society of Victoria.³⁶²

Factors working against reform

A number of factors slowed and made more difficult the process of reform.

Reform of the law was achieved despite the lack of public demand for such legislation. It was commonly thought the registration of doctors was not primarily directed to the protection of the public good but was based upon a desire to protect the interests of medical doctors.³⁶³

Prior to the 1862 legislation the inability of the profession to agree on the need for and type of regulation was a factor behind the reticence of the legislature.³⁶⁴ An important policy consideration was the difficulty for country people to obtain access to medical services except through unqualified practitioners. This meant that any professional controls restricting that access could be problematic.³⁶⁵

The passing of the 1858 Act was undoubtedly a significant influence on the *Medical Practitioners Act 1862* (Vic).³⁶⁶ The Victorian statute contained no provisions that made it illegal for unqualified persons to practice medicine. The statute did:

- limit the use of specified titles to registered practitioners (s 7).
- limit unregistered persons ability to sue for fees (s 11).

360 Richard L Abel, *American Lawyers* (1989) 20.

361 Willis, above n 127, 49.

362 Ibid 48-49.

363 Ibid 50.

364 Ibid 50.

365 Ibid 50-51.

- indicate only registered practitioners could hold certain official appointments and specified only registered practitioners could sign death certificates.(s 12) ³⁶⁷

Although the *Medical Practitioners Act* did not specifically limit the practice of medicine to registered persons it did give the registered practitioner a market advantage in the use of specified titles and the prestige as a government endorsed practitioner.³⁶⁸

The *Medical Practitioners Act* is reflected in the approach favoured by the current *Medical Practice Act 1994* (Vic). This legislation, unlike many jurisdictions, does not limit the practice of medicine to registered doctors but limits the use of titles such as ‘registered medical practitioner’ to registered doctors and the holding of certain medical positions.³⁶⁹

The statutory and code of ethics provisions that medical doctors should not consult with homoeopaths contributed to homoeopathy’s decline in Victoria in the early years of the 20th century.³⁷⁰ As the germ theory appeared to be providing benefits for public health the less dramatic therapies offered by homoeopaths became less popular. The only homoeopathic hospital in Melbourne (now Prince Henry Hospital) became OM as it was difficult to find sufficient homoeopaths to fulfil positions in the hospital. By relaxing the ethical rules about dealing with homoeopaths the hospital was able to appoint OM practitioners and gradually the use of homoeopathy in the hospital declined until in 1934 the hospital was renamed and no longer represented itself as a homoeopathic institution.³⁷¹

366 Ibid 51-52.

367 Ibid 52.

368 Ibid 52.

369 s 62.

370 Willis above n 127, 79.

371 Ibid 80.

The process of professionalization, emboldened by statutory regulation, continued into the 20th century. In line with trends in the USA the medical curriculum was focussed more on scientific medicine, courses were lengthened and the cost of tuition increased. For example, at the Melbourne Medical School in 1923 the time to complete medical training was increased by one year and fees were increased by 20%. ‘The change was introduced to deal with a concern about there being too many graduates and to make quality medical education a scarcer commodity thus strengthening the political, economic and political power of doctors.’³⁷²

USA

The legislative history in the early 19th century in the USA reflects the ambiguity of the position of OM and its meagre influence on the legislative process. At that time there was an open market in the provision of health services where orthodox practitioners competed with homoeopaths, botanic and eclectic practitioners.³⁷³ By 1849, under pressure from irregular professionals in all but two states medical licensure statutes had been repealed based on the philosophy that persons were entitled to choose the medical treatment they preferred.³⁷⁴

‘What fundamentally destroyed licensure was the suspicion that it was an expression of favour rather than competence.’³⁷⁵ The reversal of this position in the 20th century reflects important developments in how OM was organized and educated. The American Medical Association, formed in 1847, reflected the need to provide security to orthodox practitioners. Some of the objects of the newly formed AMA were quite openly directed at restricting entry into the profession to thereby financially secure practitioners and to eliminate ‘sects’ such as

372 Ibid 84.

373 Simpson, above n 154, 35.

374 Wardwell, above n 124, 211.

375 Starr, above n 6, 58.

homoeopaths, eclectic and Thomsonians.³⁷⁶ These goals do not reflect a selfless pursuit of public health issues but professional protection.³⁷⁷

Medical Education- Its Role in the Status of OM

In the early 1900's there was a very open market for medical education in the USA. Many proprietary schools and weaker university medical schools allowed the entry of working class and middle class students.³⁷⁸ This was problematic for a profession concerned to raise its status and influence. The proliferation of schools provided competition for current members of the profession and impacted negatively on the image of the profession. The process of professionalization is hindered if the members of the profession come from underprivileged backgrounds.³⁷⁹ The AMA, which had emerged in the early years of the twentieth century as the undisputed organizational head of OM, made the reform of medical schools a top priority. In 1904 the AMA established a Council of Medical Education (CME). The CME involved medical professors from major universities and had a mandate to elevate and standardise medical education.³⁸⁰

Flexner Reforms

The AMA invited the Carnegie Foundation for the Advancement of Teaching to conduct an investigation of the quality of medical education. The foundation appointed an educator Abraham Flexner to conduct the investigation. Flexner had connections with the Johns Hopkins University and the Rockefeller Institute for Medical Research.³⁸¹

376 Simpson, above n 154, 38.

377 Ronald Hamowy, 'The Early Development of Medical Licensing Laws in the United States 1875-1900' (1997) 3 *Journal of Libertarian Studies* 73, 76.

378 Starr, above n 6, 117.

379 Abel, above n 360, 24.

380 Starr, above n 6, 117.

Flexner's report 'Medical Education in the United State and Canada' released in 1906 was very critical of medical school education.³⁸² The crux of the criticism was what he saw as a discrepancy between the advances that had been made in medical science and what was provided by way of medical education. He recommended that the good medical schools be strengthened following the model of Johns Hopkins University and that many medical schools be closed.³⁸³

The Johns Hopkins model, now the exemplar model for medical education, was grounded on hard medical laboratory science and universal laws.³⁸⁴ According to Flexner 'ethical medicine targeted disease objects rather than patient complaints, and like engineering was founded upon hard science.'³⁸⁵

Because Flexner applied the images of war to medical practice, orthodox medicine became an aggressive, hands-on science. Engineering and military science shaped mainline medical attitudes and procedures, while biology, histology, embryology, anatomy, physiology, pathology and bacteriology provided the substance of orthodox medical understanding. For Flexner all other approaches were both unscientific and unethical.³⁸⁶

The Flexner Report confirmed the trend towards the amalgamation or closure of many of the weaker medical schools.³⁸⁷ This reduced the number of medical graduates, improved the quality of medical education, while the increased length of study increased the cost.³⁸⁸ As this raised the hurdle for less wealthy individuals this provided the means to raise the status of the profession.³⁸⁹

381 Ibid 118.

382 Abraham Flexner, *Medical Education in the United States and Canada*, Carnegie Foundation for the Advancement of Teaching, Bulletin no 4 (1910).

383 Encyclopedia of Bioethics, above n 4, 136

384 Ibid 135.

385 Ibid.

386 Ibid 136; Spencer, above n 23, 8.

387 Spencer, *ibid* 8.

388 Berliner, above n 259, 35.

389 Ibid 32.

The Flexner report focussed the attention of benefactors on what and where funding for medical education and research should be directed. By 1936 \$91 million dollars had been provided by the Rockefeller General Education Board to a group of seven medical schools that had an emphasis on a research based rather than medical practice model.³⁹⁰

Where previously medical education was dominated by significant part time faculty/practitioners there was now a movement towards full time academic faculty who were able to focus on the research aspects of medical education.³⁹¹ The science based educational model still impacts on medical education today.

The philosophy of scientific medicine

Modern scientific endeavour and scientific medicine is based upon a reductionist paradigm. Some aspects of OM is influenced by holism exemplified by preventative medicine and psychotherapy.³⁹² Most CAM comes from a holistic perspective. Homoeopathy is holistic but its application of precise remedies might be considered reductionist as might a symptomatic and non traditional approach to acupuncture.

‘Reductionism is the tendency to look for and focus on the parts of things whether these ‘things’ be concepts, actions, or material objects.’³⁹³ A reductionist thinker will attempt to

390 Starr, above n 6, 121; Cobb, above n 157, 8; Berliner, above n 259, 35.

391 Starr, above n 6, 123.

392 Micozzi, above n 13, 3.

393 Claire Monod Cassidy, ‘Unravelling the Ball of String: Reality Paradigms and the Study of Alternative Medicine Advances’ (1994) 10 *The Journal of Mind-Body Health* 8; Engel, above n 243, 130.

dissect a thing under consideration into its constituent parts.³⁹⁴ When applied to a physical body it involves differentiating cells, tissues, body parts, systems, diseases or conditions.³⁹⁵

An associated aspect of this process is to see those parts as existing independently of the other; thus drugs are seen as affecting parts of the body and disease is seen as separate from unaffected parts. This leads to an objectification of the object of study as the person is seen not as a holistic whole but as a sum of individual parts.³⁹⁶ The person becomes a subject and the reaction of that person is placed within a norm of what is expected for other objective parts.³⁹⁷

Western thought favours use of judgmental hierarchies, which categorise people, things or situations on the basis of comparing and deciding which is better or best.³⁹⁸ This creates a viewpoint where difference is seen as odd and opposite is seen as opposition. If scientific data does not fit into a model or theory then this is seen as noise that must be deleted from the process. Science in its insistence on randomised ‘gold standard’ clinical trials may be an example of methodological ethno-centrism.³⁹⁹

An example of this outlook might be the approach taken by OM to the placebo effect.⁴⁰⁰ A person’s expectation of benefit will often trigger a healing response that is called the placebo effect.⁴⁰¹ Reductionist thought considers this is something to be removed from consideration

394 Fulder, above n 19, 7.

395 Alan D Watkins, ‘Contemporary Context of Complementary and Alternative Medicine: Integrated Mind Body Medicine’ in M Z Micozzi (ed), *Fundamentals of Complementary and Alternative Medicine* (1996) 52.

396 Berliner, above n 259, 43.

397 Cassidy, above n 393, 8.

398 Ibid 9.

399 Ibid 20-22.

400 House of Lords, above n 310, 3.34; Cassidy, above n 393, 9.

401 Spencer, n 23, 21-22.

as ‘noise’ obscuring the ‘important data’.⁴⁰² In a reductionist placebo controlled experiment some participants are given active ingredients and some are not. This is based upon a reductionist perspective that it is possible for treatment to be inactive and patients are not perceptive enough to discover if treatment is active or not.

This biomedical approach to healing draws upon Newtonian physics and cartesian dualism which was dominant in the late 19th century and early in the 20th century.⁴⁰³ Newtonian physics viewed the world as consisting of fundamental irreducible building blocks of matter. The world is seen as being a machine observing natural laws in a complex but identifiable set of relationships. Cartesian dualism suggests that while bodies exist in time and space subject to mechanical laws, minds are found elsewhere in an independent realm.⁴⁰⁴ OM takes a Kantian view of the world and is more comfortable with a demarcation between science (that it professes and practices) and religion (which it does not).⁴⁰⁵ Vickers⁴⁰⁶ rejects suggestions that subjective influences are irrelevant in OM as exemplified by the efforts of GP’s to improve patient communications; hospice care; nursing and psychiatry. It should be noted these are not central or prestigious health care functions.

By reducing the body to the level of a mechanism made of reductionist parts illness is seen as a set of symptoms while disease is an outsider that preys on the body. The role of a doctor is to attack or beat the cancer or other pathogen by drawing on the aggressive images of war derived from the Flexner view of medical practice.⁴⁰⁷ This approach supports a mechanistic approach to regulation as the responsibility for the provision of services in the health sector is

402 Saks, above n 265, 200.

403 Cohen, above n 11, 2; House of Lords, above n 39, 2.15.

404 Cohen, *ibid*, 2; Saks, above n 265, 200.

405 Kaptchuk and Eisenberg, above n 57, 1064.

406 Vickers, above n 32, 8-9.

407 Encyclopedia of Bioethics, above n 4, 136.

carved into parts of the body ie medical specialties; physiotherapy, chiroprody and psychiatry without really dealing with the nature of healing which is inherently holistic in nature ie one part of the body effects other parts.⁴⁰⁸ This tendency emphasises specialisation that makes routine GP work seem less prestigious and boring.⁴⁰⁹

If the doctor sees himself as the expert and the patient as the subject of the scientific enquiry the relationship may not properly address the human dimension involved in that relationship as social and cultural issues are not emphasised. Vickers provides a contrary view and points to the use of patient assessment of pain and anxiety used in clinical trials as an example of where OM relies upon and respects the role of the person.⁴¹⁰

The germ theory and the reductionist focus of OM provide a good scientific model for the treatment of infectious disease, acute illness or emergency trauma that has a single specific cause. As Cohen comments 'a patient who suddenly experiences heart failure needs a cardiac specialist, not an acupuncturist.'⁴¹¹

This therapeutic model does not work as effectively with multi faceted chronic illness such as cancer, chronic fatigue arthritis, allergies or depression that account for a large percentage of the health care budget.⁴¹²

Socialization Process of OM

408 Cohen, above n 19, 139.

409 Berliner, above n 259, 43.

410 Vickers, above n 32, 8.

411 Cohen, above n 11, 2.

412 Cohen, above n 11, 2; Cohen, above n 19, 105; Ian D Coulter, *Chiropractic: A Philosophy for Alternative Health Care* (1999) 82.

The OM therapeutic approach is based partially on the scientific philosophy of OM but also on the socialisation process of medical doctors. The Flexner model confirmed the movement from proprietary medical schools to well funded university medical schools. The university began to rely upon teaching hospitals for clinical training while the hospital relied upon the universities for staffing of hospitals. Hospital training involves contact with persons often with serious illness that require hospitalisation. This environment will involve exposure to the impact of disease, traumatic injury and death. This engenders a detachment and clinical objectivity that only reinforces the scientific and objective approach supported by medical science.⁴¹³

By contrast, a chiropractor's primary exposure to clients in training is through a college clinic. Here students will rarely deal with the reality of death or be required to deal with pathological illness. Students and will not be exposed to a wide variety of illnesses and conditions.⁴¹⁴ They will often be dealing with clients they have recruited and will deal with the client from first appointment to end of treatment.⁴¹⁵ This clinical experience will not engender the same disconnection from patients as would occur in the case of medical training.

The Holistic Perspective

Most CAM modalities prefer a holistic approach to health care although this is not universal.⁴¹⁶ For example, some manipulative therapies such as chiropractic apply a 'body as

413 Coulter, *ibid*, 86; Easthorpe, above n 312, 292.

414 Robert T Anderson, 'Medicine, Chiropractic and Caste' (1981) 54 *Anthropological Quarterly* 157, 161.

415 Coulter, above n 412, 95.

416 Crellin and Ania, above n 7, 58.

a machine' approach to aspects of their therapy. Some aspects of CAM practice may reflect a reductionist tendency to categorise symptoms and to then apply an appropriate remedy.

For holistic practice 'health' is the primary focus not disease.⁴¹⁷ Smuts argued that 'a whole is more than the sum of its parts because the whole is not purely mechanical but has inner tendencies and interrelationships between the parts which give rise to something "more."⁴¹⁸

An understanding of the holistic perspective provides some appreciation of why it does not sit easily with OM. For a holistic practitioner the primary focus is upon the whole person thus creating a tendency to individualise patients and for the client to personify their situation.⁴¹⁹ A reductionist viewpoint directs attention to parts of the body and the identity of the agency of disease thus tending to depersonalise the patient.

By attempting to see the whole a practitioner is encouraged to see the diverse ways in which symptoms and health manifest itself. This encourages treatment reflecting the individual's needs and requirements rather than based upon a disease label with the application of a standard treatment.⁴²⁰ This tendency is most evident in homoeopathy where the practitioner takes a myriad of symptom details to determine a likely diagnosis based upon that person's experience. This assessment leads leading to a specific remedy that it is hoped should reflect that person's needs.

Holistic health seeks to provide an environment where the body can heal itself. A

homoeopath commented:

417 Fulder, above n 19, 4; Spencer, above n 23, 18; Berliner and Salmon, above n 240, 142.

418 Cohen, above n 11, 7.

419 Cassidy, above n 393, 11; Glaser, above n 328, 221; Fulder, above n 19, 5; Berliner, above n 259, 42; Cohen, above n 19, 99.

Patients will present their illness to the practitioner as something to be dealt with, to be got rid of, but the practitioner will consider it in 'horticultural' terms. He will try to create the right climate, give support to natural growth processes and set in motion things which will regenerate the patient.⁴²¹

CAM and Scientific Evidence

CAM does not generally deal effectively with the insistence upon scientific evidence for the efficacy and safety of CAM modalities for many cultural, historical and philosophical reasons. This reluctance or inability may derive from either a lack of money for research or an inability or unwillingness to obtain such evidence.⁴²² For a society that in the past was enamoured by the majesty of the scientific revolution this reticence reflects an inability to align with major political and economic forces in society and government.

CAM has reacted to the pressure for scientific credibility by either:

- purporting to align itself with the scientific model by using pseudo scientific language and theory such as 'chiropractic science' or the 'science of homoeopathy.'⁴²³
- by use of accepted scientific methods of assessment and experimentation.⁴²⁴
- by rejecting scientific evidence as important for or applicable to the assessment of CAM.⁴²⁵
- by amending the scientific method as it applies to CAM.

There is clearly a gap in current scientific evidence for CAM therapies in many areas.

This is partly caused by a lack of funding exacerbated by the fact that many CAM

420 Fulder, *ibid* 7; Cassidy, *ibid* 11.

421 Cassidy, *ibid* 13.

422 DP Eskinazi, 'Factors that shape Alternative Medicine' (1998) 280 *Journal of American Medical Association* 3.

423 TJ Kaptchuk, 'The Persuasive Appeal of Alternative Medicine' (1998) 129 *Annals of Internal Medicine* 1061, 1063.

424 Cohen, *above* n 11, xi; House of Lords, *above* n 39, 2.14; Crellin and Ania *above* n 7, 29-31.

practices do not have the potential financial benefits of patentable drugs;⁴²⁶ a differing philosophical outlook or a lack of research experience training for the difficult funding, procedural, design and verification issues in such research⁴²⁷ and a concern by OM researchers about the impact on their careers if they become involved in such research.⁴²⁸

As many CAM practitioners work in private sole practice this arrangement does not provide the support needed for collaborative research.⁴²⁹ Where scientific evidence has been obtained its quality has rarely satisfied OM.⁴³⁰ Spencer comments that many CAM research studies lack credibility because they⁴³¹:

- appear to be not well focused.
- do not use hypothesis testing or large numbers of subjects,⁴³² and
- tend to rely more on verbal subjective reports from the patients.

‘The quality of most CAM studies, as judged by Western trained scientists is not considered very good.’⁴³³ Other criticisms are that the research is marred by flawed technique such as poor randomisation, incomplete blinding and lack of proper placebo control.⁴³⁴

The reasons for the revival of CAM?

The revival in the use of CAM is partly a result of a reaction to OM. Scientific medicine has made many strides in the treatment of infectious disease through the use of antibiotics;

425 Crellin and Ania, *ibid* 29.

426 Calabrese, above n 69, 681.

427 *Ibid*; Julie Stone, *An Ethical Framework for Complementary and Alternative Therapies* (2002) 115.

428 Kaptchuk and Eisenberg above n 157, 1063; JM Humber and RF Almeder, *Alternative Medicine and Ethics* (1998) 72.

429 Stone, above n 427, 115.

430 Eskinazi, above n 422, 3.

431 Spencer, above n 23, 18.

432 Calabrese, above n 69, 681.

433 *Ibid* 18-19.

434 Canadian Overview, above n 10, 9.

vaccination against diseases such as diphtheria, smallpox or typhoid and advances in surgery.⁴³⁵ As people are on average living longer this has highlighted the limitations of OM in the treatment of chronic conditions like arthritis and diabetes. The damaging side effects of chemical based remedies and the impersonal nature of OM have all contributed to the crisis for OM. The profile of disease is also changing in fundamental ways:⁴³⁶

- an aging population creates a demand for therapies for chronic diseases.
- the percentage of morbidity related to non biological means such as accidents and suicide is increasing.
- an increase in disease brought about by lifestyle.

As OM places its emphasis on the biological aspects of health with less regard to social and environmental parameters it may not properly address these fundamental health issues. CAM is probably better placed to deal with chronic disease and has the advantage of having a philosophical attunement to patients under its partnership model of therapy.⁴³⁷

There have been many factors behind the dissatisfaction with OM and the popularity in CAM.⁴³⁸ These factors are:

- the increase in knowledge about health generally available threatens the ‘doctor as expert’ perspective thus undermining the status of OM. This is reinforced by a postmodernist tendency to apply less deference to professional expertise and knowledge.⁴³⁹

435 Fulder, above n 19, 14.

436 Berliner, above n 259, 40-41.

437 Berliner and Salmon, above n 240, 139 –140; I Freckelton, ‘Editorial’ (2000) 5 *Journal of Law and Medicine Journal* 5

438 Crellin and Ania, above n 7, 32-33.

439 Saks, above n 323, 202; WB Jonas, above n 13, 1616; JA Astin, A Marie, KR Pelletier, E Hansen and WA Haskell, ‘Review of the Incorporation of Complementary and Alternative Medicine by Mainstream Physicians’ (1998) 158 *Archives of Internal Medicine* 2303, 2304;

- the fact that medical science cannot cure some diseases especially chronic disease such as asthma and arthritis.⁴⁴⁰
- the fact that OM does not adequately deal with preventative medicine.⁴⁴¹
- the high cost of medical care.⁴⁴²
- less tolerance for paternalism in health care.⁴⁴³
- concerns about the impact of iatrogenic disease.⁴⁴⁴
- less faith in the value of science.⁴⁴⁵
- Many favour a holistic philosophy to health that does not fit with the OM model.⁴⁴⁶
- ‘Part of a broader value orientation and set of cultural beliefs that embraces a holistic, spiritual orientation to life.’⁴⁴⁷
- Patients need help with back problems; urinary tract infections; chronic pain and anxiety not well handled by OM.⁴⁴⁸
- Some patients have a distrust of OM.⁴⁴⁹
- That CAM provides relief from symptoms.⁴⁵⁰
- Dissatisfaction with the social interaction between MD and patient.⁴⁵¹
- Post modernists trend to seek out choice and diversity.⁴⁵²

440 Haigh, above n 152, 199; Jonas, above n 13, 1616; Berliner and Salmon, above n 240, 143.

441 Berliner, above n 259, 51; Adrian Furnham, ‘Why do people choose and use complementary therapies?’ in Edzard Ernst (ed), *Complementary Medicine: An objective appraisal* (1996) 73.

442 Jonas, above n 13, 1617; Glaser, above n 328, 215.

443 Jonas, above n 13, 1616.

444 Haigh above n 152, 197; House of Lords, above n 39, 1, 6; Glaser, above n 328, 223; Furnham, above n 441, 73; Astin and Marie, above n 439, 2304.

445 Jonas, above n 13, 1616; Easthorpe, above n 184, 294; Furnham, above n 441, 73.

446 John A Astin, ‘Why Patients Use Alternative Medicine: Results of a National Study’ (1998) 279 *Journal of American Medical Association* 1548-1553; Furnham, above n 441, 85.

447 L.J Strahilevitz, ‘Controlling the Costs of Alternative Medicine’ (1999) 28 *Southwestern University Law Review* 543, 548; Furnham, *ibid* 73.

448 Kaptchuk, above n 70, 50; House of Lords, above n 39, 1.5, 1.24; Furnham, above n 441, 84; Cant and Sharma, above n 40, 473.

449 Spencer, above n 23, 14; M Angell and JP Kassirer, ‘Alternative Medicine – The Risks of Untested and Unregulated Remedies’ (1998) 339 *The New England Journal of Medicine* 839, 840.

450 Astin, above n 439, 1552; Furnham, above n 441, 84.

451 Hensley and Gibson, above n 273, 2; Easthorpe, above n 312, 292; Spencer, above n 23; 14; House of Lords, above n 39, 3.13.

452 Easthorpe, *ibid* 294; Strahilevitz, above n 447, 550; JJ Chan and JE Chan, above n 226, 332-334.

- CAM provides a more active role in health maintenance that suits many patients.⁴⁵³
- Poor communication skills of medical doctors while CAM uses language that is easier to understand for the layperson.⁴⁵⁴
- Because of medical litigation medical doctors are more cautious and less relaxed with patients.⁴⁵⁵
- CAM is easier to use and is more cost effective.⁴⁵⁶
- Holistic health reinforces moral relativism that discounts the value of objective standards such as double blind clinical trials.⁴⁵⁷
- An increasing interest in the occult and paranormal phenomenon suggests use of CAM over OM options.⁴⁵⁸
- Dictated by fashion.⁴⁵⁹
- As there are fewer GP's and more specialists there is less opportunity for long term therapeutic relationships that many patients desire.⁴⁶⁰
- As OM developed techniques and evidence based on science and technology this has created higher expectations leading to greater disappointments.⁴⁶¹
- The emphasis by CAM on the whole person and not just disease.⁴⁶²
- The trend to consumerism in health care promotes a less authoritarian health care model that is found in CAM health care.⁴⁶³

453 Furnham in Ernst, above n 441, 77; Strahilevitz, *ibid* 549.

454 House of Lords, above n 39, 3.17.

455 *Ibid* 3.15.

456 Furnham, above n 441, 77.

457 Strahilevitz, above n 447, 550.

458 Furnham, above n 441, 73.

459 House of Lords, above n 39, 1.26.

460 *Ibid*.

461 *Ibid*; Berliner and Salmon, above n 240, 139.

462 House of Lords, above n 39, 3.17; Astin and Marie, above n 439, 2304.

463 Milburn, above n 176, 61.

The re-evaluation of the value of OM and the attention given to CAM has been influenced by the new age, self help, human potential movement that was current in parts of society from the 1970's.⁴⁶⁴ This movement was strongly influenced by Eastern philosophy and 19th century medical practice and provided fertile ground for the development of CAM.⁴⁶⁵ This movement supported a style of medicine that was less focussed on a reductionist perspective and provided clients more control over their own healing.⁴⁶⁶ This period has been interpreted by some as a watershed in the shift to a postmodernist perspective.⁴⁶⁷

Medicine appears to fail in its task of providing an emotional environment of meaning and direction and alternative therapies can hardly be blamed if they manage to convey a sense of existential protection which operates not on the basis of some truth, but by means of its soothing and comforting effects.⁴⁶⁸

These philosophies may now be interpreted by the X generation (ie post baby boomers) currently 35 years or younger who have a pragmatic approach to public policy that supports less emphasis on institutional care and a preference for individual choices. This generation may be more open to new approaches to health care.⁴⁶⁹

The Struggle between OM and CAM – Chiropractic and Homoeopathy

It is intended to analyse briefly the historical, political and legal history of chiropractic and homoeopathy to demonstrate the complexity of their relationship with OM. Despite vehement medical opposition to this modality chiropractic achieved registered status in most of the western world by the 1970's. This has not been followed by full OM acceptance. Chiropractic remains a successful and independent modality but one which struggles against the OM

464 Astin, above n 446, 1553; Berliner and Salmon, above n 240, 133.

465 Jonas, above n 13, 1616; Berliner and Salmon, *ibid*, 133; Haigh, above n 152, 197-206.

466 Glaser, above n 328, 214.

467 Saks, above n 323, 201.

468 Kottow, above n 143, 19.

469 Clement Bezold, 'Evolving Demands and Demographics in Health Care' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 24.

hegemony.⁴⁷⁰ Its success derives substantially from public support. It enjoys a utilisation growth rate of 4.1% per annum in Australia and overseas.⁴⁷¹ It is the most utilised health profession other than OM and dentistry. One survey found that 15% of the participants had visited a chiropractor in the year prior to the survey.⁴⁷²

Homoeopathy's relationship with OM has been long and difficult. Homoeopathy has failed to obtain registration anywhere except in some states in the USA where a comprehensive health practitioner licensing regime is in place and registration is limited to MD's or as part of the practice of registered CAM modalities. The history of this process is demonstrative of the issues that shall arise for the regulation of CAM in modern times.

Chiropractic

Chiropractic's position (the name is derived from the Greek word for the hand 'cheir' and practice 'praxis') in the health sector reflects the development of its relationship to OM.⁴⁷³ Its success might be considered to chart a decline in the influence of OM.⁴⁷⁴ The imprint of the struggle between chiropractic and OM has created a chiropractic profession that is fiercely independent in outlook that avoids attempts at incorporation into OM. The struggle has fostered an emphasis upon the efforts of individual practitioners rather than corporate health services providers as in the case of OM. This relationship has also required chiropractic to forge its own relationship to government; power elites and its patients. This has resulted in a

470 Ronald Lee Caplan, 'Chiropractic' in J Warren Salmon (ed), *Alternative Medicines: Popular and Policy Perspectives* (1984) 86.

471 R Layton, *Medicare Benefits Review Committee, Second Report* (1986) Chapter 10.

472 MacLennan; Wilson and Taylor, above n 108, 569-573.

473 David Chapman Smith, *The Chiropractic Profession* (2000) 11.

474 D Coburn and C Lesley Biggs, 'Limits to Medical Dominance: The Case of Chiropractic' 22 (1986) *Social Science and Medicine* 1035, 1035.

profession that although lacking in the influence of OM, has managed to survive and flourish.⁴⁷⁵

Inception and early history

The 'Discover' or 'Founder' of chiropractic was Daniel David Palmer (1845-1913). DD Palmer, a forceful and charismatic person, had previously been involved in esoteric practices including magnetic healing. Palmer claimed to have discovered the cause of disease through the manipulation of the spine in 1895.⁴⁷⁶ Palmer stated that he had cured a janitor Harvey Lilliard of deafness by adjusting his back and had successfully treated another patient who complained of heart disease.⁴⁷⁷ Palmer emphasised the basis of chiropractic as the adjustment of subluxations of the spinal vertebrae as the primary if not the only therapy of chiropractic.

Palmer described the principles of chiropractic as:⁴⁷⁸

A subluxated vertebra is the cause of 95% of all diseases. Luxated bones press against nerves. By their displacement they elongate the pathway of the nerve... This pressure upon a nerve creates greater tension, increased vibration, and consequently an increased amount of heat. Heat alters tissues; altered tissues modify the transmission or impulse; modified impulses cause functions to be performed abnormally.

Chiropractic is a part of a long tradition of the use of therapeutic manipulation as a form of healing. Even Hippocrates mentioned manipulation as a form of healing.⁴⁷⁹ Lay practitioners called bonesetters and some OM adherents have used spinal manipulative therapy. These OM practitioners often suffered opprobrium for their beliefs from their colleagues in the medical

475 Wardwell, above n 124, 208.

476 Ann Kucklemann Cobb, 'Pluralist Legitimation of American Alternative Therapy System: The Case of Chiropractic' Fall (1997) *Medical Anthropology* 2-3; Caplan, above n 470, 81.

477 Caplan, *ibid* 81.

478 Quoted from Webb Report, above n 63, 34.

479 Caplan in Salmon, above n 470, 81; Murray Goldstein, 'Introduction, Summary and Analysis' in Murray Goldstein (ed), National Institute of Health *The Research Status of Spinal Manipulative Therapy* (1975) 3. Webb report, above n 63, 22-24; Elizabeth Lomax, 'Manipulative Therapy: A Historical Perspective from Ancient Times to the Modern Era' in Murray Goldstein (ed), National Institute of Health *The Research Status of Spinal Manipulative Therapy* (1975) 11-17.

profession.⁴⁸⁰ The development of chiropractic occurred in the aftermath of the deregulation of medicine in the years after the Thomsonian experience and the eclectic medicine period. This was a period before the development of the dominance of OM when legislative limitations would not stifle the early development of chiropractic.

The Straight/Mixer Debate

Within the chiropractic profession a fundamental split developed between chiropractors who believed that spinal misalignment/or subluxation was the sole cause of disease and those who did not.⁴⁸¹ Those chiropractors who provided only spinal adjustment were the so called 'straights.' Other practitioners were prepared to accept other causes of disease and accordingly other forms of treatment such as dietary advice; hydrotherapy; massage; homoeopathy and herbal remedies. These practitioners were designated as 'mixers.'⁴⁸²

This schism was reflected in vigorous debates that waged in the profession in the USA in the early 1900's. This schism divided the profession for many years and continues today. This schism reflects an over reliance on dogma (that is not scientifically testable) by both sides of the debate, probably born from the early history of chiropractic and the semi-religious perspective of DD Palmer and his son and successor BJ Palmer.

Legislative History

One feature of the early years of chiropractic history in the USA was the campaign of prosecutions of chiropractors for practicing medicine without a licence. DD Palmer himself

480 New Zealand Government, *Chiropractic in New Zealand Report of the Commission of Inquiry* (1979) (NZ Report) 30-31; John Mc Mennell, 'History of the Development of Medical Manipulative Concepts' in Murray Goldstein (ed), National Institute of Health *The Research Status of Spinal Manipulative Therapy* (1975) 19-24. 481 Coulter, above n 412, 10; Hans AA Baer, 'Comparative View of a Heterodox Health System: Chiropractic in America and Britain' (1984) Summer *Medical Anthropology* 151, 154; Caplan, above n 470, 86; Chapman Smith, above n 473, 14.

was arrested and jailed for that offence in 1906 in Scott County, Iowa.⁴⁸³ By 1927 thousands of similar law suits resulted in many chiropractors spending time in jail. In one incident there was a mass arrest of 100 chiropractors in New York City in 1922.⁴⁸⁴ One author in 1942 stated that in the first 30 years of chiropractic in the USA there were more than 15,000 prosecutions with a conviction rate of 1 in 5.⁴⁸⁵

This campaign was followed by a gradual spread of licensure legislature throughout the USA. Kansas was the first state to licence chiropractic in 1913 though the first licences were actually issued in Arkansas in 1915.⁴⁸⁶ The last states to pass licensing legislation were New York in 1963; Massachusetts in 1966; Mississippi in 1973 and finally Louisiana in 1974. Chiropractors have been protected by registration legislation in all jurisdictions in Australia since 1985.

The Scope of Practice of Chiropractic

One aspect of chiropractic that grew partly from the mixer/straight schism is the apparent inability for chiropractors to agree on a definition of what is the nature and scope of chiropractic practice.⁴⁸⁷ This disagreement is reflected in the extraordinary variety of scope of practice definitions found in the many chiropractic registration statutes throughout the world. For example in Queensland the definition of chiropractic is:

manipulation, mobilization and management of the neuromusculoskeletal system of the human body.⁴⁸⁸

482 Caplan, *ibid* 87.

483 Russell W Gibbons, 'The Evolution of Chiropractic: Medical and Social Protest in America' in Scott Haldemann (ed), *Modern Developments in the Principles and Practice of Chiropractic* 23.

484 *Ibid*.

485 Wardwell, above n 124, 224; For a discussion of prosecutions in Australia and NZ refer to R E Peters and MA Chance, 'Chiropractic's First Half Century -1895-1945: Chiropractic and the Law: Prosecution, Persecution, Protection, Politics,' (1999) 29 *Chiropractic Journal of Australia* 55, 61-62.

486 Baer, above n 481, 166.

487 Herbert J Vear, 'Scope of Chiropractic Practice' in Herbert J Vear (ed), *Chiropractic Standards of Practice and Quality of Care* (1992) 49.

488 *Chiropractors Registration Act 2001(Qld)* s 4.

while in Western Australia it is the much narrower definition reminiscent of 'straight'

chiropractic namely:

a system of palpating and adjusting the articulations of the human spinal column by hand only, for the purpose of determining and correcting without the use of drugs or operative surgery, interference with normal nerve transmission and expression.⁴⁸⁹

In the USA there is little consistency in the use of the term subluxation in practice statutes.

Only four statutes use the word 'subluxation' in the definition of chiropractic without any

uniformity between definitions; nine practice acts include modified terms to mean

subluxation; six practice acts make no reference to subluxations; 28 acts use other terms

alone or in conjunction with subluxation such as anatomical displacements or abnormal

functioning articulations.⁴⁹⁰ The term 'adjustment' is reflected in the definitions of 52 state

statutes.⁴⁹¹

This great variety in definitions no doubt reflects the specific political circumstances and the influence of OM but also a lack of consensus within the chiropractic profession itself.⁴⁹²

Compare this with the clear consensus shown in professional practice definitions for

physiotherapy which is defined normally as 'the external application to the human body of

massage, manipulation, passive movements, remedial exercises, heat, light and sound for

curing or alleviating or preventing any abnormal condition of the human body.'⁴⁹³

489 *Chiropractors Act 1964 (WA)* s 4.

490 Herbert J Vear, 'Introduction' in Herbert J Vear (ed), *Chiropractic Standards of Practice and Quality of Care* (1992) 4.

491 Ibid.

492 Coulter, above n 412, 10; Webb report, above n 63, 119; Vear, above n 490, 8; 49; LC Lamm, E Wegner and D Collard, 'Chiropractic Scope of Practice: What the Law Allows – Update 1993' (1995) 18 *Journal of Manipulative Physiological Therapies* 16-20.

493 eg *Physiotherapists Registration Act 2001(Qld)* s 238.

This reflects badly on the ability of the profession to ensure accountability and quality assurance likely to be demanded in the 21st century.⁴⁹⁴ While there is an acknowledgment of the value of clinical research in shaping clinical practice chiropractors do not agree on principles of knowledge production in the profession.⁴⁹⁵

Relationship to Science

Chiropractic was established in the period when scientism flourished in the western world. The mechanism that propelled OM into a position of dominance as ‘scientific medicine’ provided a means to sideline chiropractic as a dissident ‘cult’. This separated chiropractic from the prestige and benefits of the scientific revolution and provided a weapon for OM to criticise the very basis of chiropractic therapy.

Where OM sought to rely on its supposed scientific basis to position itself as a rationalist scientific therapy chiropractic relied upon its empirical background to provide its therapeutic and scientific justification. The basis of the development of chiropractic ‘has not been science, but rather what works (practice empiricism)’.⁴⁹⁶ This may have been supportable in the early years of the 1900’s but became less so as OM harnessed private and government resources to establish the scientific basis of their practice.⁴⁹⁷ This history has resulted in chiropractic applying science post hoc to justify a philosophical viewpoint rather than using science to develop techniques. OM by contrast often develops procedures based on science. Thus chiropractic is involved in a scientific catch up process.⁴⁹⁸

494 Vear, above n 487, 49.

495 Quoted in JC Keating and MC Meeker, ‘Philosophy, Research Methods and Chiropractic Standards’ in Herbert J Vear (ed), *Chiropractic Standards of Practice and Quality of Care* (1992) 23.

496 Coulter, above n 412, 90.

497 Wayne B Jonas, ‘Foreword - Chiropractic: the return of philosophy to medicine’ in Ian D Coulter, *Chiropractic: A Philosophy for Alternative Health Care* (1999) 2.

In 1977 the NZ report commented:

A general theory of chiropractic is not easy to distil from the evidence we received. That may be, as the Commission suspects, because chiropractors on the whole have been primarily interested in clinical results. Their views on the neurophysical processes by which those results follow from the spinal therapy often have been scientifically naïve.⁴⁹⁹

Chiropractic's reaction to the call for greater scientific justification was typical of most modalities in CAM. Parts of the chiropractic profession reject the appropriateness of applying science to what was considered in part an art.⁵⁰⁰ Some parts of chiropractic have by contrast focussed strongly on scientism.⁵⁰¹

The theories of DD Palmer did not lead to a normal science period based upon chiropractic investigation and testing of the hypothetical viewpoints of the founder.⁵⁰² It is only in recent years that this position has changed. Coulter suggests the lack of progress in the scientific basis of chiropractic was the product of chiropractic's need to develop a distinct persona from that of osteopathy and OM. This supported the focus on metaphysical and philosophical elements of chiropractic.⁵⁰³ As they attempted to treat similar ailments to OM using a therapy that was used by OM (though rarely) the obvious defence to any charge for practicing medicine was to claim they were reliant on a very different school of healing.⁵⁰⁴ The success of this approach resulted in a focus away from scientific research. This denied access to

498 Coulter, above n 412, 89, 90.

499 NZ report, above n 480, 43.

500 Vickers comments that within OM randomised psychotherapy trials are able to test this somewhat ephemeral practice above n 302, 9.

501 Andries Kleyhans, 'A Chiropractic Conceptual Framework Part 2: Beliefs' (1998) 28 *Chiropractic Journal of Australia* 139, 143.

502 Coulter, above n 412, 16

503 VV Strang, 'The Philosophy of Chiropractic' in JP Mazzarelli (ed), *Chiropractic Interprofessional Research* (1985) 125-127; Caplan, above n 470, 92.

504 Coulter, above n 412, 16.

institutions that may have provided the means to deal with the dearth of scientific evidence for chiropractic.⁵⁰⁵

There are of course some advantages for chiropractic in this approach. The less technical approach meant that chiropractors did not develop the jargon which is reminiscent of OM and which can provide a barrier to client's understanding of treatment. By being more client focussed chiropractors are able to confirm the competitive advantage of being seen as more accessible, human and empathetic practitioners against the reductionist and objective monolith which is OM.⁵⁰⁶

Scientific Evidence for Chiropractic

To date the level of funding and support for chiropractic scientific research is not sufficient to provide scientific evidence to satisfy OM or government of its effectiveness in other than for a limited number of spinal complaints.⁵⁰⁷ The chiropractic profession has funded what evidence has been obtained. A constant theme of government inquiries in Australia and New Zealand is that more government research funding should be provided to allow a scientific perspective on the value of chiropractic treatment.⁵⁰⁸ The recommendation by the Webb Report for the provision of funds (\$100,000) for further research in chiropractic was apparently never implemented.⁵⁰⁹

In more recent years there has been more attention paid to the issue of research and scientific method. Since the 1920's and 1930's the nerve impingement theories of chiropractic have

505 Ibid 17; Refer also to William M Meeker, 'Effectiveness and Safety of Spinal Manipulation for Low- Back Pain, Neck and Head Pain' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 582-593.

506 Caplan, above n 470, 90.

507 Ibid 92.

508 New Zealand Report above n 480, 5; Webb Report above n 63, 207.

begun to incorporate reference to biomechanical and musculoskeletal aspects of subluxation.⁵¹⁰ There have been a number of significant interdisciplinary conferences on the scientific basis of chiropractic.⁵¹¹ Since 1974 there have been at least 25 randomized clinical trials for spinal manipulative therapy (SMT) and low back pain – 9 of which compared SMT to a sham intervention. Of the 9 trials (using fastidious method), 3 showed no difference to sham, 2 are positive, 1 clearly positive +injected drugs with 3 showing some benefit over sham. Two studies of hypertension over an 18 week trial showed no difference but the short term trial was positive. Some studies are for SMT but not necessarily chiropractic.⁵¹²

There is good scientific evidence for the effectiveness of chiropractic especially for lower back pain.⁵¹³ Other sources of evidence indicate that chiropractic may be more effective than hospital outpatient treatment resulting in savings.⁵¹⁴ One study suggested substantial improvements shown after receiving chiropractic for back pain⁵¹⁵ while another study showed better improvement for chiropractic patients over placebo; physiotherapy and OM.⁵¹⁶ There is strong support for the effectiveness of chiropractic against conventional treatment.⁵¹⁷

509 Medicare Benefits Review Committee *Second Report* (1996) 75.

510 D Coburn D and CL Biggs, 'Limits to Medical Dominance: The Case of Chiropractic' (1986) 22 *Society Science and Medicine* 1035-1043.

511 Murray Goldstein (ed), *The Research Status of Spinal Manipulative Therapy* (1975); C.S. Cleveland, 'Spinal Correction Effects on Motor Sensory Functions' in JP Mazzairelli (ed), *Chiropractic Interprofessional Research* (1985) 21-31– chiropractic has shown improvement in motor and sensory functions and A Rossi, G Martino and R. Hornbeck, 'Influence of Chiropractic on Lumbosciatics and Cervicobrachialgis studied through Somatosensory Evoked potentials' in J P Mazzairelli (ed), *Chiropractic Interprofessional Research* (1985) 1-6; TJ Kaptchuk, R A Edwards and D M Eisenberg 'Complementary Medicine: Efficacy beyond the placebo effect' in E Ernst (ed) *Complementary Medicine: An objective appraisal* (1996) Chapter 4.

512 Kaptchuk, Edwards and Eisenberg, *ibid* 45-46.

513 Spencer, above n 23, 5.

514 TW Meade, 'Low Back Pain of Mechanical Origin: Randomized Comparison of Chiropractic and Hospital Outpatient Treatment' (1990) 300 *British Medical Journal* 1431.

515 WH Kirkaldy – Willis and J Cassidy, 'Spinal Manipulation in treatment of low back pain' (1985) 31 *Canadian Family Physician* 535. (not double blind study).

516 BW Koes and LM Boute, 'Randomized Clinical Trial of Manipulative Therapy and Physiotherapy for Persistent Back and Neck Complaints: Results of One Year Follow Up' (1992) 304 *British Medical Journal* 601-605.

517 Encyclopaedia of Bioethics, above n 4, 140.

One difficulty for chiropractic research is how to design a double blind study to eliminate placebo. Most research on chiropractic is statistical not double blind.⁵¹⁸ Further research is required on the efficacy, safety and cost effectiveness of chiropractic treatment. After reviewing a number of scientific studies that varied in their scientific rigour the NZ Report concluded that:

spinal manual therapy, even if performed by relatively unskilled and inexperienced practitioners, is more effective in providing quick relief of pain of musculo-skeletal origin than are conservative methods. There remains a dearth of hard statistical evidence. This will only come from carefully designed controlled trials requiring close cooperation between chiropractic and medical professions and, ideally, the physiotherapists.⁵¹⁹

Chiropractic in recent years is unique amongst CAM in the amount of research of its practices it has commenced. In the report of one of these conferences it was stated:

Most participants in the Workshop felt that manipulative therapy was of clinical value in the treatment of back pain, a difference of opinion focusing on the issues of indications, contraindications and the precise scientific basis for the results obtained. No evidence was presented to substantiate the usefulness of manipulative therapy at this time in the treatment of visceral disorders.⁵²⁰

Despite the now acknowledged need for further research Kleyhans acknowledges that 'For chiropractic science and practice in present context to have credibility and gain greater acceptance, a great deal more needs to be experimentally demonstrable than is currently the case.'⁵²¹ Kleyhans comments that 'after 100 years of existence chiropractic has not been able to organize its body of knowledge.'⁵²²

Nature of conditions treated

One of the strengths of chiropractic acknowledged by most inquiries is that chiropractic appears to deliver good results based upon subjective client responses. Chiropractors have

518 Strahilevitz, above n 447, 559.

519 NZ report, above n 480, 216.

520 Goldstein, above n 479, 6-7.

521 AM Kleyhans, 'A Chiropractic Conceptual Framework': Paradigms' (1999) 29 *Chiropractic Journal of Australia* 129, 132.

been acknowledged as ‘the only health practitioners who are necessarily equipped by their education and training’ to carry out spinal manipulative therapy.⁵²³ This could also be seen as an inherent criticism of the success of OM in dealing with musculoskeletal conditions.⁵²⁴

One continuing controversy in relation to the role of chiropractic is the extent to which chiropractic is entitled to claim the ability to treat visceral complaints. The scientific evidence that is available provides clear support for the role of chiropractors in treatment of back complaints. This evidence aligns itself to the image of chiropractors as ‘bad back’ practitioners.⁵²⁵ This more limited role does not always sit well with chiropractors. Some mixers have sought to capture as much of the therapeutic market as possible and have attempted to break out of the perception that they only treat bad backs.

From the inception of chiropractic DD Palmer was not content to limit chiropractic to merely treating bad backs. Chiropractors have been faced with a dilemma. Whilst the philosophy of chiropractic may provide support for chiropractic being an alternative health care system independent of OM or any other system, any movement towards this goal will attract opposition from OM that is then directly positioned as a competitor. If chiropractic seeks acceptance as a comprehensive alternative health care system this may question the basis of the state sanctioned OM health care system and its impressive financial, political and economic resources. It is unlikely that this accommodation will be accorded in the current environment.

522 Ibid 133; Coburn and Biggs, above n 474, 1043; Jonas, above n 497, 3.

523 NZ Report, above n 480, 3; Jonas, *ibid*, 3; Coburn and Biggs, above n 474, 1043.

524 Webb report, above n 63, 50.

525 Ibid 48, 126; Glaser, above n 328, 218.

A number of government inquiries, even if generally supportive of chiropractic, have indicated that it is not and should not claim status as a comprehensive alternative system of health care.⁵²⁶

To obtain endorsement by government and grudging acceptance by OM chiropractors have been left with a decision. Should they accept registration on the basis of a more limited legislative scope of practice. Some chiropractors consider this 'selling out' the full potential of chiropractic to provide a wide range of health treatments not limited to fixing bad backs. Generally the preferred approach has been to compromise on the statutory scope of practice.⁵²⁷ This gives chiropractic a virtual monopoly on these techniques other than doctors (not normally trained in such procedures) and physiotherapists.⁵²⁸ This has been done without entirely abandoning the claims to treat visceral problems based on cautious claims of therapeutic benefits and referral for medical advice if uncertainty arises.⁵²⁹ What chiropractors say they do is not necessarily what they actually do. The difficulties in enforcement and interpretation of medical and other health professional registration statutes in Australia arguably allow some scope for broader practice options if approached cautiously.⁵³⁰

The Chiropractic in New Zealand Report that categorised health complaints into Type M and Type O complaints has underlined this sidelining of chiropractic. Type M complaints are described as:

526 NZ report, above n 480, 4.

527 D Coburn, 'Legitimacy as the expense of Narrowing of Scope of Practice Chiropractic Practice in Canada' (1991) 4 *Canadian Journal of Manipulation and Physiology Therapeutics* 14-15; Gort and Coburn, above n 153, 1062; Baer, above n 481, 164; S Cant and U Sharma, 'Professionalization of complementary medicine in the United States' (1996) 4 *Complementary Therapies in Medicine* 157, 160.

528 Baer, above n 481, 163.

529 Coburn and Biggs, above n 474, 1047; Coburn, above n 153, 16, 20.

530 Refer to pp 233-240 above.

the type of disorder whose symptoms are mainly local pain either in the spine itself (eg simple backache), or in closely associated areas (eg headache or sciatica.) These may be classified as musculo-skeletal disorders, involving essentially mechanical dysfunction.⁵³¹ Type O complaints comprises organic or visceral disorders. High blood pressure, peptic ulcer, diabetes, and so on.⁵³²

The problem for chiropractors is defined by the New Zealand report when it states 'It is the chiropractors claims of success in treatment of the *Type O* category which principally strains the credulity of medical practitioners, and in their minds invalidates the whole chiropractic system.'⁵³³

The inquiry concluded that in relation to the general role of chiropractic that 'chiropractors did not provide an alternative comprehensive system of health care and should not hold themselves out as doing so'⁵³⁴ In relation to spinal manual therapy the inquiry concluded :

it can be effective in relieving musculo-skeletal symptoms such as back pain, and other symptoms known to respond to such therapy, such as migraine. In a limited number of cases where there are organic and/or visceral symptoms, chiropractic treatment may provide relief, but this is unpredictable, and in such cases the patient should be under concurrent medical care if that is practicable.⁵³⁵

Relationship with OM

OM saw chiropractic as 'tied to a theory of disease which science does not and cannot recognize. Chiropractic is therefore a cult, and chiropractors are quacks.'⁵³⁶ OM then felt justified in applying the classic techniques of professional exclusion against chiropractic in a manner similar to those applied against homoeopathy. The vehemence of the opposition and the special place for chiropractic in that stance is reflected by the 1925 statement by Morris Fishbein, editor of the *Journal of the American Medical Association* when he stated: 'If

531 NZ report, above n 480, 43.

532 Ibid.

533 Ibid.

534 Ibid 4.

535 Ibid 3.

osteopathy is essentially a method of entering medicine by the back door ... chiropractic by contrast is an attempt to arrive through the cellar.⁵³⁷ Chiropractic has been described by medical doctors as 'completely false' while chiropractic education and theory as 'absurd;' 'a complete farce' and 'a well staged fake'.⁵³⁸

This vehement opposition may be considered somewhat disingenuous when it is understood that spinal manipulation is a part (albeit a small part) of medical practice and is a recognized speciality of physiotherapy, a OM based discipline.⁵³⁹ This reflected in constant efforts to foster the demise of chiropractic on the basis it had no therapeutic benefit and was a menace to patients. This stance was formalised by the American Medical Association in 1963 by the establishment of the Committee on Quackery whose aim was the containment and ultimately the elimination of chiropractic.⁵⁴⁰ The Committee was charged with implementing the Iowa Plan which called for the portrayal of chiropractors as 'a hazard to rational health care in the United States because of the substandard and unscientific education of it's practitioners and their rigid adherence to an irrational, unscientific approach to disease causation.'⁵⁴¹

The role of OM in actively seeking to eliminate chiropractic was laid bare in litigation in the 1970s' when various plaintiffs including chiropractors and the Attorney General of New York on behalf of the State of New York commenced a number of anti trust suits against the AMA. The plaintiffs accused the AMA and other OM professional bodies and hospital boards of unreasonable restraint of trade against the profession of chiropractic by limiting trade with

536 NZ report, *ibid* 28; Coburn and Biggs, above n 474, 1043; Baer, above n 481, 151.

537 Gibbons, above n 483, 3-4.

538 Coburn and Biggs, above n 474, 1037.

539 NZ Report, above n 480, 30-32.

540 Walter I Wardwell, 'Chiropractors - Evolution to Acceptance' in Norman Gevitz (ed), *Other Healers: Unorthodox Medicine in America* (1988) 174; Caplan, above n 470, 81.

541 COQ minutes 12/1/ 68 Quoted in J Keith Simpson, 'The Iowa Plan and the Activities of the Committee on Quackery,' (1997) 27 *Chiropractic Journal of Australia* 5, 7; Chapman Smith, above n 473, 14.

chiropractors.⁵⁴² This litigation was generally concluded in favour of the plaintiffs. This resulted in changes in approach by the defendants including a decision to remove ethical restraints against professional cooperation with chiropractors⁵⁴³ and the opening up of access to hospital facilities for chiropractors.⁵⁴⁴

Although there is no injunction against professional connections with chiropractors the long history of conflict and suspicion means there is today still limited professional cooperation. In Queensland there is still a clear reluctance for GP's to refer patients to chiropractors.⁵⁴⁵

Public Support Leading to Recognition

The role of public support and its influence on legislators is a common theme in the political history of chiropractic.⁵⁴⁶ This reflects the very high satisfaction rate for patients of chiropractors.⁵⁴⁷ The ability of chiropractic to forge a place in the health care sector in the face of vehement OM opposition is explained by Wardwell when he comments:

The simple answer is that for chiropractors the rights to practice and to be paid for their services are crucial to professional survival. Although they are a small and internally divided minority, they are dedicated and persistent. Some legislators are themselves satisfied chiropractic patients, while others have been quick to respond to the voting constituencies which chiropractors have assiduously cultivated.⁵⁴⁸

The early years of chiropractic found quick support through its appeal to rural folk. The OM complicated theory of disease was replaced by a single cause of illness that could be represented by a mechanical analogy. The treatment was provided using the laying on of

⁵⁴² *Wilk and Ors v AMA and Ors*, 719 F.2d 207 (1983).

⁵⁴³ Caplan, above n 470, 82.

⁵⁴⁴ *Ibid* 87.

⁵⁴⁵ J K Simpson, 'A Study of Referral Patterns among Queensland General Medical Practitioners to Chiropractors, Osteopaths, Physiotherapists and Others' (1998) 21 *Manipulative and Physiological Therapeutics* 225, 232.

⁵⁴⁶ Cobb, above n 476, 16; Caplan, above n 470, 104; Coburn and Biggs, above n 474, 1044; Robert D Mootz, 'The Impact of Health Policy on Chiropractic' (1996) 19 *Journal of Manipulative and Physiological Therapeutics* 257, 258.

hands which appealed to Christian conceptions of healing.⁵⁴⁹ On other occasions the support of labour unions and working people who identified with practitioners who were less status conscious and closer to them in social prestige provided important political support for the passing of registration statutes.⁵⁵⁰

The exclusion of chiropractors by OM; its distance from the support of elites enjoyed by OM; and the strength of public support, shouldered chiropractic into a very different professional profile. Unlike the corporatist model of medical production chiropractic:

is characterised largely by the individualist mode of medical production. It tends to be labour rather than capital intensive, is diffuse, non hospital based and stresses clinical experience. Such an approach to healing is a result of exclusion.⁵⁵¹

Although some have argued this individualist approach to treatment will not survive against an increasingly bureaucratic and corporatist OM to date the ability of chiropractic to obtain sufficient leeway in this environment has seen it prove this prediction incorrect.⁵⁵²

Paradoxically another reason for chiropractic's survival was medical opposition itself. The effect of a powerful dissenter outside of chiropractic and the martyrdom of jailed chiropractors created a feeling of identity, solidarity and motivation within the profession.⁵⁵³

One factor that will favour chiropractic is that it appears that OM has now switched its tactics towards chiropractic from direct opposition to containment.⁵⁵⁴

547 J Michael Menke, 'Overcoming Barriers to the Integration of Chiropractic' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 594.

548 Wardwell, above n 540, 179; Coburn and Biggs, above n 474, 1036.

549 Willis, above n 129, 170.

550 Biggs and Coburn, above n 474, 1044.

551 Willis, above n 129, 164.

552 Coburn and Biggs, above n 474, 1036.

553 Willis, above n 129, 169; Simpson, above n 154, 50.

554 W I Wardwell, 'The Present and Future Role of the Chiropractor' in Scott Haldemann (ed), *Modern Developments in the Principles and Practice of Chiropractic* (1980) 34.

Chiropractic in Australia

The conflict between chiropractic and OM in Australia was less bitter than that exhibited in the USA. The nature of the conflict has been described as ‘more exclusional than confrontational.’⁵⁵⁵ Despite this difference there is evidence of contact between the American Medical Association and the Australian Medical Association that suggests a similar approach by OM to restricting chiropractic in its development in Australia.⁵⁵⁶ The most public and active means by which OM can effect the development of chiropractic is to limit its ability to obtain statutory registration status. The first registration legislation was in Western Australia in 1964.⁵⁵⁷ Prior to this date in 1945 chiropractors were exempted from the *Medical Act* in Western Australia. In New South Wales chiropractors were exempted from the *Medical Act* and *Physiotherapist Act* in 1956 and 1959 respectively. By 1985 all Australian jurisdictions had secured registered status.⁵⁵⁸

Victoria – Registered status for chiropractic.

Willis describes the attempts of OM to avoid registration status for chiropractors in Victoria. In 1966 the Victorian State Government asked the AMA to investigate chiropractic and its suitability for registration. The AMA report advised against registration but set out the minimum criteria for registration which were:⁵⁵⁹

- accreditation of chiropractic training schools by a recognized educational or academic institution.
- registration only to graduates of those schools.

555 Peters and Chance, above n 485, 63.

556 Simpson, above n 154, 11.

557 *Chiropractors Act 1964* (WA).

558 Victoria 1978; New South Wales 1978; South Australia 1979; Queensland 1979; Tasmania 1982; ACT 1982; Northern Territory 1885.

559 Willis, above n 129, 181.

- training nothing less than that of other paramedics.

The intention of these criteria was to create requirements that chiropractic could not satisfy.⁵⁶⁰ Early attempts at passing a registration statute were unsuccessful having been stymied by OM and physiotherapist opposition and the lack of a tertiary level course in Victoria. The introduction of tertiary education for chiropractors, which was clearly in the interest of chiropractic, was not promoted by the chiropractic profession but by the universities seeking to include freestanding courses from CAE's in accordance with government policy.⁵⁶¹ It was only when a tertiary course at Preston Institute of Technology (later Phillip Institute of Technology and then the RMIT) was begun in 1976 that a registration act for chiropractors and osteopaths was passed through the Victorian parliament.⁵⁶² This was the first publicly funded chiropractic program in the world.⁵⁶³

Conclusion

Almost without exception the statutory scope of practice of current chiropractor and osteopath legislation in Australia provides protection for the manipulation and mobilisation of the spine or its immediate articulations. This is a much more limited role from that envisioned by the early theorists of chiropractic but it appears to be the role that is generally accepted by chiropractors.⁵⁶⁴ In this way chiropractic is granted by the still dominant medical profession a limited professional role as a manipulative therapist for M type conditions with

⁵⁶⁰ Willis, above n 129, 181.

⁵⁶¹ Stanley Bolton, 'Chiropractic Education in Australia: Historical Perspectives and Contemporary Issues' (1997) 27 *Chiropractic Journal of Australia* 70; Willis, *ibid* 189.

⁵⁶² Bolton, *ibid* 72.

⁵⁶³ Simpson, above n 154, 13.

⁵⁶⁴ Phillip S Erball, 'Chiropractic and the Cul-de-sac Complex' (1994) 24 *Chiropractic Journal of Australia* 106, 106.

primary contact status. In regard to O type conditions the role of chiropractors is somewhat clouded.⁵⁶⁵

Homoeopathy

Introduction

Homoeopathy has trodden a path that has many similarities to chiropractic. The description homoeopathy derives from the greek word for like ‘homoios’ and suffering ‘pathos.’ It has been excluded by OM and has been portrayed as a cult or a quack therapy. Unlike chiropractic at certain phases of its history the practice of homoeopathy was dominated by converted OM practitioners or practitioners who’s training was essentially the same. In the UK homoeopathy is acknowledged by the National Health Scheme for use by OM practitioners.

Despite this and arguably because of this historical background OM reaction to homoeopathy in modern times has been vehement.⁵⁶⁶ Homoeopathy is rarely acknowledged by OM as a modality at all and in effect is treated as if it does not exist.⁵⁶⁷ This refusal to acknowledge homoeopathy reflects in statute as homoeopathy is mentioned by name only in the *Therapeutic Goods Act Regulations*. In the Health Complaints legislation it is one of the few primary CAM modalities not specifically defined as a health service and is included as part of a general term of ‘other alternative health or diagnostic fields.’⁵⁶⁸ Homoeopathy along with

565 Coburn and Biggs, above n 474, 1043.

566 British Medical Association, above n 9, 34 - survey demonstrated continued strong opposition. Isadora Stehlin, ‘Homeopathy: Real Medicine or Empty Promises’ December (1996) *FDA Consumer Magazine* 1-5.

567 Harris L Coulter, ‘Homoeopathy’ in J Warren Salmon (ed), *Alternate Medicines: Popular and Policy Perspectives* (1984) 58.

568 For example *Health Care Complaints Act 1993* (NSW) s 4.

therapeutic massage is the only major CAM modality excluded from GST exemption provisions.

Homoeopathy has been granted registered status in only a handful of USA states where registration of health professionals is very common and has never been seriously considered for this status in Australia; NZ or UK. This treatment is evidence of the special vehemence of opposition it has attracted from OM with this attitude reflected in the legislative structure. This attitude reflects a long history of suspicion and conflict from the inception of homoeopathy.

This opposition applies despite the fact that:

- many mainstream OM therapies derive in principle from homoeopathy.
- there is a body of empirical and scientific evidence to support the efficacy of homoeopathy.
- homoeopathy was first developed by an OM doctor.
- for much of the history of homoeopathy physicians received similar training; and
- homoeopathy historically had sufficient support to fund the establishment of homoeopathic hospitals.

Historic Conflict with OM

Features of homoeopathy have appealed to sections of the community at various stages not only for their inherent virtue but also for its contrast with some of the excesses of OM. The fundamental divergence in philosophy from OM is reflected in the categorisation of OM as 'allopathy' by homoeopaths and others. Although OM rankles as being so categorised in this

way it does provide the setting for the philosophical differences between the two healing paradigms. If homoeopathy is right then allopathy must be wrong.⁵⁶⁹

In the modern era the strength of homoeopathy in its zenith early in the 1900's may be easily forgotten. The reliance upon the concept of similars has a connection to the historical basis of OM. Along with the allopathic principle of 'contraria contrariis curentur' a Hippocratic text *Of the Places in Man* written around 350 BC acknowledges another rule of healing as 'through the similar the disease develops and through the employment of the similar the disease is healed.'⁵⁷⁰

The principle of similars in a crude form is reflected in the OM treatments such as:

Nitroglycerin for angina pectoris that was used by homoeopaths in mid 19th century on the basis of proving and used by OM, though the mechanism of action is uncertain.⁵⁷¹

Quinine for malaria.⁵⁷²

Vaccination.

Allergy desensitisation.⁵⁷³

Homoeopathy is representative of an empirist approach to healing as against the rationalist approach favoured by OM. Nicholls describes a tripartite categorization of healing. He places folk and lay person healing in small 'e' 'empiricism'; Empirism that corresponds to a vitalist/holism approach and rationalism under a mechanism/ particularism theory of healing.⁵⁷⁴

Empiricism is based upon 'a theory of knowledge that accords priority to the products of

569 PA Nicholls, *Homoeopathy and the Medical Profession* (1988) 40; Patel, above n 74, 669-671.

570 Nicholls, above n 262, 16.

571 Coulter, above n 567, 69.

572 Nicholls, above n 262, 12.

573 Ibid 231.

574 Ibid 32.

perception.’⁵⁷⁵ For the empirist the complexity of the body requires attention to the idiosyncratic reactions of a human body to its environment. This philosophy is resistant to the idea that based upon some priori principle that these reactions can be predicted. It is only by the observations of a skilled observer that the processes involved in that body can be gauged thus allowing the formulation of a focussed remedy.⁵⁷⁶

Rationalism on the other hand doubts the validity of the sense and resorts to logic and ratiocination to provide the arbiter of truth.⁵⁷⁷

Rationalist approaches supported the economic interest of OM practitioners by maximising patient throughput by allowing rapid diagnosis and prescribing for symptoms. The application of rules derived from scientific methods based upon specific causes and classes of disease assists in rapidity in diagnosis. The reference to scientific and expert knowledge serves to increase the prestige of the practitioner as well as providing a differentiation in status.⁵⁷⁸

Distinguish this from the therapeutic encounter characteristic of homoeopathy. Treatment by a homoeopathic physician requires a prolonged and painstaking recording of individual symptoms to derive that individual’s pattern of symptoms.⁵⁷⁹ The physician then selects a remedy based upon the complex set of ‘provings’ of remedies previously completed. The remedy that provides the most similar symptomatology in the provings on healthy people is the one selected to provide the healing response.⁵⁸⁰ As the remedy does not have a dramatic

575 Ibid 32.

576 Coulter, above n 567, 62.

577 Ibid.

578 Nicholls, above n 262, 33.

579 Ibid 5.

580 Coulter, above n 567, 70.

direct curing effect but is designed to stimulate the curative response of the body the impact may be gradual and subtle. This individual approach to healing may mean that different remedies are applied for what others may consider to be a similar illness. This laborious approach is not conducive to maximising the through-put of patients and is less easily standardised.⁵⁸¹

Relationship With Science

Homoeopaths when challenged on the question of the scientific basis of their therapy state that homoeopathy is based on the 'true science' of therapeutics.⁵⁸² The basis of this assertion is that the basic principles of homoeopathy have not altered since Hahnemann's time unlike OM that changes with each new discovery or theory.⁵⁸³ While scientific medicine might speculate upon what reaction is occurring inside the body the homoeopath relies upon sensory perception of symptoms. This knowledge is then applied against the known impact of a remedy on a healthy person to derive the appropriate therapeutic response. This response does not satisfy OM as it relies upon a different scientific paradigm in the modern era.⁵⁸⁴

The primary area of dispute between OM and homoeopathy is the OM claim that the high dilutions of homoeopathic remedies make a mockery of homoeopathy. Hahnemann suggested the apparently paradoxical situation that the more dilute the active ingredient in a remedy the greater is its therapeutic benefit or potency while limiting any deleterious side effects.⁵⁸⁵ The dilution of some remedies is so great that based on scientific theory there may be no molecules of the active ingredient left in the remedy. Homoeopathy needs to deal with the fact that its principles of healing breached two principles of physical chemistry ie Avogadro's

581 Nicholls, above n 262, 33.

582 Coulter, above n 567, 60.

583 Ibid 71.

584 Patel, above n 74, 670.

law and the non- specificity of subatomic particles.⁵⁸⁶ Avogadro's law suggests that theoretically any substance diluted beyond 1x 10²⁴ (twelfth centesimal potency) will contain no molecules of the original material assuming a homogenous mixture at each stage. Any therapeutic effect that might still be caused by electrons that separated from the original material is negated by the principle that electrons from one atom to the next differ in no manner from any other atom.⁵⁸⁷

The response of homoeopaths has been to suggest that the active ingredient has left its mark on the diluting material thereby providing the therapeutic benefit. There remains a lack of scientific support for the action of homoeopathic remedies at these potencies except through the controversial work of Professor Benveniste who published the results of a study in *Nature*.⁵⁸⁸ This research suggested that water retained a 'memory' of chemicals placed in it even after the chemicals were diluted until the water contained no molecules of the original chemical substance. This research has been heavily criticised.

There is in fact a considerable body of scientific evidence for homoeopathy. Kaptchuk has described 107 controlled homoeopathy trials (68 randomized) for a number of ailments. Of these studies 81 had positive effects and 24 lacked positive effects.⁵⁸⁹ Most were completed using fastidious techniques and with placebo controls.

585 Nicholls, above n 262, 74.

586 Ibid 221

587 Ibid 222; Patel, above n 74, 670.

588 J Benveniste et al, 'Human basophil degranulation triggered by very dilute antiserum against Ig E' (1988) 333 *Nature* 816-818.

589 Ted J Kaptchuk, Roger A Edwards and David M Eisenberg, 'Complementary Medicine: Efficacy beyond the placebo effect' in E Ernst (ed), *Complementary Medicine: An Objective Appraisal* 46.

Hill and Doyon in 1990 made a meta-analysis of 40 randomized clinical trials but did not find evidence for homoeopathy efficacy.⁵⁹⁰ From a fastidious perspective success over placebo has not been demonstrated but there may be methodological problems and some doubt as to whether the party providing the therapy has sufficient knowledge of the therapy. The scientific evidence for homoeopathy has been criticised on the basis it often deals with illness that are highly subjective in nature.⁵⁹¹

More recently there have been published results of double blind study of 46 rheumatoid arthritis patients where homoeopathy improved the patients significantly more than placebo⁵⁹² while a similar result occurred on a similar study on hay fever.⁵⁹³ Nicholls comments on the scientific evidence that:

There does appear to be sufficient evidence to suggest that potencies beyond the Avogadro limit are active, but a consistent body of evidence is needed; by no means the least of the problems involved in generating it has been – and still is – access to research funds. The pharmaceutical industry, for obvious economic reasons, has not been interested and neither, in general, have universities. Homoeopathic research has conventionally had to rely on funds raised by its own organizations and charities, and, of necessity, these have always been relatively limited.⁵⁹⁴

Historical Issues

Homoeopathy was at first it was welcomed in the USA by OM. In 1832 the Medical Society of County of New York bestowed honorary membership on Hahnemann (later rescinded) and there was a positive review of Hahnemann book *Organon* in the *American Review of the Medical Sciences*, a OM publication.⁵⁹⁵ This acceptance was short lived. Homoeopathy came under fire from many OM figures. There were few sterner critics of homoeopathy than Oliver Wendell Holmes who in his work *Homoeopathy and Its Kindred Delusions* acknowledged the

590 Ibid 46-47.

591 Ibid 50.

592 Coulter in Salmon, above n 567, 67; Patel, above n 74, 671.

593 Patel, ibid 671.

594 Nicholls, above n 262, 226.

doctrine of similars had some validity but was not the only law of cure. Holmes denounced kindred delusions of the past that had effected great cures but which like homoeopathy rested on no scientific basis.⁵⁹⁶

OM reacted to homoeopaths by attempting to remove them from the profession.⁵⁹⁷ Some consider this approach was borne of the desire to protect their share of the medical market. Starr suggests it was because homoeopaths were highly critical of OM in front of clients and other physicians.⁵⁹⁸

The AMA in 1855 prescribed and enforced ethical rules that denied membership to practitioners who prescribed to an exclusive dogma that clearly included homoeopathy.⁵⁹⁹ This approach included limiting consultation or any professional contact with homoeopaths and denying access to hospital facilities.⁶⁰⁰ Despite these strictures the connections that homoeopaths maintained with elites permitted the establishment of homoeopathy hospitals. In 1898 there were 66 general and 74 special homoeopathic hospitals established in the USA. The establishment of such hospitals was also a feature of the history of the UK and Australia though the passing of time has seen them disappear or convert to OM. The demise of the Sydney Homoeopathic hospital is documented in the High Court decision in *The Sydney Homoeopathic Hospital v Turner and Ors.*⁶⁰¹

595 Martin Kaufman, 'Homeopathy in America: The Rise and Fall of a Medical Heresy' in Norman Gevitz (ed), *Other Healers: Unorthodox Medicine in America* 101-102.

596 Ibid 102.

597 Note conflict in Queensland along the same lines - Ross Patrick, *A History of Health and Medicine in Queensland 1824-1960* (1987) 41.

598 Starr, above n 6, 98.

599 Kaufman, above n 595, 104.

600 Ibid.

601 (1958-1959) 102 CLR 188; Ibid 105.

The medical profession was not always united in its attempts to exclude homoeopaths. The general public and the press were either even handed or supportive of the underdog homoeopathy.⁶⁰² It seems that like chiropractors, homoeopaths were strengthened by the perception of persecution that allowed an appeal to support from the public.

The signs of a resolution to this conflict came not from OM but from the legislature. This occurred in 1875 when the Michigan state legislature required the incorporation of homoeopathy in the University of Michigan Medical School.⁶⁰³ This heralded a détente between the variant sects and OM.

What is generally not acknowledged is the debt regular medicine owed in the 19th century to homoeopathic principles.⁶⁰⁴ At this time textbooks for OM noted the importance of frequent small doses of active ingredients in dilution often specifying what had been standard homoeopathic practice, but did not acknowledge the source of the remedy quoted.⁶⁰⁵

The final indication of closer ties between the sects was the adoption in 1903 by the AMA of a new code of ethics which 'while noting that it was inconsistent with scientific principles for physicians to designate their practice as exclusive or sectarian, the new code deleted any reference to the kind of medicine doctors actually practiced.'⁶⁰⁶ Subsequent to this eclectics and homoeopaths were admitted to the OM societies.⁶⁰⁷

602 Starr, above n 6, 100.

603 Nicholls, above n 262, 205.

604 Ibid 171.

605 Webb report, above n 63, 103; Nicholls, above n 262, 170-171.

606 Starr, above n 6, 107.

607 Nicholls above n 262, 210.

Starr suggests that it is a myth that homoeopaths and eclectics were suppressed by the dominant OM. He suggests that their loss of popularity occurred for other reasons after they were admitted to the relevant professional organizations. When they were shunned and derided the sectarians flourished. When they were accepted they were gradually subsumed into orthodoxy. Starr expressed this process in the following way:

Homoeopathy had one foot in modern science, the other in pre-scientific mysticism; this became an increasingly untenable position. While regular medicine was producing important and demonstrable scientific advances, homoeopathy generated no new discoveries. The contrast was not lost on many in the group. They edged further away from Hahnemann; the final dissolution came of itself. The Eclectics also succumbed to quiet co-option; they were only too glad to be welcomed into the fold.⁶⁰⁸

The price of convergence was decline.⁶⁰⁹ Nicholls considers homogenization of practice was the real reason for the decline of homoeopathy.⁶¹⁰ Pure Hahnemannism was intellectually difficult and took time to practice properly. OM was more practical to apply and it was difficult to ignore the scientific advances of OM.⁶¹¹ This led to difficulty in distinguishing what homoeopaths did from OM.⁶¹²

The position of Homoeopathy Today

After the decline of homoeopathy in the early years of the 20th century homoeopathy was practiced a small number of individuals. The extent of the decline is evidenced by the figures on the number of practitioners in the USA. In 1900 there was said to be 15,000 homoeopaths while in the late 1950's there was said to be only 100.⁶¹³ Access to university standard instruction was limited. This malaise continued until the 1960's when along with the revival in interest in holistic healing homoeopathy was pursued with new interest. There are now many MD's; other health professionals and laypersons that are practicing homoeopathy.

608 Starr, above n 6, 107-108; Nicholls, above n 262, 129, 182.

609 Nicholls, *ibid* 182.

610 *Ibid* 209.

611 *Ibid* 179.

England has always been a bastion of homoeopathic practice no doubt assisted in the last century by patronage by the British Royal family and the fact that homoeopathy is reimbursable under the National Health Scheme.⁶¹⁴ *The Faculty of Homoeopathy Act 1950* (UK) gave official recognition to the London Faculty of Homoeopathy and permitted it to offer diplomas of competence to medical doctors.⁶¹⁵ The common law freedom to practice medicine has resulted in a vibrant lay practice in homoeopathy. There continues to be a divergence in approach between lay practitioners of homoeopathy and medically trained practitioners in most countries where homoeopathy is practiced. The medically trained practitioners perceive their understanding of physiology, anatomy and medical conditions provides the only real protection against inappropriate and dangerous professional practice. Homoeopaths now tend to emphasise the less esoteric aspects of homoeopathy and are increasingly open to scientific scrutiny and principles.⁶¹⁶ This shows a preparedness to align their practice to the dominant paradigm.⁶¹⁷ Not all homoeopaths agree with this process as they see it as a selling out of fundamental ideals.⁶¹⁸ Some homoeopaths do not want registration as it could result in homoeopathy becoming subject to OM that may require practice only via referral. Homoeopathy has always had strong support from the general public as an alternative therapy. Registration or formalised relationship with the state or OM may impact on this attraction.⁶¹⁹

612 Ibid 182.

613 Coulter in Salmon, above n 567, 73.

614 Fulder, above n 19, 78.

615 S Cant S and U Sharma, 'The Reluctant Profession-Homoeopathy and the search of legitimacy' (1995) 9 *Work, Employment and Society* 743-746; British Medical Association, above n 9, 41; Coulter, above n 567, 74.

616 S Cant and U Sharma, 'Demarcation and Transformation within homeopathic knowledge: Strategy of Professionalization' (1996) 42 *Society Science and Medicine* 579, 586.

617 Cant and Sharma, above n 615, 744,749.

618 Cant and Sharma, above n 616, 586.

619 Ibid 587.

Conclusion

The review of historical issues reveals that the regulatory structure is not simply the result of an objective assessment of how the public interest is best served. The regulatory structure is a direct result of the exercise by OM of its power and influence over the power elites in society often with its self-interest as a primary motivation. This self-interest and the therapeutic philosophy of OM forged a powerful connection with important institutions under the influence of a modernist outlook.

Certainly there have been great benefits derived from the promotion of standards of practice of OM and its alignment with the advances of science. The public benefit comes with a negative limitation on the expression by consumers and practitioners of their desire to obtain good quality CAM therapies. A postmodernist perspective that encourages a more diverse approach to health care now supports this expression. The difficulty will be to make changes in the structure that is inflexible by government design and entrenched based upon 200 years of successful development of medical hegemony.

It is important for regulators to understand that OM is based on a specific philosophy of health care. The legitimacy of CAM should be assessed without an overly OM jaundiced view of the validity of CAM.

Chapter 4

Legal Regulatory Structure

Limits on Protection

Introduction

Chapters 2 and 3 described the processes that led to the current hegemony of OM. This chapter will describe and analyse the current CAM regulatory regime. This legal regulatory structure for CAM in Australia is comprised of four limbs:

Common law.

The common law regulates the provision of health services through remedies available in negligence, contract and criminal law.⁶²⁰

Health Practitioner Legislation.

Health practitioner legislation relevant to registered practitioners provides negative statutory regulation that corrals other practitioners by punishing trespass into the defined statutory scope of practice of registered health practitioners. One example is the scope of practice provisions that only registered medical practitioners can 'practice medicine.' As this term is not defined adequately it provides a broad and ill-defined limit on the practice of all non-

⁶²⁰ Erwin A Blackstone, 'Competition Within the Physicians' Services Industry: Osteopaths and Allopaths' (1982) 8 *American Journal of Law and Medicine* 137, 143.

medical practitioners. In addition, all profession registration statutes limit the use of specified titles to the specific registered practitioners.

CAM specific legislation.

There is specific statutory regulation that allows registered status for chiropractors and osteopaths in all jurisdictions and in Victoria for Traditional Chinese Medicine practitioners and acupuncturists. In addition the *Therapeutic Goods Act* regulates how most complementary medicines are manufactured and marketed.

Consumer Legislation.

Consumer legislation such as the *Trade Practices Act* and *Fair Trading Acts* in all states provide non-specific statutory controls over the representations and activities of CAM practitioners. In addition in most jurisdictions CAM practitioners are subject to regulation through Health Complaints legislation.

This chapter will suggest that a more enlightened regulatory structure would protect public health by limiting specific acts to specified registered practitioners while permitting an open market on health services activities that do not have significant public health implications. This will provide greater consumer choice without prejudicing public health. This conclusion is reached after an assessment of the Australian, USA and Canadian regulatory structure.

Characteristics of regulatory structure

Health care regulatory systems have been characterized broadly as⁶²¹:

monopolistic – where only the OM model of health care is recognized as lawful with sanctions against other forms of healing.

tolerant – where OM is the primary form of health care but other forms are tolerated even if not legally endorsed. This characterizes the system in Europe.⁶²²

integrated – where officially OM and other traditional forms are integrated. An example of this system is China where TCM and OM are integrated.

inclusive – where certain forms of traditional methods are recognized and legal and can be practiced following specified standards. The USA exhibits this model of health care.

The Australian health care system is probably correctly characterised as tolerant. OM is the primary state endorsed form of health care with some sanctions against other forms of healing while at the same time permitting in practice a degree of tolerance of CAM. This thesis will argue that the public interest indicates the regulatory structure should move to an inclusive model of health care.

To date statutory regulation and legal authority has been directed to the twin goals of controls on fraud and ensuring the competence of practitioners.⁶²³ The campaign against unlicensed practitioners in the 19 th and 20 th century discussed below was directed at practices perceived as fraudulent because they did not comply with known laws of medical science. These goals have been pursued by the legislature in response to the powerful medical lobby.⁶²⁴

621 Jan Stepan, 'Legal Aspects' in Robert H Bannerman, John Burton and Ch'en Wen-Chieh (eds), *Traditional Medicine and Health Care Coverage: A reader for health administrators and practitioners* (1983) 292.

622 Ibid.

623 Cohen, above n 15, 20.

When CAM is regulated by statute it is effected using the model of OM based statutes derived from the 1857 Act. This form of regulation suggests, from an OM reductionist and mechanist perspective, it is possible to parse and carve up the body of medical knowledge.⁶²⁵ For a medical practitioner there is perceived to be little need to differentiate a specific scope of practice except in the most general terms as medical doctors are given statutory *carte blanche* on virtually any therapy. Chiropractors and osteopaths are by statute provided with a small segment of the medical whole. This approach may be effective for chiropractors and osteopaths as those therapies are closer to the medical model than many CAM modalities. This regulatory approach involves a somewhat artificial division between what medical practitioners, chiropractors and osteopaths do and provides at the same time a legislative basis to limit their ability to compete with OM.

The regulatory structure is characterised by vagueness in how it regulates CAM.⁶²⁶ CAM practitioners have difficulty in ascertaining if they are ‘practicing medicine’ owing to the lack of a definition of that term. Unregistered practitioners run the risk of trespassing onto the scope of practice of registered practitioners for completing beneficial and harmless procedures for which they are well trained. The parsing of health care creates the need for nice legal issues to be resolved to determine the legality of an activity. CAM practitioners are required to tip toe between the statutory scope of practice of a number of registered practitioners without any clear guidance as to what is or is not legal or illegal activity.

An OM focussed licensing regime suppresses experimentation and limits the range of consumer choices.⁶²⁷ This system allows a centralization of authority over how health care is

624 Ibid 18-20.

625 Cohen, above n 19, 109.

626 Ibid 90.

627 Havigburst, above n 269, 703.

organized and delivered. Competition and consumer choice have a limited role in determining the training and availability of health workers; the allocation of tasks and the general structure of the health care sector.⁶²⁸

In Australia great reliance is placed on the common law to provide appropriate professional discipline for CAM. These remedies are expensive, uncertain and time consuming for a prospective claimant. A common law remedy is reactive not proactive as it becomes available after a breach of duty has occurred.⁶²⁹ This suggests the current regulatory system is not primarily focused on avoiding harm but punishing harm.

This thesis argues for a regulatory structure that focuses on client needs and wants, the provision of ethical high quality health care where maximum consumer choice is respected while reducing the potential for harm. The current regulatory regime is modernist in perspective and is based on an assumption of OM hegemony. In a postmodernist environment the regulatory structure needs to be reassessed in the light of the increasing professionalisation of CAM, its developing scientific basis, the high consumer demand for CAM and the alignment that many consumers exhibit with its healing philosophy.

OM by its nature is authoritarian, monolithic, defensive and expensive based on its reliance on technology. Public demand and respect for patient autonomy to choose a health service that suits their requirements suggests the need for a more inclusive health care system. Even if OM does not accept the scientific basis of some CAM modalities it is difficult to sustain an argument that consumers who use CAM are not entitled to a degree of protection and acknowledgement to assist in ensuring the safety and efficacy of CAM services and products

⁶²⁸ Ibid.

they consume. The OM approach of exclusion and criticism of CAM reflected in the regulatory system requires a reassessment to reflect changes in OM, CAM and society.⁶³⁰ As

Cohen states:

A regulatory system that historically has focused on protecting biomedicine should move towards the notion of protecting humans, who are seeking optimal health and care, at the deepest levels of being. The law thus will fulfill its highest potential, in supporting human essence and the heart of healing.⁶³¹

Barriers to Statutory Regulation of CAM

One barrier to further statutory regulation of CAM is the perception that many CAM therapies do not pose a sufficiently substantial risk to public health to justify the economic cost of regulation. Representatives of CAM claim they provide, gentler; less dangerous and enlightened treatment in accordance with the needs of the client.⁶³²

There is substantial evidence to suggest that there is a lower rate of adverse events for CAM than compared with OM and the type of adverse events are of a less serious kind.⁶³³ In the USA one study indicated that 5% of all medical malpractice was for CAM services while the number of claims against massage therapists was 10% of those against physicians.⁶³⁴ It appears that there is substantially less litigation relating to CAM. The reasons for this record might be based upon:

Better communication.

629 Ellen L Hodgson, 'Restrictions on Unorthodox Health Treatment in California: A Legal and Economic Analysis' (1977) 24 *UCLA Law Review* 647, 690.

630 Cohen, above n 15, 20.

631 Ibid 22.

632 Glaser, above n 328, 71-72.

633 Studdert, Eisenberg, Miller and Curto, above n 104, 1610.

634 Ibid 1612.

Negligence actions tend to arise in a therapeutic environment when the client–practitioner relationship has broken down and communication has failed or has been insufficient.⁶³⁵ CAM generally emphasises synergistic, client-centered healing with a focus on communication between the practitioner and client.⁶³⁶

Less intrusive.

The rate of claims made against medical doctors increases with the intrusiveness of the procedures applied.⁶³⁷ Complementary medicine is by nature less intrusive and interventionist than western medical procedures, which often rely on surgical procedures and the prescribing of potentially harmful drugs.⁶³⁸ There is simply less scope for injury in most forms of treatment by complementary medicine practitioners.⁶³⁹

Lower expectations.

As CAM may be seen as less science based the expectations for success may be lower leading to less disappointment for patients.⁶⁴⁰ Conversely the high expectations created by medical scientific advances (encouraged by the medial and health professions themselves)

635 Commonwealth Department of Human Services and Health, Review of Professional Indemnity Arrangements for Health Care Professionals, *Compensation and Professional Indemnity in Health Care: Interim Report* (1994) 144; Milburn, above n 176, 59.

636 Stone and Matthews, above n 32, 162; C. Feasby, 'Standard of Care in Alternative Contexts' (1997) 5 *Health Law Journal* 46, 51; Lori B Andrews, 'The Shadow Health Care System: Regulation of Alternative Health Care Providers' (1996) 32 *Houston Law Review* 1273, 1282; New South Wales Parliament Joint Committee on Health Care Complaints Commission, *Final Report: Unregistered Health Practitioners: The Adequacy and Appropriateness of Current Mechanisms for Resolving Disputes* (1998) 26; Studdert, Eisenberg, Miller, Curto, above n 104, 1611.

637 Ibid.

638 Ibid 1613; Salmon and Berliner, above n 240, 142.

639 A Dumoff, 'Malpractice Liability of Alternative/ Complementary Health Care Providers: A view from the Trenches' *Medical Malpractice Issues Health World Online* <http://www.healthy.net/public/legal-lg/medmalpr/dumoff.html>, 2.

640 NSW Committee, above n 636, 26; M Cohen, 'Malpractice in Complementary and Alternative Medicine' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 230.

may lead to a view that doctors can cure all afflictions. This can foster disillusionment when these expectations are not met.⁶⁴¹

Less reporting of adverse outcomes.

A stigma may attach to attending complementary medicine practitioners. This may dissuade clients from complaining of negligence and thereby exposing their use of such services.⁶⁴²

This tendency may decrease as complementary medicine becomes more accepted.

No professional indemnity insurance.

There is little point in suing someone who is not covered by professional indemnity insurance unless that person has substantial assets to satisfy a judgment. Some complementary medicine practitioners do not have indemnity insurance, which is a disincentive to litigation.⁶⁴³ There is no legal duty for a professional person to have public liability insurance.⁶⁴⁴

Difficulty in establishing standard.

It may be difficult to determine the appropriate level of competence required by a practitioner as some modalities defy scientific explanation and measurement. In addition, many modalities rely on individual treatments for a particular patient at a particular time. This makes it difficult to apply the appropriate test of negligence against which to measure the

641 Compensation and Professional Indemnity in Health Care Interim report, above n 635, 10.

642 Feasby, above n 636, 51; Victorian Ministerial Advisory Committee, *Traditional Chinese Medicine: Report on Options for Regulation of Practitioners* (1998) 11.

643 Feasby, *ibid* 51.

644 Stephen Walmsley, Abadee Alister and Ben Zipser, *Professional Liability in Australia* (2002) 135; *Normid Housing Association Limited v Ralphs* [1989] 1 Lloyds Reports 265.

competence or otherwise of the practitioner.⁶⁴⁵ There are few agreed competency standards for complementary medicine modalities.⁶⁴⁶

Monetary value of claim.

The monetary value of the claims likely to result from CAM would encourage parties to settle before any court hearing. This leaves no public record of the claim.

Less serious conditions treated.

CAM practitioners are more often involved in treating chronic, sub-acute or sub-clinical conditions that rarely involve the risky emergency treatment likely to generate negligence claims.⁶⁴⁷

Despite these disincentives to litigation, the number of actions brought against complementary practitioners is likely to increase in line with the increase in the number of visits to complementary medicine practitioners.

Injury Caused by Complementary Medicine

Although there is little relevant case law in this country, there is no doubt that complementary medicine does on occasion result in injury or harm. The paradox is that evidence of injury caused by CAM may assist the arguments to gain registration or some type of statutory acknowledgement. On the other hand the relative safety of CAM therapies is also an

645 Studdert and Eisenberg, above n 104, 1611; Stone & Matthews, above n 32, 168.

646 Exceptions are Interim Committee for Australian Homoeopathic Standards, *National Competency Standards For Homoeopathy*, (1998) and *National Competency Standard for Acupuncture*, 1995; NSW Committee, above n 636, 26.

647 Andrews, above n 636, 1282.

important attraction for many patients. These consumers may be under the false impression that as CAM is 'natural' or 'holistic' this means it is harmless.⁶⁴⁸

The concerns that are often expressed by OM about the dangers of CAM relate to the following:

Delays in obtaining OM

An often-expressed concern is that a client may present to a CAM practitioner as a primary point of contact. The client may have an undiagnosed malignancy or other serious condition that, from an OM perspective, is the cause of the symptoms. As a result of the treatment provided by the CAM practitioner the client may choose not to consult a medical doctor until the disease has progressed to a stage when OM treatment is not possible; is made more difficult, or has a reduced chance of successful treatment.⁶⁴⁹ This concern is backed by evidence to suggest that based upon the difficult relationship between OM and CAM that 90% of persons using CAM are self-referred.⁶⁵⁰

Although some may criticize this perspective a client should be provided with all possible options for treatment and that delays in obtaining OM may cause damage to a patient who is acting on information from one therapeutic perspective.⁶⁵¹

648 Wayne B Jonas, 'Safety in Complementary Medicine' in Edzard Ernst (ed), *Complementary Medicine: An objective appraisal* (1996) 127; Wayne B Jonas and Edzard Ernst, 'Introduction: Evaluating the Safety of Complementary and Alternative Products and Practices' in W B Jonas and JS Levin (eds), *Essentials of Complementary and Alternative Medicine* (1999) Chap 6.

649 Hodgson, above n 629, 665-668; *United States v Kordel* 164 F 2D 913 (7th Circ 1947); British Medical Association, above n 9, 61; Radio National Transcript, 'Alternative Medicine Part 3,' *The Health Report*, October 2000, 2; Kottow, above n 143, 21.

650 Studdert and Eisenberg, above n 104, 1610.

651 Dumoff, above n 639, 2.

The common law would appear to align itself with the OM perspective on this point. Liability may accrue to a CAM practitioner if:

- the content of the duty of care of a CAM practitioner incorporates diagnosing medical illness or requires some understanding of possible underlying medical causes for disease, or
- that duty includes an obligation to refer to a medical practitioner when the client does not respond to treatment, and
- a medical doctor would have correctly diagnosed the condition and provided successful treatment, and
- if referred for OM treatment the patient would have not suffered the injury or sickness that they have suffered.⁶⁵²

The delay in obtaining OM is perhaps an overstated concern for a number of reasons:

- Often CAM is sought after OM has proven unsuccessful.⁶⁵³
- Surveys indicate that most CAM patients are well educated and more likely to be sufficiently well informed to make decisions on such health matters.⁶⁵⁴
- There are clear risks associated with OM. Many techniques used by OM are not scientifically proven to be effective and are associated with harmful side effects. In this sense delay in obtaining OM may in some cases be in the public interest.⁶⁵⁵
- Many CAM modalities can be applied in a complementary manner while OM options are explored.
- CAM is more often employed with chronic complaints that do not raise a risk of injury if OM is delayed.⁶⁵⁶

652 *Chappel v Hart* (1998) 156 ALR 517; *Naxakis v West General Hospital* (1999) 197 CLR 269; *O'Shea v Sullivan and Macquarie Pathology* (1994) Australian Torts Reporter 81-273.

653 I Freckelton, 'Editorial', Regulation of Chinese Medicine (2000) 8 *Journal of Law and Medicine* 5, 8.
654 Freckelton, *ibid*, 7-8; Furnham, *above n* 441, 73.

- Most CAM practitioners despite their estrangement from OM are aware of this obligation as it is reflected in their training, education, codes of ethics or practice standards.
- There is evidence to suggest:
 - that practitioner based unconventional therapies serve more as a complement or add on than as an alternative to conventional medicine. Use of unconventional therapies was consistently associated with an increased likelihood and number of physician visits.⁶⁵⁷

The need to avoid injury in this way is an argument in favor of regulation once it is accepted that CAM will be a continuing feature of the regulatory regime and will be used by a significant percentage of the population.

Recent Examples

Some recent practical examples of this concern relate to:

- The treatment of prostate cancer by TCM herbal substances. The metabolic effect of some TCM herbs is to reduce the level of prostate specific antigen (PSA) in the blood as it contains a small amount of estrogen. The lowering of the PSA is usually a sign of improvement in the condition but the effect of the herbs is to artificially lower the PSA while the tumor might continue to grow.⁶⁵⁸
- The disturbing report of a 18 day old baby with a serious heart defect which was apparently curable with a surgical procedure that had a high success rate. A naturopath advised the parents that, after giving homoeopathic and herbal treatment, the baby was cured of the complaint. On the basis of the advice of the naturopath the parents chose not to proceed with surgery. The baby died shortly after. At the inquest into the death the

655 Hodgson, above n 629, 666.

656 Furnham, above n 441, 73; Studdert and Eisenberg, above n 104, 1612.

657 Benjamin G Druss and Robert A Rosenheck, 'Association Between Use of Unconventional Therapies and Conventional Medical Services' (1999) 282 *Journal of the American Medical Association* 651-656; Jonas and Levin, above n 24, 4; Ernst, above n 103, 235-236.

matter was referred to the Director of Public Prosecutions of NSW and manslaughter charges against the practitioner have been laid.⁶⁵⁹

- A Melbourne naturopath had advised the parents of a boy to stop chemotherapy that had a 60% chance of success. The boy died six months later three days after the parents had requested that chemotherapy be restarted.⁶⁶⁰

These situations emphasise the importance of education, the exchange of information between OM and CAM and observance of ethical principles for CAM practitioners.

TCM and Acupuncture

Bensoussan and Myers have recounted examples of injury to consumers of traditional Chinese medicine such as adverse herbal reactions, misdiagnosis, failure to refer, failure to explain precautions, poisoning and adverse interactions with pharmaceuticals.⁶⁶¹

Bensoussan and Myers have suggested that traditional Chinese medicine practitioners experience a client-adverse event once every eight months from consumption of substances causing toxicity, allergic reactions, infection, (almost all now use single use needles⁶⁶²) physical injury, convulsions and fainting.⁶⁶³ A recent English decision of *Shakoov v Situ* dealt with the liability of a CAM practitioner for the death of a client when prescribed a TCM remedy comprising 12 different herbs. The client suffered an idiosyncratic reaction

658 'Men's Health – Misguided Faith in Prostate Cancer Cure' *Australian Financial Review* (Sydney, Australia) 14 June 2000, 1.

659 *The Australian* (Sydney, Australia), Thursday 12 April 2001 4; Louise Milligan, 'Naturopath 'wickedly negligent' over baby', *The Australian* (Sydney), March 4 2003, 5.

660 'Call For Control on Alternative Medicine', *The Age* (Melbourne) 25 September 2002, 1.

661 Bensoussan and Myers, above n 77, 49–75; A Bensoussan, SP Myers and AL Carlton, 'Risks associated with the Practice of Traditional Chinese Medicine' (2000) 9 *Archives of Family Medicine* 1071-1078.

662 Bensoussan, Myers and Carlton, *ibid* 1075.

663 Bensoussan and Myers, above n 77, 81; National Institute of Health, *Consensus Development Statement: Acupuncture* Revised draft (1997) 8.

eventually causing liver failure and death.⁶⁶⁴ A recent report in Australia involved a woman who took black cohosh for symptoms of menopause. This treatment apparently caused liver failure.⁶⁶⁵ Despite these incidents, Bensoussan and Myers concluded: 'It is highly unlikely that the practice of TCM poses as great a risk to public safety as the practice of western medicine.'⁶⁶⁶

Risks associated with acupuncture,⁶⁶⁷ include local and systemic infection and trauma such as pneumothorax and haemothorax, nerve damage, burns and severe bruising. OM practitioners who use acupuncture in their practice have reported double the adverse event rate than lay practitioners.⁶⁶⁸ This may reflect a greater willingness by medical doctors to report adverse events and/or because generally medical doctors have more limited training in acupuncture before commencing practice.⁶⁶⁹

Herbal Medicine

Drew and Myers reported on UK research indicating adverse effects from products such as vitamin preparations, herbal extracts and royal jelly at a rate of .9 % of 5563 enquiries received by the National Poisons Unit in London.⁶⁷⁰ Drew and Myers classify adverse events associated with herbal medicine into intrinsic and extrinsic events.⁶⁷¹ Intrinsic events were subcategorized into Type A reactions such as predictable toxicity, over-dosage and interaction with pharmaceuticals while Type B reactions were idiosyncratic reactions such as

664 [2000] 4 All ER 181.

665 'Doctors warned over menopause drug', *Courier Mail*, (Brisbane, Australia) 21 October 2002, 5.

666 Bensoussan and Myers, above n77, 83; Edzard Ernst, 'Direct Risks Associated with Complementary Therapies' in Edzard Ernst (ed), *Complementary Medicine: An Objective Appraisal* (1996) 117-119.

667 Bensoussan and Myers, *ibid* 73.

668 Bensoussan and Myers and Carlton, above n 661, 1076.

669 *Ibid* 1076.

670 Drew A K and SP Myers S P, 'Safety Issues in Herbal Medicine: Implications for the Health Professions' (1997) 166 *Medical Journal of Australia* 538-541.

671 *Ibid*.

allergy or anaphylaxis.⁶⁷² Extrinsic adverse effects were associated with failure in manufacturing causing misidentification, contamination, adulteration or inappropriate labelling or advertising.⁶⁷³ Concern in recent years has centered on the possible interaction of pharmaceuticals and herbal medicine exemplified by the interaction of St John's Wort and antidepressants.⁶⁷⁴

Chiropractic

There is a substantial body of literature and cases about adverse events in chiropractic and osteopathy.⁶⁷⁵ One study found 78 significant incidents from 1934 to 1992, excluding those incidents where there was complete or near recovery or an unknown outcome.⁶⁷⁶ One complaint from chiropractors is that medical literature describes an adverse event after 'chiropractic manipulation' when further inquiry reveals the manipulation was performed by a medical practitioner; osteopath, naturopath, some other health professional or a layperson.⁶⁷⁷ Kleyhans considers that adverse events are usually a result of poor technique, knowledge or diagnosis.⁶⁷⁸

672 Ernst, above n 667, 114-116.

673 Ibid.

674 R J Huxtable, 'The Myth of Beneficent Nature: The Risks of Herbal Preparations' (1992) 117 *Annals of Internal Medicine* 165-166; Crellin and Ania, above n 7, 76-77; Francis J Brinker, 'Interactions of Pharmaceutical and Botanical Medicines' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 669-679; Ernst, above n 96, 42.

675 Modde Peter J, 'Malpractice of An Inevitable Result of Chiropractic Philosophy and Training', (February 1979) *Legal Aspects of Medical Practice* 20.

676 A. Terrett, 'Misuse of the Literature by Medical Authors in Discussing Spinal Manipulative Therapy', (1995) 18 *Journal of Manipulative and Physiological Therapeutics* 203-210; Andries M. Kleyhans, 'Complications and Contraindications to Spinal Manipulative Therapy' in Scott Haldemann (ed), *Modern Developments in the Principles and Practice of Chiropractic* (1980) 359.

677 Terrett, *ibid*, 203-210; refer also to AGJ Terrett and AM Kleyhans, 'Cerebrovascular Complications of Manipulation' in Scott Haldemann (ed), *Principles and Practice of Chiropractic* (2nd ed 1992) 579-598; *The Health Report ABC Radio National Transcript* 'Alternative Medicine Part One two and three' 18 September 2000, 25 September 2000 and 2 October 2000; Ernst, above n 667, 119-120; D J Henderson, 'Vertebral Artery Syndrome' in Vear HJ (ed), *Chiropractic Standards of Practice and Quality of Care* (1992) 115-144.

678 Kleyhans, above n 676, 376-379.

Statistically the calculated rate of cerebrovascular accidents associated with spinal manipulative therapy varies from 1:4000,000 to 1:100,000,000.⁶⁷⁹ There is some evidence that the rate of complications may be greater than the published studies suggest.⁶⁸⁰

Orthodox medicine often counsels against manipulation of the neck on the basis of the risk of complication such as stroke, vascular accident, paraplegia, tetraplegia, dislocation of vertebrae and fractures. OM often states that what they consider the doubtful benefits of this type of therapy do not justify the substantial risks of this therapy.⁶⁸¹ Chiropractors are now moving towards obtaining written consent forms noting these risks.⁶⁸²

The New Zealand Report concluded that:

the manual therapy offered by chiropractors is carried out with every effort at safety and in most cases with refined skill and judgment. We saw a number of demonstrations of chiropractic manual therapy techniques and were generally impressed with the obvious skill and control that were used. We have no doubt that the chiropractors training adequately equips him to carry out his techniques without harm to the patient.⁶⁸³

One perspective not often brought to bear on this subject is the comparison of the rate of adverse events in neck manipulation and other OM procedures. Rome indicates in his article that the rate of complications from spinal manipulative therapy as against most other medical

679 Peter L Rome, 'Perspectives: An Overview of Comparative Considerations of Cerebrovascular Accidents' (1999) 29 *Chiropractic Journal of Australia* 87; Edzard Ernst, 'Adverse Effects of Spinal Manipulation' in WB Jonas and JS Levin, *Essentials of Complementary and Alternative Medicine* (1999), 177; Menke, above n 547, 595.

680 Chiropractic and Osteopathic College of Australia, *Risk Management: Continuing Education Module* (2002) 10; DM Rothwell, SJ Bondy and JI William, 'Chiropractic and Stroke: A population based case control study' (2001) 32 *Stroke* 1054-60.

681 Roy G Beran, Andrew Schaefer and Toos Sachinwalla, 'Serious Complications with Neck Manipulation and Informed consent' (2000) 173 *Medical Journal of Australia* 213-214; Radio National Transcript, *The Health Report* 'Neck Manipulation' 28 August and 4 September 2000; Crellin and Ania, above n 7, 78;

682 COCA, above n 680, 17-20.

683 NZ Report, above n 480, 78.

interventions is very low.⁶⁸⁴ This is also reflected in the rate of malpractice for chiropractors that is 50x less than comparable medical coverage.⁶⁸⁵

Homoeopathy

Any OM assessment of the risks of this modality is affected by the OM view that homoeopathy has no effect at all.⁶⁸⁶ For its critics the risk of homoeopathy is not the direct risk of the substance used but the indirect risk of delay in obtaining proper medical treatment.

Homoeopathy may involve the application of very dilute poisonous substances. Reported nocebo effects include headache, drowsiness, nausea and pain that would often not be at a level to cause concern.⁶⁸⁷ There are some reports of adverse reactions (including allergic reactions) to very dilute homoeopathic substances and potentially toxic levels of arsenic and cadmium found in some remedies.⁶⁸⁸ Currently there is no clear evidence of the incidence of adverse reactions to homoeopathic substances.⁶⁸⁹

Naturopathy

For a naturopath the risks of treatment could encompass the following issues:

At-risk substances. Some substances have the potential for adverse reactions. There is some evidence of allergic reactions to royal jelly, echinacea and many other substances.⁶⁹⁰

684 Michael J Haynes, 'Stroke Following Cervical Manipulation in Perth' (1994) 24 *Chiropractors Journal of Australia* 42.

685 Caplan in Salmon, above n 470, 88.

686 Ernst, above n 667, 112; Wayne B Jonas and Edzard Ernst, 'The Safety of Homoeopathy' in Wayne B Jonas and Jeffrey S Levin (eds), *Essentials of Complementary and Alternative Medicine* Chap 8.

687 Ernst, *ibid* 113; Crellin and Ania, above n 7, 79.

688 Ernst *ibid*.

689 *Ibid*.

690 Bensoussan and Myers, above n 77, 66.

Reaction to pharmaceuticals. There is a possibility of incompatibility of naturopathic regimes with pharmaceuticals prescribed by a medical doctor.

Diabetics. Diabetics may be susceptible to illness if insufficient food or the wrong type of food is eaten. The client may not be aware of this susceptibility, as many diabetics are undiagnosed.⁶⁹¹

Persons with imbalances. Clients may have hormonal imbalances or be mineral depleted because of illness, prescribed drugs or pharmaceutical substances. A specific diet may accentuate this imbalance.

Radical diets. Any diets that might be perceived as radical in nature, such as fasting or water-only diets, raise particular potential liability issues for practitioners especially for susceptible people.

Therapeutic Massage

The application of therapeutic massage in its many forms is almost always beneficial and benign though the contraindications of therapeutic massage may suggest some risks of treatment such as:⁶⁹²

- massage should not be attempted at or near the site of a fracture or suspected fracture.
- massage of areas of infections or infectious disease.
- massage of area where there is deep vein thrombosis, unexplained lumps or in the case of pregnancy.
- Advanced heart disease.
- High fever.
- Kidney failure.
- Varicose veins.

⁶⁹¹ Dimond, above n 25, 363.

- Open wounds.

Adverse Events Associated with OM

To contextualise the risks of CAM it should be understood that OM has a well documented long history of risks and adverse events. Properly delivered OM is the 6th leading cause of death in the Western countries.⁶⁹³ Information is readily available on the risks and frequency of most normal OM procedures. There is considerable evidence that iatrogenic injury is disturbingly common for OM treatment.⁶⁹⁴

In one American study it was found that twenty percent of patients admitted to hospitals suffered iatrogenic injury and 20% of these injuries were serious or fatal.⁶⁹⁵ Another study has indicated in a review of 30,195 hospital records that in 3.7% of hospitalizations there were adverse events of which 27.6 % were by medical negligence and 69% by human error.⁶⁹⁶ This suggests that approximately 1% of hospital patients suffered an adverse event caused by negligence. The study then suggested that if these figures were applied to the USA population that medical injury caused more deaths than all other forms of accident combined.⁶⁹⁷

692 Ibid, 128; Linda Chrisman, 'Therapeutic Massage: An Overview of the Discipline' in Nancy Faas (ed), *Integrating Complementary Medicine into Health Systems* (2001) 609.

693 Jonas and Levin, above n 24, 5.

694 I Chalmers 'Evidence of the effects of health care: a plea for a single standard across 'orthodox' and 'complementary' medicine' (1998) 6 *Complementary Therapies in Medicine* 211, 212; Ivan Illich *Limits to Medicine Medical Nemesis: The Expropriation of Health* (1976) 23-41.

695 E M Schimmel, 'The Hazards of Hospitalization' (1964) 60 *Annals of Internal Medicine* 100, 101.

696 TA Brennan, LL Leape and N Laird, 'Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study' (1991) 324 *New England Journal of Medicine* 370-376.

697 AMPS Patients, 'Doctors and Lawyers' (1990); For reference to other studies refer to Review of Professional Indemnity Arrangements Interim Report, above n 635, 21-26.

One significant Australian study involved a review of 14,000 admissions in 28 hospitals in NSW and SA. The study found that 16.6% of these admissions were associated with an adverse event resulting in disability or a longer hospital stay. More than one half of the adverse events were deemed to have been preventable. In 77.1% of the cases the disability was resolved in 12 months in 13.7% of the cases the disability was permanent and in 4.9 % of the cases the patient died.⁶⁹⁸

This wide reporting and focus on iatrogenic injury by OM derives partially from its emphasis on self- scrutiny. This has revealed the failures of OM while CAM, less focussed on self- scrutiny and scientific evaluation, will more easily be portrayed as a gentler and safer form of therapy.⁶⁹⁹

COMMON LAW

Lack of Authority

The dearth of case law relevant to the negligence of complementary medicine practitioners in the UK, Australia and New Zealand means there is no well-developed set of legal principles that can be applied to determine the appropriate standard of care for complementary medicine practitioners.⁷⁰⁰ For this reason, reference to case law that is relevant to the negligence of medical doctors will be applied by analogy to complementary medicine practitioners.

Medical doctors and complementary medicine practitioners approach their tasks differently, so a court may not always apply the same principles, but there is enough similarity to suggest a likely result.

698 Ross McL Wilson, William B Runciman, Robert W Gibberd, Bernadette T Harrison, Liza Newby and John D Hamilton, 'The Quality in Australian Health Care' (1995) 163 *The Medical Journal of Australia* 458-471.

699 Davidoff, above n 38, 1069.

There is some useful case law in the USA, where many issues relevant to complementary medicine have been litigated. The principles of law discussed in these cases provide some assistance on what might be the issues and possible conclusions in Australia.

Liability in Contract

Whenever a therapeutic relationship is created an implied contract will be formed and will be usually quoted as a head of claim in any action. A term will be implied in this contract that the practitioner will perform to the level of a reasonably competent practitioner.⁷⁰¹ Lord Templeman has noted ‘The relationship between doctor and patient is contractual in origin, the doctor performing services in consideration for fees payable by the patient.’⁷⁰² It is likely that the duty of care in tort and implied in contract are coextensive.⁷⁰³ Although the duty may be calculated similarly there are differences in regard to matters such as the measure of damages and the test for remoteness of damages.⁷⁰⁴

Some commentators have suggested that one way to regulate CAM is to provide a contract based control system.⁷⁰⁵ Rian considers that the tort based ‘reasonable person’ test of standards of practice downplays the role of individual responsibility.⁷⁰⁶ In the context of CAM, where client responsibility is emphasized this may not be appropriate. The use of a contract to determine the duty of care can avoid the difficulty in applying legal principles observed from an OM perspective to the very different environment of CAM.

700 S Fulder and R Monro, *The Status of Complementary Medicine in the United Kingdom* (1982) 7.

701 *Breen v Williams* (1996) 186 CLR 71, 91, 97, 104.

702 *Sidaway v Board of Governors of Bethlehem Royal Hospital* [1985] AC 871, 904.

703 Walmsley, above n 644, 51.

704 *Ibid*; *Gates v City Mutual Life Association Society Ltd* (1986) 160 CLR 1; *Astley v Austrust Ltd* (1999) 179 CLR 1.

705 Cohen, above n 11, 62; Rian, above n 54, 197.

706 Rian, *ibid* 197.

A contract for services can describe and specify matters such as:

- What services are to be provided including reference to the nature of the qualifications and training of the practitioner.
- Indicate what services are not to be provided, such as, services expected of a medical practitioner.
- The risks of treatment.
- A protocol for referral to an MD.
- Expected standard of performance of the client ie attention to diet, exercise regimes.
- The nature and extent of the duty of care in regard to that modality.
- The cost and length of treatment.
- The likely or expected results for treatment.
- The susceptibilities and capabilities of the client.
- The extent to which the practitioner may seek to limit their liability to the client.

This form of contract could avoid misunderstandings and disappointments for both the practitioner and client. It would provide an opportunity for the parties to the contract to specify what considerations are at play in the legal relationship and aspects of the duty of care that will apply. Some CAM practitioners currently obtain from patients a written statement in the form of a questionnaire and a medical history. This statement may also specify the features of the modality that is to be provided. The contract contemplated above would be much more substantial and would be aimed at expressly specifying the terms of the contract that applies between the parties. There may be merit in the use of an express contract in circumstances where misunderstandings could arise. This could be effective to protect both

the practitioner and client who may be under some misapprehension about what each other expects from the therapeutic relationship.

In the case of any ambiguity courts tend to read such contracts in favour of the client. For this reason there would have to be clear words to exclude liability for negligence.⁷⁰⁷ Where the practitioner is incorporated the provisions of s74 of the *Trade Practices Act* (Cth) applies a statutory duty for due care and skill that cannot be excluded.⁷⁰⁸ This approach may be vulnerable to common law and statutory claims of undue influence by the practitioner against a powerless client.⁷⁰⁹

This process would be potentially complex for both practitioner and client and would possibly on occasion involve the input of lawyers. The expense and complexity of this process may cast doubt on its practicality. This type of contract may not be readily incorporated into the partnership model style of therapeutic relationship contemplated by CAM practitioners if it is intended to aggressively limit or exclude practitioner liability. It is doubted if this approach would have the broader public policy protection of other forms of regulation.

Negligence

The law relating to negligence seeks to compensate a party who has suffered an injury because of the conduct or omission of a practitioner that falls below the standard of a

707 *Davis v Pearce Parking Station Pty Ltd* (1954) 91 CLR 642, 649; *Gillespie Bros Pty Ltd v Roy Bowles Transport Ltd* [1973] Q.B. 400, 419; *Darlington Futures Ltd v Delco Australia Pty Ltd* (1986) 161 CLR 500, 510.

708 *Trade Practices Act 1974* (Cth) s 68.

709 Rian, above n 54, 202 and *Trade Practices Act 1974* (Cth) s 52A and *Fair Trading Act 1989* (Qld) s 39.

reasonably competent practitioner. There is no doubt that negligent acts by a CAM practitioner will provide the basis of a claim by a client.

Liability for negligence involves consideration of a number of questions:

- Did a duty of care exist?
- Has this duty been breached?
- Was injury caused by the act in question?
- If liability applies what might be the damages recoverable and are they too remote?

Duty of Care

A duty of care exists when the relationship between the parties warrants the imposition on one party of an obligation of care for the benefit of the other. The law asks whether the person in question should have had the other person within their contemplation as possibly being injured by their negligent act. Health care professionals do not owe a duty of care to the world at large. It is necessary to establish some type of legal relationship between the plaintiff and defendant.

In most situations involving health care professionals including complementary medicine practitioners, there is no difficulty in establishing the existence of a duty of care.⁷¹⁰

It is normally a simple task to demonstrate that, if a complementary medicine practitioner provides negligent treatment or advice, it is reasonably foreseeable that injury could occur to a client. There is no doubt that the law implies an obligation on that therapist to use care, diligence and skill in the treatment and advice given.

⁷¹⁰ Dimond, above n 25, 20; *Shakoor v Situ* [2000] 4 All ER 181.

Breach of Duty of Care - General Test

If a duty of care exists, has a breach of duty occurred? The law applies the standard of a 'reasonable person' to provide a model of what conduct is required to satisfy a duty of care.⁷¹¹ For professionals such as medical doctors and complementary medicine practitioners, the standard required is the proficiency of a reasonably competent member of that profession.⁷¹² It is worthwhile to briefly consider aspects of the negligence liability of medical practitioners. For many modalities, this is the area of practice most closely aligned to complementary medicine.

General Duty

This relevant test for a medical practitioner is described by McNair J in *Bolam v Friern*

Hospital Management Committee:⁷¹³

The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill at the risk of being found negligent. It is a well-established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.

The High Court of Australia recently confirmed in *Rogers v Whitaker*⁷¹⁴ that the law imposes on a medical practitioner a duty to exercise reasonable care and skill in the provision of professional advice and treatment. The duty is a 'single comprehensive duty covering all the ways in which a doctor is called upon to exercise his skill and judgment'. It extends to the examination, diagnosis and treatment of the patient and the provision of information in an appropriate case.'⁷¹⁵

711 John G Fleming, *The Law of Torts* (9th edition 1998) 117.

712 *Shakoor v Situ* [2000] 4 All ER 181.

713 [1957] 1 WLR 582, 586

714 (1992) 175 CLR 479.

715 *Ibid* 483.

Specialists

The content of the standard of care can vary if the doctor professes to have a particular skill or specialty. The High Court in *Rogers v Whitaker* stated that, for specialists⁷¹⁶:

The standard of reasonable care and skill required is that of the ordinary skilled person exercising and professing to have that special skill, in this case the skill of an ophthalmic surgeon specialising in corneal and anterior segment surgery.

It was necessary in that case to apply an appropriate test based on the particular and quite narrow specialty of the doctor involved. It would have been inappropriate to apply a test relevant to a general surgeon or a general practitioner. Thus, the particular knowledge and expertise of an individual will impact on the standard expected where it can be shown that a practitioner holds himself or herself out as having an acknowledged specific speciality.⁷¹⁷

For a general practitioner, the standard would be that of a reasonably competent general practitioner. A specialist standard of care for a complementary medicine practitioner might be applied if it could be shown they profess to have the additional training and experience to undertake a higher level practice. For example, an osteopath might hold herself out as having a specialty in relation to subtle manipulations of the cranium. The chiropractic profession acknowledges some chiropractors as having practice specialties.⁷¹⁸ This might allow the imposition of a higher standard of care in relation to those types of procedures. A naturopath might be deemed to specialise in treating chronic fatigue syndrome based on a differential fee structure, educational level, professional acknowledgment, advertising and promotional activities of the practitioner.

716 Ibid.

717 *Yates Property Corporation (In Liq) and Another v Boland and Ors* (1998) 157 ALR 30, 51.

718 R Graham Hunt and A M Kleynhans, 'Chiropractors Evidence' in I Freckelton and H Selby, *Expert Evidence* 42.380.

Approved Professional Practice

The determination of whether negligence has occurred is based on what would be expected of a reasonably competent practitioner.⁷¹⁹ If the act was in accordance with accepted practices of the profession, this will assist in showing that negligence did not occur. Conformity with standard practice will often (but not always) dispel negligence, as it indicates that the defendant has acted as other professionals in the field would have acted.⁷²⁰

Failure to comply with standard procedures is a strong indication of negligence, especially if the injury caused was the injury that the standard procedure is intended to avoid. In this situation, the onus of proof to prove there was no negligence would switch to the defendant practitioner.⁷²¹

In England, the courts have accepted, based on *Bolam*'s case, that the standard of care of a doctor is a matter of medical judgment. The court is loath to impose their own standard, especially when dealing with a matter relevant to diagnosis and treatment. The Australian High Court in *Rogers v Whitaker* has stated in relation to diagnosis and treatment that the *Bolam* principle has not always been applied. Although professional standards and procedures are important, the 'standard is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or trade.'⁷²² Rather, the court is the ultimate determinant of what is or is

719 *Rogers v Whitaker* above n 714, 483.

720 *Rosenberg v Percival* (2001) 205 CLR 434, 439.

721 *Clark v McLennan* [1983] 1 All ER 416.

722 *Rogers v Whitaker* above n 714, 487.

not negligent activity. More recent authority from the High Court seems to more empathic that the court determines the standard of care not the medical profession on all matters.⁷²³

The High Court in *Rogers v Whitaker* approved a statement by King CJ in *F v R* in which he stated:⁷²⁴

The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.

This issue has particular importance for complementary medicine practitioners, as in some situations the accepted professional practice may be difficult to ascertain.⁷²⁵ There is a distinct lack of settled protocols and procedures that make more difficult the task of ascertaining accepted professional practice.⁷²⁶ Increasingly, modalities are adopting competency standards that may provide some guidance for a court when assessing professional behavior.⁷²⁷ In the USA the American Association of Naturopathic Physicians has issued guidelines for practice including requirements for referrals; record keeping and the need for appropriate examination of clients. Similar guidelines are established in acupuncture and chiropractic.⁷²⁸

In considering the appropriate standard of care of complementary medicine practitioners, a court may be more likely to make its own assessment of what should be the practice of a particular modality. This would apply more forcefully the further away from the accepted and

723 *Naxakis v West General Hospital* (1999) 197 CLR 269, Gaudron J 275-276, McHugh J 285-286, Kirby J 297-298.

724 [1983] 33 SASR 189, 194.

725 Dimond, above n 25, 23.

726 Cohen, above n 11, 65; Spencer, above n 23, 17; Crellin and Ania, above n 7, 72; Michael Cohen, 'Malpractice in Complementary and Alternative Medicine' in Nancy Faass (ed), *Integrating Complementary and Alternative Medicine*, (2001) 229.

727 Dumoff, above n 639, 2.

728 Cohen, above n 726, 229.

well-regulated professions that one gets. The legal system is fundamentally conservative in nature.⁷²⁹ When dealing with complementary medicine, a court may be more likely to consider as negligent an activity that the profession may consider appropriate.

Causation

Once the plaintiff has established that a duty of care has arisen and has been breached, it is necessary to show that, on the balance of probabilities, the breach of care caused the damage that was suffered. This relies on a commonsense assessment of the connection between the negligent act and the damage suffered.⁷³⁰ The question is whether a particular act or omission can fairly and properly be considered a cause of the damage suffered.⁷³¹ If there is evidence that, despite the negligent act, the damage would have occurred anyway, there is no causation and therefore no liability.

Kirby J in *Chappel v Hart*⁷³² provided a list of possible reasons to displace a finding of causation in relation to an event, including:

- that the damage was coincidental and not related to the breach.
- that the damage was inevitable and would have occurred even without the breach.
- that the event was the result of unreasonable action by the plaintiff.

Causation may be problematic in CAM where the nature of the action of a substance or technique may be difficult to demonstrate.⁷³³ This may not be so problematic with modalities close to the medical model such as chiropractic. For a patient who suffers a stroke, heart

⁷²⁹ Stone and Matthews, above n 32, 161.

⁷³⁰ *Bennett v Minister of Community Welfare* (1992) 176 CLR 408, 413, 428.

⁷³¹ *Chappel v Hart* (1998) 156 CLR 517, 523.

⁷³² *Ibid*, 547.

⁷³³ Dimond, above n 25, 25.

attack or illness after taking a herbal substance or receiving therapeutic massage it may it may be a difficult task to show the connection between the adverse event and the treatment.

Damage

Once negligence and causation are established, if a plaintiff suffers damage, damages may be awarded if they were a reasonably foreseeable result of the breach of duty. Damages cover such matters as:

- hospital, nursing and medical expenses.
- loss of wages up to the trial.
- loss of capacity for future earnings.
- nervous shock and pain and suffering.

The family of a deceased client may be entitled to the recovery of damages under statute.⁷³⁴

Complementary and Alternative Medicine and Negligence

What is likely to be the appropriate test of the standard of care? Authorities in Australia, the USA and Canada suggest that the standard of care for a complementary medicine practitioner is the same test that applies to professionals generally. Some have suggested that the same standard of practice applied to medical practitioners in particular should apply to CAM practitioners.⁷³⁵ There is some indication from USA cases that if a CAM practitioner provides treatment outside their scope of practice and within the scope of practice of OM then an OM

⁷³⁴ For example, *Law Reform (Miscellaneous) Provisions Act 1944* (NSW) part ii; *Common Law Practice Act 1867* (Qld), s 15 D; *Administration and Probate Act 1958* (Vic.) s 29.

⁷³⁵ Feasby, above n 636, 57; Studdert, Eisenberg, Miller and Curto, above n 104, 1614.

standard of care may be applied.⁷³⁶ By providing this disincentive to practice outside of standard CAM scope of practice this has been suggested as one means to regulate CAM practice.⁷³⁷ In some American cases the appropriate standard applied for an unlicensed profession was the test of a lay standard of care.⁷³⁸

The task for a plaintiff is to demonstrate that the complementary medicine practitioner has fallen below the level of expertise or skill required of ‘an ordinary competent person exercising that particular art’. Normally, assistance in ascertaining the appropriate standard is provided by expert witnesses from the particular discipline under consideration.

Specific Case Law on CAM from Australia and England

Bawden v Marin

Facts

One of the few cases in Australia that deals with the tortious liability of a CAM practitioner is the South Australian Supreme Court Full Court decision in *Bawden v Marin*.⁷³⁹ The extempore judgment of the court provides an insight into the integration of the principles of tort law with the liability of CAM practitioner, in this case a chiropractor. This was an appeal from a decision of a judge of the District Court in which he dismissed a claim for damages brought by the appellant against the respondent registered chiropractor. The plaintiff had

736 John Barry Stutt, 'Negligence of Drugless Healers, Chiropractors' July 1985 *Wisconsin Bar Bulletin* 22, 24; *Treptau v Behrens Spa Inc*, 247 Wis 438 20 N.W. 2D 108 (1945); *Metzler v New York State Board for Professional Medical Conduct*, 610 NYS 2d 334 (1994); Cohen, above n 640, 231.

737 Cohen, above n 19, 142-143.

738 *Boudreaux v Panger*, 481 So 2d 1382 (1986) (La App 5th circ 1986); *State of North Carolina v Howard*, 78 NC App 262; 337 SE 2d 598 (1985).

739 *Bawden v Marin* (Unreported, Jacob J Cox J and Matheson J, Full Court of the Supreme Court of South Australia, BC 9000321 2 July 1990).

sought damages for what was said to be negligent spinal manipulation causing broken ribs. The appeal was dismissed and the District Court decision was confirmed.

The primary issue on appeal was the finding by the District Court judge that although he accepted that the defendant's treatment caused the broken ribs, he did not consider the defendant had fallen short of the appropriate standard of care.

The court heard the evidence of a medical doctor who suggested that for a person of her age (the plaintiff's age is not mentioned) the treatment should not have been undertaken. The plaintiff also relied on the evidence of a chiropractor who suggested that the defendant could have used a chiropractic device called an 'activator' to limit the amount of force used in the manipulation.⁷⁴⁰ The court noted that the failure to use such a device was not outside the normal discretion relating to chiropractic practice and there was in fact ample evidence that there was nothing unreasonable in the defendant's decision to not use the activator in that case. The crux of the judgment was that:

there was a total absence of any evidence to suggest that on the case history as disclosed to the respondent, and having regard to the number of occasions upon which he had in fact treated her and many other patients in much the same way and without ill effects, that his treatment on the last occasion which caused injury was in the circumstances negligent or as the learned judge said, was in breach of his duty of care to her.⁷⁴¹

The court concluded unanimously that this was a case of an injury occurring by misadventure and there was no evidence to support the conclusion that the respondent's treatment failed to attain the appropriate standard of care.

The case is significant as that court preferred the evidence of a chiropractor to that of a medical practitioner and it applied the test of competence appropriate to a chiropractor not an

⁷⁴⁰ Ibid 2.

MD. By admitting into testimony the evidence of the medical practitioner the case also suggests that it is appropriate evidence in a case involving the liability of a chiropractor. This is similar to the approach taken in the USA where medical evidence is available to deal with questions of liability where there is an overlap in expertise with the practice under question.⁷⁴² In *Bawden v Marin* the court applied standard principles of negligence relevant to medical doctors to this factual situation.⁷⁴³

Helpful Authority?

This authority is not entirely satisfactory. The judgment was delivered extempore so the full gamut of legal issues and authorities were not quoted or openly canvassed. This case was delivered a few years before the decision in *Rogers v Whitaker*. Perhaps for this reason there was no discussion of whether the court should support the professional practice under consideration. At that time Australian law was more influenced by the English *Bolam* test that gave considerable respect to the professional opinion of the medical profession. The court did not appear to inquire as to whether in accordance with the approach subsequently preferred in *Rogers v Whitaker* or in the earlier South Australian case of *F v R*⁷⁴⁴ that the final arbiter of what is negligence was the court.

It is arguable that any procedure that results in broken ribs may be a breach of duty even if performed in accordance with standard procedure. Had the court heard the matter after *Rogers v Whitaker* it may have looked more closely at this issue. In addition, there was either no claim made by the plaintiff or no discussion of the issue of the lack of warning of risks of treatment. Broken ribs are an inherent risk of chiropractic manipulation. Even if the court

⁷⁴¹ Ibid 2.

⁷⁴² Cohen, above n 19, 142.

⁷⁴³ Compare with very conservative and critical view of chiropractic treatment in *Miller v. Eric Roberts and Co* (1981) 1 SR (WA) 370.

concluded that chiropractor was not negligent in his treatment procedures the client may have chosen not to receive treatment if warned of the risk of injury that subsequently occurred.

That would have required an assessment of the nature of risk of treatment, the client and whether she would have considered it a material risk.

Shakoor v Situ

The other very significant case that involved the liability of a TCM practitioner for negligence is the recent English decision in *Shakoor v Situ*.⁷⁴⁵ This authority confirmed that the law will apply the standard of care of a TCM practitioner not an OM practitioner in determining liability for negligence by a TCM practitioner. This authority further suggests a court in applying this test will require CAM practitioners to acknowledge that they practice within a predominantly OM context.

Facts

Shakoor v Situ involved a claim by the widow of Abdul Shakoor who died after receiving a course of Chinese herbal medicine from the defendant. She contended his death was caused by the negligence of the defendant thereby entitling her to claim for damages under the *Fatal Accidents Act 1976* (UK) and the *Law Reform (Miscellaneous Provisions) Act 1934* (UK).

The defendant was trained in China in both traditional and modern medicine and had been practicing in the UK for a number of years. He was not a registered medical practitioner but was a member of a TCM professional association.

744 *F v R* [1983] 33 SASR 189.

The deceased consulted the defendant about multiple benign lipomata (fatty deposits below the skin). His general practitioner had previously told him that the only remedy for this condition was surgery. The defendant prescribed a decoction of 12 herbs to be taken on alternate days. After taking the herbs he became ill and eventually suffered from liver failure and died after a liver transplant.

Causation

The issue of causation was not a matter of controversy in this case. Judge Bernard Livesley QC (Deputy Judge of the High Court) held that:

each side is in agreement that the injury to and failure of the deceased's liver (and therefore his death) were, on the balance of probabilities, caused by the decoction, and that the ingredients are biologically active but not toxic or hepatotoxic either individually or collectively; that in the deceased they induced an 'idiocyncratic' reaction; that such a reaction was extremely rare and cannot be predicted in any person.⁷⁴⁶

The claimant argued that the defendant should have performed a liver function test prior to commencing the treatment and monitored the deceased during the 18 days that the substance was being used. These assertions were considered by Livesley QC to not have any prospect of success as the prior liver test would likely not have shown any abnormality and the monitoring would not have been able to ascertain damage was being done before it was too late.⁷⁴⁷

The judge summarised the case as:

The case for the claimant must therefore stand and fall on the allegation that it was negligent of the defendant to prescribe the decoction; alternatively to do so without warning the deceased of the risk of the injury to which ingestion of the decoction would expose him.⁷⁴⁸

⁷⁴⁵ *Shakoov v Situ*, above n 712, 181.

⁷⁴⁶ *Ibid* 184.

⁷⁴⁷ *Ibid* 185.

⁷⁴⁸ *Ibid*.

Appropriate Test re Negligence

The significant argument presented by the plaintiff in this case was that the defendant had held himself out as the equivalent of a general medical practitioner specializing in skin complaints and should be judged by the standard of reasonably competent medical practitioner in that field in the UK. It was argued that on that test he should have known about the possibility of injury as medical journals such as *Lancet* had warned of the known risk of liver damage and in one case of death involving the ingestion of similar herbal medicine. If this type of test was accepted it could expose a CAM practitioner to liability for negligence even if they were acting in accordance with the requirements of their profession and would subject their practice to an entirely foreign healing philosophy.

It was also argued from the western medicine perspective that as this concoction would have no prospect of curing or ameliorating the deceased's ailment on a cost/ benefit analysis it should never have been used. The plaintiff suggested that if a practitioner decided to use the concoction then it should have be preceded by a suitable warning, which the plaintiff maintained the deceased would have heeded, and therefore refused treatment.

The defendant contended that the appropriate test to be applied was that of a reasonably competent TCM practitioner. He also argued that even if the test asserted by the plaintiff was applied he was not negligent by that standard. The defendant also argued that as the plaintiff had not provided evidence of appropriate professional practice from a TCM practitioner it was not possible to find negligence against the him.⁷⁴⁹

749 Ibid 187.

Duty of Care

Livesey QC accepted that the defendant had a duty to use reasonable care and not to cause harm. Livesey QC noted that there was no authority in the common law system on the negligent liability of TCM practitioners. The judge accepted the defendant's argument in part by accepting that TCM practitioners should not be judged by the same standards as a medical doctor.⁷⁵⁰

In an important paragraph the judge indicated⁷⁵¹:

The Chinese herbalist, for example, does not hold himself out as a practitioner of orthodox medicine. More particularly, the patient has usually had the choice of going to an orthodox practitioner but has rejected him in favor of the alternative practitioner for reasons personal and best known to himself and almost certainly at some personal financial cost. Those reasons may include a passionate belief in the superiority of the alternative therapy or a fear of surgery or reliance (perhaps dependence) on orthodox chemical medications which may have known undesirable side effects either short or long term or both. (In the instant case, where the deceased was not known to have been predisposed to favor alternative medicine, his motivation may, for all we know, have been a fear of surgery or merely a desire to avoid the delays attendant nowadays on non-urgent surgical cases.) The decision of the patient may be enlightened and informed or based on ignorance and superstition. Whatever the basis of the decision, it seems to me that the fact that the patient has chosen to reject the orthodox and prefer the alternative practitioner is something important which must be taken into account. Why should he later be able to complain that the alternative practitioner has not provided him with skill and care in accordance with the standards of those orthodox practitioners whom he has rejected?

While rejecting the application of the OM standard of care the judge acknowledged:

it will ..., often (perhaps invariably) not be enough to judge him by the standard of the ordinary practitioner 'skilled in that particular art', it will often be necessary to have regard to the fact that the practitioner is practising his art alongside orthodox medicine, the court will need to consider whether the standard of care adopted by the alternative practitioner has taken account of the implications of this fact. The implications may vary depending upon the area of expertise and specific art or omission that is under scrutiny in the individual case.⁷⁵²

750 Also accepted in the USA Alan Dumoff, above n 639, 1.

751 Above n 712, 188.

752 Ibid 188, 189.

Content of Duty of Care

The judge then discussed the content of the duty of an alternative medicine practitioner. He considered there were three important points that needed to be made in the context of a practitioner prescribing a chemical or herbal remedy for internal consumption⁷⁵³:

- a practitioner had to recognize he is holding himself out to practice within a system of law and medicine which will review the standard of care that has been taken in the care of a client.
- where a remedy is prescribed it is not enough to say that the remedy is traditional and considered not harmful it is the practitioner's duty to ensure the remedy is actually not harmful or potentially harmful.
- He must recognize the probability that any person suffering an adverse reaction to such a remedy is quite likely to find his or her way into an orthodox hospital and the incident may be written up in an orthodox medical journal. Such a practitioner should take steps to ascertain this evidence that could be satisfied by being a member of an association that searches the relevant literature and reports any relevant material to the practitioner.

Evidence re Duty of Care

The judge held that a claimant can succeed in a claim against an alternative practitioner either:⁷⁵⁴

- by calling an expert in the modality specialty in question (this was not done in this case); or
- by proving that the prevailing standard of care and skill in the art in question is deficient in regard to the risks that should have been taken into account.

⁷⁵³ Ibid 189.

The latter argument was what the plaintiff relied upon in this case. The judge dealt with the evidence presented to the court for:⁷⁵⁵

- damage caused by some TCM remedies (which normally was resolved after the treatment was stopped); and
- the case of the death of one patient from liver failure.
- evidence from some sources of the benefits of this treatment.

The judge rejected the argument that this provided the basis for liability on four bases:⁷⁵⁶

- He was not prepared to accept that TCM could not cure lipomata. OM may argue this point but the judge made this conclusion in the absence of contrary evidence.
- He noted the conflict in evidence as to whether the equivalent OM practitioner namely a GP would have noted the evidence of the potential damage caused by the herbs in question.
- The information in the literature would not have put a practitioner on notice the herbs were too hazardous to prescribe or would have caused the reaction that occurred in this case. This case and increasing understanding of potential adverse effects of herbs might suggest that this conclusion may become more difficult to make in the future.
- That there is a risk of unpredictable responses to CAM medicines and this is much lower than that seen in western medicines.

Warning of risks of treatment

In regard to the obligation to warn of the possible side effects the judge considered:

754 Ibid.

755 Ibid.

756 Ibid 191.

the adverse reaction of the type which occurred is such a rare event that I do not believe that a doctor would be obliged to give a warning and, if a warning were to be given, the risk could legitimately have been presented as so small that I do not believe that an appropriate warning would have had the effect of dissuading anyone, let alone the deceased, from making the treatment.⁷⁵⁷

Implications of *Shakoor v Situ*

The significance of this authority is that:

- It confirms the approach taken in *Bawden v Marin* that a similar test applied to medical doctors will be applied to CAM practitioners but based upon the expertise not of a medical practitioner, but a reasonably competent member of the CAM specialty under consideration.
- Practitioners are not able to ignore the information and scientific evidence that may be provided by OM which should impact upon the content of their duty of care to their client. This means for example that if an OM journal describes an adverse event from a CAM procedure (such as chiropractic cervical manipulation) or substance (adverse reactions to royal jelly) the CAM practitioner may be advised to warn of that risk and take steps to limit the risk of injury.
- It is important in any proceedings brought against a CAM practitioner to obtain expert evidence of what is or is not competent practice for that modality.
- A court will assess whether in its view a particular practice is objectively appropriate to determine if the standard professional practice might be deemed negligent. This case echoes the principles discussed by the High Court in *Rogers v Whitaker* that does not allow the medical profession the role as final arbiter of competent practice.

⁷⁵⁷ Ibid 191-192.

The factor that ultimately weighed against the plaintiff in this case was that the adverse reaction was idiosyncratic and not possible to be predicted. This authority provides good guidance as to relevant considerations for a negligence claim against an unregistered CAM practitioner. The application of the varied OM standard test, that is, a 'reasonably competent TCM practitioner' test was appropriate on the facts and is consistent with approaches taken in regard to other professions where a profession specific approach to liability is applied.⁷⁵⁸ The inappropriateness of applying the standard of an OM practitioner based upon the choice made by the consumer was clear. It is appropriate that the element of consumer choice in the type of therapy chosen should impact upon the duty of care that is provided. To apply an MD standard of care would ignore the different healing philosophy and principles between TCM and OM. This approach is given maximum force when the consumer has been provided with adequate information as to the nature of the modality that has been chosen and the implications, risks and advantages of that therapeutic approach.

The application of a modality specific test permits a balancing of the interests of the practitioner who conforms to standard professional practice and the entitlement of a client to protection from injury. This balancing was in this case provided by the stated necessity for the TCM practitioner to maintain contact with OM sources that could impact upon the standard of care required of the TCM practitioner.

Inherently Negligent Treatment

One issue not developed in this case was the circumstances where a court might conclude that the provision of standard TCM professional practice was inherently negligent based on the

⁷⁵⁸ Walmsley, above n 644, 37.

Rogers v Whitaker approach. Perhaps this point would have been more specifically dealt with if it had been heard in Australia.

The difficulty for the law is that the CAM treatment may conform with its own parameters for successful practice without reference to OM standards of practice. Should it be deemed negligent to apply herbal medicine for a client with diagnosed cancer or heart disease when there are proven OM treatment options?

Any concern about this issue could be balanced by a well-developed protocol for referral to a medical doctor or other practitioner should a patient not respond or their condition worsens. A CAM practitioner who ignores the necessity to refer to an OM practitioner or to practice in a way complementary to OM options could attract liability.

In addition, the judgment made it clear that the considerations relevant to the application of standard negligence tests were flexible pertaining to the particular modality under consideration. As TCM involves the ingestion of herbs that created the need to consider knowledge of adverse reactions to such herbs from OM sources. In another fact scenario different requirements might be applied to satisfy that consideration. For example, chiropractors would be expected to understand OM sources about the risk of neck manipulation, naturopaths would be expected to appreciate the OM evidence of the interaction between certain herbs and some pharmaceutical substances and an acupuncturist would be obliged to understand the risk of infection from acupuncture.

Liability of an MD For Referral to a CAM Practitioner

Until recent years there may have been very significant ethical barriers to a medical doctors referring a patient for treatment by a CAM practitioner. These barriers are no longer in place.⁷⁵⁹ Part of the reason for the continued lack of referral by MD's may relate to the view that to make such a referral may expose the practitioner to liability in negligence.

An MD will risk liability for a referral to a CAM practitioner if it is found the referral for the treatment contemplated was contraindicated. In *Mc Groder v Maguire*⁷⁶⁰ a GP was deemed negligent for a referral to a chiropractor when medical evidence indicated that spinal manipulation was contraindicated. Potential liability could also occur where a referral is made by an MD when he or she knew or ought to have known that the CAM practitioner was not competent or was unethical.⁷⁶¹ A negligent referral might occur where referral to another practitioner would have been more appropriate or the referral to the CAM practitioner has delayed appropriate OM treatment to the extent it is not now possible or is likely to be less effective.⁷⁶² If an MD referred a patient to a competent and qualified practitioner for CAM for a chronic condition where there was no effective OM treatment and there was no evidence suggesting that CAM was unsafe in those circumstances this would appear to be a low risk exercise for the MD.

Liability could accrue to the MD if there was sufficient control and supervision of treatment by the MD such that there was considered to be vicarious liability for the negligence of the CAM practitioner. The degree of control that would establish this potential liability would be unlikely to occur where the CAM practitioner is an independent practitioner as is usually the

759 Simpson, above n 154, 324-325.

760 (Unreported, Handley JA, Sheller JA and Beazley JA, New South Wales Court of Appeal 13/8/2002)

761 Ibid.

762 Studdert and Eisenberg, above n 104, 1612.

case. In a situation of substantial integration of the CAM practice with the medical practice this may become an issue.⁷⁶³

Contributory Negligence

In the application of torts law to CAM one principle of law that could be more broadly applied is contributory negligence. With OM the patient's subordinate role attracts principles of law that do not require a high standard of behaviour from a patient.⁷⁶⁴ The law applies an expert/ layperson test to the relationship on the basis the MD is expected to have the knowledge and the client is not. This means that less than sensible behaviour by a patient, such as not taking medication; overdosing on medication⁷⁶⁵ or not following a prescribed diet⁷⁶⁶ will not absolve the medical doctor of liability or will not greatly reduce that liability, if the practitioner has not taken reasonable steps to avoid that result.

One could argue for a more extensive role for contributory negligence in the CAM therapeutic relationship. Contributory negligence is not a major consideration in reducing claims in OM in the UK because of the reliance by patients on doctor's expertise.⁷⁶⁷ In Australia and Canada the greater incidence of contributory negligence in reducing claims is perhaps based on cultural and social differences.⁷⁶⁸ The less hierarchical relationship between CAM practitioners and their patients might suggest a broader application of contributory negligence to reduce any claims for damages.

⁷⁶³ Ibid 1614.

⁷⁶⁴ Ian Kennedy and Andrew Grubb, *Medical Law* (3rd edition, 2000) 507.

⁷⁶⁵ *Crossman v Stewart* (1977) 82 DLR (3d) 672.

⁷⁶⁶ *Schliesmann v Fisher* (1979) 158 Cal Rptr 527.

⁷⁶⁷ Walmsley, above n 644, 245.

Contributory negligence may be particularly relevant when dealing with CAM treatments that rely on lifestyle programs such as diets and exercises that may be applied in naturopathy. If a client fails to follow a diet or exercises incorrectly, and reasonable steps were taken by the CAM practitioner to explain correct procedures and their importance, contribution negligence should be available to reduce any claim.

Summary of Appropriate Negligence Model

The model of negligence liability for CAM practitioners suggested by the discussion above involves:

- a modality specific test of what constitutes negligence.
- the duty of care including an appreciation of the scientific evidence of the risks and contraindications that arise from the OM context in which the CAM practitioner performs.
- a practitioner acknowledging the necessity to refer to an OM doctor when appropriate or to practice in a complementary manner.⁷⁶⁹
- contributory negligence is given a broad application especially in modalities that rely upon patient cooperation and behaviour where it is shown a patient has not demonstrated a reasonable level of performance ie following diets or taking herbal or vitamin substances following appropriate instructions and information from the practitioner.

768 Ibid 246, 247; *Locher v Turner* (1995) Australian Torts Reporter 81-336; *O'Shea v Sullivan* (1994) Australian Torts Reports 81-273; *Crossman v Stewart* (1977) 82 DLR (3d) 672.

769 Walmsley, above n 644, 205; *Tran v Lam* (Unreported, Badgery – Parker J, Supreme Court of New South Wales, 20 June, 1997).

Regulatory effect of Negligence Claims on CAM practitioners

The cases above are examples of the regulatory role played by the common law in the practice of CAM. Statutory and voluntary self-regulation can directly impact upon the quality of the provision of professional services prior to its provision while the common law can impact on professional performance through the threat of legal liability for negligent practice.⁷⁷⁰

The regulatory impact of the law of negligence is based on the assumption that by demonstrating the requisite skill a practitioner avoids the adverse consequences of litigation and damages. In this way the deterrence effect has a salutary effect on a practitioner.

The impact of the common law is reflected in its engendering of defensive medical practice characterized by overly cautious diagnosis and an over-reliance on pathology tests.⁷⁷¹

Medical doctors have indicated that their practice has changed based upon developments in legal principle. An example is the need to describe procedures in more detail based on *Rogers v Whitaker*.⁷⁷²

Although a blunt weapon, persons who have suffered injury as a result of the activities of a CAM practitioner can use common law remedies to seek recovery of damages for that loss.⁷⁷³

770 Stone and Matthews, above n 32, 161.

771 J Robert S Prichard, 'Professional Civil Liability and Continuing Competence' in Philip Slayton and Michael J Trebilcock (eds), *The Professions and Public Policy* 303, 317-318; Review of Professional Indemnity Arrangements Interim Report, above n 635, 44; The ability of CAM therapists to use pathology tests is limited. Some pathology firms accept referrals for tests and some do not. Many chiropractors perform their own x-rays using a radioactive substances licence or have arrangements with cooperative radiologists.

772 Review of Professional Indemnity Arrangements Interim Report, *ibid*, 44.

773 Editorial, Regulation of Chinese Medicine (2000) 8 *Journal of Law and Medicine* 5.

Some doubt the role of negligence in regulating conduct.⁷⁷⁴ The process of litigation requires a private initiative by a plaintiff and focuses attention on individual needs and liability and not on public policy issues. The delays in and the cost of litigation are major disincentives.⁷⁷⁵ As a claim in negligence is a private cause of action the commencement and result of a claim may not be widely disseminated to provide the desired salutary effect on the profession. This is exacerbated in the case of CAM as the smaller size of claims encourages the settlement of claims before court action. This means few reported cases arise. Even if a patient of a CAM practitioner considers that they have a claim in negligence this knowledge will not avail them unless they are able to afford the costs of such an action including a possible adverse costs order that could follow an unsuccessful action.⁷⁷⁶ These factors reduce the regulatory impact of litigation.⁷⁷⁷

Classical economists rely on the salutary impact of potential liability in tort as a justification for its effectiveness as a regulatory instrument. The full impact of the deterrence effect would apply if the market for health services were perfect. In a perfect market consumers and practitioners would have full knowledge of all errors that were made and practitioners would be fully personally liable for those errors. This could impact on the behaviour of consumers who would avoid practitioners who had a history of adverse events. This would support greater care by practitioners to avoid the economic effect of that liability. The uncertainty about what is a good or negative health outcome, the pervasive use of professional indemnity insurance that means the practitioner does not normally risk substantial direct economic risk;

774 Prichard, above n 771, 303; Kleynhans, above n 3, 106-108.

775 Review of Professional Indemnity Arrangements Interim Report, above n 635, 162-167.

776 Stone and Matthews, above n 32, 161.

777 Kathryn McMahon, 'Health – Wealth Tradeoffs: National Competition Policy and Public Health Law' (2000) 8 *Journal of Law and Medicine* 170, 193.

the fact that most errors do not result in litigation and recovery of compensation,⁷⁷⁸ and the imperfect market knowledge by consumers makes torts liability inefficient in controlling behaviour for the public benefit.⁷⁷⁹

Although liability in negligence is an imperfect regulatory factor it has the virtue of flexibility. The required standard will change based upon developments in knowledge and technology. The low incidence of claims made against CAM practitioners would suggest any disciplinary impact of common law liability would not be strong.

Application of Negligence to CAM treatment

The common law is based on an assumption of a disparity in power between the doctor and patient. The professional relationship is based upon a doctor/expert treating a patient as the passive recipient of the professional skill.⁷⁸⁰ This common law construct leaves little room for patient participation and control in the decision making process.⁷⁸¹ This may not be a major factor in the context of a modality which is close to the medical model such as chiropractic or osteopathy but more problematic where the relationship is based upon the practitioners intuition and subtle variations in energy.⁷⁸²

Matthews and Stone explain this dilemma:

There are conceptual difficulties in applying legal standards of objective reasonableness to holistic practitioners. If the therapy is truly patient-centred it is not objective and, it could be argued that the therapy given is the only appropriate treatment for that particular patient at that particular point in time. So individualized can the treatment claim to be that it would be almost impossible for another practitioner who did not observe the patient at that time to say

778 2% of negligence results in a claim, Review of Professional Indemnity Arrangements Interim Report, above n 635, 43.

779 Ibid.

780 Rian, above n 54, 185, 186.

781 Stone and Matthews, above n 32, 119.

782 Ibid 167; Rian, above n 54, 197.

whether he would or would not have treated them in the same way. Individualized treatment may work against at patient, in that almost any treatment could be justified retrospectively by the practitioner. Thus, in practice, it could be very hard for a plaintiff to disprove the practitioner's assertion that what he did was the appropriate thing at that particular time (except, of course, in situations where the course of action was clearly one which no reasonable practitioner would ever have taken.)⁷⁸³

The difficulty in applying objective criteria to complementary medicine will be lessened where:

- the act of the therapist was clearly not what a reasonably competent therapist would do (for example where an acupuncturist causes infection by not following proper hygiene practices).⁷⁸⁴
- there is an obvious connection between the practice involved and the injury suffered (for example fractured ribs after chiropractic or osteopathic treatment).⁷⁸⁵
- there are burns from moxibustion or similar therapy.
- a patient falls from a table because of the practitioner's lack of care in mounting and dismounting.
- there are on-table incidents such as a finger being caught in treatment table caused by negligent maintenance or faulty equipment.
- the modality is closer to the medical model and the procedures are more standardised (for example chiropractic or osteopathy).

This difficulty should not be overstated. Even if the modality relies on intuition and subtle energy effects at a particular point in time this diagnostic process could be distinguished from the form of treatment actually provided. If the professional service is manual, medicinal or oral advice it may be possible to ascertain what is reasonably competent professional practice

⁷⁸³ Stone and Matthews, *ibid* 167, 168; Dimond *above* n 25, 23.

⁷⁸⁴ Stone and Matthews, *ibid* 167.

and to ascribe fault where necessary. For example, if a spiritual healer counsels against use of OM, a manipulation is given based upon intuitive feel or a herb is prescribed based on impediments in the patient's 'chi' the result of treatment, if negative, can be judged for their appropriateness based upon the tests discussed above in *Shakoor v Situ* and *Bawden v Marin*.

Difficult issues could arise where there is no scientific evidence for the injury said to have occurred or there is no clarity on the impact of a therapy. For example, assume it is alleged a reflexologist has exacerbated a pre-existing condition not directly related to the foot where a reflexologist usually works. How could this effect be proven if there is no scientific evidence of the nature of the effect of reflexology on the body?

Warnings of Risk of Treatment

If a health practitioner fails to give a client sufficient warning of potential risks of treatment, the practitioner may be deemed negligent by allowing a person to undertake a procedure without the opportunity to give proper consent to that treatment. This has been described as a 'rigorous legal obligation' and is based upon 'the paramount consideration that a person is entitled to make his own decisions about his life.'⁷⁸⁶

This issue was highlighted by the High Court decision in *Rogers v Whitaker*.⁷⁸⁷ The court perceived that there was a fundamental difference between on the one hand diagnosis and treatment, and on the other hand the provision of advice and information to the patient⁷⁸⁸:

785 Note the facts and decision in *Bawden's* case where broken ribs from chiropractic manipulation was deemed not negligent; L Campbell, C Ladenheim, R Sherman and L Sportelli, *Risk Management in Chiropractic: Developing Risk Management Strategies* (1990) 3.

786 *F v R* [1983] 33 SASR 189, 193.

787 Above n 714.

788 *Ibid* 489.

Whether a medical practitioner carries out a particular form of treatment in accordance with the appropriate standard of care is a question in the resolution of which responsible professional opinion will have an influential, often a decisive, role to play; *whether* the patient has been given all the relevant information to choose between undergoing and undergoing treatment is a question of a different order. Generally speaking, it is not a question the answer to which depends upon medical standards or practices.

On the facts of that case, despite the fact that medical opinion favoured not revealing the very rare complication of the eye surgery, (sympathetic ophthalmia which meant that the good eye not being operated on would become blind) the doctor was found negligent. The High Court considered the appropriate test to apply for a doctor was⁷⁸⁹:

a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patients position, if warned of the risk would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.

The important factors in that case were that the patient was very concerned with possible complications, and the drastic outcome if there was any negative impact upon the good eye. For the court this suggested that, despite medical opinion to the contrary, the doctor was negligent to fail to warn of the risk of the treatment.

This obligation was discussed and broadened in the recent High Court case of *Chappel v Hart*⁷⁹⁰ where the High Court concluded that a doctor was negligent in failing to warn of a rare complication of damaged vocal chords on a patient who underwent esophagus surgery. Despite evidence the fact the doctor did not perform the surgery negligently, liability accrued to the doctor for the failure to warn. The High Court by majority concluded that the patient would not have had the surgery by the defendant doctor if warned about the risk of this complication. Important to this finding was the fact that as a relatively inexperienced surgeon

789 Ibid 490.

790 *Chappel v Hart* (1998) 195 CLR 232

he had a greater incidence of such a complication than the most experienced surgeons did.⁷⁹¹ If properly warned, the patient might have used a more experienced doctor, which would have reduced or excluded the possibility of such a complication. These authorities provide a very broad obligation on medical doctors to warn of risks.

Complementary Medicine – Warnings of Risk

The above authorities suggest a broad obligation upon complementary medicine practitioners to inform clients of risks of treatment. The possible side effects and adverse events associated with CAM are discussed above.⁷⁹²

Although most of these reactions are often mild, and a client will often be prepared to accept them as a price for the treatment, a failure to warn and to take appropriate steps to alleviate these symptoms may result in a negligence claim.

The client could argue that if told of the possible side effects they would not have undertaken the treatment offered. In the context of western medicine, when dealing with a serious illness such as heart disease or cancer, it may be difficult for a plaintiff to demonstrate that if they were given the appropriate warnings they would not have undertaken the treatment. Where a medical patient is considering a risky but potentially life-saving operation a court may conclude that despite inadequate warnings, the patient would still have decided to continue with the procedure. In this case the practitioner would not be liable for negligence in failing to inform of the risk that eventuated as causation would not be proven.⁷⁹³ This issue was underlined in the recent case of *Rosenberg v Percival*⁷⁹⁴ where the plaintiff's claim that the

791 Ibid Gaudron J 522; Kirby J 552.

792 Above pp 153-163.

793 *Green v Chenoweth* (1998) 2 Qd R 573.

794 (2001) 75 ALJR 734.

doctor had failed to warn of a complication of surgery founded on the conclusion drawn by the trial judge and supported by the High Court that even if warned of the risk of treatment that did eventuate she would have still continued with the procedure.

The same could not be said about a less serious ailment or chronic condition that may be presented to a complementary medicine practitioner. A client might wish to seek other options without the attendant risk. It may be more difficult to argue that the patient would have proceeded anyway even if the risks were fully described.⁷⁹⁵

Defence to Wrongful Non-disclosure of risk.

A CAM practitioner may argue that the risks of a negative outcome were so low that it is not necessary to mention it to a client. The determination that a risk did not require a warning would depend on the current state of scientific knowledge and all the relevant circumstances of the case. Note in *Rogers v Whitaker* the risk was calculated as 1 in 14,000 but the drastic consequences of the risk eventuating and the nature of the client's concerns about the procedure meant the High Court considered it was a risk that should have been revealed. In different contexts the duty to warn of risks will vary depending upon the nature of the risk, the patient under consideration, and the general circumstances such as the other treatment options or whether it was an emergency situation.

One possible defence for a CAM practitioner might be the lack of scientific evidence for a specific risk of treatment. It might be possible to argue that no advice of a risk of treatment was given as there was insufficient evidence of this side effect occurring. Owing to the dearth of scientific evidence for CAM this argument might carry some weight though a court could

⁷⁹⁵ Stone & Matthews, above n 32, 170.

accept evidence from professionals in a particular modality to determine what is a likely risk of treatment.⁷⁹⁶ This was the basis upon which the plaintiff foundered in *Shakoor v Situ* as the adverse reaction to the herbal substance in that case could not have been expected.⁷⁹⁷

Chiropractic - Risks of cervical manipulation

Although chiropractic has an impressive safety record one risk of chiropractic is the possibility of stroke after cervical manipulation.⁷⁹⁸ There is evidence that chiropractic neck manipulation may cause strokes or other serious or less serious results.⁷⁹⁹ The risk of complication caused by cervical manipulation varies widely depending upon the seriousness of the reactions. Less serious reactions such as post-manipulative diffuse pain lasting less than 2 days has been quoted as occurring in 40% of cases while fainting, cold perspiration and nausea is expected in 1-2 cases out of 1000.⁸⁰⁰

In relation to manipulations causing death figures are quoted suggesting this event is said to occur in 1 out of 10 million manipulations or 10 s of millions of manipulations while serious reactions occur in between one in one million adjustments or one in 400,000 adjustments.⁸⁰¹ The authority of *Rogers v Whitaker* provides a somewhat strict test of the risks for which a warning should be given.

It is a confronting activity for a practitioner and a client to warn of the risk of death or serious injury from manipulation but the legal principles discussed above might suggest that this warning is required. If a practitioner chooses not to warn of the risk of death, stroke or other

⁷⁹⁶ This occurred in *Rogers v Whitaker*, above n 714, 482.

⁷⁹⁷ *Shakoor v Situ*, above n 712, 191-192.

⁷⁹⁸ J. D Harrison, *Chiropractic Practice Liability: A Practical Guided to Successful Risk Management* (1990) Chapter 19.

⁷⁹⁹ Kleyhans, above n 676, Chapter 16; Terrett and Kleyhans, above n 677, Chapter 32.

⁸⁰⁰ Kleyhans, *ibid* 377.

serious injury any claim could be met by the argument these complications are *extremely* rare and in considering the factors discussed in *Rogers v Whitaker* there was no legal requirement to warn of that risk for that patient.

It could also be argued that if warned of the risk the client would still have chosen to proceed with the manipulation. In recent times the chiropractic profession has begun to warn clients of these risks of treatment. Some practitioners now obtain written consent from patients that quotes these very rare complications of cervical manipulation and other risks.⁸⁰²

Interestingly, it has become apparent that on very few occasions has a client decided not to proceed with the treatment after being formally advised of the risk.⁸⁰³

Medical Practitioner Obligation to Advise of Options for Treatment

Based on the ethical principle of autonomy, the common law and statute medical doctors have an obligation to provide patients sufficient information to allow them to determine what is for them the best course of treatment. This obligation is reflected in professional guidelines including the National Health and Medical Research Council.⁸⁰⁴ The NHMRC Guidelines indicate doctors should discuss with patients the proposed approach to treatment and other options for investigation, diagnosis or treatment. The *Consent to Medical Treatment and Palliative Care Act 1995* (S A)⁸⁰⁵ requires the doctor to advise of treatment options (including the option of no treatment) that are available.

801 Terrett and Kleyhans , above n 677, 580.

802 COCA, above n 680, 81.

803 COCA, *Risk Management Continuing Education Module* (2002) statement made at training session 20 April.

804 National Health and Medical Research Council, 'General Guidelines for Medical Practitioners on Providing Information to Patients' 5.

This duty is emphasized where the contemplated procedure has substantial attendant risks and there is evidence that no treatment or a less risky or non-interventionist treatment may prove successful even if it produces a lower rate of success. A client complaining of back pain would not be well served if one safe but often successful alternative to surgery namely, bed rest and exercise, is not canvassed. The obligation to advise of this option would apply even if this procedure did not have the same degree of success or permanency as surgery. The necessity to discuss the less dramatic intervention is further emphasised if the riskier procedure is still possible after the more conservative option has proven unsuccessful. To deny a patient the information to be able to choose the appropriate procedures offends the ethical principle of autonomy.

Case Law on Options for Treatment

Authority suggests that 'In order to enable a patient to give informed consent, a surgeon must also, where the circumstances require it, explain to the patient the consequences of leaving the ailment untreated, and alternative means of treatment and their risks.'⁸⁰⁶

The obligation to advise of options for treatment will normally require some particularity in advice. Although the High Court has acknowledged the impracticality of requiring 'a professional person to communicate the detail of every tiny complication that may accompany medical procedures'⁸⁰⁷ this advice should deal with the nature of the procedure; the apparent risks and success rates. Without that detail it would be difficult for a doctor and a patient to properly compare the virtues and risks of treatment between different therapies and procedures. Without that information if a court is subsequently asked to consider

805 s 15 (a)-(c).

806 *Haughian v Paine* 37 DLR (4th) 624; Refer also to *Gover v South Australia* (1985) Australian Torts Reports 80-758, 69, 545.

807 Kirby J in *Rosenberg* above n 794, 758.

whether the patient would have proceeded with the treatment, if armed with the relevant information, it would be difficult to ascertain the patient's likely decision. Kirby J states in *Rosenberg v Percival* that health providers have a duty 'to inform patients contemplating invasive procedures (such as surgery) of the material risks involved in the treatment proposed, and any available alternatives. Any 'choice' by the patient, in respect of such procedures, without the provision of such information, is meaningless.'⁸⁰⁸

Do CAM practitioners have an obligation to advise of the OM options for treatment?

The query that arises for CAM practitioners is what is the extent of their duty to advise of options for treatment. Does it encompass only CAM options or does it include the need to deal with OM options for treatment? Professor Freckelton considers that CAM practitioners have a broad obligation to advise of CAM options of treatment including OM options for treatment.⁸⁰⁹ Haigh appears to support this type obligation for CAM practitioners.⁸¹⁰ There are a number of reasons why this proposition is rejected.

Medical Doctors are unlimited practitioners

The obligation for medical doctors to advise of potential options for treatment derives from the assumption they are entitled to perform any medical procedure.

A registered medical practitioner is in some jurisdictions exempted from the scope of practice provisions of the health practitioner registration acts (in some cases partially) that specify those persons entitled to perform particular health related activities such as:

- Dentistry.⁸¹¹

808 Ibid 751.

809 Ian Freckelton, 'Book Reviews', (2000) 8 *Journal of Law and Medicine* 224, 225.

810 Haigh, above n 152, 205.

811 *Dental Act 1939* (WA) s 50 (2).

- Physiotherapy.⁸¹²
- Chiropractic and osteopathy.⁸¹³
- Podiatry.⁸¹⁴

Most doctors are not trained to perform these disciplines or are trained at a less sophisticated level to the specifically trained health professional. Few would argue that a medical doctor is better trained to perform chiropractic procedures than chiropractors. The health sector is arranged so that a medical practitioner is entitled to supply the full gamut of services. All other registered health professions are given a subset of the medical profession's whole.

This hegemony supports a broad ethical and legal obligation upon medical doctors to outline the various options for treatment. If an MD can provide virtually any form of therapy it is not unreasonable to expect a broad discussion of treatment options. If a GP is not sufficiently experienced or knowledgeable to discuss the various options for treatment and their risks the GP would be expected to refer to a specialist. Patients will usually expect medical doctors to indicate what medical science currently considers is the appropriate form of treatment whether it be surgical; pharmaceutical or nutritional.

The Limited role of a CAM practitioner in Law

A CAM practitioner may not be entitled by law to perform the broad range of treatments that may be available for a particular malady. In South Australia, Western Australia, Tasmania the Australian Capital Territory and the Northern Territory, only medical doctors are entitled to 'practice medicine' or 'to provide medical treatment'.⁸¹⁵

812 *Public Health Act 1991* (NSW) s 10 AC.

813 *Chiropractors and Osteopaths Registration Act 1997* (Tas) s 56 (2).

814 *Podiatrists Act 1989* (NSW) s 4 (2).

815 Refer to discussion above 209-218.

The practice of medicine is not defined but could include a medical diagnosis, medical procedures and advice on medical options for treatment. These provisions suggest that in the above jurisdictions, it is an offence for a CAM practitioner to provide medical services, to practice medicine and in some cases to give medical advice.

The current statutory background supports the role of CAM as practitioners who are obliged to advise of treatment options within the range of their modality but cognizant they are practicing within an OM context. This was the sentiment of the most significant common law case on CAM practitioners in the English case of *Shakoor v Situ*.⁸¹⁶

Boundaries Between CAM and OM – the USA example

The appropriate professional boundary between MD's and CAM practitioners has been an important issue in the USA for chiropractors. If a patient attends at a chiropractor and it becomes obvious that the complaint is more appropriately dealt with by a medical practitioner a chiropractor is obliged to refer to an MD.

Chiropractors are educated in anatomy, chiropractic diagnosis and the treatment of spinal related conditions.⁸¹⁷ Despite the sophistication of the training of chiropractors and their registered status in most western countries⁸¹⁸ chiropractors are not considered to have an obligation to indicate OM options for treatment. Chiropractors are obliged to:⁸¹⁹

- Identify problems that are medical and those that are amenable to chiropractic.

816 Above n 712.

817 David Chapman-Smith, *The Chiropractic Profession: Its Education, Practice, Research and Future Directions* (2000) 46.

818 Ibid 30.

819 Rian, above n 54, 192; *Mostrom v Pettibon*, 25 Wash App 158, 607 P.2d 864 (1980); *Kelly v Carroll*, 36 Wash. 2d 482 (1950).

- To withhold treatment when they should reasonably be aware that chiropractic is not indicated and may aggravate the condition.
- Refer patients to a medical practitioner when medical treatment is indicated.

Different categories of CAM

There is a wide range of modalities that are for the purposes of discussion placed under the heading of CAM. Within this designation there is an extraordinary continuum of sophistication in training and healing philosophy. Some modalities such as therapeutic massage; reflexology and feldenkrais are inherently limited in scope. Practitioners of these modalities would be unlikely to make broad claims about the potential benefits of their modality. It is most difficult to apply with any practicality any broad obligations to advise on the broad range of treatment options. These practitioners have no pretensions to being trained for that purpose and their aim is to provide non-invasive techniques often with no more specific therapeutic goal than the promotion of health and harmony. To require these types of practitioners to undertake the onerous task of advising of treatment options would be unrealistic and potentially dangerous.

Slightly different considerations might apply for those CAM modalities that have either a claim to be an entire healing system or their level of training and education is long and at a high level. Chiropractic; osteopathy and TCM might be deemed to satisfy this description.

For the reasons discussed above this group should not be burdened with the same level of obligation to describe the options for treatment within another school of healing. This group of practitioners does need to understand their legal and ethical obligations to refer to a

medical practitioner when the patient does not respond to treatment or the condition is outside their scope of practice.

Regulatory Impact of Criminal Law Controls ⁸²⁰

Rarely will a CAM practitioner become involved in an act that involves criminal intent. The consequences for a CAM practitioner of a criminal charge for a matter associated with his or her practice could be the virtual termination of their professional career.

The concern about criminal charges can impact upon how a practitioner provides his or her services. The extent to which the criminal law can provide this control is limited by aspects of the criminal law process. If an accusation of rape or sexual assault is made it is often difficult for a complainant to undertake the personal anguish involved in bringing the relevant charges. The burden of proof (beyond reasonable doubt) is higher in criminal charges as against the balance of probability test for civil actions. For this reason the controlling influence of the criminal law is potentially less significant than the civil law.

There have been a number of cases involving massage therapists that have involved criminal charges. A constant concern for CAM practitioners is the possibility of a claim of sexual misconduct against the therapist. This risk applies to virtually any profession involving the provision of personal services but this risk is more evident with therapeutic massage as a result of the nature of the profession and the type of services provided. This is illustrated by a couple of recent court cases where massage therapists have been charged with sexual

820 Kleynhans, above n 3, 108-109.

offences. These cases provide a helpful insight into the issues that may arise for a practitioner particularly a male practitioner.

The South Australian Supreme Court decision of *Malcolm John McEachern v R*⁸²¹ was an appeal against a rape conviction against a polarity therapy practitioner (a form of therapeutic massage). The treatment involved massage conducted in the clinic at the accused's residence. The prosecution alleged that during this treatment the accused placed two fingers into the vagina of the prosecutrix and that he kissed her back. The prosecution alleged she then complained and left the clinic immediately.

At the trial of the case the accused stated that working close to the genitals was part of the polarity therapy. He stated that he advised the client by using diagrams where the therapy was applied and obtained her consent. The prosecutrix did not recall that this had been done. The accused said he obtained consent for each stage of the treatment and in particular for treatment 'just underneath the pubic bone.' When he started this treatment she jumped off the table and left.

The judgment acknowledged that the ultimate question for the jury was whose version of events they believed. It was a case of 'oath against oath.' The jury found the accused guilty of rape that was confirmed by the Court of Appeal.

The second case of *The Queen v Robert Cecil Russell*⁸²² involved charges of indecent assault with circumstances of aggravation on the basis of the insertion of the accused finger in the

821 (Unreported, South Australian Court of Criminal Appeal, Doyle CJ, Perry J and Duggan J, 21 June 1996, 95/593.)

822 (Unreported, Queensland Court of Appeal, McPherson J, Thomas J and Muir J, No 455 of 1998, 24 March 1999).

complainants vagina (counts 1 and 2) and unlawful and indecent dealing in that the accused had flicked her nipple. (count 3)

The appellant was convicted of indecent assault. The jury acquitted him on counts 1 and 3 and in relation to count 2 convicted him of unlawful and indecent assault without the circumstance of aggravation.

The accused was a part time massage therapist. The allegation was that on 4 occasions the accused had completed full body massages while the complainant was naked and on each occasion he inserted his fingers into her vagina. The accused admitted providing the massage while the complainant was naked but denied he ever touched her vagina.

The evidence from the complainant involved the accused describing the muscles that needed to be massaged through the vagina including the use of a diagram and the description of the therapeutic benefits of checking for discharge and assessing damage to the tail bone. On one occasion the complainant was accompanied by her young daughter.

The Court of Appeal concluded that if the jury had acquitted on the more serious charge on count one they could not convict on the lesser charge. On this basis the appeal was allowed and an acquittal on the second count entered.⁸²³

Another recent case involving a massage therapist was *Andropoulos Pana v Peppers Delgany Portsea*.⁸²⁴ Here a massage therapist was subject to a complaint claiming sexual harassment in the provision of goods and services under the *Equal Opportunity Act 1995* (Vic). The

⁸²³ Ibid 6.

claim made was that the therapist sexually harassed the client in accordance with s 85 of this statute when he massaged the client's buttocks without consent as part of a full body massage. The court considered that the test of whether contact is sexual could not rely on the subjective views of the participants and should be based on an objective test and take account of general standards in the community.⁸²⁵ Here the court considered the act under scrutiny lacked the sexual element that was necessary in the circumstances to constitute a breach of the statute.⁸²⁶

These cases indicate that it is possible to legally obtain consent to massage intimate areas of the body but that the risk of misunderstanding and the possible consequences so substantial as to suggest that these techniques should never be attempted even if consent is sought and obtained.

Statutory Regulation Provisions – Regulation by exclusion

A number of statutes regulate CAM in a negative sense by excluding some activities from unregistered practitioners. These practitioners are obliged to practice in ways that do not breach these provisions or risk criminal or quasi-criminal prosecution. The policy objective of these provisions is the protection of the public health by directing such services to be provided by registered practitioners.⁸²⁷ If a consumer knows the titles used by registered practitioners this might assist a consumer to choose a practitioner. Limits on the use of

824 (Unreported, Victorian Civil and Administrative Tribunal , John Wolters, 6th May 1999).

825 Ibid 8.

826 Ibid 9.

827 Cohen, above n 19, 85-86.

protected titles by non-registered practitioners avoid consumers being deceived by marketing practices of unregistered practitioners.⁸²⁸

The ability to use a registered title may provide status for a profession and permit the establishment and preservation of a market share for a consumer product.⁸²⁹ For many professions the ability to restrict the use of a title may be the primary purpose of regulation. Statutory regulation of health care favors the western medicine model and its attendant technological approach to health care thus entrenching the pre-eminence of OM.⁸³⁰ Some disciplines such as chiropractic, osteopathy and physiotherapy have obtained registered status by statute while others were sidelined. To a large extent, this position is maintained today.

Prohibition on the Practice of Medicine

In a number of states of Australia, the practice of medicine by other than a registered medical practitioner is an offence.

There is no common law limitation on the practice of medicine.⁸³¹ The common law permits a person to do what is not expressly restricted by statute.⁸³²

If defined widely, 'the practice of medicine' is not restricted to the provision of western medical services and can incorporate the type of activities undertaken by medical doctors, allied health practitioners and complementary medicine practitioners.⁸³³ The lack of a

828 LS Bohnen, *Regulated Health Professions Act: A Practical Guide* (1994) 31.

829 Ibid.

830 Cohen, above n 19, 86.

831 *Younghusband v. Luftig* [1949] 2 KB 72; *Norris v. Smallman* [1872] 3 VR 25; *Ex parte Tziniolis Re Harvey* 76 WN (NSW) 686; *Smith's Newspapers Ltd v. Becker* (1932) CLR 279 at 288, 298; Fulder, above n 19, 71; Danuta Mendelson, 'Disciplinary Powers of Medical Practice Boards and the Rule of Law' (2000) 8 *Journal of Law and Medicine* 142, 142; Baer, above n 291, 717.

832 *Australian Communist Party v Commonwealth* (1951) 83 CLR 1.

833 Kleyhans, above n 3, 98.

definition of the practice of medicine may be explained by the fact that the practice of medicine was not defined in the 1858 Act because ‘it would appear to be impossible to define in a way which does not overlap with general health care which lay persons, obviously, regularly, and properly undertake.’⁸³⁴

Statutory Definitions

In four states, the Australian Capital Territory and the Northern Territory, only medical doctors are entitled to ‘practice medicine’ or ‘to provide medical treatment’. The relevant provisions are listed below.

New South Wales

Medical Practice Act 1992 (NSW) s 99: ‘A registered medical practitioner may practice medicine.’

Medicine is defined as ‘includes surgery’. This provision presumably means that unregistered practitioners cannot practice medicine. There is an exemption in this legislation for registered chiropractors and osteopaths.⁸³⁵

South Australia

Medical Practitioners Acts 1983 (SA) s 31(1): ‘No person may (a) provide - (i) medical treatment of a prescribed kind; or (ii) medical treatment of any kind in relation to a prescribed illness or disease; or (b) recover a fee or other charge for medical treatment provided by him

⁸³⁴ A Ogus, *Regulation: Legal Form and Economic Theory* (1994) 221.
⁸³⁵ s 111.

unless he was' a qualified person such as a registered medical practitioner or another authorised or qualified person.

Medical treatment is defined broadly as 'all medical or surgical advice; attendances, services, procedures and operations'. Medicine is defined as 'includes surgery'.⁸³⁶

Western Australia

Medical Act 1894 (WA) s 19: 'No person other than a medical practitioner shall be entitled to: (1) Practice medicine or surgery in all or any one or more of its branches'.

'Practice medicine' is not defined.

Tasmania

Medical Practitioners Registration Act 1996 (Tas) s 63: 'A person who is not a registered medical practitioner must not practice medicine or carry out an act that by or under an Act is required to be carried out by a registered medical practitioner.' An exemption is provided for registered health professionals.⁸³⁷

Northern Territory

Medical Act 1995 (NT) s 56: 'A person other than a medical practitioner shall not practice medicine.'

'Practice medicine' is defined in section 3 as 'give or perform, for fee or reward, any medical or surgical service, attendance, operation or advice'.

836 s 5.
837 s 84.

Australian Capital Territory

Medical Practitioners Act 1930 (ACT) s 46: '(1) A person other than a registered medical practitioner shall not — (a) give or perform, for fee or reward, a medical service'.

The provisions in the Australian Capital Territory and the Northern Territory appear to limit the prohibition to circumstances where payment is contemplated.

Implications

Each circumstance needs to be considered in the light of the wording of the relevant statute and the circumstances of the case at hand. These provisions suggest that, if a complementary medicine practitioner in the above jurisdictions provides services deemed to be the practice of medicine, this would be an offence. The equivalent Queensland⁸³⁸ and Victorian⁸³⁹ statutes do not prohibit medical practice by unregistered persons, suggesting that the common law entitlement to practice medicine continues other than a prohibition against 'holding out'.⁸⁴⁰

Definition by the Courts

There is no clear authority on what constitutes 'the practice of medicine' in the context of complementary medicine. Any treatment of human ailments might arguably constitute the practice of medicine, but common sense suggests that this term requires some limitation. The

838 *Medical Practitioners Registration Act 2001* (Qld).

839 *Medical Practice Act 1994* (Vic).

840 *Medical Practice Act 1994* (Vic) s 62; *Medical Practitioners Registration Act 2001* (Qld) s 157.

*Macquarie Dictionary*⁸⁴¹ defines medicine as ‘the art or science of restoring or preserving health or due physical condition, by means of drugs, surgical operations or appliances, manipulations etc. (often divided into medicine proper, surgery and obstetrics).’ This broad definition covers virtually all western medicine modalities. The practice of a profession may require some habitual or customary exercise of a craft⁸⁴² suggesting that isolated activities might not constitute the practice of medicine.

Definition from Holding Out Cases

The courts have been required to consider what the practice of medicine is when determining whether a person has been holding out as a registered medical practitioner. The definition of the practice of medicine taken from these cases is broad.

In *Van der Hope v The Medical Board of Victoria*⁸⁴³ the test of whether a person has acted as a medical practitioner was when they were seen to ‘examine patients and prescribe for or treat their ailments.’

In *Stephens v Jayasinga*⁸⁴⁴ the court said:

It appears to me that a person who designates a complaint as being a certain disease and then expresses his capability of curing that disease, is a person, who by such means, holds himself out as able and willing to give that advice, and therefore should be convicted of an offence against the statute.⁸⁴⁵

841 Macquarie University, *The Macquarie Dictionary* (1988) 1069.

842 *Knott v Physiotherapists Registration Board* (1961) WAR 70.

843 [1950] VLR 310.

844 [1913] 15 WAR 55.

845 The offence was giving medical advice.

In *Mayo v Harris*⁸⁴⁶ Mayo J stated: ‘a medical practitioner is a person, who, by the application of remedies ... cures, or alleviates, or attempts to cure or alleviate, physical or mental ailments’.

In *Kimberley Ian Bradbury v Sarath Jayawardana*,⁸⁴⁷ Beach J stated: ‘Anything that concerns a treatment or advice for treatment of bodily ailments is a medical service’.

These statements provide a general guide to the interpretation of the terms ‘medical practice’ or ‘medical treatment’. The broadest interpretation of these cases is that any practice involving the treatment of human ailments is the practice of medicine. This may be too broad an interpretation as otherwise even registered professions such as physiotherapy, chiropractic or optometry would be prohibited. Only some states exempt those registered professionals from the various medical statutes. A very broad definition of the practice of medicine could mean that a practice of giving friendly back massages would be caught by the prohibition, as would parents treating their children’s cuts and bruises on a daily basis.

The difficulty with this question was confirmed in *Allchurch v Drew*⁸⁴⁸ where Poole J indicated that on occasions it is difficult to determine whether a person has held themselves out as a medical practitioner. He stated:

By giving advice in respect of health, by representing that he can cure some ailment or malady, or by doing these things in conjunction with prescription of remedies and the supply of medicine, a man does not necessarily represent that he is a medical practitioner. No one can say, for example, that the man who merely represents that he can cure and practices the art of curing corns or baldness represents that he is a medical practitioner. On the other hand the advice may be of such a nature, and so given, and the ailments so many or of such importance, that the fair inference is that he did do so.⁸⁴⁹

846 [1945] SASR 151.

847.(Unreported, Beach J, Supreme Court of Western Australia, Appeal, 1992) 9.

848 [1926] SASR 280.

This judgment suggests that, to determine whether a practitioner is involved in the practice of medicine, the important factors are:

- the nature of the ailments treated, that is, how serious those ailments are.
- the number of different types of ailments treated.
- the type of treatment given.

This is confirmed by the Napier CJ in *In Re Ward*⁸⁵⁰ where a physiotherapist was suspended from practice for providing treatment for a child with cancer. Part of the treatment given was the supply of drugs. Napier CJ stated:

Having regard to the period over which the services were rendered, to the number and nature of the drugs and nostrums which were prescribed and supplied, and to the fact that, in prescribing and supplying them, the respondent was doing what he was employed to do, and paid for doing, it seems to me that the respondent accepted a retainer to practice medicine under the guise of physiotherapy.⁸⁵¹

The case of *Kimberley Ian Bradbury v Sarath Jayawardana*⁸⁵² suggests a more robust and modern conception of what is the practice of medicine. Beach J dealt with an unregistered doctor in Western Australia (qualified in Sri Lanka) giving acupuncture in a medical clinic.

Beach J held that the doctor had been held out as willing to provide a medical service that included the provision of acupuncture. The judge noted that the registrar of the medical board accepted that a person other than a medical practitioner was not prohibited from providing acupuncture. The judge stated:

Counsel for the appellant does not suggest that a person other than a medical practitioner is prohibited from giving acupuncture. Such a person is not necessarily practicing medicine as that term is included in s19. Acupuncture is not recognised in this State as part of the practice of medicine. That does not mean it is not a medical service. This is not the case of someone

849 Ibid 283-284.

850 [1953] SASR 308.

851 Ibid 314-315; Abbott J expressed similar sentiments 319.

852 Above n 847, 9.

giving “medical service” as such. It is the case of someone holding himself out to be a registered doctor giving that service.⁸⁵³

The crux of the offence in that case was the holding out that the doctor was registered rather than the practice of medicine. The provision in the *Medical Act 1894* (WA) against the practice of medicine by unregistered persons was not relied on, presumably because the registrar considered that the provision of acupuncture was not prohibited by s 19(1) as it did not constitute the practice of medicine. This case suggests that the practice of medicine in the relevant legislation is western medicine or techniques that are accepted as appropriate for registered medical practitioners.

The Role of Diagnosis

Many complementary medicine practitioners aware of the concern about practicing medicine avoid statements to suggest that they diagnose. If a practitioner does not diagnose, it is unclear whether this avoids the possible implication that the practice of medicine has occurred. In the USA where the practice of medicine is statutorily defined the undertaking of diagnosis by a practitioner is often an important element in a finding that the practice of medicine has occurred.⁸⁵⁴

In *Mayo v Harris*⁸⁵⁵ a person describing himself as a professor carrying on the business of Indian Science Massage or special Indian Science for the cure or relief of nerve disorders was charged with holding himself out as a medical practitioner. One defence to this action was that he did not involve himself in diagnosis.

853 Ibid 10.

854 Crellin and Ania, above n 7, 74; *The People of the State of New York v Reuben Amber*, 349 N.Y.S 2d 604 (1973).

855 [1945] SASR 151.

Napier CJ considered that some type of diagnosis is essential to the concept of a medical practitioner. He stated: 'it is difficult to see how anyone can hold himself out as a healer unless he professes the ability to recognise the ailment or ailments which he proposes to treat, and to appreciate the progress of the disorder.'⁸⁵⁶ Richards J did not consider that diagnosis was necessary before a person could be deemed a medical practitioner.⁸⁵⁷ Mayo J did not fully discuss this issue, but indicated that a person may hold themselves out as medical practitioner without undertaking all the usual steps undertaken by a medical practitioner.⁸⁵⁸

The courts have indicated that they will take a broad and non-technical view as to what constitutes diagnosis. Even if the practitioner does not employ the type of diagnosis undertaken by a medical doctor, an assessment of a client's condition may be considered a form of diagnosis. Using a process called 'assessment' or 'analysis' might be considered, in substance, a diagnosis. Although diagnosis may be one indicator of medical practice, it is unsafe to rely only on the lack of medical-type diagnosis to avoid the implication that the practice of medicine has occurred.

Application of Techniques Without Variation

A practitioner who applies techniques without variation and without reference to a particular illness or complaint is probably not involved in the practice of medicine.⁸⁵⁹ This might apply to practitioners such as massage therapists who apply similar techniques in all cases for therapeutic benefit without any intention to deal with a particular complaint. A naturopath

856 Ibid 153.

857 Ibid 158.

858 Ibid 162.

859 *Mayo v Harris* above n 855, 163.

who applies a regime for all clients on the basis of upgrading their overall health, without dealing with a particular malady, may be able to show they have not diagnosed nor been involved in the practice of medicine.

A practitioner can approach the treatment of a client on the basis that any ill health is a result of imbalance in the chi, meridians or energy flows. The practitioner then applies techniques to create balance and harmony, though not necessarily to deal with a diagnosed illness or disease. Even if the court takes a broad view of what diagnosis is, this process is not diagnosis in the medical sense and may suggest that the practice of medicine has not occurred.

Faith Healers

The concern about the practice of medicine may not apply to faith healers. A faith healer does not rely on the application of skill, knowledge and training but 'claims to be no more than a passive instrument, to do no more than invoke, or secure the transmission in some manner, of curative benefit emanating from some extraneous agency'.⁸⁶⁰ In Australia this activity is usually in Australia not considered the practice of medicine though there were some authorities early in the 1900's in the USA that would suggest otherwise though based on a very broadly defined statutory definition of the practice of medicine.⁸⁶¹

The Need for Reform in Australia

⁸⁶⁰ Ibid 151.

⁸⁶¹ *Smith v The People*, 51 Colo 270 (1911); Most states in the USA exempt healers; practicing in a religious context as part of a recognised religious tradition. Cohen, above n 640, 224.

The risk that certain forms of complementary medicine may be deemed to involve the practice medicine should not be overstated. Most regulatory bodies are currently more concerned with 'holding out' offences, which are easier to prove than enforcing the practice of medicine provisions.⁸⁶²

Although the role of complementary medicine is now well entrenched in the health sector while the current regulatory structure is vague about the role of CAM it is a considerable disincentive to its use. This reflects an attitude derived from many years of conflict. The regulatory structure should now acknowledge the significant contribution by complementary medicine in health care and remove any vagueness as to its appropriate role. Any limitation on the practice of complementary practitioners must be justified by public safety and unnecessary limitations should be removed. Rather than protecting patients, the regulatory apparatus protects medical orthodoxy and is effective in shutting off innovative and competing approaches to healing.⁸⁶³ Patients use CAM for a number of reasons not necessarily related to OM concepts of healing. Patients may make decisions on an intuitive basis and may not be concerned with the issue of scientifically proven efficacy but are seeking:

meaning and context for their illness, thus allowing them the freedom to benefit from therapeutic consultations within their own chosen milieu. Why should we impose our medical model on patients? Their use of CAM may be their process of empowerment, which in turn allows them to contain and manage their chronic illness. It is perhaps difficult for those of us educated within the conventional medical system to allow our patients the freedom to make such journey in a truly egalitarian system.⁸⁶⁴

862 Queensland Health, Review of Medical and Health Practitioner Registration Acts Draft Policy Paper (1996) 55-56.

863 Cohen, above n 19, 86.

864 George T Lewith, 'Complementary and Alternative Medicine: An Educational and Attitudinal and research challenge' (2000) 172 *Medical Journal of Australia* 102, 103.

The ability to choose the type of health services one desires is a fundamental entitlement. This comes from the ethical principles of autonomy and is supported by postmodernist concepts of individuality.

The arguably unduly broad interpretation of the practice of medicine detailed above is an expression of medical dominance. The underlying philosophy is that healing derives its validity in terms of its relationship to the dominant biomedical paradigm and that biomedicine has exclusive control over healing. This view is born from a historical context that permitted the exclusion of CAM because it did not conform to biomedical concepts of appropriate therapeutic approaches.⁸⁶⁵

In the USA in a number of states there is an acknowledgement that some CAM therapies have their own form of diagnosis and treatment within a specific modality context.⁸⁶⁶ For example chiropractors and acupuncturists can diagnose and treat based upon very different considerations and these modes are supported by statutory regulation.⁸⁶⁷ The choice is available for courts to interpret medical scope of practice provisions to limit only diagnosis and treatment done on a biomedical basis and not the provision of diagnosis pursuant to the very different holistic approach.

Although CAM practitioners may be healing if treating within normal parameters they are not providing biomedicine and this could be seen as outside the purview of medical legislation. This more generous approach would accord with the principle that criminal legislation should be interpreted narrowly as it that has the potential to impact negatively on a person's

⁸⁶⁵ Cohen, above n 640, 222.

⁸⁶⁶ Ibid.

⁸⁶⁷ Refer above 234-241.

freedom.⁸⁶⁸ The solution may be to permit CAM practitioners to carve out their portion of the healing continuum that acknowledges their different roles.

History of Cynicism

Many of the authorities discussed above are pre-1945. In that period, ignorance of the basis of complementary medicine resulted in a deep cynicism regarding its effectiveness. Many practitioners were either self-trained or trained in a non-systematic way, and were subject to loose professional controls. At that time, much regulatory effort was directed to protecting the general public from ‘quacks’, and legal action against fringe medicine was seen as important for the public interest.⁸⁶⁹

The law is not static, and must change to take into account changes in society. To interpret the practice of medicine to unnecessarily limit the practice of complementary medicine is out of touch with modern circumstances and with the important role played by complementary medicine in the health care sector.

Chiropractic and osteopathy are acknowledged as registered professions in all states. These practitioners are primary care-givers, not reliant on supervision or referral from medical doctors. Complementary medicine practitioners are acknowledged as health service providers in health rights complaints legislation in all states and territories except South Australia, and are given responsibility for dispensing therapeutic goods under the *Therapeutic Goods Act 1989* (Cth). It would be peculiar if the competent practice of a statutorily acknowledged modality was deemed illegal. The grey areas that currently exist between the practice of

⁸⁶⁸ *Chew v The Queen* (1992) 173 CLR 626; Cohen, above n 640, 222.

western and complementary medicine should be resolved for the benefit of practitioners and the general public.

Holding Out as a Medical Practitioner

Consumers are entitled to understand the nature of the services that a practitioner will provide. In all states, it is an offence to hold oneself out as a medical practitioner unless duly registered as such.

Statutory Examples

The purpose of these provisions is to restrict the use of terms associated with medical practice by non-registered persons.⁸⁷⁰ This is a separate offence from the practicing of medicine by an unregistered person. The breadth of these provisions varies. Some offences relate to holding out as a *registered* practitioner or *registered* medical practitioner.⁸⁷¹ Other provisions provide broader grounds, including a prohibition on the use of various titles, such as ‘doctor’ or ‘surgeon’, that might suggest that the person was a medical practitioner.⁸⁷²

Section 62 of the *Medical Practice Act 1994* (Vic) is representative of the narrower provision: ‘(1) A person who is not a registered medical practitioner must not
(a) take or use the title of registered medical practitioner or any other title calculated to induce a belief that the person is registered under this Act’.

869 Cohen, above n 15, 20.

870 *Medical Practice Act 1992* (NSW) ss 105–107; *Medical Practice Act 1994* (Vic) s 62; *Medical Practitioners Registration Act 2001* (Qld) ss 157–162; *Medical Practitioners Act 1983* (SA) s 30; *Medical Act 1894* (WA) s 19; *Medical Practitioners Registration Act 1996* (Tas) ss 64–65; *Medical Act 1995* (NT) s 56; *Medical Practitioners Act 1930* (ACT) ss 46(1)(b) and (c).

871 *Medical Practice Act 1994* (Vic) s 62.

Medical boards usually act on complaint before investigating an alleged offence.⁸⁷³ The New South Wales Medical Board has indicated it has a ‘shot across the bows’ approach in regard to unregistered practitioners holding out as an MD. If the matter proceeds to a prosecution there are often difficult evidentiary and burden of proof issues to overcome.⁸⁷⁴ The Board indicated that they emphasise ‘holding out’ offences rather than ‘practice of medicine’ offences and that their attempts to prosecute under the relevant legislation were ‘singularly unrewarding.’⁸⁷⁵

Does Practicing Medicine Constitute Holding Out?

In those states and territories where the practice of medicine by unregistered persons is prohibited, an offence under that provision could mean an additional offence of holding out. There is legal authority to suggest that the practice of medicine may also involve a ‘holding out’ as a medical practitioner.

Dixon J stated in the High Court decision of *Smith’s Newspapers v Becker*:⁸⁷⁶

The unlawful conduct of which the respondent was guilty consisted, not in the performance of medical work for reward, but in advertising and holding himself out as being a doctor of medicine, doctor, or medical practitioner. *It is true that the habitual practice of attending, advising and prescribing for the sick for remuneration will seldom occur without an unlawful holding out.* (my emphasis)⁸⁷⁷

872 *Medical Act 1894* (WA) s 19.

873 NSW Health Complaints Committee, above n 636, 33.

874 *Ibid* 34.

875 *Ibid* 34.

876 (1932) 47 CLR 279.

877 *Ibid*, 298, Evatt J endorsed similar view at 305.

'Holding Out' Cases

Each decision relies to some extent on the particular wording of the statute under consideration (often repealed or amended from that currently applying), but these cases provide some guidelines for practitioners. The cases can be categorised as follows.

Using Titles Such As 'Doctor' and 'Specialist'

Where a person has used a term that is often associated with medical practice, a holding out offence may be committed. One judge described these provisions as aimed at:

the representation by any person that he is a medical practitioner within the meaning of the Act, when he is not so in fact. It prohibits the use by unregistered persons of titles ordinarily associated with the legitimate practice of medicine by registered practitioners enumerating such titles, and ... declaring that each of such titles connotes a "medical practitioner" when used in relation to the practice of medicine in any of its various branches.³¹

*Horseman v Nairn.*⁸⁷⁸ A sign stating 'Dr H.W. Nairn, NDDC. Consulting hours ...' was deemed a holding out as a medical practitioner.

*Allchurch v Harden.*⁸⁷⁹ In a newspaper advertisement, a person described himself as: Dr Francis L. Harden Dsc BBiologist Specialist in diagnosis of social diseases. Scientific analysis in all bladder ... and skin diseases. Formerly chief medical officer HM Hospital Ship 'Persic' Late Surgeon-major Chinese Army'. This was deemed a breach of the provision against holding out as a medical practitioner.

878 [1926] SASR 268.

879 [1927] SASR 26.

*Ex parte Tzioniolis; Re Harvey.*⁸⁸⁰ A sign outside the practice stated: ‘Dr J Tzioniolis Physician Registered in Athens Greece Not Registered in NSW’. This was deemed to be advertising as if entitled to practice medicine.

*O’Connell v Culley and Others.*⁸⁸¹ A clinic used the following: ‘Osteopathy Edgar W Culley, DO, Martha Pattie DO and Milton Conn DO’. One defendant had used the term ‘doctor’ for many years. A newspaper advertisement referred to the term Dr. This was deemed a breach of holding out as medical doctors. This may not be considered an offence today, based either on the fact that many statutes or regulations now permit the use of the term ‘doctor’ by osteopaths or on social acceptance of the use of the term by osteopaths and chiropractors.

*The Medical Board v Du Maurier Ex Parte Du Maurier.*⁸⁸² An advertisement stated: ‘Northey Du Maurier, M.D.E.T, L.R.C.C, Fully Qualified Doctor of Medical Electro Therapy, British Government Degrees ... Specialist in Rheumatism, Paralysis, Blood Pressure and Obesity. Wrote for Book on Bergonie Treatment’. This was deemed a breach of advertising himself as a doctor.

*Willis v Hunyan.*⁸⁸³ The defendant described himself on sign as ‘H.C. Hunyan Chinese Physician and Surgeon’. This was deemed to imply that he was a legally qualified medical practitioner.

880 (1959) 76 WN (NSW) 686.

881 [1927] VLR 502.

882 [1927] St R Qld 169.

883 (1901) WN (NSW) 97.

Medical Board of Queensland v Stifler.⁸⁸⁴ A defendant who displayed a sign stating 'Psychotechnical Institute Dr A Stifler' was deemed to hold himself out as medical practitioner.

Many of these decisions were dealt with early this century. Some of the above cases may today be differently decided owing to a more sophisticated and well educated public, who are better acquainted with traditional and alternative modalities and who are less likely to be confused.⁸⁸⁵

Implying Some Contact with Medical Profession

In this category there is an implied connection with the medical profession but not the use of words such as doctor or physician. These cases deal with specific facts and statutory provisions, so the conclusions reached cannot automatically be applied to every similar situation.

Stephens v Taufik Raad.⁸⁸⁶ A defendant carrying on business as a 'herbalist' published an advertisement explaining the curative properties of a 'blood specific' prepared and sold by him, and invited the public to purchase it. He claimed to be 'qualified' and to hold university diploma. He stated that 'If you have blood trouble, or any other ailment, consult him. Advice Free'. This was deemed to be intimation of willingness to give medical advice.

Allchurch v Olsen.⁸⁸⁷ On a letter, the defendant used the title 'Mrs Carl Olsen, Tuberculosis Specialist'. She stated that she did not examine her clients but reached conclusions on disease

884 [1940]QWN 10.

885 Stanley P Bolton 'Doctor ...' Usage, Law and Culture (1998) 28 *Chiropractic Journal of Australia* 116.

886 [1914] WAR 136.

887 [1927] SASR 16.

based on looking at clients. She stated that she was not a doctor, and charged for medicine and advertisements only and not for services. She was deemed to hold herself out as a medical practitioner.

Ridland v Amburlah.⁸⁸⁸ In a newspaper, the defendant described herself as ‘Indian Herbalist’ and stated that she ‘treated with genuine Indian herbs and oils handed down by her ancestors’ and specialised in asthma, bronchitis, arthritis, rheumatism, lumbago, gout and so on. Consultation was free. She was deemed to hold out as a medical practitioner.

Mayo v Harris.⁸⁸⁹ Signs stated: ‘Free demonstrations. Nerve diseases, Rheumatism, Fits, Blood Pressure, and various other complaints removed by special Indian science. Massage only. No drugs or Chemicals used’. The defendant used the title Prof Stanley Mayo. ‘Cured without needle or medicine. Consultation free’. He was deemed to hold out as a medical practitioner.

General Principles

The principles of law that emerge from these cases are as follows:

Relevant test

A breach of the legislation depends on a question of fact and degree.⁸⁹⁰ These provisions may restrict a person’s practice and therefore their ability to earn a living, so they should only apply if the specified activity is clearly in breach.⁸⁹¹ The test of whether a person has held out

888 [1956] SASR 118.

889 [1945] SASR 151.

890 *Mayo v Harris* above n 855, 153.

891 *O’Connell v Culley and Anor* [1927] VLR 502; *Norseman v Nairn* [1926] SASR 268, 272.

is ‘what an ordinary intelligent person reading the advertisement would understand’ the party involved to be advertising.⁸⁹² The practitioner’s intentions are irrelevant; the offence is based on what another person reading the advertisement would think.⁸⁹³ Representations or holding out might be in formal advertisement, letters or signs.⁸⁹⁴

Use of the term ‘doctor’

If the term doctor or medical practitioner is used, it is not necessary that the advertisement contain an undertaking to heal or cure ailments as this may in some circumstances be implied by the use of the medical title.⁸⁹⁵ If a term such as ‘doctor’ is used where there is a representation of a connection to the treatment of human diseases or ailments, then the offence might occur. The attachment of other words or conduct contrary to this assumption, such as ‘not registered in Victoria’, does not avoid liability unless they indicate that the party is not a medical doctor but a Doctor of Philosophy, chiropractor or osteopath.

No use of the term ‘doctor’

An offence may occur even if the term ‘medical practitioner’ or ‘doctor’ is not used,⁸⁹⁶ where the person represents that they practice the art of healing or an ability to achieve the result a medical practitioner might achieve, by the application of a special skill or qualification.⁸⁹⁷ It may not be necessary to show that diagnosis has occurred.⁸⁹⁸ If the methods used in the practice or advertised by the practitioner are unorthodox, this does not affect liability. The important issue is whether the party is held out as having the ability to heal, cure or alleviate

⁸⁹² *Allchurch v Harden* [1927] SASR 26.

⁸⁹³ *O’Connell v Culley and Anor* [1927] VLR 502; *Horseman v Nairn* [1926] SASR 268, 272; *Stephens v Taufik Raad* [1914] WAR 136, 139.

⁸⁹⁴ *Ibid.*

⁸⁹⁵ *Allchurch v Harden* [1927] SASR 26.

⁸⁹⁶ *Allchurch v Harden* [1927] SASR 26.

⁸⁹⁷ *Mayo v Harris* [1945] SASR 151.

⁸⁹⁸ *Ibid* Richards J 158, though note comments by Napier J, 153.

diseases in human beings.⁸⁹⁹ Stating that you are not a doctor when questioned does not avoid liability.⁹⁰⁰ A person who claims to be an exponent of some science, and advertises that he or she is prepared to treat various disorders and effect cures by some form of science, may constitute an illegal holding out.⁹⁰¹

Offers to treat without variation.

A person who offers treatment to the public indicating that treatment is unvarying in its nature, or who advertises that he accepts persons with a variety of ailments for massage, will probably not breach the holding out provisions.

Payment for medicine only

Stating that you do not charge for your services but only for medicine will not avoid liability if, in substance, you are holding yourself out as a medical practitioner.⁹⁰² The historical basis for this approach may be *The Herbalists Charter* that proscribed practice by punishing the practice but not the sale of herbs.⁹⁰³

In the modern era, the greater acceptance and understanding of complementary medicine and its integration into the health care sector suggests that it is less likely a practitioner will be found to have held out as a medical doctor under this heading, as the likelihood of misapprehension is reduced.

Use of the Title ‘Doctor’

899 *Allchurch v Harden* [1927] SASR 16, 25; Mayo J in *Mayo v Harris* [1945] SASR 151, 161.

900 *Allchurch v Olsen* [1927] SASR 16, 20.

901 *Mayo v Harris*, above n 855, 162 Mayo J.

902 *Allchurch v Olsen* [1927] SASR 16.

In many states, chiropractors use the titles doctor or Dr, either with or without the letters DC or the words 'chiropractor' or 'chiropractic.'⁹⁰⁴ The specific requirements of each state differ.

New South Wales

Chiropractors can only use the title 'Dr' if awarded a degree from a university that entitles it use and the degree is a recognized qualification by regulation or the relevant board.⁹⁰⁵

Western Australia

Recent amendments to the Chiropractors Registration Board rules permit the use of the title Doctor if used with the qualifier 'chiropractor' or 'chiropractic'.

Queensland

Section 160 of the *Medical Practitioners Act 2001* (Qld) suggests that this practice is not permitted in Queensland as the exemption from the *Higher Education (General Provisions) Act 1993* (Qld) allowing medical doctors to use the title 'Dr' does not apply to chiropractors and osteopaths.

Note section 8 of the *Higher Education (General Provisions) Act 1993* (Qld), which states that 'a person, with a view to obtaining an advantage or benefit for the person or another person, must not —

(a) use, or attempt to use, a higher education award; or

903 Refer to p 95 above.

904 On the connotation of using the title Doctor refer to Clair Cassidy, 'Social Science Theory and Methods in the Study of Alternative and Complementary Medicine' (1995) 1 *The Journal of Alternative and Complementary Medicine* 19, 29.

905 *Chiropractors Act 2001* (NSW) s 18; refer also to *Medical Practice Act 1992* (NSW) s 105 re misleading titles.

(b) induce, or attempt to induce, the belief that the person has a higher education award;
unless the award was conferred on the person by –

(c) a university; or

(d) a non-university provider that was authorised to confer the award.’

If the chiropractor or osteopath has not been awarded a doctorate then the use of this term may be a breach of this provision.

Victoria

There are no legislative provisions that limit the use of the term Dr, other than the need to avoid holding out as a medical doctor.

South Australia

The Chiropractors Board Code of Conduct and Practice clause 2.1.7 permits chiropractors (this term includes osteopaths) to use the term Dr if it is used in a manner that associates its use with the practice of chiropractic.

Australian Capital Territory

There is no specific statutory provision on this point. Current policy permits chiropractors and osteopaths to use the term Dr or Doctor if used with the terms DC or DO.

Tasmania

The technical legal position is not entirely clear. If the chiropractor and osteopath makes reference to the fact that they are involved in chiropractic and/or osteopathy, current practice suggests that the use of the term doctor or Dr is uncontroversial.

Northern Territory

The practice is to allow chiropractors the use of the title Dr. There is no specific statutory provision in relation to this issue.

Purveyors of Herbs

A practitioner who advertises as a purveyor of herbs may escape liability for the practice of medicine or holding out provisions. In *Allchurch v Drew*,⁹⁰⁶ a practitioner placed a sign that stated ‘John Drew, Agent for Herr Rasmussen Danish Herbalist, Alfaline Herbal remedies. I cure the nerves. I cure kidney troubles and other diseases’. These words and others stating ‘try my famous rheumatic tablets’ were in the shop front of his establishment.

The court held that the offence was to hold out as a medical practitioner, not just that the person could cure a malady or illness. The judge held that the appearance of the shop and the advertisement suggested that the defendant was merely the vendor of ‘nostrums’, and no one would think when entering the shop that they were visiting a medical practitioner.⁹⁰⁷ This argument was applied unsuccessfully in *Allchurch v Olsen*,⁹⁰⁸ where the general circumstances suggested that the practice was more than the sale of medicine but included conduct consistent with a medical practice.

906 [1926] SASR 280.

907 Ibid 284.

908 [1927] SASR 16.

CAM Specific Registration Acts

Relevant Issues for Chiropractors and Osteopaths

Professional registration acts define a profession's scope of practice and create offences for unregistered persons undertaking those activities or holding themselves out as registered practitioners.

In all states, chiropractors and osteopaths enjoy statutory acknowledgment. This section will discuss, from the perspective of these disciplines:

- the statutory scope of practice of chiropractors and osteopaths.
- the issues that arise for these practitioners in terms of their ability to act outside the statutory scope of practice.
- the relationship with physiotherapy registration statutes.

Statutory Scope of Practice

Five jurisdictions define chiropractic and or osteopathy.

Queensland

Chiropractic is defined as 'the manipulation, mobilisation and management of the neuromusculoskeletal system of the human body.'⁹⁰⁹

⁹⁰⁹ *Chiropractors Registration Act 2001* (Qld) s 237; *Osteopaths Registration Act 2001* (Qld) does not contain a scope of practice provision.

New South Wales

Recently passed legislation in New South Wales, namely the *Osteopaths Act 2001* (NSW) and *Chiropractors Act 2001* (NSW) do not contain scope of practice provisions as provided under the previous legislation. Section 10AC of the *Public Health Act 1991* (NSW) provides that spinal manipulation (defined as the rapid application of a force whether by manual or mechanical means to any part of a person's body that affects a joint or segment of the vertebral column)⁹¹⁰ can only be practiced by a chiropractor, osteopath, MD or physiotherapist.

South Australia

‘Chiropractic’ includes:

- (a) the manipulation or adjustment for therapeutic purposes of the spinal column or joints of the human body,
- (b) osteopathy, or
- (c) any related service or advice.⁹¹¹

Western Australia

‘Chiropractic’ means ‘a system of palpating and adjusting the articulations of the human spinal column by hand only, for the purpose of determining and correcting without the use of drugs or operative surgery, interference with normal nerve transmission and expression’.⁹¹²

‘Osteopathy’ means:

⁹¹⁰ s 10 AC (4).

⁹¹¹ *Chiropractors Act 1991* (SA) s 4.

⁹¹² *Chiropractors Act 1964* (WA) S4.

‘the static and dynamic assessment of human bio-mechanics, the diagnosis of somatic dysfunction, and the alleviation of somatic dysfunction by the application of manual treatments complemented by health education, but does not include the use of drugs or operative surgery’.⁹¹³

Tasmania

‘Chiropractic’ means that:

‘A person who is not a registered chiropractor or osteopath must not:

(a) manipulate the joints of the spinal column or its articulations; or

(b) use or apply a prescribed procedure’.⁹¹⁴

Implications of the Definitions

These definitions raise interesting issues:

- In many states the prescription of drugs and the use of surgery is specifically prohibited.⁹¹⁵
- In South Australia and Tasmania, the definition incorporates both chiropractic and osteopathy.
- In all cases, the definition incorporates manipulations of the spinal column and in some cases includes manipulation of articulations, health advice, therapeutic exercise and related services.⁹¹⁶
- In New South Wales and Western Australia (chiropractic definition), the definition limits practitioners to manipulation of the spinal column.
- In Victoria and the Territories, there is no definition of chiropractic and osteopathy.⁹¹⁷

⁹¹³ *Osteopaths Act 1997* (WA) s 3.

⁹¹⁴ *Chiropractors and Osteopaths Act 1997* (Tas) s 56(1).

⁹¹⁵ *Chiropractors Act 1964* (WA) s 4; *Osteopaths Act 1997* (WA) s 3.

⁹¹⁶ *Chiropractors Act 1991* (SA) s 4; *Osteopaths Act 1997* (WA) s 3.

⁹¹⁷ There is no prohibition on non-registered persons doing chiropractic in Victoria.

- The Queensland definition is broadened by the reference to ‘management of the neuromusculoskeletal system of the human body’, which could be interpreted to incorporate a wide variety of treatments outside standard manipulation techniques.
- Medical doctors are exempted from the chiropractic legislation in all jurisdictions even though they have little training in spinal manipulation.⁹¹⁸

Cases

Chiropractors and osteopaths are primary care providers dealing with a wide array of medical problems not including surgery or the prescription of drugs. In one view, a defined scope of practice definition makes this broad approach to practice potentially problematic. A court may interpret these definitions strictly to limit practitioners to the procedures defined.

*In Re Ward*⁹¹⁹ provides a narrow view of how these provisions may be interpreted. That authority involved an appeal by a physiotherapist against his suspension from practice for unprofessional conduct. The practitioner treated a child with cancer outside the scope of his training and in breach of the statutory scope of practice provisions. Abbott J thought that the definition of physiotherapy provided a statutory limit to the practice of physiotherapy.

This approach has an expansive aspect in that, within the statutory scope of practice, a registered physiotherapist is not limited by a lack of training. For example, if the statutory definition permitted use of ultrasonic equipment, the practitioner could provide this treatment

918 NZ Report, above n 480, 3.
919 [1953] SASR 308.

even if they had no training in that equipment. The limiting aspect of this approach is that a physiotherapist could not use techniques outside that statutory definition.⁹²⁰

Abbott J stated:⁹²¹

it is immaterial what the previous training of the practitioner may have been; when practicing as a physiotherapist and holding himself out as so practicing, he is confined to the forms of treatment comprised in the definition of physiotherapy laid down in the Act.

This might suggest that the statutory definition of chiropractic and osteopathy or any other registered practitioners strictly limits the techniques that chiropractors are entitled to use in their practice.

A contrasting and more recent authority is the West Australian authority of *Bradbury v Wayte*.⁹²² This case suggests that a broader view is appropriate. Here, a chiropractor was charged with practicing physiotherapy in breach of the *Physiotherapists Act* by treating a client using heat and equipment (a Curapulse 418 machine). The Supreme Court decision not to convict was based on the specific wording of the *Physiotherapists Act*, which defines physiotherapy as including the application of heat or massage and states that only physiotherapists can practice physiotherapy, subject to exemptions under s 12. Section 12 states that it is not unlawful to apply massage or heat to the human body if the practitioner is engaged in the practice of chiropractic, defined as manipulation by the hand only.

The Chiropractors Registration Board, as a party to the appeal, argued successfully that the exemption from the provisions of the *Physiotherapists Act* applied to manipulation by the

920 Webb report, above n 63, 128; Note normally physiotherapists do not manipulate the spine without postgraduate level training in this practice. This was one basis for exemption given for physiotherapists from chiropractic legislation.

921 *In Re Ward*, above n 850, 320-321.

922 (Unreported, Owen J, BC 910118, Supreme Court of Western Australia, 10 April 1991).

hand and also to activities involving the application of massage and heat, which may not be strictly within the definition of chiropractic.

Important in this judgment were the facts that:

- The chiropractor was registered and had been so since 1975.
- The chiropractor had used the machinery in question in his practice.
- He had been trained in the equipment.
- Two Australian teaching institutions teach these techniques.
- Chiropractors have traditionally used these machines worldwide since their inception.

This convinced the Court that the use of such techniques was an element of the practice of chiropractic. He then added ‘that is not to say that the fact of the customary use within a calling would excuse the use if it were contrary to the provisions of the Act’.⁹²³ He continued: ‘when the definition of “chiropractic” speaks of “by hand only” it is referring to palpating, adjusting and articulating and not to adjuncts or elements bona fide and substantially involved in the overall concept of the calling of chiropractic’.⁹²⁴

As this authority is based on an exception applying under the *Physiotherapists Act*, some caution in applying it in all contexts is required. It does, however, represent a more liberal interpretation because it doesn’t limit practitioners to activities strictly within the statutory practice definition, and permits techniques that may be an adjunct to the primary practice.

A recent case of *Bradbury v Cumming*⁹²⁵ confirms the need to apply *Bradbury v Wayte* conservatively. In this Western Australian decision an occupational therapist was said to have

⁹²³ *ibid* 9.

breached the terms of the *Physiotherapists Act 1950* by using ultrasound therapy which was a proclaimed method of physiotherapy under s 11 and 14 of that Act. The accused argued that as the equipment was not used for the purpose of curing or alleviating an abnormal condition it did not satisfy the statutory definition of physiotherapy. The accused said the equipment was used to increase the ability of the patient to bear the pain of myofascial therapy and was not itself directed to the treatment of an abnormal condition. The court rejected this argument as artificial. The court considered that the ultrasound was used in conjunction with myofascial therapy as ‘the best way of ensuring that a cure or alleviation could be achieved successfully and without undue pain.’⁹²⁶ Thus the charges of breaching the *Physiotherapy Act* were confirmed.

Scope of practice provisions may not present major concerns for chiropractors in some states where broader definitions apply. Chiropractors in South Australia and Queensland, and Osteopaths in Western Australia, have a more expansive scope of practice incorporating such matters as:

- ‘includes any related service or advice’ (South Australia).⁹²⁷
- osteopathy includes the use of ‘health education’ (Western Australia).⁹²⁸
- ‘management of the neuromusculoskeletal system of the human body’ (Queensland).⁹²⁹

Practicing Outside the Statutory Definition

The use of exercise, heat and nutrition advice

924 *ibid* 10.

925 (Unreported, Wheeler J, (20 December 1999 [1999] WASC 301).

926 *Ibid*, 4.

927 *Chiropractors Act 1991* (SA) s 4.

928 *Osteopaths Act 1997* (WA) s 3.

929 *Chiropractors Registration Act 2001* (Qld) s 237.

In many states, this will be outside the statutory definition of chiropractic and osteopathy. These procedures are, however, probably within the standard practice procedures and ethical boundaries of the profession.

In Re Ward might suggest that the practice of chiropractic and osteopathy is limited by the specific definition in each state. The more recent authority of *Bradbury v Wayte* suggests a broader and more commonsense approach to this issue.

The purpose of practitioner registration statutes is to restrict a defined practice to registered practitioners for the protection of the general public. The profession is thereby given a monopoly on those services, subject to exemptions for certain practitioners such as medical practitioners. No practitioner can use the procedures specified in the statute, such as spinal manipulation, unless registered or exempt. The statutes are not intended to limit the registered practitioners to those procedures solely. If the training and experience of a registered practitioner permits, a practitioner can apply techniques and procedures outside the statutory scope if they don't constitute a trespass onto the scope of practice of another registered profession. The practitioner of course does not enjoy a monopoly on services that are outside the defined statutory scope of practice.

Prescribing vitamins, minerals or nutrition supplements for specified complaints

In no state or territory does the scope of practice specifically incorporate such practice. If this practice falls outside the statutory scope of practice, then this is not of concern unless the strict *In Re Ward* approach is applied. Although access to vitamins and minerals can be obtained through retail outlets, a distinction might be drawn between supplying these

substances and prescribing for specific complaints. If the medical practice provisions are not breached this activity would appear to be uncontroversial.

Physiotherapist Registration Acts

Before 1945, physiotherapy was not considered a distinct profession but was grouped together with chiropractors and massage therapists. Physiotherapy is now registered in all the states and territories.⁹³⁰

All jurisdictions have a statutory scope of practice, except Queensland, Victoria and the Northern Territory. Tasmania does not have a specific scope of practice provision but it is an offence for a person other than a registered physiotherapist to manipulate the joints of the human body or use or apply a prescribed electrical or physical modality.⁹³¹ The statutory scope of practice provisions in the various states are similar, and generally describe the external application to the human body of massage, manipulation, passive movements, remedial exercises, heat, light and sound for curing or alleviating or preventing any abnormal condition of the human body.⁹³² In New South Wales s 10AD of the *Public Health Act 1991*(NSW) provides that prescribed electrophysical treatments must only be provided by chiropractors; medical doctors; osteopaths; physiotherapists and podiatrists.

Exemptions for Chiropractors

930 *Physiotherapists Act 2001* (NSW); *Physiotherapists Act 1998* (Vic); *Physiotherapists Registration Act 2001* (Qld); *Physiotherapists Act 1991* (SA); *Physiotherapists Act 1950* (WA); *Physiotherapists Registration Act 1999* (Tas); *Physiotherapists Act 1977* (ACT); *Health Practitioners and Allied Professionals Registration Act 1985* (NT).

931 *Physiotherapists Registration Act 1999* (Tas) s 58.

932 NSWs 2; Vic s 2; SA s 4; WA s 2; Tas s 2; ACTs 3; Qld s 238.

Chiropractors and osteopaths in most states have limited exemptions from these provisions:

South Australia.

There is exemption for chiropractors only in relation to use of the title ‘manipulative therapist’, not in relation to practices.⁹³³ Note, however, that expansive definition of chiropractic in this state includes ‘any related service’, which arguably may cover many physiotherapy techniques.

*Australian Capital Territory.*⁹³⁴ Osteopaths and chiropractors are exempt ‘in accordance with the laws of the Territory’.

*Western Australia.*⁹³⁵

Osteopaths and chiropractors are exempt in relation to application of physiotherapy related to heat or massage. Note the narrow definition of chiropractic for the purposes of the *Physiotherapists Act (1950)* (WA) and the expansive definition of osteopathy.⁹³⁶

*Tasmania.*⁹³⁷

There is exemption for a person registered as a chiropractor or osteopath ‘in the normal course of his or her profession’.

Queensland.

There is no exemption for chiropractors, thus creating the possibility of trespass into physiotherapy, but the expansive definition of chiropractic does provide some comfort.⁹³⁸

933 s 28 (4).

934 s 3 (2).

935 s 12 Refer to *Bradbury v Wayte* (Unreported, Supreme Court of Western Australia, Owen J, 10 April 1991)

936 s 12.

Chinese Medicine Registration Act 2000 (Vic) (CMRA)

Introduction

Victoria is the first state that has moved to provide registration status for three types of practitioners under the CMRA:⁹³⁹

- Chinese herbal medicine practitioners.
- Acupuncturists.
- Chinese herbal dispensers.

The term ‘registered Chinese medicine practitioner’ includes people registered as Chinese herbal medicine practitioners and acupuncturists. This legislation may provide a model for other states and territories. The Act came into effect on the 1 December 2002.

Statutory Purpose

The CMRA has the statutory purpose of:⁹⁴⁰

- protecting the public by providing for registration of practitioners, investigation into professional conduct and fitness to practice.
- regulating the advertising of Chinese medicine and Chinese herbal dispensing services.
- establishing the Chinese Medicine Registration Board of Victoria and the Chinese Medicine Registration Board Fund.
- amendments to the *Drugs, Poisons and Controlled Substances Act 1981*.

937 s 58 (2)(b).

938 s 240(2).

939 Freckelton, above n 653, 6.

940 s 2.

Chinese Medicine Registration Board of Victoria

The CMRA constitutes a board of nine members nominated by the Minister and appointed by the Governor in Council. The members are comprised of six registered practitioners, a lawyer and two persons not registered practitioners. At least two members of the board must be able to communicate in English and either Mandarin or any other Chinese dialect.

The powers, functions and consultation requirements of the board include:

- registering persons under the legislation.
- approving courses that provide qualifications.
- regulating standards of practice.
- investigating professional conduct and imposing sanctions where necessary.
- issuing guidelines about professional indemnity insurance.
- promulgating codes of practice for traditional Chinese medicine and dispensing Chinese herbs.
- promulgating standards of training and standards for prescribing, labelling, storage, dispensing and supplying Chinese herbal substances, including schedule 1 poisons.

Protection of Title Not Practice

The focus of the legislation is not the regulation of particular practices but protection for the *title* of registered Chinese medicine practitioner, registered acupuncturist and Chinese herbal dispenser. This means that a person can practice those modalities as long as they do not offend the provisions of part 5 of the statute. Part 5 makes it an offence for an unregistered person to hold out as a registered practitioner, claim to be registered or claim to be qualified

to practice as a Chinese medical practitioner, a Chinese herbal medicine practitioner, an acupuncturist or a Chinese herbal dispenser.

The only indication of a limit on practice is s 61(1)(c), which states that a person who is not registered as a practitioner must not carry out any act that is required under an Act to be carried out by a registered person. To date no such act has been specified.

Limits on Registration

The provisions of part 2 contain important requirements for registration. The board receives applications for registration as one of the three types of practitioners. Before registration, evidence of professional indemnity insurance will be required. In addition, evidence is required of the successful completion of a course of study approved by the board or that the applicant has passed an examination set by the board or has a qualification substantially equivalent. Registration will require renewal yearly.

In transitional provisions, existing practitioners who do not satisfy the educational requirements may be permitted registration if they have equivalent qualifications based on training or practice. Applicants may be asked to complete an examination.⁹⁴¹

Register

Division 2 of part 2 requires the board to keep a register called the 'Register of Chinese Medicine'. This register is to include three divisions:

- Chinese herbal medicine practitioners.
- Acupuncturists.

⁹⁴¹ CMRA s 94.

- Chinese herbal dispensers.

Complaints against Practitioners: Part 3

A person can make a complaint to the board about a registered practitioner. If the complaint is of a kind that might be made under the *Health Services (Conciliation and Review) Act 1987*, the board must notify the Health Services Commissioner and then determine which body will deal with the complaint.

If the board decides to deal with the matter, it can be referred to preliminary investigation and involve formal and informal hearings. If the board thinks that a registered practitioner's ability may be affected by their physical or mental health or incapacity, or that they are alcohol or drug dependent, then the board can conduct a preliminary investigation that may involve a medical examination. The board is vested with the power to caution; require a practitioner to undergo counselling; reprimand; require further education; impose conditions, limitations or restrictions; impose fines; and suspend or cancel registration.⁹⁴² Parker criticizes the definition of unprofessional conduct in s 3 as it does not clearly include misconduct in the nature of negligent treatment as is found in other medical practice statutes.⁹⁴³ There is provision under part 4 for a review of some determinations of the board to the Victorian Civil and Administrative Tribunal.

Offences

Section 61 contains a number of offences for unregistered persons, including:

- using the title of a registered practitioner calculated to induce a belief the person is registered.

⁹⁴² s 48.

- a claim or holding out to be registered under the Act.
- carrying out any act required by an Act to be carried out by a registered person.
- a claim to be qualified to practice as a Chinese medicine practitioner, a Chinese herbal medicine practitioner, an acupuncturist or a Chinese herbal dispenser.

Protected Titles

Protected titles in the legislation include:⁹⁴⁴

- A person who is not a registered Chinese herbal medicine practitioner must not use the following titles whether in English or any other language: ‘Chinese herbal medicine practitioner’, ‘Chinese herbalist’, ‘Chinese medicine practitioner’, ‘Oriental medicine practitioner’, ‘Chinese herbal dispenser’.
- A person who is not registered as an acupuncturist must not use these titles whether in English or any other language: ‘acupuncturist’, ‘Chinese medicine practitioner’, ‘Oriental medicine practitioner’.
- A person who is not registered as a Chinese herbal dispenser must not use the title ‘Chinese herbal dispenser’ whether in English or any other language.

These provisions mean that an unregistered practitioner would need to use some other title to describe the services they provide.

Provisions in Relation to Prescribing and Dispensing Scheduled Herbs

An important purpose of the legislation is the regulation of the dispensing of Chinese herbs.

The *Towards a Safer Choice Report* recommended the provision of labelling requirements

943 Parker, above n 331, 292 Eg *Health Practitioners (Professional Standards) Act 1999* (Qld) Dictionary.
944 s 61.

and making available substances under the Standard for the Uniform Scheduling of Drugs and Poisons to traditional Chinese medicine practitioners.⁹⁴⁵

The board has the power under section 8 to endorse the certificate of registration of Chinese medicine practitioners and Chinese herbal dispensers to possess, use, sell or supply Chinese herbs classified as schedule 1 poisons under the *Drugs, Poisons and Controlled Substances Act 1981*. The entitlement for Chinese medical practitioners to prescribe, dispense and supply Chinese herbs would include raw Chinese herbs and medicines containing ingredients of scheduled herbs. In relation to dispensers, the endorsement would allow raw or prepared medicines based on a prescription from an endorsed registered practitioner or authorised practitioner (this would include medical doctors and pharmacists endorsed as authorised by the board). The dispenser will need to establish that the prescription or order is in accordance with any endorsement of the relevant practitioner.

Amendments to the Drugs, Poisons and Controlled Substances Act 1981

Section 12A of the *Drugs, Poisons and Controlled Substances Act 1981* (DPCS Act) contains as a schedule the Poisons List, comprised of nine groupings of substances that are generally in accordance with the Poisons List set out in *The Standard for the Uniform Scheduling of Drugs and Poisons*. These are recommendations of the Public Health Committee of the National Health and Medical Research Council.

Section 97 of the CMRA amends this list by incorporating, as grouping no. 1, the following: 'Poisons of plant, animal or mineral origin that in the public interest should be available only

⁹⁴⁵ Bensoussan and Myers, above n 77, 9-10.

from a person registered under the Chinese Medicine Registration Act 2000 or authorised under another Act’.

Included in this schedule will be a list of Chinese herbs that have the potential to be toxic and dangerous if used incorrectly and it is considered in the public interest to regulate their prescription and dispensing/supply. This list may also include substances that have already been on a schedule, such as the Chinese herb *Fu Zi* (schedule 4 poison) or included because they include a scheduled substance such as *Ma Huang*, which contains Ephedrine (schedule 4 poison).

The DPCS Act has been amended by the CMRA to include as authorised practitioners a registered medical practitioner or pharmacist expressly authorised by the board to perform acts required to be done by practitioners under the CMRA. The provisions of s 13A of the DPCS Act states that a registered Chinese medicine practitioner or authorised practitioner (this would include some endorsed medical doctors and pharmacists) must not administer, prescribe, sell or supply a schedule 1 poison unless it is for the therapeutic use of a person who has consulted the practitioner and the practitioner has taken all reasonable steps to ensure that the person has a therapeutic need for the schedule 1 poison.

Control of Prescribing, Labelling and Supply of Chinese Herbal Substances

Section 68 of the CMRA permits the board to promulgate codes about the practice of Chinese medicine and dispensing, and recommended standards for prescribing, labelling, storage, dispensing and supplying of Chinese herbal substances, including schedule 1 poisons. The provisions of the DPCS Act, which applies a Poisons Code including labelling requirements, does not apply to a registered Chinese medicine practitioner, registered Chinese herbal

dispenser in accordance with the endorsement of that person's registration or an authorised practitioner.⁹⁴⁶ The Codes of Practice discussed above will presumably supply guidance in regard to these matters. If this system is not successful specific statutory regulation under the DPCS may be required.

Conclusion

The CMRA is a significant stage in the development of CAM regulation in Australia. It provides what could be the first part of a national model of regulation of TCM and acupuncture. This act provides a type of regulation that is similar to the registration statutes provided to OM, chiropractors and osteopaths. An important aspect of the legislation is that it reflects an acknowledgement of the role and expertise of TCM practitioners over and above OM practitioners untrained in this discipline. Under this legislation OM doctors are not permitted to prescribe schedule 1 substances unless properly endorsed under the CMRA. This is a breach of the OM hegemony and sovereignty that applies in other health practitioner statutes where OM practitioners are exempted and assumed to be competent even if they are not trained in the discipline. The difficulty with the legislation identified by Freckleton is how the endorsement of MD's for TCM will be assessed and what this endorsement will mean for OM practitioners practicing TCM. Will an MD who practices TCM be assessed based on OM or TCM parameters or a combination of both?⁹⁴⁷

Registration Acts and the Unregistered Practitioner

946 s 27A (4).

947 Ian Freckleton, 'Complementary Medicine and Challenges for Western Medical Practice' (2003) 10 *Journal of Law and Medicine* 257, 258-259.

The flexibility provided to unregistered practitioners is counterbalanced by the need to tread wearily between statutory definitions to ensure that breaches of professional registration statutes do not occur.

Effect of Chiropractor and Osteopath Acts

The statutory designated scope of practice discussed above varies somewhat between states. Manipulation of the spinal column and their articulations by unregistered practitioners, which is the focus of chiropractic and osteopathy, could involve a breach of the provisions of the chiropractor and osteopath registration acts. This is particularly relevant for practitioners of therapeutic massage, touch for health therapists, shiatsu and other similar modalities.

Intended Manipulation

A practitioner who applies a technique to manipulate the spine or its articulations may be involved in the practice of chiropractic and/or osteopathy. If the practitioner is not registered or exempt from the various registration statutes, this activity will be an offence.

Unintended Manipulation

A practitioner of therapeutic massage or other similar modality may indirectly or unintentionally cause a manipulation or adjustment of the spinal column or its articulations. The terminology used in the various statutes would suggest that the prohibition relates to purposeful or intended manipulation or adjustment of the spinal column or articulations. If the purpose or aim of the technique was not the manipulation or adjustment of the spine or articulations, it is unlikely a breach would occur.

Tasmania is alone in exempting massage therapists from the chiropractic and osteopathy legislation in a limited way. The exemption states that a person is not involved in chiropractic or osteopathy 'by reason only of the fact that he applies massage to a person engaged in playing or training for any game, sport, or athletics without the intention of manipulating the joints of the spinal column or its immediate articulations'⁹⁴⁸

Effect of Physiotherapist Acts

Of concern to some unregistered CAM practitioners especially therapeutic massage therapists is the statutory scope of practice of physiotherapy, which covers many procedures preferred by practitioners who emphasise or incorporate therapeutic massage. A massage therapist, by applying massage techniques, may surprisingly undertake procedures that are within the scope of practice of a physiotherapist. In most states, there is special provision for massage to be exempted, though in many cases in a limited way.

State jurisdictions with no exemption

The *Physiotherapists Act 1998* (Vic) does not have a scope of practice provision and merely limits 'holding out' as a physiotherapist. This means that a massage therapist will comply with the holding out provision by avoiding the use of titles such as 'registered physiotherapist', 'registered physical therapist' or other title calculated to imply they are registered under the act as a physiotherapist.⁹⁴⁹

⁹⁴⁸ *Chiropractors and Osteopaths Act 1997* (Tas) s 56(2)(b).
⁹⁴⁹ s 57.

State jurisdictions with limited exemption

In Queensland there is an exemption for application of massage by any person⁹⁵⁰:

- in the course of training persons engaged in playing or training for physical culture or any games, sports or athletics, or
- for the purpose of alleviating injuries received by persons in the course of their being engaged in or training for physical culture or any games, sports or athletics, or
- for cosmetic purposes only (the practice of face massage or scalp massage).

This means that massage not for the purpose specified in the exemption could constitute physiotherapy by an unregistered practitioner. This is a position that is hard to justify on public interest grounds. A counter-argument is that the use of massage is only *one* procedure contemplated by physiotherapy as part of a regime involving a complex set of procedures, appliances and techniques directed at curing or alleviating abnormal conditions. By contrast, a massage therapist is not involved in the application of physiotherapy equipment, diagnostic techniques and theory, nor do they apply massage for curing or alleviating abnormal conditions. In *Bradbury v Wayte* this type of argument was not successful.

Broad Exemption

*Western Australia.*⁹⁵¹ It is not necessary for a practitioner to be registered, nor is it unlawful to apply massage or heat to the human body in the practice of his calling, by reason only of the fact that:

- he/she practices face massage or scalp massage for cosmetic purposes only,

950 *Physiotherapists Registration Act 2001* (Qld) s 240 (2)(b) and (c).

951 *Physiotherapists Act 1950* (WA) s 12.

- he/she applies massage or heat to persons engaged in playing or training for any game, sport or athletics for the purpose of training such persons, or alleviating injuries received by such persons in the course of such playing or training, or
- he/she practices massage otherwise than for the curing or alleviation of any abnormal condition.

*Australian Capital Territory.*⁹⁵² The legislation defines physiotherapy as ‘the application to the body, for the purpose of curing or alleviating any abnormal condition, of manipulation, massage, therapeutic exercise, electricity, heat, or any prescribed treatment’. Section 3(2) exempts from the Act ‘the carrying on by a person, in accordance with the laws of the Territory, of the business or profession of beautician, chiropractor, masseur, medical practitioner, nurse, osteopath or podiatrist’.

The term ‘masseur’ is not defined, and would likely incorporate the use of massage for therapeutic purposes or otherwise, assuming that the masseur does not, by the breadth and complexity of the techniques and appliances used, practice physiotherapy.

*South Australia.*⁹⁵³

The prohibition against the practice of physiotherapy by unregistered persons in s 26 does not apply to ‘a person who practices physiotherapy only by reason that he or she massages another or provides advice related to massage’. There is also an exemption for a person who is a trainer of a sporting team who treats injuries under the supervision of a doctor or physiotherapist for no longer than one month. Note that the offence of holding out as

⁹⁵² *Physiotherapists Act 1994 (ACT)* s 3.

⁹⁵³ *Physiotherapists Act 1991 (SA)* s 26(2)(e) and (f).

physiotherapist incorporates the use of certain words such as ‘manipulative therapist’, ‘physical therapist’ and ‘electrotherapist.’⁹⁵⁴

Diseases

Notifiable Diseases

Medical practitioners have an obligation to report to health authorities if they become aware of the existence of persons with infectious diseases such as tuberculosis, cancer and venereal disease.⁹⁵⁵ Complementary medicine practitioners do not have this obligation.

Diseases Only a Medical Practitioner Can Treat

In South Australia some diseases can be treated only by medical practitioners. It is an offence for a person other than a registered medical practitioner to treat cancer, diabetes, epilepsy, gonorrhoea, Hepatitis B and C, AIDS, HIV, poliomyelitis, syphilis and tuberculosis.⁹⁵⁶

These statutory provisions elucidate that ‘In our culture there is a silent assumption that people can be allowed to dabble provided nothing is too seriously wrong, but that when they are diagnosed as having a serious condition, they should be really be persuaded to have ‘proper’ medicine’ thus confirming culturally the hegemony of OM.⁹⁵⁷

Regulation by Australian Consumer Legislation

954 *Physiotherapists Act 1991 (SA) s 28(3); Physiotherapists Act 1977 (ACT) holding out provision s 32 in relation to terms physiotherapist, physiotherapeutist, physical therapist, physical therapeutist, electrotherapist; Physiotherapists Act 1965 (WA) s 11(1), restriction limited to use of term physiotherapist.*

955 For example *Health Act 1937 (Qld) s 32A.*

956 *Medical Practitioners Act 1983 (SA) s. 31(1)(a); s. 31(3); Medical Practitioners Regulations r 20.*

957 Stone and Matthews, above n 32, 262.

Introduction

State and federal consumer legislation imposes obligations on health practitioners as to how goods and services are advertised and supplied. Health practitioners have generally been untouched by those provisions to date but increasing awareness by consumers of their rights suggests that there is now greater potential for action being taken under these provisions.

The intersection between the practice of CAM and the consumer regulatory structure relate to making claims for therapeutic benefit for services or goods that might be considered to be misleading or deceptive or likely to mislead or deceive. Examples of proscribed activities might relate to:

- Exaggerated or unsubstantiated claims of the effectiveness of services or complementary medicine.
- Use of titles or qualifications that a practitioner is not entitled to use. For example indicating you are a 'Dr' when you are not may breach health practitioner legislation and ss 52 and 53 of the *Trade Practices Act 1974* (Cth) and the equivalent state Fair Trading Acts.
- False Claims of certification or approval.
- Use of testimonials that are presented in a way that is likely to deceive.
- Guarantees of successful treatment.

The Australian Consumer and Competition Commission (ACCC) appears now to be focusing on dealing with unjustified claims by marketers of devices and substances for health care.⁹⁵⁸

This greater interest in health matters reflects in a recent announcement by the New South Wales government that it will move to investigate 'miracle cures, wonder drugs and

misleading health claims and advertisements’ and to combat ‘dodgy cures and health practices; under the chairmanship of Professor John Dwyer Professor of Medicine at University of New South Wales.’⁹⁵⁹

This is an issue especially relevant for CAM practitioners as many treatments and/or substances they may employ may have little supporting scientific evidence. Evidence of effectiveness or safety may rely upon anecdotal evidence or traditional claims. This type of evidence may not necessarily protect against a claim of false and misleading behaviour. The less stringent non legislative ethical standards imposed on many CAM practitioners could encourage more expansive statements about the likelihood of successful treatment.

Is consumer legislation effective to control CAM?

The practicality of applying remedies derived from consumer legislation to health professionals has been doubted. The NSW Health Complaints Commissioner Walton has commented in regard to some complaints referred to the Fair Trading Department that:

We do not see it as a successful or viable alternative, because they do not look at the standards of care. They are not concerned with about what we would call the care of the complainant, which is about preventing harm, or investigating the clinical aspects of the treatment. So it is not very good.⁹⁶⁰

This comment suggests that these statutes are not effective in relation to controlling standards of care but may be mor effective in clear cases of unsubstantiated claims by practitioners or merchants about the value or quality of their goods or services.

958 ACCC, ‘Update – Protecting Consumers’ Issue 12 January (2003) 6-7; Australian Consumer and Competition Commission, *Fair Treatment: Summary of the Guide to the Trade Practices Act 1974 for advertising or promotion of medical and health services* (2000).

959 ‘New South Wales Government Crackdown on Wonder Drugs and Miracle Cures’ (2002-2003) 2 *Diversity* 13.

960 NSW Committee, above n 636, 41.

Relevant Statutes

The most important consumer statutes are:

- *Sale of Goods Act* (almost identical provisions in all states) (SGA).
- *Trade Practice Act 1974* (Cth) (TPA).
- *Fair Trading Acts* (similar provisions in all states) (FTA).

These statutes apply provisions relevant to how a contract is formed and provides some implied warranties as in any other consumer transaction. Probably most important in the regulation of CAM are the provisions that deal with misleading and deceptive behavior.

Misleading or Deceptive Behaviour

‘A person shall not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive’.⁹⁶¹

This is a very broad provision that covers many specific circumstances also dealt with under other sections. An important first issue is whether the activities of a CAM practitioner is ‘in trade or commerce.’ In the context of a professional relationship if a CAM practitioner provides advice or a diagnosis this does not relate to the commercial relationship between practitioner and patient and is not ‘in trade of commerce.’ A statement made to induce the entering into of the relationship may be in trade or commerce and would be subject to these types of provisions.⁹⁶² This might include false advertising or exaggerated claims about the effectiveness of a treatment. Thus the content of the advice given is not in trade or commerce.

In one case the court stated:

⁹⁶¹ *Trade Practices Act 1974* (Cth) s 52; Refer also to s53 on more specific issues and s55A re services; *Fair Trading Act 1989* (Qld) s 38.

⁹⁶² Bernard McCabe ‘Revisiting Concrete Constructions’ (1995) 3 *Trade Practices Law Journal* 161 –176; *Multiplex Constructions Pty Ltd v Amdel Pty Ltd* (1991) ATPR 41-154.

An expression of opinion which is identifiable as such conveys no more than that the opinion expressed is held and perhaps that there is basis for the opinion. At least if these conditions are met, *an expression of opinion, however erroneous, misrepresents nothing.*⁹⁶³

This distinction may not always be easy to make but must be made to ascertain the possible liability of professional activities under these provisions.

These provisions require a representation that misleads or is deceptive. This test is applied in one to one contractual relationships and to classes of people. Where a class of people is involved, which is likely in the context of advertising or public statements, then a court will apply a test of what would be the reaction of an ordinary and reasonable member of the class likely to be affected by the representation.⁹⁶⁴ If only a foolish person would be misled and no reasonable member of the relevant class would have been misled no breach is likely to occur. For example, if a claim was mere puffery it is unlikely that liability would arise.

A breach of this provision might include exaggerated claims of the effect of services, such as 100% cures for conditions like back pain or miracle slimming techniques where the claims are not verifiable.

Scientific Evidence

Is it necessary to provide scientific evidence for a device, substance or treatment to avoid the possible implication that claims made about these matters are false and misleading? There is a dearth of cases involving health claims related to CAM services and products.

963 *Global Sportsman Pty Ltd v Mirror Newspapers Ltd* (1984) 2 FCR 82.

964 *Campomar Sociedad, Limitada v Nike International Ltd* (2000) 202 CLR 45, 85.

In *ACCC v Giraffe World Australia Pty Ltd*⁹⁶⁵ Giraffe World marketed an 'ion mat'. This product was a mattress connected to electricity. This mattress was said to emit negative ions that was represented in various ways to cure or alleviate a long list of medical conditions. The company was subject to litigation in regard to its marketing process that was found to be a form of pyramid selling in breach of s 61 *Trade Practices Act 1974* (Cth).

Another aspect of the proceedings related to whether the claims made about the therapeutic benefits of the mat and the endorsement of the mat by certain bodies were misrepresentations under s52; s51A; s52; s53 (c) and s57 of the *Trade Practices Act*. Representations were made on many matters including that the mat cured bad backs; improved circulation and alleviated heart problems.

The judge suggested that the 38 representations about the mat and its effects fell into 3 categories:

- those that explained how the mat operated in regard to negative ions.
- those dealing with official or institutional approval for the mat.
- the health benefits of the mat.

The judge held that most of the representations about the health benefits of the mat were not merely representing a matter of past or present fact but represented that mat would repeat its performance for those who bought the mat. Section 51A provides that if that type of representation is made and the corporation does not have 'reasonable grounds' for making the representation the representation is taken to be misleading.⁹⁶⁶ The judge considered Giraffe World had not discharged its onus to show reasonable grounds for making the representation.

⁹⁶⁵ (1999) 166 ALR 74.

The judge also considered the representations were misleading if considered to be representations of present fact.⁹⁶⁷

Giraffe World attempted to rely upon evidence of a naturopath and chiropractor for the health claims. The judge accepted the evidence of the naturopath though it appeared to be a general statement about alternative medicine that did not properly deal with a matter before the court. The evidence of a chiropractor was not accepted but the judge noted the ACCC's concession that manipulative therapy can alleviate suffering despite the lack of scientific evidence to support it. The judge preferred the scientific evidence of the ACCC as to the lack of support for the health representations of Giraffe World.⁹⁶⁸

In regard to personal oral testimonials provided in support of the mat's virtues the judge indicated in his view it is not misleading or deceptive for a person to provide their personal experience *in a non-commercial setting* to another even if there is no scientific support for the statement. The judge made obiter comments that if Giraffe World had relied on testimonials without adding their own representations of the benefits of the mat in front of a group of prospective purchasers, without reasonable grounds for the statements made, then there may still have been misleading or deceptive conduct.⁹⁶⁹

Traditional or Empirical Evidence

What is not really answered by this authority is whether it is possible to rely upon traditional use or empirical data as evidence for the benefit that is represented to occur if using a substance or procedure. That is an important issue for the marketing of CAM products that

966 Also refer to equivalent provision relevant to non-corporate entities under *Fair Trading Act 1989* (Qld) s 37.

967 *ACCC v Giraffe World Australia Pty Ltd*, above n 965, 103.

968 *Ibid* 111.

may lack clear scientific evidence. If a representation is made that a product or technique has a specified benefit scientific evidence of a high standard may be required to avoid liability for false and misleading statements. Traditional or empirical evidence may not be sufficient depending on the nature of the matter and what representation is made. It is noted however that section 51A does not refer to the need for scientific evidence to provide ‘reasonable grounds’ so the use of other forms of evidence may be contemplated.

It is relevant that the Therapeutic Goods Administration allows traditional evidence to support therapeutic claims for complementary medicines based upon the ‘Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For non-registerable medicine, including Complementary Medicines, and other Listable medicines).’ These guidelines require that the marketer specify the nature of the evidence as the basis of the representation made. These guidelines although not legally binding are likely to be influential in determining what is or is not an appropriate representation in regard to a CM product.

The cautious approach would be to limit representations in a way that specifies the nature of the evidence available as indicated in the guidelines ie ‘This substance has been traditionally used for the treatment of’ Or ‘There is a University of Smithfield study which indicates that’ The argument against liability would then be that the representation contains within it an indication of the nature of the evidence to support the claim. For claims on the performance of services provided by CAM practitioners cautious statements or reference to the strength of the evidence available to support the treatment would be suggested.

Health Rights Complaints Legislation

Complementary medicine is acknowledged in all states (except South Australia) through health rights complaints statutes.⁹⁷⁰ These statutes permit complaints in relation to health professionals, including medical doctors, dentists and a range of health professionals, including complementary medicine practitioners.

The proliferation of health rights legislation reflects the trend towards health care consumerism dating from the 1960's.⁹⁷¹ This trend focused attention on the need to respect patient's rights and entitlements and the obligations of health practitioners beyond purely contractual or tortious obligations of reasonable care. Health rights legislation requires health practitioners to understand the human being they are treating and to concern themselves with issues such as caring; communication and respect.

The use of health complaints legislation has been partly a response to the increasing level of medical litigation. The intention is to provide an alternative to the difficult and expensive route of civil litigation. The use of such complaints mechanisms has been attributed with a slowing in the growth of medical litigation.⁹⁷² The use of health complaints legislation also reflects the greater attention to consumer concerns and issues that is an aspect of the post-

970 *Health Services (Conciliation and Review) Act 1995* (W.A); *Health Care Complaints Act 1993* (NSW); *Health Services (Conciliation and Review) Act 1987* (Vic); *Health Rights Commission Act 1991* (Qld); *Health Complaints Act 1995* (Tas); *Health Complaints Act 1993* (ACT); *Health and Community Services Complaints Act 1998* (NT).

971 Milburn, above n 176, 61.

972 S Buetow, 'Formal complaints and disciplinary proceedings involving medical practitioners' (1995) 14 *Medicine and the Law* 559-561.

modernist trend in society.⁹⁷³ The reference to health rights and responsibilities suggests the need for both practitioner and patient to shoulder some part of the responsibility for health care outcomes. This accords with the partnership model of therapy promoted by CAM practitioners. This is expressed in the Tasmanian Charter of the Rights and Responsibilities of Health Service Users and Providers when it states:⁹⁷⁴

When viewed as a partnership, the relationship between the health services consumer and the health service provider is more likely to benefit the health outcomes of the service consumer. While the health service provider has a responsibility to meet certain rights of the health service consumer, the consumer in turn, should also assume some responsibility for their own health care.

This legislation is significant because:

- it provides statutory acknowledgment of the role of complementary medicine in the health sector.
- it provides a regime for health service consumers to bring complaints about services to the notice of the practitioner and relevant authorities such as the various Health Complaints Commissioners and police if appropriate.
- this mechanism provides information on the general pattern of complaints against health professionals and establishes structures for complaint, investigation, mediation and arbitration to assist in resolving disputes on health related matters.
- it provides guiding principles to improve the professionalism of practitioners while avoiding approaches to practice that may encourage negligence actions by clients.

973 S Linden-Laufer, 'A code of health rights and responsibilities: the adequacy of existing recognition and protection' (1993) 1 *Journal of Law and Medicine* 168.

974 Department of Health and Human Services, *Tasmanian Charter of the Rights and Responsibilities of Health Service Users and Providers* (1995) 3.

Services Covered

The statutes make provision for complaints by persons against most health professionals. In all cases, the legislation covers virtually all CAM practitioners.

Specifically incorporated are chiropractors, osteopaths, massage therapists or masseurs, naturopaths, acupuncturists and others in the alternative health care or diagnostic fields.⁹⁷⁵

In Western Australia, complementary medicine is probably within the definition of 'health service', which includes a service 'provided by way of:

- (a) diagnosis or treatment of physical or mental disorder or suspected disorder,
- (b) health care'.⁹⁷⁶

Arguably, all therapists not specifically mentioned, such as homoeopaths, would be within the general description of alternative health care and diagnostic fields.

Objects of the Legislation

The general scheme common to most statutes will be outlined with reference to particular features of some individual statutes. Each statute has an object section, preamble or long title that indicates the objectives of the legislation. In most statutes the following principles or aims are significant:

- Improve the quality of provision of health services.

⁹⁷⁵ Tas s 3 Part 1 Schedule 1; Vic s 3, (s 3(1)(ka) now mentions practitioners of Chinese Herbal medicine, acupuncturists and dispensers of Chinese Herbs); Qld s 3 Schedule 1 Part 1; NSW s 4; N.T. s 4; ACT s 4 Part 1 Schedule.

⁹⁷⁶ *Health Services (Conciliation and Review) Act 1995* (WA) s 3.

- Provide an accessible and independent regulatory mechanism for the making and resolution of complaints.
- Preserve and promote health rights such as respect for individual dignity, access to adequate information on health services, participation in decision-making and confidentiality of health records.
- Promote education and advice in relation to health services and obligations of practitioners.
- Establish a code of health rights.⁹⁷⁷
- Establish advisory boards, review committees or similar bodies to review the activities carried out under the Act.⁹⁷⁸
- Appoint health rights commissioners or similar officers to implement and administer the legislation.⁹⁷⁹

Complaints

The basis for a complaint is similar in all legislation except New South Wales. In all other states, the grounds for a complaint generally include that a health provider has acted unreasonably:⁹⁸⁰

- in providing the service.
- in the manner of providing the service,
- in not providing the service.
- by denying or restricting access to records.
- by not providing information about the user's condition.
- by disclosing information in relation to a user.

977 Qld; Tas; ACT and NT.

978 NSW; Vic; Qld and NT.

979 All jurisdictions.

- by failing to exercise due care and skill.
- by failing to treat the user in a way to respect a user's needs, wishes and background.
- by failing to respect a user's privacy or dignity.
- by failing to provide the user with information on treatment or health services available in language the user can understand to allow an informed decision, or on the availability of further advice or relevant education programs, or on the treatment or services received.
- by failing to provide user with reasonable opportunity to make informed choice of treatment or services available.
- by failing to provide user with a prognosis that would have been reasonable to be provided with.
- by acting in disregard of the code or charter of health rights and responsibilities.⁹⁸¹
- as the provision of a health service was not necessary.
- as a complaint has been made to the provider but was not properly investigated.

In determining what is reasonable behaviour, a number of statutes make reference to the principles of a code or charter of health rights or guiding principles.⁹⁸²

Who May Make the Complaint?

The user, the user's parents or guardian, health service provider or a person on behalf of the user may make a complaint. In some states, other persons who can complain include the relevant Minister.⁹⁸³

⁹⁸⁰ Vic s 16; Qld s 57; WA s 26; Tas s 23; ACT s 22 and NTs 23.

⁹⁸¹ Tas s 23(1)(k); NT s 22(1)(g).

⁹⁸² Vic s 21(2); Qld s 58(2); Tas s 75; ACT s 5 and NTs 5.

⁹⁸³ Tas s 22; Qld s 59; NT s 22 NSW s 8 the Health Minister, the Secretary of the Health Minister or similar official (Tas s 22 NT s 22 NSW s 8) or a person approved by the relevant Commissioner (Tas s 22 ACT s 21 Qld s 59 Vic s 15, member of parliament (NSW s 8), donee of a power of attorney NT s 22).

A complaint should be in writing, though provision is made for complaints to be made orally in some circumstances. In New South Wales, a complaint cannot be acted on until it is put in writing.⁹⁸⁴

Assessment of a Complaint

Once a complaint is made, the relevant authority must assess the complaint to determine whether the matter should proceed. The relevant matters in the assessment of the complaint are:

- The complainant has failed without reasonable cause to cooperate with attempts to resolve the complaint.⁹⁸⁵
- The complaint is frivolous, vexatious, misconceived, lacking in substance or trivial.
- The matter has been resolved by another body or tribunal or relates to a matter currently being heard in a court of law.
- The complainant has delayed the complaint for a period of 12 months without due cause.⁹⁸⁶
- An oral complaint has not been confirmed in writing.
- There will be no referral to conciliation unless steps have been taken by the complainant to resolve the dispute.
- The complaint should be referred to a registration board.
- The complaint should be referred to another appropriate body such as the ombudsman.
- The complaint should be referred to conciliation.
- The complainant has been given reasonable explanations.⁹⁸⁷

984 s 9.

985 Vic s 19(5); Qld s 79 (2).

986 NSW 5 years; s 27(1)(f); no specified limit in WA; Tas 2 years s 25(5) (c); ACT 24 Months, s 28; NT 2years, s 30(1) (c).

- The complaint has been resolved or withdrawn.
- The complainant has not provided further information on request by the commissioner.

Some statutes indicate that conciliation and referral to another body is not appropriate where a significant matter of public health or safety is raised.⁹⁸⁸ In other states, the provisions require the conciliator to consider public interest in the conciliation.⁹⁸⁹ In the Northern Territory, significant issues of public interest or significant issues about the practice and procedures of a provider can be investigated by the commissioner without interfering with any conciliation.⁹⁹⁰

Notice of Complaint

Not surprisingly, a health service provider should be given notice of the complaint made.⁹⁹¹ In some states, a decision to accept a complaint for action will only be made when the commissioner is satisfied that all reasonable steps have been taken by the complainant to resolve the complaint, unless the circumstances would not allow this.⁹⁹²

Conciliation

An important focus of the health rights complaints statutes is the resolution of complaints by conciliation. In all statutes, after assessment one option is to refer the matter to conciliation by a conciliator. In New South Wales, the process is voluntary.⁹⁹³

987 ACT s 28(1)(g).

988 NSW s 26(2)(a); Tas s 25(4)(a)(i); ACT s 23 (3)(a)(ii); Tas s 25(4)(a) (ii); ACT s 23(3)(a)(ii) Victoria no similar provision. Qld- in deciding if a complaint should be conciliated the public interest should be considered.

989 Qld s 85; Tas s 32; NTs 39.

990 s 39, s 48(1) (c) (2).

991 NSWss 16, 28; Qld s 69, s 70; Tas s 27; WA s 33; ACT s 30.

992 Qld s 71.

993 s 48.

The purpose of the conciliation is to resolve the issue and if necessary to enter into enforceable agreements. Normally, a party cannot be represented in the conciliation process unless the conciliator thinks this will assist in the resolution of the dispute.⁹⁹⁴ If a resolution is achieved, the commissioner then has the option of not proceeding with the complaint.

If the conciliation does not result in agreement, the matter may be further investigated, referred to a relevant registration body or not proceeded with.⁹⁹⁵ It is significant that statements made in conciliation cannot be used outside those proceedings to allow the commencement of an action against a health service provider.⁹⁹⁶

Investigation of Complaint

Whether or not the matter proceeds to conciliation, more formal investigations may be made where the relevant Minister or the commissioner considers it appropriate.⁹⁹⁷ In the Northern Territory, the legislative assembly can refer a matter for investigation.⁹⁹⁸ In Victoria, one ground for investigation is whether the complaint is not suitable for conciliation.⁹⁹⁹ In some jurisdictions, the investigation can be commenced where a complaint raises a significant issue of public safety or public interest or a significant question as to the practice of a provider.¹⁰⁰⁰

The purpose of this investigation is to obtain information and then to determine what action should be taken. The investigation need not stop because the complaint has been resolved.¹⁰⁰¹

994 NSW s 50; Vic s 18(1) ; Qld no mention of this issue; WA s 39(a); Tas s 33; s 34; Tas s 40.

995 Vic s 20(1); Qld s 90; ACT s 37.

996 Vic s 20(14)(15); Qld s 91; WA s 42; Tas s 37; ACT s 39; NT s 47.

997 Qld s 95; Vic s 21(1); Tas s 40(1)(2); WA s 44; ACT s 40; NT s 20, s 48(1).

998 s 21(1).

999 s 21(1).

1000 WA s 45; Tas s 40; ACT s 40; NT s 48(1)(c).

1001 ACT s 41(2); s 41.

The commissioner has substantial powers of investigation, namely:

- seeking from a person relevant information and or documents,¹⁰⁰²
- obtaining oral information on oath,¹⁰⁰³
- referral to another appropriate body,¹⁰⁰⁴
- establishing a formal inquiry that would allow oral hearings and the attendance of witnesses,¹⁰⁰⁵
- power to enter and search premises and to obtain a warrant for the purpose of seizing evidence.¹⁰⁰⁶

Once an investigation is complete, a report is given to the complainant, the health service provider, the employer.¹⁰⁰⁷ if applicable, the relevant registration board, professional association, and the Minister.¹⁰⁰⁸ If the report contains an adverse comment about a person, they should be given the opportunity to make comment and lodge a written statement before the report is completed.

Charter of Health Rights

In some states, there is provision for a code or charter of health rights to be prepared, providing expectations for the performance and obligations of health professionals.¹⁰⁰⁹ In the Australian Capital Territory and the Northern Territory, it is specifically stated that in

1002 Qld s 96; ACT s 45; Vic s 25, 26; NT s 55; Tas s 45; WA s 60.

1003 Qld s 97; WA s 60; Tas s 46; ACT s 46; NTs 56.

1004 Qld s 101; Tas s 49; NT s 57.

1005 Qld ss 104-110.

1006 NSW s 32, 34; Vic s 27; Qld Division 3; ACT s 49; Tas s 47 and Division 3; WA s 63 – 67; NT s 58, s 62-64.

1007 Not applicable ACT s 51(5).

1008 NSW s 39,41,42; Qld sc126; In Tasmania the Health Minister s 55(2)(b) or another person with power to take action ie Ombudsman, police or Director of Public Prosecutions s 65(3) Tas s 55; ACT s 51; if applicable the Speaker NT s 65(2)(a).

1009 Qld Part 3, Tasmania Part 3 ; ACT Part VI and Northern Territory s 104 and; ACT and Qld - Code of Health Rights and Responsibilities, Tas - Charter of Health Rights; NT - Code of Health and Community Rights and Responsibilities

determining whether a provider has acted unreasonably the commissioner is obliged to consider the code or, until the code is approved, the principles at the basis of the code in the legislation and generally accepted standards.¹⁰¹⁰ In Western Australia and Victoria, the preamble to the statute includes a list of guiding principles for the provision of health services.

In Queensland, ACT and Tasmania, the principles to be considered in developing the code are very similar, comprising the following:

- An individual should be entitled to participate effectively in decisions about their own health.
- A person is entitled to receive appropriate health services of a high standard (ACT only).
- A person is entitled to be informed and educated about health matters that may be relevant to him or her and about available health services (ACT only).
- An individual should be entitled to take an active role in their health care.
- An individual should be entitled to be provided with health services in a considerate way that takes into account the individual's background, needs and wishes.
- An individual who provides a health service, or provides care for another individual receiving a health service, should be given consideration and recognition for the contribution the individual makes to health care.
- The confidentiality of information about an individual's health should be preserved.
- An individual should be entitled to reasonable access to records concerning their own health.
- An individual should be entitled to reasonable access to procedures for the redress of grievances.

1010 ACT and NT s 5.

To date, there is no code in Queensland, Tasmania, Northern Territory or the ACT. Tasmania has completed the *Tasmanian Charter of Health Rights and Responsibilities*.¹⁰¹¹

Health Rights Commissioners and Review Councils

In all states, a public servant is appointed to administer and implement the legislation. This person is appointed under various titles.¹⁰¹² Many jurisdictions establish a review body to advise the Minister and or the commissioner in relation to health service complaints.¹⁰¹³

Representatives of users, health service providers and independent persons make up the membership of these review bodies. The Northern Territory requires one member of the body to be a legal practitioner of five years' standing.

Limitations of Provisions

This legislation provides a standard against which a health care practitioner can judge the quality of his or her service. By providing principles or objectives in treatment, this legislation can educate and encourage practitioners to consider the purpose of their professional endeavor, which is to provide a service to a client.

The ability to enforce standards of treatment under this legislation is limited because there are no sanctions available for unregistered professions unless there are grounds for referral to the

1011 Office of Health Complaints Commissioner, *Tasmanian Charter of Health Rights and Responsibilities*, (1999).

1012 NSW Health Care Commissioner s 76; Victoria Health Services Commissioner s 5; Qld Health Rights Commissioner s 7, 9; Tasmania Health Complaints Commissioner s 5; WA Director of Health Review s 7; ACT Commissioner for Health Complaints s 8; NT Commissioner for Health and Community Services Complaints s 9(1).

1013 Vic Health Services Review Council s 12; ACT Health Rights Advisory Council s 61; Qld Health Rights Advisory Council s 40; NT Health and Community Services Complaints Review Committee s 78. In NSW a review function is provided by a Parliamentary Committee on Health Care Complaints Commission s 64.

police for criminal matters or unless it involves a breach of health practitioner statutes.¹⁰¹⁴

This limits the effectiveness of this legislation to promote higher standards of practice. If a CAM practitioner's activities are considered important enough to be subject to this legislation why do they not justify more specific legislation? The embarrassment and inconvenience of a complaint made against a practitioner may not always be sufficient to improve their performance.¹⁰¹⁵ For chiropractors and osteopaths, a complaint may generate grounds for referral to the relevant professional board under the state registration statute.

The history of complaints against CAM practitioners indicates that the level of complaint remains relatively low when compared to registered health professionals.¹⁰¹⁶ In the period 1997-1998 there were 54 complaints in New South Wales about unregulated health professionals associated with¹⁰¹⁷:

- Clinical standards (20)
- Provider/ patient relationships (8)
- Business practices (10)
- Fraud (3)
- Patient rights and professional practice (13)

In Queensland the Health Rights Commission reported 29 complaints against CAM practitioners out of a total of 1768 complaints in the 2001/2002 year.¹⁰¹⁸

1014 Victorian Options, above n 642, 17.

1015 The 1998/1999 Health Care Complaints Commission Annual Report (NSW) recommended that greater power be given to control the activities of unregistered practitioners, above n 636, 55.

1016 Committee on Health Care Complaints, above n 636, 15.

1017 Ibid 55.

1018 Queensland Health Rights Commission, *10th Annual Report 2001-2002*, 10.

It has been acknowledged that the problems of performance by unregistered practitioners was larger than complaint figures may indicate as many complainants may access consumer complaints mechanisms or professional association procedures.¹⁰¹⁹

International Models of Regulation

USA Model

Overview

The USA model of regulation for CAM and OM exhibits many similarities to the position in Australia. There are some important distinctions that provide some guidance as to what is the appropriate model for Australia. In Australia, as in the UK there appears to be a reluctance both to define ‘the practice of medicine’ or to enforce the relevant legislative provisions that proscribe that activity. Regulatory focus is placed on the activity of ‘holding out’ as a medical practitioner or other registered practitioner. All state jurisdictions in the USA. define ‘medical practice’ in their medical practice statutes.¹⁰²⁰ There is a practice of enforcing these provisions against CAM practitioners.¹⁰²¹ Associated with these provisions is the licensing or statutory acknowledgement of a wide variety of CAM practitioners in statutes that define and thereby protect their statutory scope of practice.

Regulation of CAM in the USA.

At state level in the USA the following modalities are regulated:

1019 Committee on Health Care Complaints, above n 636, 18.

1020 Hodgson, above n 629, 650.

1021 Cohen, above n 19, 85.

Acupuncture

Acupuncture is formally regulated in 26 States.¹⁰²² In those states where acupuncture is not statutorily regulated, practitioners of acupuncture run the risk of being deemed to be involved in the practice of medicine. Regulation is by licence in 16 states; three states provide for registration of practitioners while 5 states issue certificates. There appears to be little difference in the administrative arrangements between these forms of regulation.¹⁰²³ OM control is maintained in some states as the practice of acupuncture requires supervision by a licensed physician¹⁰²⁴ or referral from a physician after assessment.¹⁰²⁵ In some jurisdictions other practitioners such as medical doctors; chiropractors and naturopaths are eligible to practice acupuncture.¹⁰²⁶

Homoeopathy

Homoeopathy is formally regulated in only 3 states. Homoeopathy practice acts currently exist in Arizona, Connecticut and Nevada. Practitioners are licensed in all three states with an independent board established in Arizona and Nevada. Nevada requires homeopaths to have a medical degree.¹⁰²⁷ Although only three states specifically regulate homoeopathy, in a number of states it is considered part of the scope of practice of health professionals such as naturopaths and osteopaths.¹⁰²⁸

Massage therapy

1022 DM Sale, *Overview of Legislative Development Concerning Alternative Health Care in the United States* 5.

1023 Ibid 6.

1024 La Rev Stat 37: 1358 ; Ibid 6.

1025 NJ Stat 45: 2 C-5.

1026 Sale, above n 1022, 6.

1027 Ibid 9.

1028 Eg Alaska Stat. 08.45.2000(3) - Naturopathy includes homoeopathic remedies ; Wash Rev Code Ann 18.36A.040.

Massage therapy is regulated in twenty states. In a number of jurisdictions local authorities regulate massage therapy. Most states specify that the permitted modality includes the manipulation or treatment of the soft or superficial tissues or muscles of the body by mechanical or manual means.¹⁰²⁹ In most states where massage therapy is regulated massage therapists are issued with licences; three require registration and one state issues certificates. Reflexology is regulated in North Dakota; Arkansas and Washington; Florida and Texas by regulation within the definition of massage.¹⁰³⁰

Naturopathy

Naturopathy is regulated in 12 states. In those states where naturopathy does not enjoy statutory protection the practice of naturopathy may constitute the practice of medicine requiring a medical licence or a licence for another health profession where naturopathy is part of the defined scope of practice. As is the nature of the modality the definition of naturopathy when regulated is very broad. Naturopathy is normally defined to include the use of physical agents such as air, water, heat and cold and diathermy; ultrasound; diet; food; food additives etc and in some states the use of acupuncture; natural childbirth; x-rays; and minor surgery.¹⁰³¹ As the scope of practice for naturopaths is so broad it encompasses parts of the scope of practice of other registered providers who are normally specified as exempt from the applicable registration statutes.

The Practice of medicine

1029 Eg Idaho Code Ann 54-704(1)(c) 7; Sale, above n 1022 , 10.

1030 Raymond Beck, 'An Overview of State Alternative Healing Practices Law ' (1996) 2 *Alternative Therapies* 31.

1031 Eg Haw Rev Stat 455-1(1); Sale, above n 1022, 13.

Out of the political foment of the end of the 18th century and early in the 20th century OM was able to marshal its considerable political and economic influence to successfully lobby state legislatures to enact medical registration statutes.¹⁰³² These statutes confirmed the pre-eminence of OM as the arbiter of acceptable medical practice. These medical acts were justified on the ground of the protection of the public against unskilled charlatans when at least part of the reason for their passing was to secure the then insecure professional status of OM by limiting the practice of CAM practitioners.¹⁰³³

The connection between OM and legislative protection was forged in the USA by the preparedness of the U.S. Supreme Court to uphold a state's entitlement to use the police power to regulate health care. This was obtained in the face of arguments that this was a diminution of an unregistered practitioner's entitlement to earn an income.¹⁰³⁴

In *State of Nebraska v Hinze*¹⁰³⁵ a licenced pharmacist was convicted of practicing medicine without a licence by holding seminars where he introduced himself as a doctor and provided information about homoeopathic and naturopathic remedies. The pharmacist's argument that the statute under which he was convicted infringed his freedom of speech foundered on what the court considered was the legitimate interest of the state in regulating the health and welfare of its citizens.¹⁰³⁶

Medical licensing statutes define the practice of medicine widely but 'all states include some of the following':¹⁰³⁷

1032 Cohen, above n 11, 16.

1033 Ibid 24.

1034 *Dent v West Virginia*, 129 U.S. 114 (1888); Ibid 24.

1035 232 Neb 550 (1989).

1036 Cohen, above n 11, 25.

1037 Ibid 26.

- '(1) diagnosing, preventing, treating, and curing disease;
- (2) holding oneself out to the public as able to perform the above;
- (3) intending to receive a gift, fee, or compensation for the above;
- (4) attaching such titles as M.D. to one's name;
- (5) maintaining an office for reception, examination, and treatment ;
- (6) performing surgery ; and
- (7) using, administering, or prescribing drugs or medicinal preparations.'

New York defines the practice of medicine very expansively as 'diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity or physical condition.'¹⁰³⁸ These provisions reflect the Australian provisions to the extent that reference is made to 'holding out' offences including the use of terms such as 'M.D' and to the inclusion of surgery as the practice of medicine. The contrast is the attempt made in these provisions to broadly define the practice of medicine.

These very broad but precisely defined USA definitions of the practice of medicine suggests that any CAM practitioner who does not have a medical licence is at risk of being deemed to be practicing medicine unless they are protected by their own health practitioner statute.

Scope of Practice Issues

The vulnerability for unregistered practitioners in the USA is accentuated on two counts: Firstly, the practice of medicine is so carefully and broadly defined in virtually all states and it appears there is the legislative and administrative will to enforce these provisions.¹⁰³⁹

1038 Ibid.

1039 Rian, above n 54, 195.

Secondly, there are many more OM and CAM health practitioner statutes such that the unlicensed health professional can easily transgress scope of practice provisions of other CAM practitioners.

Court decisions in the USA suggest that greater attention is given to prosecuting for the unlicensed practice of medicine than is evident in Australia. This means if a registered practitioner, such as a chiropractor, moves outside their defined scope of practice then they will be at risk of prosecution by a medical board.¹⁰⁴⁰

USA – the case of chiropractic

Early Legal History

The role of the courts in enforcing the scope of practice of chiropractors provides an insight into that profession's historic conflict with OM and exemplifies some of the difficulties with the USA form of regulatory control.

The history of the development of case law relative to chiropractic and other healing modalities in the USA has witnessed a progression from non-acceptance to comparative accommodation. In the early years of the 20th century with no legislative protection chiropractors were prosecuted for practicing medicine in large numbers.¹⁰⁴¹ One court when dealing with an argument by a chiropractor that the practice of medicine legislation under which she had been convicted was unconstitutional stated that:

To call the method of treatment 'chiropractic' and the treatments given 'adjustments' does not change its nature. If the practice has any beneficial purpose at all its purpose is to heal the sick

1040 Cohen, above n 11, 49.

1041 Eg *The State of Washington v Matilda Greiner*, 63 Wash 46; 114 P. 897 (1911).

and afflicted, and to regulate the practice of healing the sick and afflicted is unquestionably with the acknowledged powers of the state.¹⁰⁴²

The prosecution of chiropractors for the unlawful practice of medicine became redundant as states passed chiropractic registration legislation. The primary legal issue was then whether a chiropractor had acted outside his/her scope of practice.

Did acupuncture constitute the practice of medicine?

One issue that arose was whether a chiropractor was entitled to use acupuncture as part of their practice. Acupuncture was usually viewed as involving the practice of medicine until legislative acknowledgement for this practice was granted.¹⁰⁴³ Acupuncture was considered to involve surgery through the use of acupuncture needles to pierce the skin. A chiropractor entitled by statute to practice chiropractic was often deemed to practice medicine if he or she applied acupuncture. This approach suggests a strict application of professional registration statutes such that an activity outside the approved chiropractic scope of practice involving attention to a person's ailments constituted the practice of medicine.¹⁰⁴⁴ The provision of acupressure, which involved the application of external pressure on acupuncture points without piercing the skin was deemed not to be surgery and thereby did not constitute the practice of medicine.¹⁰⁴⁵

Dispensing Drugs

Chiropractors are not entitled to dispense drugs as part of the practice of chiropractic. In the *Raguckas* case the Court of Appeal for Michigan rejected an argument that the statute under

1042 Ibid 49.

1043 J.N. Benedict, Albert J Pirro and J R Pisani, "Acupuncture: The Practice of Medicine?" (1974) 38 *Albany Law Review* 633-690.

1044 *The State of Ohio v Rich*, 44 Ohio St. 2d 195; 339 N.E. 2d 630 (1975); *State of Oregon v W. Sam Won*, 19 Ore App 580 (1974) 528 P.2d 594 (1974); *Attorney General v Raguckas*, 84 Mich. App 618 (1978). 270 N.W. 2d 665.

consideration, that permitted ‘procedures preparatory to’ manipulation, permitted the prescription of drugs.¹⁰⁴⁶ The court considered ‘A logical extension of this argument would allow chiropractors to do anything as long as it was somehow ‘preparatory to’ the manual adjustment of spinal vertebrae.’¹⁰⁴⁷

Dietary Advice

Many chiropractic statutes allow chiropractors to give dietary advice without being deemed to be involved in the practice of medicine. This has been distinguished from the prescribing of vitamins for the treatment of disease.¹⁰⁴⁸ In *Beno* chiropractors were deemed entitled to prescribe vitamins or food supplements if part of a program to correct a subluxation or misalignment of the spine though this excluded prescribing of drugs and medicines.¹⁰⁴⁹

Diagnosis

It has been acknowledged that chiropractors as part of their practice are obliged to use a type of diagnosis to properly perform their function.¹⁰⁵⁰ The question is whether that diagnosis trespasses into the area of medical diagnosis thereby potentially creating liability for the unauthorised practice of medicine.

The Supreme Court of Michigan in *Attorney General, On Behalf of the People of Michigan v James J Beno*¹⁰⁵¹ provided a progressive approach to this issue. This authority confirmed that merely because an activity was beyond the statutory scope of practice of a chiropractor did

1045 *In the Matter of M. Ross Stockwell v Washington State Chiropractic Disciplinary Board*, 28 Wn. App 295 622 P. 2d 910 (1981).

1046 Raguckas, above n 1044, 624.

1047 *Ibid.*

1048 Stockwell, above n 1045, 301; *State v Wilson* 11 Wn. App.916, 528 P.2d 279 (1974).

1049 Based upon s16401 of The Public Health Code Michigan, *Attorney General On Behalf of the People of Michigan v James J Beno* 422 Mich.293; 373 N.W. 2d 544 (1985).

1050 *Raguckas*, above n 1044, 627.

1051 *Beno*, above n 1049.

not indicate that an illegality had occurred. What must be shown was that this activity also breached the provisions of another statute such as a medical practice act so as to constitute the non-licensed practice of medicine.¹⁰⁵² This conforms to the broader interpretation of the professional registration statutes suggested in the Australian decisions discussed above. The breadth of this approach found in *Benio* is reduced by their suggestion that the scope of practice of limited professions should be construed strictly.

The court states:

Where there are hazy lines between the jurisdiction of health-care professions, we think the public health and safety is best protected by more strictly construing the jurisdiction of the more specialized and limited health profession in favor of the more comprehensively trained and licenced profession. It would seem to be more in keeping with public protection to have the broader discipline making diagnostic observations about those things within the specialities of the narrower discipline, rather than vice versa.¹⁰⁵³

Based upon their interpretation of the relevant chiropractic statute *The Public Health Code*

1978 PA 368 the court held that chiropractors were entitled to use x-rays of the spine.

Chiropractors could diagnose subluxations or misalignments but were not entitled to x-ray other parts of the body to rule out causes in other parts of the body not related to spinal misalignment. They also considered that chiropractic did not include an entitlement to order medical pathology tests, as this would take the practice outside the scope of practice in the statute.¹⁰⁵⁴

By limiting the testing and investigations that could be made by a chiropractor this may not permit chiropractors to act fully for the benefit of their patient. It is consistent with the view that chiropractors are trained to deal with spinal matters and if a malady does not respond to is outside their scope of practice they should refer to an OM doctor.

¹⁰⁵² Ibid 303.

¹⁰⁵³ Ibid 312.

Other practitioners

For non-chiropractic practitioners or osteopaths, professional registration issues also involve the determination of whether the practitioner has indulged in activities that constitute the practice of medicine. The authorities suggest a somewhat strict approach to the interpretation of medical practice legislation. This interpretation is justified on the basis of what is perceived as the public interest that overrides the personal liberty of patients to choose a modality of choice and for the practitioner to earn a living.¹⁰⁵⁵

In *State of Nebraska, Department of Health v John Hinze*¹⁰⁵⁶ the court enjoined Hinze who was said to have practiced medicine by:

- holding out as a ‘Dr’ (he had a doctorate in pharmacy); and
- providing advice for naturopathic and homoeopathic remedies; and
- selling remedies.

Any infringement of Hinze’s freedom of speech was outweighed by the public interest in avoiding the practice of medicine by untrained persons.¹⁰⁵⁷ Similar sentiments have been expressed in other cases.¹⁰⁵⁸

In *State of North Carolina v F. Belle Howard and J.C. Howard*¹⁰⁵⁹ a naturopath treated a patient with terminal pancreatic cancer by applying Herbal Tumor Removal (HTR) involving application of two salves to the skin in the vicinity of the cancer. The naturopath also used the

1054 Ibid 326.

1055 Rian, above n 54, 196.

1056 Hinze, above n 1035.

1057 Ibid 557.

1058 Iridologist and naturopath in *State of North Carolina v Joseph Nelson*, 317 S.E.2d 711 (1984); A nutritionist (using designation of Dr) in *Carey A Reams v State of Florida*, 279 So. 2d 839 (1973).

term ‘dr’, used medical equipment and told the client not to attend hospital. The court rejected an argument that the naturopath had done nothing wrong as the substances used or books on self-cures for cancer could be purchased at a health store. They distinguished between merchants that sold publications and the defendant who diagnosed and offered a remedy specifically designed for an individual.¹⁰⁶⁰ The court did not find a constitutional right for terminally ill to choose unorthodox treatment as this would undermine public interest in protection of public health and safety.¹⁰⁶¹

A homoeopath in *Roget. I Sabastier v State of Florida*¹⁰⁶² was considered to have practiced medicine based upon the need to protect the public from unsafe practice. The argument that the statute discriminated against non-allopathic therapists was not supported, as there was no evidence of why this choice had been made by the legislature.¹⁰⁶³ The court noted the expressed intention of the statute:¹⁰⁶⁴

The Legislature recognizes that the practice of medicine is potentially dangerous to the public if conducted by unsafe and incompetent practitioners. The Legislature finds further that it is difficult for the public to make an informed choice when selecting a physician and that the consequences of a wrong decision could seriously harm the public health and safety. The sole legislative purpose in enacting this chapter is to ensure that every physician practicing in this state meets the minimum requirements for safe practice. It is the legislative intent that physicians who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

In *The People of the State of New York v Reuben Amber*¹⁰⁶⁵ the practice of acupuncture was deemed the practice of medicine. This finding was made even though the practice involved a specific and distinct type of assessment based upon the principles of TCM as it required a diagnosis and treatment within the terms of the medical practice statute.

1059 78 N.C. App. 262; 337 S.E. 2d 598 (1985).

1060 Ibid 267.

1061 Ibid 269.

1062 504 So.2d 45(1987).

1063 ibid 46.

1064 s 458.301 Purpose; Ibid 46.

1065 349 N.Y.S. 2d 604 (1973).

A healer Janice Stetina who provided advice on nutrition was charged with the unlicensed practice of medicine.¹⁰⁶⁶ Stetina argued that the purpose of the *Medical Practice Act* was to protect against a person's own credulity. in accordance with and the application of the act to her did nothing to assist her educational role.

The Court stated:

The purpose of the *Medical Practice Act* is to protect people. It is not, however, solely designed to protect people in a vulnerable position from gullibility in medical matters. The Act's scope is broader—it protects people generally in their relationships with professionals to whom they entrust medical judgements. That protection does include protection against charlatans, quacks and frauds. Yet the regulatory scheme also protects against those well-intentioned and skilled practices which simply exceed the scope of acceptable health care. Consequently, one need not violate or seek to violate the patient trust to come within the intent and words of the *Medical Practice Act*'s prohibitions.¹⁰⁶⁷

The Court noted the difference between the ability to purchase vitamins and other dietary supplements through a store, which was permitted, and the prescription of such substances to cure an ailment or disease for compensation that was permitted only with the protection of registered practitioners.¹⁰⁶⁸ The principles applied here appear more directed to protecting medical practice than promoting public health. Here the practice involved advice on general health matters and there appears little purpose in unduly limiting its expression. The clear public detriment by this practice is not readily evident here.

General Comments

The scope of practice provisions in the USA and to a lesser extent in Australia suggest that:

1066 *Janice R Stetina v State of Indiana ex rel Medical Licensing Board of Indiana*, 513 N.E. 2d 1234 (1987).

1067 *Ibid* 1238.

1068 *Ibid* 1240.

the enterprise of healing can be carved into neatly severable and licensable blocks. Provisions defining a scope of practice, however, is inherently reductionist and problematic. For example, chiropractors are understood (as in Beno) to address only spinal problems, psychologists to address only emotional issues, massage therapists to address only musculoskeletal issues, and physicians to address only physiological and biochemical dysfunction, as if these various aspects of the human organism are disconnected rather than unified.¹⁰⁶⁹

It is difficult to fit a holistic approach to healing within this statutory regime as this practice does not normally differentiate between the physical, mental, emotional and spiritual. CAM does not limit the practitioner to particular parts of the body.

Cohen suggests that scope of practice provisions might be better drawn by specifying what providers may not do, such as massage therapists cannot manipulate rather than specifying a broad scope of practice which inevitably creates a fuzzy lines between what is or is not permitted activity.¹⁰⁷⁰ This was the approach favoured by Queensland Health in a *Review of Medical and Health Practitioner Registration Acts*.¹⁰⁷¹ This view was not reflected in the legislation subsequently enacted. Cohen suggests that CAM practitioners who do not hold out a biomedicine approach to healing and whose aim is to seek to nourish the system and to stimulate a person's own healing response should be seen as outside the biomedicine regulatory structure relying instead on tort liability for regulatory control.¹⁰⁷²

The regulatory structure in the USA reflects a gradual acceptance of the role of CAM that is much more developed than in most parts of the western world. This is reflected in the number of CAM practitioner regulation statutes and in recent years the expansion of this statutory acknowledgement to modalities such as Alexander technique¹⁰⁷³ and feldenkraais. Reflexology

1069 Cohen, above n 19, 109.

¹⁰⁷⁰ Ibid

1071 Queensland Health, above n 862, 56.

1072 Cohen, above n 19, 110.

1073 Del. Code Ann.tit.24 5306(1) (Supp 1992).

and rolfing are acknowledged as part of bodywork or massage therapies in a number of states.¹⁰⁷⁴

The USA regulatory structure favors the registered CAM modalities as they are provided with some certainty in relation to their scope of practice and protection from scrutiny while practicing within that scope of practice. The consumer can assume that the registered health professional has a minimum level of training and education and are subject to specified ethical precepts.

One difficulty with this structure is its cost based on the required bureaucracy and quality control measures that must be borne by the consumer or government. The limitations placed on practice outside the various statutory scope of practice provisions, inevitably reduces competition thus increasing the cost to consumers.

For the unregistered professional who has not yet obtained the endorsement of statutory regulation, whether because of a lack of political influence; evidence of efficacy; public support or the availability of quality education in the discipline, their practice is restricted and subject to proactive legislative enforcement. The flip side to the provision of a large number of registered professions is the restriction on unregistered practice. This does not support the development of new and creative ways of dealing with the provision of health services nor respect the autonomy of consumers in choosing non-conventional health practices.

Canada

1074 Eg reflexology – North Dakota N.D. Cent Code 43-4941 to 43-49-13.

Overview

Canada shares a number of features with the USA regulatory structure. Courts in Canada have often been asked to adjudicate upon the question of whether a CAM practitioner has breached medical practice statutes. These statutes normally deem the practice of medicine by other than a registered medical practitioner as an offence. As in the USA the statutes provide a very broad definition of the practice of medicine.

By contrast Canadian courts are more likely to consider the primary intent of professional regulation statutes is the protection of a professional monopoly rather than the protection of the public. This provides support for a narrow interpretation of the statute. This approach is not effective to save CAM practitioners when they clearly venture onto the territory of medical practice.

Case Law

In *College of Physicians and Surgeons v Lesage*¹⁰⁷⁵ a chiropractor was convicted of the unregistered practice of medicine after manipulating a client's back. At that time chiropractors did not enjoy registered status. Today that activity would be uncontroversial. The case is significant for its rejection of the argument that liability for the practice of medicine occurs only when the practitioner is using techniques used and recognized by the medical profession. Judge Guerin J Sess considered:

To accept (the) defendant's theory, it would have to be admitted that even the most injurious treatment of sick persons would not be prohibited because that treatment would be foreign to medical science; this would be ignoring the purpose of the *Medical Act* which was enacted to protect the public health.¹⁰⁷⁶

1075 (1943) 80 CCC 139.
1076 Ibid 149.

The most liberal interpretation of the medical practice legislation came in the decision of *Regina v Wong*.¹⁰⁷⁷ In that case a charge was brought against an acupuncturist who was said to have practiced medicine by diagnosing rheumatoid arthritis and applying acupuncture to assist in healing this affliction. Important in the court's considerations was the question of whether the *Medical Profession Act 1975* (A) was passed to protect the public interest or to protect OM monopoly against competition. If the latter was the purpose of the statute a narrower interpretation of the practice of medicine could be appropriate.

Judge Stevenson in this case preferred the minority decision of Garrow J in *Re Ontario Medical Act*.¹⁰⁷⁸ Garrow J was of the view the purpose of these statutes was 'to organize the profession of medicine, and to create an examining and licensing body, and to prohibit the unlicensed from practicing in competition with the licensed, and whatever protection the public receives comes incidentally.'¹⁰⁷⁹

Also important in his considerations was the approach taken by the court in *Laporte v College Des Pharmaciens de la Province de Quebec*.¹⁰⁸⁰ Here the court held that when dealing with:

The statutes creating these professional monopolies, sanctioned by law, access to which is controlled and which protect their members in good standing who meet the required conditions against any competition, must however be strictly applied. Anything which is not clearly prohibited may be done with impunity by anyone not a member of these closed associations.¹⁰⁸¹

By interpreting the medical practice legislation narrowly, Stevenson J in *Regina v Wong* was able to conclude that:

1077 (1980) 50 CCC (2d) 162.

1078 (1906) 13 O.L.R 501.

1079 Ibid 511; Richards J in referring to this case doubted if this principle would apply to the *Medical Practice Act* under consideration in that case *Mayo v Harris* (1945) SASR 151, 157.

1080 58 D.L.R. (3d) 555.

The thing practiced must, to be illegal, be an invasion of similar things taught and practiced by the regular practitioner, otherwise it does not affect his monopoly, and is outside the statute. And it must be practiced as the regular practitioner would do it - that is, for gain, and after diagnosis and advice. And it must be more than a mere isolated instance, which is insufficient to prove a 'practice.'¹⁰⁸²

In *Regina v Wong* the provision of acupuncture was deemed not to be the practice of medicine. This conclusion was based on the strict interpretation of the medical practice legislation in this case and the fact that acupuncture was at that time not recognized as a branch of medicine nor taught as an approved course at any medical schools.¹⁰⁸³

The progression of authority since this case has been to limit this authority to its facts though on most occasions a narrow interpretation of the medical practice legislation was endorsed.

In *R v Harbakhsh Singh Sandhar*¹⁰⁸⁴ a man purporting to practice homoeopathy examined a patient and stated she had lung congestion and kidney inflammation. Despite the courts acceptance of the need to interpret such statutes narrowly based upon the principles in *Laporte* the court could not find any interpretation which would exculpate the practitioner's acts from liability. The argument that the practitioner did not use standard OM techniques and therefore was not practicing medicine was rejected on the basis the type of diagnosis given was within the province of OM.¹⁰⁸⁵

This viewpoint is confirmed by the decision of *R v Kish*.¹⁰⁸⁶ Here the charges related to the practice of medicine by the application of hydrogen peroxide to a patient for the purpose of treating what was inoperable lung cancer. This treatment was provided by persons who held

1081 Ibid 556.

1082 *Wong*, above n 1077, 169.

1083 Ibid 170.

1084 (1988) 86 A.R. 24.

1085 Ibid 242.

1086 (1993) W.C.B.J. 17010; 20 W.C.B. (2d) 309.

themselves out as ‘physiotherapists,’ but their qualifications were not obtained from an acknowledged institution. The court rejected the view expressed in some cases that the purpose of the relevant statute was to protect the monopoly of the medical profession. The court considered that the accused had suggested treatment for cancer and this activity was the practice of medicine as defined.

Interestingly, the court also rejected the argument that the British ‘Herbalist Charter’ still had force in Canada and this permitted the accused activities. The court concluded the *Medical Professions Act* repealed the *Herbalist Charter* and made it inapplicable and in any event the *Herbalist Charter* not cover this type of treatment.¹⁰⁸⁷

Ontario

The statutory regulatory system in Canada differs substantially between the different provinces but generally resembles the USA model with some significant differences. This discussion will deal with the statutory scheme in two provinces namely Ontario and British Columbia.

Ontario has an omnibus statute called the *Regulated Health Professions Act 1991(O)(RHPA)* that deals with the health professions listed in Schedule 1. Schedule 1 includes a long list of regulated health professions including:

- Audiology and speech language pathology.
- Chiropody.
- Chiropractic.

¹⁰⁸⁷ Refer also to *R v Windrum* (1994) W.C.B.J 18651; 25 W.C.B (2d) 497(1994).

- Dental hygiene.
- Dentistry.
- Dietetics.
- Massage Therapy.
- Medicine.
- Nursing.
- Physiotherapy.

The statute establishes individual Colleges. These colleges have the role of administering the registration of qualified practitioners and the provision of health services by the profession generally, including ethical requirements.

This scheme is striking in that it regulates a long list of professions previously unregulated and places all health professions under a similar legislative template with some significant exceptions.¹⁰⁸⁸ Naturopaths are not regulated by the RHPA but by the *Drugless Practitioners Act 1990 (O)* as natural healing methods made the articulation of common standards of practice difficult.¹⁰⁸⁹

The RHPA regulates both the practitioners and the professional practice.¹⁰⁹⁰ Each regulated profession also has a separate statute that should be read with the RHPA or in some cases a statute that includes other professions such as osteopaths and physicians under the *Medicine Act (O)*.¹⁰⁹¹

1088 Canadian Overview, above n 10, 8-9.

1089 Ibid 56.

1090 Bohnen, above n 828, 1.

1091 Ibid, 10.

These modality specific statutes define a scope of practice and any authorized acts of that profession.¹⁰⁹² It should be noted the statutory scope of practice provisions constitute a description of professional activities and does not provide (as was the case with the repealed legislation) an exclusive right to provide those services.¹⁰⁹³ This scope of practice provides a frame of reference or context for the performance of their authorized ‘controlled acts.’¹⁰⁹⁴

Controlled Acts

The heart of the professional regulation model is found in s27 of the RHPA. Section 27 specifically defines 13 ‘controlled acts.’ It is an offence for a person to perform a controlled act in the course of providing health services to an individual unless that person is authorized to do so by a health profession act, or the performance of the controlled act has been delegated to the person by an authorized person.¹⁰⁹⁵

The controlled acts are in summary:

- Communicating a diagnosis identifying a disease or disorder in the circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
- Performing a procedure on tissue below the dermis; mucous membrane; cornea or teeth.
- Setting or casting a fracture of a bone or dislocation.
- Moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
- Administering a substance by injection or inhalation.

1092 Ibid.

1093 Ibid 22.

1094 Ibid.

1095 s 40.

- Putting an instrument, hand or finger beyond specific orifices including external ear canal; anal verge and labia majora.
- Applying a form of energy prescribed by regulation.
- Prescribing, dispensing, selling or compounding controlled drugs.
- Prescribing or dispensing for vision or eye problems.
- Prescribing hearing aids.
- Fitting or dispensing dental prosthesis or orthodontic appliances.
- Managing labour or conducting the delivery of a baby.
- Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.

Section 29 RHPA contains a number of exemptions from s 27 covering first aid; treating a person by prayer or spiritual means in accordance with the tenets of the religion of the person giving the treatment, and certain acts done to a member of the person's household.

The individual professional registration statutes then specify which controlled acts can be performed by the registered health professional. Medical doctors are permitted to perform all controlled acts except for the provision of dental devices.¹⁰⁹⁶

Chiropractic is defined in s 3 of the *Chiropractic Act 1991 (O)* as 'the assessment of conditions related to the spine, nervous system and joints and the diagnosis, prevention and treatment, primarily by adjustment, of:

- dysfunctions or disorders arising from the structures or functions of the spine and the effects of those dysfunctions or disorders on the nervous system; and

- dysfunctions or disorders arising from the structures or functions of the joints of the extremities.

Chiropractors are authorized to communicate a chiropractic diagnosis; moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust and putting a finger beyond the anal verge for the purpose of manipulating the tailbone.¹⁰⁹⁷

Massage therapy is defined broadly in s3 of the *Massage Therapy Act 1991* (O) to be 'the assessment of the soft tissue and joints of the body and the treatment and prevention of physical dysfunction and pain of the soft tissues and joints by manipulation to develop, maintain, rehabilitate or augment physical function, or relieve pain.'

There is no specified controlled acts that can be performed by massage therapists. This suggests that the mention of the term 'manipulation' would not include the controlled act of moving the joints of the spine beyond the individuals usual physiological range of motion using a fast, low amplitude thrust.

Physiotherapy is defined somewhat similarly in s 3 *Physiotherapy Act 1991* as 'the assessment of physical function and the treatment, rehabilitation and prevention of physical dysfunction, injury or pain, to develop, maintain, rehabilitate or augment function or to

1096 *Medicine Act 1991* (O) s 4.9; Section 5.1 deems it not misconduct or incompetence solely on the basis therapy is non traditional departs from prevailing medical practice unless evidence it provides a greater risk to a patients health.

1097 *Chiropractic Act 1991* (O) s 4.

relieve pain.’ Physiotherapists are authorized to perform the controlled act of moving joints beyond a person’s usual physiological range of motion and tracheal suctioning.¹⁰⁹⁸

Harm Clause

Some health professions expressed concerns that the controlled acts regime could be circumscribed by unregulated healers by acts that might not exactly come within the definition of a controlled act. As a response to this concern section 30(1) RHHP provides that no person other than a regulated health professional within his or her scope of practice is permitted to treat or advise a person with respect to his or her health where it is reasonably foreseeable that serious physical harm may result.¹⁰⁹⁹

Procedural Codes (RHPA)

Each health profession act is deemed to include a Health Professions Procedural Code found in Schedule 2 of the RHPA. This code establishes Colleges as the administering bodies for the various professions providing for complaints against practitioners; procedures to deal with sexual misconduct and disciplinary matters.¹¹⁰⁰

Purpose of RHPA

The RHPA has some arguably contradictory purposes. In line with previous legislation an important legislative goal is the protection of consumers. The other legislative purposes are to avoid unnecessary costs of regulation (both direct or indirect), to maximize consumer freedom of choice, improve the opportunity for the evolution of roles played by health professionals and to permit more creative use of health professional’s expertise.¹¹⁰¹ By

1098 *Physiotherapy Act 1991*(O) s 4.

1099 Bohnen, above n 828, 26.

1100 *Ibid* 9.

1101 *Ibid* 1.

applying this regime across the whole gamut of health professionals it is hoped this would result in ‘a more efficient, more egalitarian and less costly health care delivery system.’¹¹⁰²

Some doubt if the laudatory aim of the protection of the public can be achieved when the scheme is administered by the relevant profession and is funded by member fees.¹¹⁰³

In simplest terms, the contradiction is between regulation in order to protect patients from quacks and incompetents, and deregulation in order to restore a competitive market in health services. Historically, most governments have opted for public protection at the expense of competition. With the RHPA, the Ontario government aimed to have both.¹¹⁰⁴

British Columbia

British Columbia regulates health professions through the *Health Professions Act 1996* (RSBC) (HPA). ‘Health Profession ‘ is defined very broadly to include ‘a profession in which a person exercises skill or judgment or provides a service related to: a the preservation or improvement of the health of individuals, or b the treatment or care of individuals who are injured, sick, disabled or infirm.’¹¹⁰⁵ This could cover all CAM and OM professions. Designated health professions are prescribed by regulation¹¹⁰⁶ and includes OM; physiotherapy; chiropractic; podiatry; acupuncture; naturopathy; massage therapy.

The practice of medicine or an offer to practice medicine is confined to registered medical doctors.¹¹⁰⁷

The practice of medicine is defined s 81(2) to include:

1102 Ibid 2.

1103 Canadian Overview, above n 10, 12.

1104 Bohnen, above n 828, 2.

1105 Section 1.

1106 HPA s 12.

1107 *Medical Practitioners Act 1996* (BC) s 81.

- (a) holding out or implying one can diagnose prescribe for or prevent or treat any human disease, ailment, deformity, ailment, or to perform and operation to remedy a human disease or providing such a diagnosis
- (b) prescribing a drug; serum, medicine or a substance for the cure, treatment or prevention of a human disease, ailment or defect etc.
- (c) administers a treatment; performs surgery; midwifery or manipulation.

Exceptions to this provision contained in s 82 relate to the practice of registered professions such as chiropractors; dentists; podiatry and designated health professions under the *HPA*.

Physical therapists are designated under the *Physical Therapists Regulation* of the HPA. This regulation preserves for these practitioners titles including ‘physical therapist’ and ‘physiotherapist.’¹¹⁰⁸ Physiotherapists only are permitted to practice the defined practice of physiotherapy subject to section 14 of the HPA that allows others to perform similar tasks if permitted by legislation or regulation ie Medical doctors under the *Medical Practitioners Act 1996* (BC). Physiotherapists are not entitled to prescribe or administer drugs or anesthetics or treat a recent fracture of a bone except under the direction of a medical practitioner.¹¹⁰⁹

Naturopaths are designated health professionals in British Columbia under the *Naturopathic Physicians Regulation* of the HPA. ‘Naturopathic medicine means the art of healing by natural methods or therapeutics, including the first aid treatment of minor cuts, abrasion and contusions, bandaging, taking of blood samples, and the prescribing or administering or authorized preparations and medicines.’¹¹¹⁰

1108 r 3.

This regulation preserves for naturopaths the use of titles including ‘naturopath’ ‘naturopathic physician’ and ‘drugless physician’. Naturopaths can use the title ‘Dr’ but only when reference to naturopathy is used ie Dr of Naturopathic Medicine. No one other than a registrant may practice naturopathic medicine unless permitted by another statute or regulation.¹¹¹¹ Naturopaths cannot prescribe or administer drugs for internal or external use; use or administer anesthetic or practice surgery.¹¹¹²

Massage Therapists are permitted to practice under the *Massage Therapists Regulation* of the HPA. The definition of massage therapy is broad but does not include any form of medical electricity. This regulation preserves for massage therapists titles such as ‘massage therapist’ and ‘registered massage practitioner.’¹¹¹³ Only massage therapists can practice massage therapy unless authorised by another statute or regulation.¹¹¹⁴ Massage therapists cannot prescribe or administer drugs or anesthetic, or treat a recent fracture of a bone.¹¹¹⁵

Acupuncturists are permitted to practice under the *Traditional Chinese Medicine Practitioners and Acupuncturists Regulation*. Acupuncture is defined as:

an act of stimulation, by means of needles, of specific sites on the skin, mucous membranes or subcutaneous tissues of the human body to improve health or alleviate pain, laser acupuncture, magnetic therapy or acupressure and moxibustion (JIU) and suction cup (Ba Guan).¹¹¹⁶

Acupuncturists are entitled to practice acupuncture based upon the traditional Oriental method including:

(a) the use of TCM diagnostic techniques;

1109 r 6.
1110 r 1.
1111 r 5.
1112 r 6.
1113 r 3.
1114 r 5.
1115 r 6.

(b) the administration of manual, mechanical, thermal and electrical stimulation of acupuncture needles; and

(c) the recommendation of dietary guidelines or therapeutic exercise while a TCM practitioner may practice TCM.¹¹¹⁷ Only an acupuncturist or TCM practitioner can insert acupuncture needles under the skin for the purposes of practicing acupuncture unless that practitioner is permitted by some other statute or regulation.¹¹¹⁸

The limited nature of the permission granted by this regulation is found by the limitations on practice outlined in regulation 6. Regulation 6 indicates that:

no acupuncturist or herbalist can treat ‘active serious medical conditions’ unless the client has consulted with a medical practitioner, naturopath, dentist or TCM doctor as appropriate. ‘Active serious medical condition’ is a disabling or life threatening condition that will not improve without intervention.

This would presumably include conditions such as cancer, heart disease, diabetes etc.

The concern for an acupuncturist is the vagueness of this provision. Does this regulation require the client to consult on a specific malady that they then consult the acupuncturist about? This will require the acupuncturist or herbalist to be able to identify a serious medical condition so as to understand the need to have a prior consultation with a MD; naturopath, dentist or TCM doctor. Other features of regulation 6 are:

- A registrant may only administer acupuncture as a surgical anesthesia if a medical practitioner or dentist is physically present and observing the procedure.
- An acupuncturist or herbalist must advise the client to consult a medical practitioner naturopath, dentist or TCM doctor if there is no improvement in the condition for which the client is treated within 2 months of receiving acupuncture treatment.

1116 r 1.
1117 r 4.
1118 r 4.

- If a client does not consult with an MD, naturopath, dentist or TCM doctor the acupuncturist must discontinue treatment if there is no improvement after 4 months from date treatment commenced or the condition worsens or new symptoms develop.

Regulation 6 provides fertile ground for interpretation and potential liability for an acupuncturist. Questions that arise from regulation 6 relate to issues such as:

- how does one define improvement or worsenment in a condition?
- does any new symptom require discontinance?
- How should a practitioner react to a healing crisis when the patient may seem to become worse before getting better?
- What if a client does not return after 1-2 visits in the first week does this obligation still apply?

The significance of the British Columbia Regulation on TCM and Acupuncture is that it provides both protection of title and scope of practice provisions for acupuncture and TCM. It acknowledges TCM by providing that (subject to the entitlements of other registered practitioners) only a TCM practitioner; acupuncturist or herbalist can make a traditional Chinese medicine diagnosis and only a TCM practitioner or acupuncturist may insert acupuncture needles under the skin. This is broader than the Victorian CMRA that only provides for protection of title.

Conclusion

Currently the regulatory structure in Australia is based upon an approach that exposes CAM to a vague definition of the practice of medicine without acknowledging its role in the

provision of health services. The regulatory structure is the historical deposit of an OM approach to CAM that focussed on the destruction of CAM or its incorporation. The success of OM in grasping the hegemony in the provision of health services has been matched by their influence on policy debate and legislative initiatives derived from that influence. This approach is based on the modernist perspective that only scientific evidence of efficacy and safety should provide the measure of the benefits of a therapy and CAM does not provide this evidence. This has resulted in the neglect of necessary reforms to the regulatory structure. Consumers have few quality indicators and are left to expensive and arguably ineffective remedies should they be subject to negligent or unethical treatment at the hands of an unregistered practitioner. It is time for the regulatory structure to accept that CAM practitioners will be a continuing feature of the health sector and they should be acknowledged appropriately in the regulatory structure.

The level of consumer demand for CAM supports moving to more substantial and effective regulation of CAM. The Ontario reflects a more flexible approach to the regulation of CAM by limiting specified acts that may have public health implications to specified registered practitioners while supporting the quality of education and professional standards of registered CAM practitioners. This allows consumers to access the therapist of their choice without unduly compromising public health considerations. The current regulatory structure does not reflect the public need for access to these therapies and militates against the protection consumers are entitled to expect from the health sector.

If it is accepted that:

- consumers demand access to CAM, and

- that there are significant risks associated with CAM.
- that the current legal regulatory structure provides inadequate proactive protection to consumers.
- the current legal regulatory structure discriminates against the consumers of CAM.
- the current legal regulatory structure does not provide consumer friendly remedies.
- That the regulatory structure restricts unreasonably the free expression of many well trained and educated CAM practitioners of what they are able to achieve as healers and places them in a regulatory twilight zone between the common law and health practitioner registration statutes.
- that Australia lags behind other significant international jurisdictions in relation to what modalities have legislative acknowledgment.

Then the case for increased effective statutory regulation of CAM is strong. The lack of scientific evidence of safety and effectiveness for CAM continues to hinder its progress. If governments are concerned to resolve this issue then the provision of sufficient research funds to overcome that lack of evidence will be necessary.

Chapter 5

Therapeutic Goods Act and the Regulation of Complementary Medicine

Introduction

Even a well-educated health practitioner may endanger a client if they prescribe a herb; vitamin or other substance that is toxic; impure; adulterated or not in conformity with its description. For this reason an effective regulatory structure relevant to complementary medicine (CM) (herbs, vitamins and remedies used by CAM practitioners) must secure the supply of reasonably priced, safe and effective goods without unduly stultifying the industry by applying an overly prescriptive regime. The manufacture and supply of herbal medicine is a large and expanding industry. In Australia the market was estimated at \$1671 million dollar in the year 2000.¹¹¹⁹ The manufacturing, sale and supply of CM medicine in Australia is regulated by the *Therapeutic Goods Act 1989* (Cth) (TGA) and complementary state legislation in two states. The TGA provides a regulatory system that accommodates CAM within the framework of the standard regulatory structure for pharmaceuticals.¹¹²⁰ This regulatory structure primarily impacts on homoeopathy; TCM, herbal medicine and naturopathy as they rely heavily on the prescribing of ingested substance such as herbs, vitamins and remedies.

¹¹¹⁹ MacLennan, Wilson and Taylor, above n 110, 169.

The regulation of CM is a controversial issue for a number of reasons:

- The already high and increasing level of usage of herbs and dietary supplements has meant their manufacture and sale is a lucrative industry. This has impacted upon the fierceness of debate that occurs when reform of regulation is contemplated.
- The manufacture and sale of complementary medicines and their regulation involves a clash of healing paradigms. For many adherents, CM is not simply a pharmacological substance but is imbued with sacred properties that can impact upon energy flows; chi or spiritual dimensions. These perspectives do not always accommodate the mechanistic regulatory regimes imposed on their manufacture and use and can create regulatory dissonance between the public policy objectives and the therapeutic objectives of practitioners.¹¹²¹

History of the TGA

The enactment of the TGA in 1991 provided a national framework to the regulation of therapeutic goods in Australia. This legislation replaced legislation that had its derivation in the *Therapeutic Substances Act 1937* (Cth) and subsequent legislation.¹¹²² Successive statutes have become increasingly complex as the demands of scientific medicine required stricter controls. The TGA was the first national legislation to provide a register of therapeutic substances.¹¹²³ The TGA has been substantially amended since its enactment to incorporate

1120 Commonwealth Government, *Government Response to Recommendations Arising from Therapeutic Goods Administration Review* (1997) 28.

1121 Cohen, above n 15, 107.

1122 *Therapeutic Goods Act 1938* (Cth); *Therapeutic Substances Act 1953* (Cth) and *Therapeutic Goods Act 1966* (Cth).

1123 This was recommended by Parliament of Victoria Social Development Committee, *Inquiry into Alternative Medicine and the Health Food Industry* Vol 1 (1968) 213.

controls over complementary medicines. The Therapeutic Goods Administration is the Commonwealth government organization that administers the legislation.

The Basic Scheme of the TGA

The Type of Goods Covered

Therapeutic goods are goods that are, or are represented as being, for therapeutic use.¹¹²⁴

‘Therapeutic use’ is defined widely in section 3 to include use in preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or influencing, inhibiting or modifying a physiological process in persons. The statute controls the supply, import, export, manufacture and advertising of goods that are, or are represented as likely to be, for therapeutic use. This covers most drugs, herbs and remedies used by complementary medicine practitioners.

Object of Legislation

The objects of the Act include the desire ‘to promote the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere’.¹¹²⁵

The TGA regime reflects a balancing of the policy objectives of:

- Appropriate market access for CM.
- Consumer protection from the potential risks of these substances.

1124 s 3.
1125 s 4.

- Adequate information as to the nature of and efficacy of CM.¹¹²⁶

A national scheme incorporating complementary state legislation was deemed necessary because, under the *Commonwealth Constitution*, the Commonwealth has a limited ability to pass laws on therapeutic goods. The Commonwealth has power to legislate only on the activities of a corporation, related to trade and commerce across state or national borders or in relation to providing pharmaceutical or repatriation benefits or in the territories.¹¹²⁷ State legislation plugs the gaps in the scheme for things done *within* a state. To date, only New South Wales and Victoria have passed complementary legislation.¹¹²⁸

The limited constitutional powers of the Commonwealth impacts on the effectiveness of the legislation. For example, a non-corporate practitioner who prepares a homoeopathic treatment or prescribes a herb in a state other than Victoria or New South Wales is not affected by the TGA so long as the transaction has no international or interstate aspect.¹¹²⁹ This would apply to most transactions of a homoeopath, herbalist or TCM practitioner. For practitioners within New South Wales and Victoria, either the state or Commonwealth legislation will apply to most activities. The National Competition Review of Drugs, Poisons and Controlled Substances legislation recommends all states adopt the TGA model legislation.¹¹³⁰

The TGA attempts to achieve its statutory objectives through:

1126 Government Response, above n 1120, 28.

1127 *Australian Constitution* s 51(i),(xx),(xxiiiA).

1128 *Therapeutic Goods Act 1994* (Vic) and *Poisons and Therapeutic Goods Act 1966* (NSW).

1129 Bensoussan and Myers, above n 77, 236.

1130 Commonwealth of Australia *National Competition Review of Drugs, Poisons and Controlled Substances Legislation*, Final Report Part B, (December 2000), xxii Executive summary.

- the granting and enforcing licences to manufacture incorporating Good Manufacturing Practice (GMP). GMP is designed to ensure manufacturing processes comply with specific requirements for quality and integrity.
- pre-market assessment of products that varies in intensity between listed and registered goods.
- Post-market supervision of outcomes using audits of claims on listed goods; laboratory testing of products and ingredients; audits of GMP compliance, controls on advertising and monitoring of adverse reactions.¹¹³¹

There is a continuing debate about the appropriate level of regulation of CM. Some commentators suggest the need for a pharmaceutical level of evidence of safety and efficacy. This high level of regulation may be difficult to justify as the risk to consumers of CM has been assessed as lower than food at low risk.¹¹³² The low risk categorization no doubt reflects the low level of adverse events associated with CM. The Australian Drug Reactions Advisory Committee (ADRAC) reports 149 adverse events for CM between 1976-1998 against total adverse events for all medicines of 12,000 per annum.¹¹³³

The Role of Complementary Medicines Evaluation Committee

Amendments to the TGA in December 1997 established a Complementary Medicines Evaluation Committee (CMEC) to evaluate and report on the registration or listing of complementary medicines. The CMEC is part of the Office of Complementary Medicines

1131 Dr Fiona Cumming, 'Regulation in Australia – the therapeutic goods model ' (Paper presented at *Natural Futures– Building the Global Network for Natural Medicine Regulation: An International Forum on the regulatory future of phytomedicines, essential oils, nutraceuticals and cosmeceuticals* Conference Proceedings, Ballina New South Wales, 13-14 August 2001) 22.

1132 Val Johanson, 'Industry Challenges in Herbal Safety' (Paper Presented at *Naturally Safe: The Challenge to the Herbal Medicine Industry Conference* , Brisbane, 27-28 June 2002); Fiona Cumming, 'Regulating Complementary Medicines-The TGA Point of View' (2001) 4 *Natural Health Review* 34, 34.

1133 Ibid.

(OCM). OCM focuses on the regulation of complementary health care products.

Complementary medicines are defined as therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and (a) a traditional use; or (b) any other use prescribed in the regulations.¹¹³⁴ Traditional use relates to use of a designated active ingredient that is well documented, or otherwise established according to the accumulated experience of many traditional health care practitioners over an extended period of time; and accords with well-established procedures of preparation, application and dosage.¹¹³⁵ Schedule 14 of the regulations contains a complete list of substances deemed to be a designated active ingredient.

The definition of CM is somewhat limiting as it ties the definition to the ability to demonstrate a ‘traditional use.’ This may mean that substances manufactured using extracts and sophisticated technology may take these substances outside the definition of CM. For example, herbal substances extracted using a crystallization process may be excluded from the definition of CM.¹¹³⁶ This could mean that they will require very expensive Australian Drug Evaluation Committee (ADEC) evaluation as a ‘New Chemical Entity.’ This is not likely to be economically feasible.¹¹³⁷ A new more inclusive definition of CM or prescription of other substances under regulation could deal with this concern.

Standards

Part 2 of the TGA allows the Minister to publish a standard for particular therapeutic goods that sets minimum requirements for matters such as quantity in containers, quality and

1134 s 52 F.

1135 Ibid.

1136 Val Johanson , above n 1132.

1137 Ibid.

manufacturing process. A person must not import, export or supply therapeutic goods if they do not conform with a standard applicable to the goods.¹¹³⁸

Complementary medicine practitioners are not exempted from this provision. Currently, there are no standards for raw Chinese herbs.¹¹³⁹ This means that a person can import or supply raw Chinese herbs without complying with a standard. The lack of standards is a concern in relation to the ability of the TGA to control the quality of CM.

Part 3: Australian Register of Therapeutic Goods

Section 20 prescribes certain offences in relation to therapeutic goods for use in humans. It is an offence to import, export, manufacture or supply therapeutic goods unless they are registered or listed goods *in relation to the person*, are exempt goods, or the TGA otherwise permits. Similar provision in relation to wholesale supply is found in s 21. That means that a party must apply for registration or listing for a specific product and obtain approval from the Therapeutic Goods Administration if it is intended to legally import, export, manufacture or supply the therapeutic good.

Part 3 of the TGA requires the Secretary of the relevant department to establish the Australian Register of Therapeutic Goods (ARTG) for compiling information in relation to therapeutic goods and their evaluation for use in humans. The register contains registered goods and listed goods. The registration or listing of goods requires an application to be made under s 23 and payment of the applicable fee.

¹¹³⁸ s 14.

Registered goods

Registration involves an exhaustive appraisal of the quality, safety and efficacy of the goods for the purpose intended. Registration is necessary for substances considered high risk, and includes all prescription medicines containing ingredients included in schedule 4 or schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons. Some low-risk non-prescription drugs may be registered if it is considered necessary to ensure adequate labeling for safe use. Registered goods are also assessed for presentation, conformity with an applicable standard, and appropriateness of manufacturing process. For complementary medicines, the Complementary Medicines Evaluation Committee provides expertise to the relevant department in relation to registration. Only a handful of complementary medicines are registered.¹¹⁴⁰ Registered products can be recognised by the notation 'AUST R no. xxx' shown on the label.

Listed goods

These are goods with a perceived lower risk, usually self-selected by consumers and used for self-treatment. The ability to list a substance may be restricted when it contains a substance that may have an element of toxicity.¹¹⁴¹ Listing involves assessment of the quality, safety, presentation, manufacturing process and conformity with standards. Listing does not require prior scientific justification of claims made, though a person who has listed goods may be asked to provide evidence of the formulation, composition, methods of manufacture, and

1139 Bensoussan and Myers, above n 77, 236.

1140 AK Drew and SP Myers, 'Safety Issues in Herbal Medicine: Implications for the Health Professions' (1997) 166 *Medical Journal of Australia* 538-541, 539.

1141 David R Briggs, 'Regulatory Challenges: Safety of Herbal Substances' (Paper Presented at *Naturally Safe: The Challenge to the Herbal Medicine Industry Conference*, Brisbane, 27-28 June 2002.)

safety of the goods. The lesser requirements are based on the view that listed goods are generally used for simple self-limiting conditions.¹¹⁴²

This further evidence is rarely requested by the TGA and may only be sought when electronic advertising approval is sought from the Proprietary Medicines Association of Australia.¹¹⁴³

Goods not for export can be listed subject to the applicant certifying as to matters such as safety, presentation, conformity to a standard, and the appropriateness of manufacturing process.¹¹⁴⁴ Most complementary medicines are listed substances. The ‘AUST L. No xxx’ notation on the label identifies listed substances.

Most CAM practitioners will not wish to be involved in listing or registering their own substances and will purchase substances from suppliers who will have obtained either registration or listing for the substance. Thousands of complementary medicines have been listed.¹¹⁴⁵ This form of regulation is very light as it is easy to list a therapeutic good and it appears there are inadequate resources to properly police the evidentiary burden for formulation and safety.

Exemption From the Need to Register or List the Product?

CAM practitioners may be able to take advantage of the substantial exemptions from many provisions of the TGA. Schedule 5 describes therapeutic goods exempt from the operation of part 3 of the TGA, that is, they do not require registration or listing and can be imported, exported, manufactured and supplied either by retail or wholesale. The exemptions likely to be relevant to complementary medicine practitioners include therapeutic goods that are:

1142 KPMG for Department of Health and Family Services, *Review of Therapeutic Goods Administration*, January (1997) 101.

1143 Ibid 53.

1144 s 26A.

- imported for use in the treatment of the importer or the importer's immediate family, as long as they come within the terms of column 1 item 1 of schedule 5;
- homoeopathic preparations.¹¹⁴⁶
 - more dilute than a one thousand fold dilution of a mother tincture, and
 - which are not required to be sterile.
- unless the indications proposed by the sponsor (generally the person who imports, exports or manufacturers the goods) are in the treatment of a serious conditions such as anemia, blindness).¹¹⁴⁷
- starting materials (this term is not defined but would likely include raw Chinese herbs used in the manufacture of therapeutic goods, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form).
- medicines¹¹⁴⁸ that are dispensed or extemporaneously compounded for a particular person for therapeutic application to that person such as herbal substances, homoeopathic preparations (not exempt as above) given to clients or compounded at the time of a consultation.

These very broad exemptions raise concerns about the quality of goods used and in the case of unregistered practitioners the level of training to safely prescribe these substances. These provisions assume their competence when the unregulated state of most of these practitioner's professions means their professional status relies upon self-regulation with little or no statutory control.

1145 Myers and Drew, above n 670, 538.

1146 Defined in regulation 2 as 'a preparation a. formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and b. prepared according to the practices of homoeopathic pharmacy using the methods of 1. Serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or ii serial trituration in lactose.'

1147 Full list in appendix from clause 4 *Therapeutic Goods Advertising Code*.

1148 Defined in *Therapeutic Goods Act 1989* (Cth) s 3.

Manufacturing Part 4

Manufacturing is defined widely in section 3 to include producing goods or engaging in any part of the process of producing the goods or bringing the goods to their final state such as processing, assembling, packaging, labeling, storage, sterilising, testing or releasing for supply. This would include the processes of preparation involved in, for example, the preparation of herbs or the final preparation of homoeopathic medicine for a client from a mother tincture.

Section 35 states that a person must not carry out a step in the manufacture of therapeutic goods unless:

- the goods are exempt, or
- the person is exempt, or
- the person is the holder of a licence that authorises the carrying out of a step in relation to the goods at those premises.

This potentially makes many activities of CAM practitioners an offence of manufacturing without a licence under the TGA. The concern is avoided if either the practitioner or the goods are deemed exempt from the legislation.

Goods Exempt From the Manufacturing Requirements of the TGA

Schedule 7 of the regulations exempts some therapeutic goods from the provisions of part 4.

So far as is relevant for complementary medicine practitioners, this would relate to:

- ingredients, except water, used in the manufacture of therapeutic goods where the ingredients do not have a therapeutic action.

- homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and that are not required to be sterile.

Exempt persons

Of even more importance is schedule 8 of the regulations, which exempts particular persons from the operation of part 4 of the Act. These include herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation, where:

- the preparation is for use in the course of his or her business, and
- the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public, and
- the person carrying on the business supplies the preparation for administration to a particular person after consulting with that person and uses his or her own judgment as to the treatment required.

Accordingly, within the parameters of this exemption, there is no obligation on a practitioner to comply with the requirements of part 4, which requires the obtaining of a licence to manufacture therapeutic goods. Once again this legislation relies upon the activities of unregistered practitioners who are not subject to specific statutory controls.

Labeling and Promotion under the TGA

Therapeutic Goods Order no. 48 contains ‘General Requirements for Labels for Drug Products’. This order sets out many requirements for labeling of drug products that are therapeutic goods. General requirements are set out in regulation 3(1)(e). They include:

- label in English language.
- label in durable and legible characters of not less than 1.5 millimeters.
- particulars of what is in the substance.

Clause 9 provides an exemption for goods ‘made up or compounded extemporaneously for a specific individual in that person’s presence by a practitioner of alternative medicine which includes herbalists, homoeopaths, chiropractors, naturopaths, nutritionists, traditional Chinese medicine practitioners, osteopaths in the lawful practice of their profession’.

These requirements appear to be somewhat vague and limited and not designed to maximize issues of public health protection. A basic requirement for labelling should require in addition indications of dosage (to assist in avoiding over or under use); the name of the consumer (to protect against use by someone other than the person for whom the substance is meant) a date of manufacture and, if appropriate, a use-by date to ensure the continuing integrity of the substance.

More prescriptive provisions will come into force in July 2004 under *Therapeutic Goods Order no 69*. This order will not exempt unregistered CAM practitioners and will require much greater details to be provided on labels for therapeutic goods provided by unregistered CAM practitioners. This detail will include batch number; expiry date and storage conditions.¹¹⁴⁹

¹¹⁴⁹ *Therapeutic Goods Order no 69, General Requirements for labels for medicines* regulation 3.

Issues in Regulation

The TGA imposes a strict regime of controls over therapeutic goods and complementary medicine. Complementary medicines in many countries are regulated as 'food' that disallows medicinal claims to be made. The regulatory structure under the TGA is based upon a model that allows products to be presented to the market and to make claims about the effect of those substances within specified boundaries.¹¹⁵⁰

Cultural Issues

Quite apart from efficacy and safety issues, access to and the use of CM, such as Chinese herbal medicines, is an aspect of the cultural identity of many consumers. A regulatory system sensitive to cultural perspectives should be slow to restrict access to a substance merely because under the Western OM criteria it does not comply with scientific standards of evidence. A perspective not often contemplated is the connection that western culture has to traditional healing through the Anglo-Saxon cultural heritage in herbal medicine.¹¹⁵¹

This point is underlined when it is understood that OM is based upon a philosophy in the same way that Chinese herbal medicine relies on its own distinct healing philosophy. As the western medical tradition is imbedded in the western way of thought it is very easy to assume a position of cultural superiority and condescension when assessing these types of remedies.

1150 Cumming, above n 1131, 21.

1151 Stephen Myers, 'Safety and Efficacy: Finding the Balance' (Paper presented at the *Natural Futures Conference: Building the Global Network for Natural Medicine Regulation Conference Proceedings* Ballina NSW, 13-14 August, 2001) 152.

The nexus between OM and the legislative framework throughout the western world results in an undervaluing of the traditional evidence supporting the safety and efficacy of CM.¹¹⁵²

The OM stance on CM is impacted upon by ethnocentricity about the philosophy of healing and health. A reductionist system is directed to measuring the active ingredient and its specific impact on a human subject. Another healing philosophy may emphasize empiricism and rely upon generations of tradition. To deny this alternative way of understanding the healing process is to deny a person's ability to choose how they are healed. This impacts upon how they express themselves culturally.¹¹⁵³ If a person is not provided with the means to obtain good quality substances prescribed by practitioners who conform to basic educational and ethical guidelines it could be argued the regulatory structure lacks appropriate sensitivity to different models of healing.

Guidelines on Therapeutic Claims for Listed Medicines including Complementary Medicines.

Outline

Most CM are not 'registered' but 'listed' substances. These listed CM are not assessed for safety, quality and efficacy as are registered products but evidence of the indications or claims made by the sponsor should be available if requested.¹¹⁵⁴ For registered goods the intensive investigation of efficacy of the product based upon good quality scientific evidence justifies the ability to make higher-level claims to treat or cure specific diseases or disorders.

1152 Julian Clark, 'The Critical Issues of Regulation from a Consumer and Supplier Perspective', (Paper presented at the *Natural Futures Conference: Building the Global Network for Natural Medicine Regulation Conference Proceedings* Ballina, New South Wales 13-14 August, 2001) 7.

1153 Ibid 4-5.

For listed goods the Therapeutic Goods Administration, ‘Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For non-registrable medicine, including Complementary Medicines, and other Listable medicines)’ (here called ‘Guidelines’) indicate a range of low level health claims that can be made such as health maintenance; health enhancement and symptomatic relief of non-serious conditions.¹¹⁵⁵ These claims may be supported by scientific evidence but can be supported by traditional use. Scientific evidence refers to quantifiable evidence such as human clinical trials; epidemiological evidence and animal studies. The scientific evidence is assessed for quality and relevance to the claim made for the substance.¹¹⁵⁶

The guidelines apply three principles to indications and claims about therapeutic goods:¹¹⁵⁷

- ‘Before claiming an intended use or indication sponsors must hold adequate evidence of support all claims made about a product;
- Claims must be true, valid and not misleading; and
- Claims should not lead to unsafe or inappropriate use of a product.’

These guidelines have been developed by the CMEC to provide parameters for the type of therapeutic claims that can be made and the evidence that should be available to prove these claims. These guidelines may be helpful though not determinative as to what might be considered false and misleading claims about CM under legislation such as the s 52 *Trade Practices Act 1974* (Cth) or for example s 38 *Fair Trading Act 1989* (Qld).

1154 *Therapeutic Goods Act 1989* (Cth) s 31(2).

1155 Therapeutic Goods Administration, ‘Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For non-registerable medicine, including Complementary Medicines, and other Listable medicines)’ October 2001. These guidelines regulate the level of claims that can be made by listed substances 21.

1156 Ibid 10-12. These guidelines have been developed from the National Health and Medical Research Council *Designation of Levels of Evidence* (1999).

1157 Ibid 7.

Policy Considerations

These guidelines are necessary because of a lack of gold standard scientific evidence for the efficacy of most complementary medicines. This must be balanced with government policy that seeks to maximize public access to complementary medicine while satisfying public health considerations. Some OM authorities point to the risks of CM; the documented adverse reactions and call for the same level of assessment of CM as for pharmaceutical substances that require good quality scientific evidence of safety and efficacy.¹¹⁵⁸ The provision of scientific evidence of this type would involve massive expenditure that is currently not available from government and private resources. Most CM substances have been used over many centuries in the public domain and are not patentable. This lack of exclusivity provides little incentive for the costs of compiling pharmaceutical standard evidence for CM products.¹¹⁵⁹ Ernst suggests that this concern does not reflect the huge value of sales of herbal products. He argues the necessary funding for this research could be found by the industry through levying a percentage of profits to be applied to research.¹¹⁶⁰ The lucrative nature of this industry, that was established without scientific evidence, and the risk research may make adverse conclusions about the efficacy and safety of some CM may not encourage the funding of this research by the industry.

In terms of public policy the question is whether it is justifiable to require scientific evidence of the safety and efficacy of CM and thereby restrict the access to these substances or allow access relying on more limited or different evidence with controls on therapeutic claims. It appears the policy of the Federal government is to apply the latter approach to regulation.

1158 M Angell and JP Kassirer, 'Alternative Medicine: the Risk of untested and unregulated remedies' (1998) 339 *New England Journal of Medicine* 839, 841; Jane E Brody, 'Americans Gamble on Herbs as Medicine,' *The New York Times* (New York, USA), 9 February 1999, Section F, 1; KPMG Review of TGA, above n 1142, 58. 1159 Myers, above n 1151, 153; Myers and Drew, above n 670, 4; Ernst, above n 96, 52.

Indications Reliant on Traditional Use

When relying on traditional use over many centuries there may be a tendency to not closely interpret the historical record to understand¹¹⁶¹:

- the cogency of the sources relied upon;
- whether there were any quoted adverse effects and whether these have been ignored in completing the historical record;
- whether the historical record was compiled at a time that the substance was in common use.

The folly in relying uncritically on traditional sources is exemplified by the reliance upon traditional use of tobacco to support its safety.¹¹⁶² These historical sources may be simply copied from earlier sources and lack modern standards of cost/ benefit analysis. These sources may focus on issues of acute toxicity and symptoms and not on long -term effects of toxicity and adverse results. When the average life expectancy was forty one might be less concerned about the potential for cancer in 20 years time from the prescribing of a particular herb.¹¹⁶³ As herbs are in modern times taken in larger amounts than that used historically and for prophylactic purposes, there is now a higher risk of drug-herb interactions. This suggests historical sources should be treated with caution.¹¹⁶⁴

1160 Ernst, *ibid* 51-52.

1161 Crellin and Ania, above n 7, 81.

1162 *Ibid*; Eskinazi, above n 422, 8; Ernst, above n 96, 51.

1163 RJ Huxtable, 'The Myth of Beneficent Nature: The Risks of Herbal Preparations' (1992) 117 *Annals of Internal Medicine* 165-166.

1164 Crellin and Ania, above n 7, 60-77.

The evidence required for particular claims can be either scientific or based upon traditional use.¹¹⁶⁵ The Guidelines indicate that:

Traditional use may infer community knowledge of the existence and application of a substance but does not necessarily carry with it any scientific assessment or scrutiny. For many products and substances there has been little quantifiable scientific research undertaken into their mode of action and effect. Evidence of traditional use may however be used to support claims for therapeutic goods.¹¹⁶⁶

The definition of ‘traditional use’ adopted by the CMEC for the Guidelines is ‘documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose.’¹¹⁶⁷

For therapeutic goods relying on traditional use the therapeutic claims that can be made are categorized into two levels – medium and general – depending to the relative strength of the claim.¹¹⁶⁸ These different levels of claim demand differing levels of evidence in support. Specific approaches have been developed for homoeopathic and aromatherapy products. The guidelines suggest appropriate wording for the claim.

For a medium claim which would include ‘relief from symptoms of a disease’ ‘health enhancement’ or ‘reduction of risk of a disease’ the guidelines suggest the claim should be worded in the following way or using words to this effect¹¹⁶⁹

‘This (tradition) ie Chinese Herbal medicine has been used for (indication) ie asthma’

The evidence required to support this claim requires *two* of either:

- TGA-approved Pharmacopoeia.

1165 Above n 1155, 7.

1166 Ibid 8.

1167 Ibid.

1168 Ibid 14.

1169 Ibid 15.

- TGA-approved Monograph.
- Three independent written histories of use in the classical or traditional medical literature, or
- availability through any country's government public dispensary for the indication claimed.¹¹⁷⁰

Lower level 'General' claims include claims about 'health maintenance'; 'relief of symptoms' or 'claims for traditional syndromes and actions.' The wording of the claim is similar 'This (tradition) ie TCM medicine has been traditionally used for asthma' but the level of evidence to support the claim is only one of the above named sources.¹¹⁷¹ Similar but more specific provision is made for homoeopathy and aromatherapy products.

A number of points made by the guidelines raise issues relevant to the way in which claims should be made:

- Indications or claims based upon traditional or historical use should be substantiated by scientific evidence or presented in a way that consumers appreciate that the sole support for the product is traditional use.
- The indications should avoid the implication the product has been scientifically evaluated for efficacy.
- There may be cases where based upon risk to consumer health or safety a higher level of proof may be required.¹¹⁷²

1170 Ibid 15.

1171 Ibid 16.

1172 Ibid 20.

Reliance on Scientific evidence for claims or indications

If a sponsor of a CM intends to make a 'high level' claims such a substance treats; cures a disease or disorder; prevents a disease, disorder or condition or treats a specifically named vitamin or mineral deficiency this requires a high level of scientific evidence. This normally requires access to randomized controlled trials confirming the claim being made.¹¹⁷³

For medium claims, such as health enhancement, reduction in risk of disease etc evidence from non-randomized studies and multiple time series may be sufficient.¹¹⁷⁴ For general claims, ie health maintenance and relief of symptoms, descriptive studies, case series and texts may be sufficient.

Some serious diseases, disorders or conditions (known as 'registrable diseases' defined on the basis that a substantial body of medical opinion considers it necessary to only be diagnosed and treated by MD's eg cancer or diabetes) can only be the subject of indications or claims if the product is registered thus allowing an evaluation of the product's safety and efficacy.¹¹⁷⁵

Poisons Schedules

In addition to the controls provided by the TGA the provisions of the Poisons Acts in all states and territories restricts the supply of certain substances.¹¹⁷⁶ The National Health and Medical Research Council has published the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) that has been adopted in all states and territories. This standard

1173 Ibid 21.

1174 Ibid 4.

1175 Ibid Table 6.

1176 *Poisons and Drugs Act 1978* (ACT); *Poisons and Therapeutic Goods Act 1966* (NSW); *Poisons and Dangerous Drugs Act* (NT); *Health Act 1937* (Qld); *Controlled Substances Act 1984* (SA); *Poisons Act 1971* (Tas); *Drugs Poisons and Controlled Substances Act 1981* (Vic); *Poisons Act 1964* (WA).

contains Nine Schedules that describe various types of drugs and poisons and specifies those that can only be dispensed by medical doctors, pharmacists, veterinary surgeons or dentists. Other schedules require specific precautions for handling; storage labeling or availability.

A summary of the Schedule is:

Schedule 1 – Poisons of plant origin of such danger to health as to warrant their being available only from medical practitioners, pharmacists.

Schedule 2 – Poisons for therapeutic use that should be available to the public from pharmacies or licensed persons only.

Schedule 3 – Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners.

Schedule 4 – Poisons that require a prescription and substances intended for therapeutic use but which require further evaluation.

Schedule 5 – hazardous poisons available to the public such as domestic poisons, disinfectants and cleaning products.

Schedule 6 – poisons similar to schedule 5 but more dangerous used by farmers, manufacturers and scientists.

Schedule 7 – Poisons that require special precautions in manufacture, handling, storage or use or special individual regulations regarding labeling or availability.

Schedule 8 – drugs of addiction ie narcotics.

Schedule 9 – poisons of drug abuse but may be necessary for medical or scientific research.

Drugs in Schedules 2, 3, 4 and 8 must be ordered by a doctor or dentist before being dispensed by a pharmacist. A written prescription is required for schedule 3, 4 or 8 drugs.

Schedule 1, 5 and 7 drugs are not for therapeutic use while Schedule 2 drugs are those that can be brought over the counter at a chemist shop.¹¹⁷⁷

For a CAM practitioner the schedules contain a number of substances that cannot be used or can only be used at a very high dilution. The issue for regulators is whether appropriately qualified and or trained CAM practitioners should be permitted to prescribe the TCM; homeopathic and herbal substances that are currently restricted by the SUSDP to medical practitioners; pharmacists, dentists and veterinary surgeons. The paradox is that most of these authorized professionals would have little expertise, knowledge of nor interest in prescribing these substances.¹¹⁷⁸ The Review of Therapeutic Goods Administration¹¹⁷⁹ recommended training and accreditation standards to be set to allow TCM practitioners to prescribe scheduled herbs.

This issue has been addressed directly by the Victorian *Chinese Medicine Registration Act* 2000 (CMRA) where registered practitioners have been given an entitlement to prescribe certain substances as discussed above. Medical practitioners and pharmacists can only do the same if they are also similarly registered under the CMRA or specifically endorsed by their registration board to deal with those substances.¹¹⁸⁰

International Perspectives

1177 Peter MacFarlane, *Health Law: Commentary and Materials* (3rd edition 2000) 272.

1178 Kleyhans, above n 3, 105.

1179 KPMG Review of TGA, above n 1142, 4.9.

1180 refer to pp 248-250 above.

Australian controls over therapeutic goods as they pertain to CM are amongst the world's strictest and provided a model for the UK legislative framework.¹¹⁸¹ A comparison with the USA indicates the strengths and weaknesses of both systems. The USA has in recent years reformed its controls over CM to a less prescriptive model that provides some interesting contrasts with the regulatory position in Australia.

USA – DSHEA

The philosophical and economic trend towards consumerism and its tendency to support the concept of self-choice has been evident in both the USA and Australia. In Australia it is reflected in the broad exemptions given to practitioners in the supply of CM products and in the guidelines allowing specified health claims on CM. In the USA the passing of substantial amendments to the *Food and Drug and Cosmetic Act* (FFDCA) by the *Dietary Supplement Health and Education Act 1994* (DSHEA)¹¹⁸² in 1994 witnessed a liberalisation of the availability of CM products. The DSHEA exempted claims about the effects of 'dietary supplements' on the human body from the drug provisions of the FFDCA.¹¹⁸³ This liberalization, not without its critics, underlines many important issues for consideration in the debate over regulatory control of therapeutic goods.¹¹⁸⁴

The legislation regulates 'dietary supplements' that includes vitamins; minerals; herbs or other botanicals; amino acids or a dietary substance for use by man to supplement the diet by increasing the total dietary intake. A dietary supplement should not be represented as a

1181 KPMG Review of TGA above n 1142, 102.

1182 108 Stat (1994) 21 USC.

1183 Margaret Gilhooley, 'Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice' (1997) 49 *Florida Law Review* 665.

1184 Angell and Kassirer, above n 1157, 840.

conventional food or as the sole item of a meal or diet.¹¹⁸⁵ The previous regime was not conducive to herbal substances. Previously, if the promoter of a herbal substances made statements that the substance impacted on the structure/function of the body they were required to survive the expensive New Drug Assessment (NDA) process. As herbal substances are normally natural botanicals and not patentable, it is difficult to justify spending the substantial funds necessary to obtain the required scientific evidence to satisfy FDA requirements when the exclusivity of the substance cannot not be protected.¹¹⁸⁶

The DSHEA provides a more welcoming regulatory environment. One of the major justifications for the statute (similar to the policy objectives behind the Australian TGA) was the desire to protect consumer access to safe dietary supplements to promote good health.¹¹⁸⁷ A herbal product that meets the statutory definition of dietary supplement is exempt from being classified as a drug that would otherwise require further assessment under the FDCA.¹¹⁸⁸ The DSHEA also creates a statutory presumption that all dietary supplements present in the food supply on October 15 1994 are safe.¹¹⁸⁹ The FDA is obliged to demonstrate that a dietary supplement presents a significant or unreasonable risk of illness or injury under recommended or ordinary conditions of use before it can prevail in a court action against a manufacturer to withdraw its product from the market.¹¹⁹⁰ The lack of safety provisions in the DSHEA was described as the FDA'S Commissioner Kessler's 'greatest failure'.¹¹⁹¹

1185 s 321(ff)(1).

1186 C E Zuk, 'Herbal Remedies are not Dietary Supplements: A Proposal for Regulatory Reform (2000) 11 *Hastings Women's Law Journal* 29, 38; Michael T Murray, 'Herbal Medicine: A Modern Perspective' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 654.

1187 DSHEA s 2; Cohen, above n 15, 108.

1188 Zuk, above n 1186, 38-39.

1189 DSHEA ss 3, 4 and 8 and FFDCFA s 413 (c); Cohen, above n 15, 109.

1190 DSHEA s 4 and FDCA s 402(f)(1); Zuk, above n 1186, 39; Brody, above n 1157, 1.

1191 Gilholly, above n 1183, 667; Cohen, above n 15, 114.

One aim of the DSHEA is to permit controlled dissemination of information about dietary supplements to encourage informed decisions by consumers.¹¹⁹² This is achieved primarily in two ways.

Firstly, dietary supplements can be marketed with specified informational claims about their products. Manufacturers of these substance can make statements of nutritional support about the role of a nutrient or ingredient in effecting the structure or function of humans although they cannot make statements suggesting the substances can diagnose, treat or prevent disease.¹¹⁹³ Before DSHEA these claims may have triggered the FDA drug approval processes.¹¹⁹⁴

The DSHEA regime does not allow a claim on a label for a dietary supplement for specific health benefits ie '*Valerian is a herbal therapy for insomnia*' but could state the effect of the product on the structure or function of the body such as that '*Valerian nutritionally promotes restful sleep.*'¹¹⁹⁵ These statements must be accompanied by a disclaimer 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.' Claims must be substantiated and not be misleading based on 'Regulations on Statements Made for Dietary Supplements Concerning the Effect produced on the Structure or Function of the Body.' The substantiation of a claim for these substances can be difficult when there is a lack of scientific evidence of its effect on

1192 Zuk, above n 1186, 38.

1193 DSHEA s 6; FDCA S403 (r); J Chang, 'Scientific Evaluation of Traditional Chinese Medicine under DSHEA: A Conundrum' (1999) 5 *The Journal of Alternative and Complementary Medicine* 181, 183; Gilholly, above n 1183, 666.

1194 Gilholly *ibid.*

1195 Zuk, above n 1186, 40.

a healthy person.¹¹⁹⁶ This evidence cannot rely solely on historical data but there are no clear guidelines as to how the substantiation should be made.¹¹⁹⁷

Secondly, DSHEA allows claims on associated marketing materials and brochures if they are not false and misleading, they do not promote a particular manufacturer or brand, they present a balance view of the available scientific data and are displayed separately from the dietary supplement.¹¹⁹⁸ The burden of proof is on the FDA to prove a breach of these requirements.¹¹⁹⁹ This means that many broader claims can be made on this material ie that a substance will lower cholesterol or improve the immune system.¹²⁰⁰ The Federal Trade Commission (FTC) can deal with misleading claims though its jurisdiction is different and does not deal with pre market approval of drug claims.¹²⁰¹ In 1998 the FTC brought action against a number of manufacturers that breached rules relating to misleading advertising. The FTC has also issued guidelines for advertising for dietary supplements.¹²⁰²

The DSHEA regime aims to accommodate the needs of the herbal produce industry, the desire for freedom of choice in health care and the marketing demands of the consumer market. This regime has been criticized for not providing the type of information a consumer needs. The regime of permitted nutritional support claims ie Ginko biloba 'improves memory and concentration' or palmetto can 'maintain prostate health and well being' has been criticised on the basis that it may be difficult to distinguish between the effect on a consumer

1196 Chang, above n 1193, 183.

1197 Ibid 183-184.

1198 Cohen, above n 15, 110; DSHEA s 5 and FDCA s 403 B.

1199 DSHEA s 5; FDCA s 403 B (c); Zuk, above n 1186, 40.

1200 DSHEA s 5; FDCA s 403B (c).

1201 15 USC 45, 52, 55 1988; Gilholly, above n 1183, 673.

1202 Brody, above n 1157,1; United States Federal Trade Commission, *Business Guide For Dietary Supplement Industry Released by FTC Staff* (1998). These guidelines have been adapted into the Australian guidelines discussed above.

between permitted and impermissible statements.¹²⁰³ It may also confuse consumers by allowing labeling that might suggest therapeutic potential but the disclaimer in relation to FDA assessment suggests they should be skeptical without indicating side effects or contraindications.¹²⁰⁴ Chang comments that this regime is said to allow the marketing of ‘herbal products of low quality and suspect efficacy.’¹²⁰⁵

Zuk has suggested that instead of providing only vague reference to health indications that herbal substances be permitted to make assertions based on their traditional use as herbal substances. This could allow marketing of herbal substances with labelling specifying the effect of the herb, (based on herbal monographs to specify safety, dosage and efficacy) on particular maladies to provide more useful information to consumers.¹²⁰⁶ The labelling could provide whatever necessary disclaimers as to scientific evidence or warnings as might be considered necessary. This is a more open, honest approach that acknowledges a consumers entitlement to information, access and clear details of the expected effect of taking a substance. This reflects to some extent the process permitted for herbal products under the *Australian Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* that appears to provide consumers with more balanced information with which to base health care decisions.

Gilholly has argued:

consumers would be better served by clear information about the traditional therapeutic uses of botanicals when they have scientific support, rather than by the use of DSHEA to suggest such uses without overtly stating them, a process which may ‘create a climate of deception that serves neither the industry nor consumers.’¹²⁰⁷

1203 Cohen, above n 15, 114.

1204 Zuk, above n 1186, 41.

1205 Chang, above n 1193, 181, 182.

1206 Zuk, above n 1186, 53-55.

Suggested Reforms to the Regulatory Regime in Australia

Introduction

The dilemma for government is that there is a substantial and growing demand for CM products and a potential public health risk if the industry is not properly regulated.

Consumers are entitled to economically justifiable protection against useless or dangerous remedies. A balance is needed between over regulating an industry that may not have the resources to absorb its impact and insufficient regulation leading to useless remedies or injury to consumers.

Constitutional Issues

The constitutional limitations on the TGA and the fact that only NSW and Victoria has passed complementary legislation means the impact of the TGA is greatly limited. A national scheme is essential to permit consistent and effective regulation either through the arduous route of constitutional reform; by complementary legislation by all jurisdictions or by ceding of power by the States to the Commonwealth.

Quality of Raw Herbs

Raw herbs that practitioners use for compounding are exempt from the registration or listing requirements. This creates potential for improper prescribing, manufacturing and adulteration

1207 Gilholly, above n 1183, 669.

of products.¹²⁰⁸ There are few controls on the testing and reliability of raw herbs. This provides a risk for adulteration and substitution.¹²⁰⁹ There are no set reference standards for Chinese medical substances or raw herbs.¹²¹⁰ The relevant Minister under s 10 could set a standard. ‘Such a standard could set quality criteria applicable to the import and supply of specified raw Chinese herbs and would help to assure the quality of the herbs prepared or dispensed by TCM practitioners as it is an offence to import, export or supply therapeutic goods which do not comply with the standard.’¹²¹¹ A small number of these substances have a standard applied by the British Pharmacopoeia.¹²¹² This concern is compounded, as there is a substantial black market in Chinese medicinal substances that the TGA does not have the resources to quell.¹²¹³

Control on the quality of raw herbs requires a multi-pronged approach that focuses on import quality control; producing and manufacturing controls in Australia; education in identifying herbs and a program of testing and certification of purity across the gamut of toxicity; adulteration; toxins and microbiological agents. The most effective means to ensure the efficacy and safety of herbal substances is to subject them to rigid scientific testing not unlike the FDA New Drug Regime for the testing of pharmaceuticals.¹²¹⁴ The costs and time delay in this process and the reality of the lack of economic incentive to do this research means that this would almost certainly be over-regulation. The current regime does emphasise limits on the claims made for herbal substances without unduly regulating the industry. The most cost effective means to augment consumer safety would be to register practitioners who have

1208 Bensoussan and Myers, above n 77, 235.

1209 Brody, above n 1157, 1; Bensoussan and Myers, above n 77, 235; KPMG review of TGA, above n 1142, 121.

1210 KPMG review of TGA, *ibid* 122.

1211 Bensoussan and Myers, above n 77, 236.

1212 KPMG review of TGA, above n 1142, 120.

1213 Bensoussan, above n 77, 236.

1214 Ernst, above n 96, 51.

appropriate training in the identification and use of herbal substances and more exhaustive testing of substances for toxicity; compliance with description and adulteration both on imports and local manufacturing. The government funding for these steps would indicate its commitment to the attainment of these goals.

Manufacturing Process

An appropriate regulatory structure is particularly important for TCM herbs as there may be great variation in the quality and effectiveness of these herbs depending on the region where they are grown; and the part of the plant harvested or processed. There is also some difficulty in identifying herbs from the same family and a practice of substituting a similar but pharmacologically different herbal substance. This is a particular problem in substances like black cohosh and skullcap.¹²¹⁵ Identification is most accurately done before harvest.¹²¹⁶ The assumption appears to be made that if individually the herbal substances contained in a remedy are considered safe that the combination of these herbs must be safe and are what they are identified as being. This assumption is reliant on the correct identification of herbs and does not consider the issue of interactions between herbs. This can cast doubt on the purity and safety of some herbal medicines.¹²¹⁷

The Good Manufacturing Practices Code (GMP) code provides some measure of control over the manufacturing quality of herbal substances. Manufacturers are obliged to provide certificates of analysis for screening of known contaminants such as aconite and steroids.¹²¹⁸

Bensoussan and Myers doubt whether manufacturers are aware of which potential

1215 Johanson, above n 1132.

1216 Ibid.

1217 Edward Croom, 'Botanical Safety: Plant to Final Product' (Paper Presented at *Naturally Safe :the Challenge to the Herbal Medicine Industry Conference*, Brisbane, 27-28 June 2002.)

contaminants should be tested for. Testing for toxicity, unlike micro-organisms is discretionary.¹²¹⁹ The extension of the need to test for certain contaminants and for random surveillance of herbs and other therapeutic substances after marketing could address this concern.¹²²⁰

Prescribing Practices

Currently ‘any herb (except those found in the schedules to the drugs and poisons legislation) can be sold over the counter without any prescription and without any clear requirement for dispensers to instruct the recipient in its proper use.’¹²²¹ Provision is needed to ensure the herb is properly labelled when sold alone or properly identified when sold as part of a prescription to ensure the herb is safe enough for free use by the public.¹²²² ‘Prescriptions can be filled by a retail shop without any restriction on the number of repeats; the age of the prescription; the provision of proper instructions; or whether the prescription was provided by a qualified TCM practitioner or copied from a book.’¹²²³ ‘There is no requirement for dispensers of herbs in retail outlets to have the ability to identify herbs accurately; identify errors in labeling; and to identify errors in prescriptions.’¹²²⁴ There is no standardised prescription or labelling system for chinese herbs.¹²²⁵

The most complete regime would be to apply strict labelling requirements on CM substances prescribed by a practitioner that indicate the ingredients; use by date (if applicable)

1218 Bensoussan and Myers, above n 77, 237.

1219 Ibid 237-238; KPMG Review of TGA, above n 1142, 121.

1220 Ibid Bensoussan and Myers, 239.

1221 Myers and Drew, above n 670, 3.

1222 Victorian Options report, above n 642, 34.

1223 Ibid.

1224 Ibid.

1225 Bensoussan and Myers, above n 77, 235.

instructions for use and preparation (this can be vital for some raw herbs that require preparation to ensure efficacy and safety); dosage and identifying the person who should be taking the substance. A regime involving registered practitioners could require proper instruction in the use of CM by the client. Therapeutic Goods Order no 69 that comes into force in 2004 will cover unregistered practitioners. Its more prescriptive requirements on labeling will deal with some of these concerns. The prescription requirements that are soon to be specified under the Victorian CMRA may provide an appropriate model for these provisions.

Training of Practitioners

Schedule 8 of the regulations exempt herbalists; nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation from the manufacturing provisions of part 4 of the TGA based upon criteria discussed above. This provision exemption does not require any testing of the qualifications of the quoted professionals nor even membership in a professional association.¹²²⁶ As these professions are generally unregulated there is little to stop a person with limited training to be entitled to exemption under the legislation.

The membership of a professional association would provide some measure of quality control. This is used in Schedule 1 of the TGA to exempt members of a long list of CAM professional associations from the advertising regulations.¹²²⁷

¹²²⁶ Ibid 238.

This highlights the need to be able to identify qualified practitioners in many different contexts. The provisions of the SUSDP in all states and territories means that some herbal substances are effectively withdrawn from use by TCM practitioners as they require a prescription by a medical doctor or are limited to pharmacists or veterinary surgeons. In many cases these authorized practitioners are not well trained to deal with such substances. Many CAM practitioners would have the requisite training.

The application of a sophisticated registered practitioner regime would provide evidence of those practitioners who have been identified as competent to use these substances. The CMRA provides the model to regulate the use of these poisons by CAM practitioners.

Adverse Reactions

More scientific evidence of the effect of herbal substances and their interaction with other herbs and pharmaceuticals is needed to secure greater safety in the use of herbs.¹²²⁸

Important market and scientific evidence is provided by details of what adverse reactions have occurred by the use of particular CM substances. Currently there is no legal obligation to report adverse reactions for listed goods and possibly a lack of understanding of the importance of this activity amongst CAM practitioners. This suggests the need for a statutorily established obligation to report adverse reactions in the use of CM. A register that deals specifically with CM would allow a focus on the specific issues involved in the use of CM and may encourage a culture of reporting by CAM practitioners.¹²²⁹

Industry Based Self Regulation

¹²²⁷ Regulation 4 (2).

The establishment of a Herbal Task Force involving consumers; government; importers; growers and manufacturers could coordinate advice to government on regulatory; quality and research needs for the industry. The establishment of a reference bank of herbs could provide a reference point to allow proper quality control for the identification of good quality substances. This structure could have connections to a global network alert information system to identify potentially important misidentification and adulteration events that may impact on the Australian market. This could assist in allowing focussed compliance activities by the TGA.¹²³⁰ The industry could also establish an industry Code of Practice and Standards to provide a benchmark for the industry. To assist in ensuring quality an industry certification for suppliers and growers would provide an incentive to choose quality outcomes for industry participants.¹²³¹

Conclusion

The manufacturing and supply of CM involves the provision of therapeutic goods for substances that are intended to impact on the biological processes of human beings where there are documented risks of adulteration and toxicity. There is a lack of firm scientific evidence of the safety or effectiveness of many substances. The cost to industry, government and consumers to comprehensively deal with these concerns may be prohibitive and could unduly limit access to these substances. The cultural aspect of the need for access to CM substances should not be ignored. The fact that many consumers are satisfied for themselves of their efficacy and consider it irrelevant that there is no gold standard evidence for their

1228 Brody, above n 1157, 2.

1229 Myers and Drew, above n 670, 541; KPMG Review of TGA, above n 1142, 127.

1230 Val Johanson, above n 1132.

1231 Ibid.

effectiveness is a factor that should temper any trend to over-regulation. With the reforms suggested above the regulatory structure would satisfy the difficult balancing act that this industry requires.

Chapter 6

Ethics and Professional Misconduct

Introduction

This chapter analyses the nature of ethical practice as it relates to the regulation of CAM. While medical ethics may provide guidance for ethical CAM practice it is argued that it is inappropriate to simply apply OM ethical principles without differentiation to the practice of CAM.¹²³² The abundance of literature on medical ethics contrasts with the dearth of material relevant to CAM ethics.¹²³³ This chapter will also indicate how ethics can assist in achieving public policy goals in the regulation of CAM.

While ethical boundaries are fundamental to any professional practice the OM ethical framework derives from a specific context. The simple application of the OM ethical framework to CAM fails to consider that relevant context.¹²³⁴ The indiscriminate application of biomedical ethics to CAM could stifle CAM and represent an application of OM hegemony to control CAM. From a OM perspective if a CAM modality or treatment is not scientifically proven it is a small step to suggest that it is unethical to provide that type of treatment.

¹²³² Canadian Overview, above n 10, 2.

¹²³³ Julie Stone, *An Ethical Framework for Complementary and Alternative Therapies*, (2002) (viii).

The various modalities that comprise CAM derive from various and distinct historical periods and healing philosophies. It is difficult to accept these constructs without accepting the different ethical parameters that they suggest. For OM, much ethical debate revolves around the scientific evidence of efficacy and safety and the resultant measures of ethical practice. These ethics are shaped by that context.

CAM has a different self-concept and relies on different rules. This suggests a new model should be applied. This model does not reject the application of basic ethical principles but suggests a model that draws upon the unique position of CAM.

Summary of suggested model

As CAM treatment relies on empirical evidence the ethical model suggested here places emphasis on a client's autonomy to choose a therapy relying on their experience of the treatment. If a client feels better from a massage – they do feel better.¹²³⁵ If a client takes TCM in accordance with his or her cultural practice does it become unethical practice if a practitioner cannot point to scientific evidence of its effect? If a client experiences relief from back pain through chiropractic – is this subjective experience not real because there may or may not be scientific evidence of the efficacy of the treatment? To state that these treatments perform no better than placebo may threaten that experience or cast doubt on the cultural construct that explains the healing or informs the patient what healing is for them. O'Connor

1234 Vimal Patel, 'Understanding the Integration of Alternative Modalities into an Emerging Healthcare Model in the United States' in James M Humber and Robert F Almeder (eds), *Alternative Medicine and Ethics* (1998) 73.

1235 O'Connor, above n 35, 163.

calls for a culturally sensitive approach to health care and an acknowledgment of a patient's authoritative agency.¹²³⁶ She states¹²³⁷:

Patients evaluate health care options in a range often much broader in scope than that of the conventional medical system. They make decisions on the authority of their own knowledge and experience – which differ from the knowledge and experience of health professionals – and they do so notwithstanding professional disagreements with many of their choices and conclusions. They pursue the therapeutic goals most valued by themselves, whether or not these coincide with the goals most valued by clinicians. Patients, in the end, not health professionals, determine the actions they will take with respect to health and illness, including when, how, and from whom they seek care, and how they pursue the recommendations of their various care providers. “Patient” is a small part of most people's identity, and not generally the one that supplies the main frame of reference within which important decisions about life are made.

This approach could of course open the door to the exploitation of patients who are hoodwinked into treatment that a practitioner insists is beneficial and necessary.

The required balance to this reliance on the autonomous choices of a client is the external parameters drawn from professional requirements. This is where legal and ethical considerations intersect. A practitioner should avoid undue augmentation of the effectiveness of treatment other than a description of the modality's beliefs of its effects. The level of traditional evidence of safety and or efficacy should be canvassed as well as the practitioner's own experience of the impact of the treatment contemplated. Within this concept scientific evidence of efficacy or otherwise should be described and discussed and indications of harm canvassed.

Ethical justifications

This approach to ethics derives from an emphasis on the ethical experience of practitioners that Moreno refers to as ‘ethical materialism’ whereby ‘moral values emerge from actual human experience and are not superimposed on it by some transcendental reality represented

¹²³⁶ Ibid 162.

by some traditional modernist ethics.’¹²³⁸ The OM ethical framework derives from a modernist perspective that assumes that morality is concrete, absolute, universal and ‘available to all through rational reflection,’¹²³⁹ Medical ethics is derived from an authoritarian Hippocratic ethical background that envisages a ‘beneficent’ practitioner who makes therapeutic decisions affecting a client who is obliged to obey.¹²⁴⁰ This brings with it a compensating attachment to scientific proof of efficacy to guard against inappropriate use of that authority. Johnstone embraces a more fluid view of ethics that acknowledges from a post modernist perspective other ethical realities and subjective perspectives.¹²⁴¹ Johnstone states ‘contrary to modernist assertions, ethics is multiperspectival and multicultural (or pluralistic) in its vision and, as such, is open to a diversity of interpretation and understanding.’¹²⁴²

This approach to moral theory seeks to deal with ethical problems not known to earlier generations and suggests new methods to deal with moral questions.¹²⁴³ Johnstone notes that a postmodernist perspective:

makes visible a perspective ... that has previously been marginalized and rendered invisible in the hierarchy of contemporary moral discourses, and in making visible this perspective, challenges the hegemony of other dominant discourses; for example, those of medical ethics and mainstream bioethics..¹²⁴⁴

This model incorporates cultural relativity.¹²⁴⁵ Cultural sensitivity may be perceived as a function of ethnicity. Another concept of culture is the acceptance by consumers of another health philosophy, that is CAM, within the dominant OM culture.¹²⁴⁶ In this model, morality is derived from the nature and quality of the therapeutic relationship and not on rational non-

1237 Ibid.

1238 M Johnstone, *Bioethics- A Nursing Perspective* (1999) 66.

1239 Ibid 67.

1240 Milburn, above n 176, 39.

1241 Johnstone, above n 1238, 67

1242 Ibid.

1243 Ibid 68.

1244 Ibid.

1245 Ibid 145.

involved decision-making processes that may characterise the dominant culture. This moral durability, no doubt influenced by traditional ideals, permits a broader approach to bioethics that can incorporate the different perspective of CAM. This model draws on concepts such as intuitionism that relies upon ideas that a party (patient and practitioner) simply knows to be true. This approach can be augmented by an act deontology approach as distinct from a rule deontology approach. This permits a practitioner to consider the specific facts of a situation before determining the ethical approach as distinct from application of broader ethical principles no matter what the circumstances.¹²⁴⁷ In different contexts different considerations may apply. In some communities group goals and outcomes may be considered more important than those of the individual and may require a very different approach to moral questions.¹²⁴⁸

This conflict is placed in stark relief when differing cultural perspectives are considered. For some cultures, for example Greek or Italian culture, the family may provide an important filtering device for bad news. A doctor if delivering a negative prognosis may consider it his ethical duty to indicate the nature of the prognosis to the patient directly. This may have a negative effect on the patient who may expect to receive such information through his or her family. The contemplated action may accord with normal ethical obligations but may in fact be not in the interests of the patient.¹²⁴⁹ Culturally appropriate responses may avoid a negative result in this situation.

The necessity to deal with the different context of CAM is described in the *Encyclopedia of Bioethics* where it states:

1246 O'Connor, above n 35, 170.

1247 Johnstone, above n 1238, 81.

1248 Stone, above n 1233, 39-40; Refer also to John Devereux, *Australian Medical Law* (2002) 14-24.

1249 Johnstone, above n 1238, 153.

the historical and cultural content of conventional and alternative medicine is an important consideration wherever legal and ethical issues are addressed. What is ethically right cannot simply be reduced to what is culturally dominant. Cultural dominance does not equate with ethical correctness; immorality status or identification with another culture does not reduce to moral incorrectness. Only when cultural and historical factors are identified on both sides can ethical and legal questions about alternative medicine be clearly addressed. Then dialogue can be substituted for hostility and common ethical standards can be developed for both types of practices.¹²⁵⁰

Some OM commentators do not accept this argument for cultural relativity. One commentator suggests that ‘any practice – if it calls itself medicine- whether it uses the term alternative complementary, or integrated medicine must adhere to these goals and standards.’¹²⁵¹ This viewpoint is borne of the power ascendancy of OM drawing on its scientific ascendancy and focusing on CAM’s weakness in that area. This view fails to plumb the differences in the CAM approach to healing. This difference supports a different approach to ethical questions on some fundamental matters.

What are Ethics?

It is appropriate to define ethics for the purposes of this discussion. Johnstone defines ethics as ‘a critically reflective activity fundamentally concerned with a systematic examination of the moral life and is designed to illuminate what we ought to do by asking us to consider and reconsider our ordinary actions, judgments and justifications.’¹²⁵² Johnstone notes, from her perspective as a nursing practitioner, that the model of ethical philosophy as it has been applied to the healing professions is medico-centric, reflecting the predominant philosophical influence.¹²⁵³ The very different therapeutic approaches taken by CAM and OM practitioners

1250 Encyclopedia of Bioethics, above n 4, 135; Spencer, above n 23, 9; Lynn Payer, *Medicine and Culture Varieties of Treatment in the United States, England, West Germany, and France* (1988) - re differences in medical viewpoints between different countries; O’Connor, above n 35, 22.

1251 LJ Schneiderman, 'Medical Ethics and Alternative Medicine' (1998) 2 *Scientific Review of Alternative Medicine* 63, 63; Jonas, above n 13, 1616.

1252 Johnstone, above n 1238, 42.

1253 Ibid 43-44.

and their diverse philosophical backgrounds requires an assessment of how ethical practice should be interpreted in this different context.¹²⁵⁴

The considerations relevant to chiropractic or osteopathic practice, which relies upon a substantial body of biomedical information and training, may suggest a close relationship to medico-centric ethics. This may be less relevant to modalities such as homoeopathy or spiritual healing where the biomedical dimensions are less important or are peripheral to day-to-day practice.

CAM – application to traditional ethical concepts.

The underpinning of the ethical concepts discussed in this chapter owes a debt to principled based ethics:¹²⁵⁵

- the principle of beneficence (the principle of healing),
- the principle of non-maleficence (refrain from causing harm, including physical, financial and emotional exploitation),
- the principle of respect for autonomy (which emphasises informed consent for procedures and allowing patients to be active in the healing process).¹²⁵⁶ This principle provides a balance to medical paternalism where autonomy and beneficence encounter may conflict.¹²⁵⁷
- The principle of justice.¹²⁵⁸

1254 K. Danner Clouser, David J Hufford and Bonnie Blair O'Connor, 'Informed Consent and Alternative Medicine' (1996) 2 *Alternative Therapies* 76-78.

1255 Stone and Matthews, above n 32, Chapter 13.

1256 E Ernst, 'The Ethics of Complementary Medicine' (1996) 22 *Journal of Medical Ethics* 197.

1257 Howard Brody, Janis Mygwelski and Michael D Fetters, 'Ethics at the Interface of Conventional and Complementary Medicine' in Wayne B Jonas and Jeffrey S Levin (eds), *Essentials of Complementary and Alternative Medicine* (1999) 49.

1258 Stone and Matthews, above n 32, 235; T Beauchamp and J Childress, *Principles of Bioethics* (4th ed 1994) 309.

These principles have been criticised for not indicating how they can be reconciled when in specific factual situations they may appear to be irreconcilable.¹²⁵⁹

Beneficence

The principle of beneficence may apply somewhat differently in relation to CAM. For OM, derived from Hippocratic tradition, the relief of suffering is a primary concern. This goal involves curing those who can be cured and caring for those who cannot.¹²⁶⁰ An MD may consider a medical intervention for an asymptomatic person is unnecessary and unethical. A MD uses allopathic techniques or other interventions to counteract symptoms through the use of pharmaceutical substances or surgical procedures. For a CAM practitioner ‘curing’ may be defined in different terms. The CAM concept of healing, through the promotion of harmony across a patient’s physical, spiritual and emotional dimensions, is foreign for OM. A CAM practitioner practicing under a wellness model may perceive OM as overly symptomatic and narrow in approach. For a CAM practitioner beneficence may not require the curing of any condition. Rather the practitioner may see their role is to promote harmony by encouraging their patient’s own restorative forces to establish wellness and vitality not simply a lack of symptoms.¹²⁶¹ What is unethical or over-servicing for a MD may be at the heart of what a CAM practitioner seeks to provide.

This principle requires a practitioner to consider the benefit a treatment provides as against any potential harm. From an OM perspective this creates an ethical dilemma for a CAM practitioner who may be unable to point to scientifically based evidence of benefit or

1259 Stone and Matthews, above n 32, 235.

1260 Devereux, above n 1248, 6.

1261 Stone and Matthews, above n 32, 237; Stone, above n 1233, viii, 3, 13.

safety.¹²⁶² OM may demand scientific evidence of efficacy but CAM may rely on traditional, empirical or anecdotal evidence. Drawing on the principle of autonomy many patients will choose a therapy with knowledge of the available level of evidence of efficacy. Some patients will rely on a personal empiricism approach 'it works for me' and may choose to ignore evidence to the contrary. Within the culture of the CAM modality the use of this treatment would be ethical if a patient is not misled as to the nature of the treatment and evidence for benefit.¹²⁶³

Despite this perspective at some point if the evidence of efficacy and safety is completely absent it may be unethical to provide that treatment.¹²⁶⁴ This would occur most clearly when there is no traditional or well-based empirical evidence to support its use. This ethical concern would apply unless the client is fully informed of the lack of a valid knowledge base and indications of therapeutic benefit and that it is possible any benefits are reliant on patient perceptions of benefit or placebo.

Non-Maleficence

The principle of non-maleficence requires a practitioner to avoid behaviour that negatively affects a client's interests. It is said that in OM 'safety is sacred.'¹²⁶⁵ Examples of a breach of this principle might be an injury suffered by a negligently applied procedure or application of a procedure that is inherently dangerous. It could include a breach of confidence that injures a client; using an unequal bargaining position to unduly influence a client to their detriment; becoming sexually involved with a client or treating a patient when impaired. This principle would designate as unethical applying a treatment that harms the patient without a

1262 Ernst, above n 1256, 198.

1263 N Lynoe, 'Ethical Professional aspects of the practice of alternative medicine' (1992) 20 *Scandinavian Journal of Social Medicine* 217-221.

1264 Stone, above n 1233, 34.

compensatory benefit or undertaking expensive treatment with little or no prospect of success or improvement.

Autonomy

Respect for autonomy is maintained by protecting a person's entitlement to make decisions affecting their health. One useful definition of the ethical principle is: 'personal rule of the self that is free from both controlling influences by others and from personal limitations that prevent meaningful choice, such as inadequate understanding.'¹²⁶⁶ The emphasis on this aspect of ethics is based on its relevance to the primacy given to personal values and individual autonomy in the Western culture.¹²⁶⁷

This principle is reflected in the legal concepts of consent and the requirement to advise of risks of treatment.¹²⁶⁸ For a CAM practitioner the obligation is emphasised when a client contemplating treatment has little or no specific or general knowledge of the nature of a modality. A practitioner should obtain consent to touch and to the modality contemplated based upon adequate information. This point is underlined where a number of different modalities eg massage, acupuncture and heat are used over a number of treatments. A separate consent should be obtained at each juncture for each intervention.

Justice

The concept of justice can be conceived of in two ways. One perspective is as 'distributive justice' in the sense of the just and equitable distribution of benefits in society.¹²⁶⁹ The other perspective is the ability to obtain compensation for wrongs done. The distributive aspect is

1265 Fulder, above n 9, 6.

1266 Beauchamp and Childress, above n 1258, 121; Stone and Matthews, above n 32, 257.

1267 O'Connor, above n 35, 181.

1268 *Rogers v Whitaker* above n 714.

reflected in *The United Nations Declaration of Human Rights*¹²⁷⁰ that suggests ‘everyone has the right to a standard of living adequate for the health and well being of himself and his family...including medical care.’¹²⁷¹

With the limited funding available for health care should society support unproven therapies?

¹²⁷² Many OM commentators would answer this in the negative ¹²⁷³arguing decisions on government funding should be made on the basis of scientific evidence. This approach involves a government denying funding for treatment that is desired by a citizen based upon the OM therapeutic model that rejects CAM as appropriate. That could be seen as a form of medical chauvinism. One solution to this dilemma is for more research to become available on the effects, costs and benefits of CAM.¹²⁷⁴ Private individuals in a just society people should be entitled to choose and to be afforded appropriate protection for that choice.

By government policy CAM is unsupported by Medicare. For this reason access to CAM is primarily through the private sector. This excludes many potential clients on a financial basis. This lack of access may offend the principle of justice.

The increasing coverage of CAM by private health insurance broadens access to CAM services but this coverage is only available for those able to afford what is normally the maximum level of health insurance.

1269 Johnstone above n 1238, 203

1270 Article 25 (10 December 1948).

1271 Johnstone above n 1238, 203.

1272 House of Lords, above n 39, 4.7; Ernst, above n 1256, 199.

1273 Kottow, above n 143, 21.

1274 J Sugarman and L Burk, 'Physicians Ethical Obligations Regarding Alternative Medicine' (1998) 280 *Journal of American Medical Association* 1623, 1625.

The principle of justice as it relates to compensation for harm requires consideration of the need for professional indemnity insurance. Professional associations normally require professional indemnity insurance as a requirement of membership and will often provide it at a competitive price. For non-members professional indemnity insurance is not compulsory before practice is commenced. Some practitioners decide to avoid this obligation and risk personal liability. This decision is made either relying upon their confidence about the quality of their practice; the benevolent nature of the modality and their clients and more worryingly their lack of personal assets to justify legal action against them.

The ethical issue arises if injured clients are not able to recover compensation for loss if the practitioner does not have sufficient assets to satisfy any possible liability in negligence or contract. This strongly supports registration or substantial incentives for membership of responsible professional associations that require practitioners to obtain professional indemnity insurance.¹²⁷⁵

OM and CAM – relationship to ethical questions

The extensive literature on medical ethics reflects OM's longevity and its connection to the sources of power and influence in society. This has permitted the financial provision for academic philosophers to ponder the ethical and philosophical aspects of what medical practitioners do as well as providing the incentive of prestige to undertake such ruminations. Medical practice is a fertile source of ethical dilemmas as it so often involves a focus on life and death issues such as the scientific experimentation in organ transplants or sustaining life for comatose patients. OM's involvement in scientific endeavour pushes forward

¹²⁷⁵ Stone and Matthews, above n 32, 268.

philosophical frontiers. This is evidenced by the ethical debate on the morality of cloning techniques using human embryos to achieve positive therapeutic outcomes for patients.

CAM will rarely involve matters of life or death and will usually be provided for chronic conditions delivered to patients who will be in a fit state to receive information about the suggested treatment.¹²⁷⁶ The ethical underpinning of CAM is derived from its connections to healing philosophies that gave birth to the modality such as the philosophical background for traditional Chinese medicine and in the principles established by Hahnemann for homoeopathy. CAM practitioners are generally actively involved in treating patients with less time and funding to devote to development of the philosophy on ethical thought in the modern context. Professional ethics for CAM practitioners will no doubt be influenced by concepts relevant to medical ethics. It should not be assumed however that the concepts are interchangeable.

CAM without scientific evidence

Is it unethical for a practitioner to apply a technique for which there is no scientific evidence of safety?¹²⁷⁷ OM may suggest that ethical practice requires the pre-market testing of materials and scientific trials for procedures to test safety. Traditional or anecdotal evidence that indicates safety over many generations could be sufficient unless there is contrary scientific evidence to the contrary. This form of evidence is accepted in a number of contexts (including by OM) as sufficient.¹²⁷⁸

¹²⁷⁶ Stone, above n 1233, 15.

¹²⁷⁷ NZ Report, above n 480, 4.

There is a debate about the percentage of OM treatments based on good scientific evidence.¹²⁷⁹ Even if the most optimistic figures are accepted a significant percentage of OM interventions lack appropriate support by scientific evidence.¹²⁸⁰

Most CAM interventions have little or no high quality research to support it. Evidence at the basis of CAM tends to rely upon statistical or non-double blind research studies. The education and information process with clients should indicate to a patient how these approaches differ.¹²⁸¹

The ethics of the provision of treatment by an MD or any practitioner involves a cost/benefit analysis within the non-maleficence and beneficence concepts.¹²⁸² Treatments may be painful; have risks associated with it and have substantial side effects. The decision to treat involves determining if the costs or potential risks of treatment are outweighed by the benefit. It is difficult to give full advice of risks if there is no information available on this issue.¹²⁸³ If the potential harm of a CAM intervention (which should be explained before the treatment) is not associated with an offsetting benefit then it would appear appropriate to state the treatment is unethical unless the client has a clear understanding of the experimental nature of the treatment.¹²⁸⁴ Harm can include inconvenience; financial cost; physical pain and stress.¹²⁸⁵

1278 For example the Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For non-registerable medicine, including Complementary Medicines, and other Listable medicines)* October 2001.

1279 Berliner, above n 259, 47; Refer to pp above

1280 A point not quickly acknowledged by many OM writers – Schneidermann, above n 1251, 63.

1281 Brody, Rygwelski and Fetters, above n 1257, 52.

1282 House of Lords, above n 39, 14.20.

1283 Sugarman and Burk, above n 1274, 1625.

1284 Encyclopedia of Bioethics, above n 4, 141.

1285 House of Lords, above n 39, 3.3; Hodgson, above n 629, 647.

What is the appropriate evidence of benefit? Much of the proof available for CAM comes from traditional use, sometimes from many years of treatment from anecdotal or empirical data. When dealing with an essentially harmless therapy (at least in terms of pain and physical injury) it is easier to accept that ethically this evidence will suffice.¹²⁸⁶ This approach may also be appropriate for chronic conditions for which there are no successful OM treatments.¹²⁸⁷

Ethical Protocol for CAM practitioners

For more serious conditions harm could result in preventing or delaying potentially beneficial OM. The following ethical precepts are suggested for CAM practitioners in dealing with any condition but especially one that is of a serious nature:

- It should be ascertained if the patient has either received a medical diagnosis or treatment and the result of that diagnosis or treatment. The issue of diagnosis is important as the role of a CAM practitioner when not relying on an OM diagnosis can be problematic. If no OM diagnosis is available (which may be of variable quality) the CAM practitioner is undertaking the sole ethical responsibility to provide the client with the necessary information to make therapeutic decisions. This should bring with it the responsibility to refer to an MD if the treatment does not appear to provide benefits or there is suspicion of another condition that the practitioner is not trained to treat. If OM has proven ineffective or its side effects are problematic and the patient is seeking an alternative therapy this should be discussed and noted.
- The practitioner should communicate what he/she thinks can be done for the patient. The practitioner should give the likely therapeutic result of treatment indicating the

¹²⁸⁶ Sugarmann, above n 1274, 1623.

strengths and weaknesses of the therapy. The likely costs and length of treatment should be canvassed. The options available to the practitioners within their modality should be discussed. The evidence supporting the therapy should be discussed (if any) or the basis of the intervention.

- The patient should be encouraged not to abandon OM unless they themselves determine this course of action. Any problems with combining OM with the CAM therapy should be canvassed and addressed, such as problematic drug/herb interactions.
- If the malady does not respond or requires therapy beyond the scope of the practitioner a referral to an MD should be made and the treatment stopped unless with all the information available the client wishes to continue and this would not be harmful. This point is especially important when a therapy derives its proof of efficacy and safety from empirical or non-scientific data. If the patient does not respond as expected the treatment should be reviewed.¹²⁸⁸ If practicable contact or cooperation with the patient's MD would be preferable to avoid misunderstanding and maximise complementary treatment.

The criteria could be incorporated into an express contract between the practitioner and client. This protocol acknowledges the importance of communication with the patient that is at the heart of ethical conduct. A patient is entitled to be given sufficient information to understand what is being agreed to and the limits and nature of the evidence for a particular therapy.¹²⁸⁹ It suggests that it is not ethical to provide a treatment for which there is no evidence of safety.¹²⁹⁰ To withhold treatment in that circumstance respects a client's autonomy and

1287 Lynoe, above n 1263, 223; Sugarmann, *ibid*.

1288 Lynoe, *ibid* 218.

1289 House of Lords, above n 39, 4.8.

1290 Crellin and Ania, above n 7, 27.

complies with the ethical precepts of beneficence and non-maleficence. A patient provided with the information to make an informed choice to use CAM (which may not have scientific proof of efficacy) over what may be scientifically proven OM treatment is a patient choosing their autonomous path. Any attempt to dissuade a person from this course may interfere with any possible placebo effects that may be available to them in that treatment in addition to any substantive improvement.

Patient autonomy requires a balancing of the beneficence/ non-maleficence principle when a patient requests a treatment. From a OM perspective provision of treatment not scientifically proven is the provision of useless treatment. But clients are entitled to choose another way based on their viewpoint of what is healing is and what healing should be like.¹²⁹¹ This principle sits best in an information rich environment when a patient appreciates the factors that should be considered in making that decision. This ethical dilemma for a CAM practitioner reflects the tension that exists between being consistent with scientific method and respecting the decision of a patient to use a treatment that may not be backed by scientific evidence.¹²⁹²

There are potentially significant ethical problems that can arise where a client has determined not to commence or continue OM especially where those treatments have scientifically proven benefits. If a CAM practitioner seeks to dissuade a client from taking advantage of those options then the ethics of the approach could be questioned as potentially in breach of the non-maleficence precept.

1291 Lynoe, above n 1263, 218.

1292 Crellin and Ania, above n 7, 27.

Where the CAM treatment does not rely on scientific evidence; if promoted as being an alternative therapy not simply a complementary therapy an ethical dilemma arises for a CAM practitioner. Is this course of action in the best interests of the client? The client may, armed with the knowledge of OM options, determine to take that course based upon their autonomous choice for many valid reasons such as spiritual beliefs; lifestyle; age; and concerns about OM side effects. A CAM practitioner in that case has an ethical obligation to indicate the cost/benefit analysis of their therapy and the evidence of efficacy and safety of the therapy. Only then can the autonomy of the client and the ethical concepts of beneficence and non-maleficence be reconciled. The more cautious ethical procedure is to attempt complementary treatment (if practicable).

Ethical Duty to refer to medical doctor

The recent English authority of *Situ v Shakoor* confirms the common law requires CAM practitioners to understand that they practice within an OM context. This suggests they should not ignore OM knowledge that may apply to a given situation and should avoid dissuading a client to seek OM assistance. This means that the duty of beneficence requires CAM practitioners to understand the limitation of their competence and to refer patients to another CAM practitioner or to a MD if required. This may be problematic for CAM practitioners for a number of reasons:

- OM has a hierarchical structure of GP's and specialists supported by a strong tradition and a legal obligation to refer to a specialist for matters outside the expertise of the GP.¹²⁹³ This tradition involves mutual obligations and specialised practice that involves no loss of face and limits the potential for a referring practitioner to lose a

client. The tradition of referring to specialist colleagues is not as well established for CAM practitioners though it is supported by some professional association codes of ethics.¹²⁹⁴ The potential loss of face and the possibility of losing a client after referral is a disincentive for a CAM practitioner. The hostility that applies between OM and CAM makes referral between CAM and OM professionals less likely to occur though OM is now becoming more open to closer ties with CAM practitioners.¹²⁹⁵

- The training of CAM within a separate healing paradigm may not encourage referral. Practitioners may simply apply their modality without considering the possibility of OM treatment options. The exclusion of CAM from the orthodox health sector only encourages this isolationist stance. This divisiveness does little service to the patient and does not take advantage of the potential benefits of integrated treatment.¹²⁹⁶
- CAM practitioners may not be trained in biomedical physiology or are trained to a lower standard than MD's. These practitioners may not recognize a situation requiring medical intervention.

A patient's good sense in understanding what health issue is appropriate for referral to a medical doctor is often underestimated by OM. Most consumers of CAM are well educated and do not fit the description of people incapable of discriminating choices.¹²⁹⁷ Survey evidence suggests that the 'vast majority of individuals appear to use alternative therapies in conjunction with, rather than instead of, more conventional treatment.'¹²⁹⁸

1293 Walmsley, above n 644, 205; *Tran v Lam* (Unreported, Supreme Court of New South Wales, 20 June 1997).

1294 AACMA Code of Ethics clause 5, 7 and 8; Jocelyn Bennett, 'Practitioners and Collaboration' (2002-2003) 2 *Diversity* 40-46; Stone, above n 1233, 102.

1295 Australian Medical Association, *Policy on Complementary Medicine* (2001); Nancy Faass, 'Utilization Data on Complementary and Alternative Medicine' in Nancy Faass (ed), *Integrating Complementary Medicine in Health Systems* (2001) 15.

1296 Crellin and Ania, above n 7, 31.

1297 Eisenberg et al, above n 102, 1569.

Many clients have actively chosen to apply CAM to a particular malady or only after OM has proven ineffective. The high level of use of OM by clients of CAM practitioners suggests an appreciation of the benefits of OM and indicates that most patients do not neglect OM in the pursuit of CAM options.¹²⁹⁹ In addition there is evidence that patients tend to apply CAM for general health promotion and for chronic conditions such as back problems and chronic pain that OM does not always provide a ready solution. This evidence suggests caution in an overly prescriptive approach to limiting access to CAM because patients will rely unreasonably on CAM treatment.

Nature of Therapeutic relationship

Duty to provide information

There are significant differences in the therapeutic relationship between patients of CAM practitioners and MD's. Medical doctors by training and culture have a more objectivised therapeutic model. The role of the doctor is to 'do something to' the patient by overcoming the identified pathogen or malevolent factor. The patient is a comparatively inert recipient of this treatment. The very limited provision for contributory negligence in OM jurisprudence reflects the nature of the OM therapeutic relationship.¹³⁰⁰ At law a patient of a MD is entitled to place substantial degree of trust in the doctor and their ability to provide appropriate treatment. This more authoritarian and autonomous stance taken by medical doctors demands a balancing emphasis on the principle of autonomy. This requires a doctor to obtain proper consent for a procedure after giving full details of what is contemplated. For a CAM practitioner:

1298 Astin, above n 446, 1551; Furnham, above n 441, 73; Faass, above n 1295, 12.

1299 Faass *ibid* 13.

1300 Walmsley, above n 644, 123-125.

The therapist acts as a conduit to activate the patient's own self healing mechanism. Within this relationship, greater reliance may be placed on self-responsibility, change coming from within patients themselves. Thus, the patients consent and cooperation is not something which the therapist needs in order to be allowed to do something to the patient, rather, it is central to the process of healing, in which the patient is an active participant.¹³⁰¹

In the context of holistic healing excellent communication skills are necessary as some treatment regimes may be based on a very detailed assessment of the symptoms of a client. Based upon subtle differences in symptoms and medical history homoeopathic practice may suggest different remedies for what might appear to be similar maladies.

A patient centred treatment requires the maximum level of information to involve patients in the healing process. This participation suggests the need to reassess the duty of beneficence to ensure that client participation is central to the therapy.¹³⁰² This might express itself in the ethical obligation to provide even greater information to a patient to obtain consent and cooperation to any procedure. Arguably, if the therapy involves a self-healing process, such as a naturopath advising a client to change their diet radically, then the quality of the result may depend on the quality of the communication of the therapeutic objectives of the treatment. Without that communication the practitioner may fail to maximise the chances of success of the treatment to justify the cost and sacrifice it will entail for client. A failure to attend to that communication is a fundamental failure of the practitioner's ethical obligation to maximise the chance of effective treatment that derives from the beneficence precept.

Therapeutic Distance – ethical implications

The less objective and more emotionally open approach of CAM practitioners who have the time and inclination to relate to their client is a strength of CAM. It also provides a potential for ethical concerns in relation to sexual, financial or emotional exploitation. Although this is

¹³⁰¹ Stone and Matthews, above n 32, 238.

clearly an issue for MD's the more distant and objective demeanour of MD's provides some therapeutic distance though the cultural power of OM may balance this effect. This distance can provide an environment that will avoid misunderstanding as to what is occurring between the client and therapist.¹³⁰³

Exploitation by a CAM practitioner may involve indoctrinating a patient with their own view of health and disease; convincing clients to use only vitamins herbs and remedies provided by themselves when other sources are available; or continuing treatment when it is obvious there is no benefit being obtained. This may be the result of a needy client or a practitioner who is not able to deal with his or her shortcomings or needs for emotional support or justification.¹³⁰⁴ The individual nature of CAM, without the massive structures characteristic of OM supports the development of gurus or apostles for particular modalities. This may promote practices that involve the exploitation of clients.¹³⁰⁵ This potential requires protocols and education to avoid this exploitation. The nature of OM and the statutory regulation of OM provide some protection from excesses for MD's. This may not currently apply for CAM that currently relies on self-regulation.

Therapeutic privilege and principle of autonomy

The principle of autonomy is intersected by the concept of therapeutic privilege. Therapeutic privilege permits a doctor to withhold information, such as the risks of treatment or a patient's prognosis, if this information being released would have a negative impact upon the patient. In this way a practitioner is acting in a paternalistic manner.¹³⁰⁶ This is an exception

1302 Ibid 239.

1303 Ibid 254.

1304 Ibid.

1305 Ibid 266.

1306 Stone and Matthews, above n 32, 264.

still acknowledged by the law though it is accepted as being of limited scope.¹³⁰⁷ Therapeutic privilege should not apply to CAM. It has been said that:

Paternalistic behaviour is rarely justified in orthodox medicine. In complementary medicine it strikes at the heart of patient- empowerment and self-responsibility, and will rarely, if ever, be defensible. Especially given the non-acute setting in which most complementary consultations take place, few situations will demand that a practitioner acts against the expressed wishes of the patient. Likewise, for there to be a truly collaborative relationship between therapist and patient, there must be a full and frank disclosure which facilitates the patient making decisions on the basis of all information available.¹³⁰⁸

Professional Ethics for CAM practitioners - Current situation

Professional ethics for CAM practitioners reflects the tapestry of controls that characterise the legal framework for CAM in this country.¹³⁰⁹

Statutory ethics

For chiropractors, osteopaths and in Victoria acupuncturists, TCM practitioners and Chinese medicine dispensers the relevant professional statutes make provision for the establishment of professional boards whose role includes the establishment and enforcement of professional ethics.

In all states, there is provision for complaints to be made against chiropractors and osteopaths for professional misconduct. In Victoria, complaints can be made to the Chinese Medicine Registration Board of Victoria in relation to a Chinese medicine practitioner, acupuncturist or Chinese herbal dispenser.¹³¹⁰ These complaints are either dealt with by the relevant

1307 *Rogers v Whitaker* above n 714, 634, 637.

1308 Stone and Matthews, above n 32, 265.

1309 For the approach in USA refer to Cohen, above n 11, Chap 7, 87-108.

1310 Refer to pp 246-247 above.

professional board, or referred to specially constituted disciplinary committees or health complaints bodies.

Provision is made for various types of orders by these bodies, including:

- reprimands.
- orders for counselling.
- suspension.
- de-registration.
- fines.

Generally, the provisions require a practitioner to be given notice of the proceedings and of the charges made. Where de-registration is possible, the practitioner will usually be entitled to legal representation and will enjoy a right of appeal to a court or tribunal.

The common law requires tribunals and bodies charged with the role of adjudicating on the registration status of practitioners to apply procedural fairness unless the statute specifically excludes this requirement. A court will be slow to exclude the obligation to observe procedural fairness unless clearly specified in the legislation.¹³¹¹

Procedural fairness (sometimes called natural justice) requires an individual to be afforded the opportunity to be heard and to present their case before a tribunal or other body makes a decision that will affect that person's rights or entitlements. Additionally, the body making

¹³¹¹ *Romeo v Asher* (1991) 29 FCR 343.

that decision should not be perceived as biased or prejudiced. The requirement for procedural fairness will vary, depending on the particular circumstances of a case.¹³¹²

Statutory Disciplinary procedures

Here an overview of the recently passed Queensland provisions will be canvassed as an example of the nature of the professional control provided by this type of legislation.

Queensland

The scheme for the regulation of professional ethics for Chiropractors in Queensland is found primarily in the *Health Practitioners (Professional Standards) Act 1999* (HPPSA) and *Chiropractors Registration Act 2001*(CRA).

The HPPSA has:

- retained some disciplinary functions within the professional board under the CRA; and
- integrated some aspects of the *Health Rights Commission Act 1991* (Qld).

These statutes with other health professional statutes are intended to integrate professional matters to allow a consistent approach to health practitioner regulation. This attempt has resulted in a complex mass of interrelated legislation when more concise legislation could have served a similar purpose.

¹³¹² *Kioa v West* (1985) 159 CLR 550, 585, 612.

Chiropractors Registration Act

Objects of CRA

The objects of the CRA are the protection of the public by ensuring health care is delivered in a professional, safe and competent way, upholding standards of practice and maintaining public confidence in the profession.¹³¹³

The CRA establishes the Chiropractors Board of Queensland.¹³¹⁴ The board is comprised of at least 7 but not more than 11 members appointed by Governor in Council. The board consists of registrants, one lawyer and persons with an interest in and knowledge of consumer health issues but who are not nor have been registrants under health practitioner legislation.¹³¹⁵ The functions of the Board include assessing applications for registration; registering eligible persons; monitoring and assessing registrants; keeping a register; promoting high standards of practice; development of CPE programs and monitoring and enforcement of compliance with the Act.¹³¹⁶

Complaints

The HPPSA makes provision for complaints to be made to the Board and for those complaints to be investigated and dealt with through the disciplinary provisions of the HPPSA.¹³¹⁷ A complaint about a practitioner can be made in writing with particulars of the allegation.¹³¹⁸ A complaint made to the Board can be either referred to the Health Rights

1313 CRA s 7.

1314 CRA s 9.

1315 CRA s 15.

1316 CRA s 11.

1317 HPPSA s 11.

1318 HPPSA s 49.

Commissioner; to the investigative, disciplinary or impairment parts of the HPPSA or dealt with by the Board itself.¹³¹⁹

Board disciplinary proceeding

The board can investigate a complaint.¹³²⁰ After investigation the Board can either:¹³²¹

- refer the matter to the Health Rights Commission.
- refer the matter for hearing by the Health Practitioners Tribunal.
- refer for hearing by a Professional Conduct Review Panel.
- take disciplinary proceedings itself.¹³²²
- enter into an undertaking in regard to the registrant's practice.
- deal with matter under the practitioner impairment part.
- decide to take no further action or such action as is approved by the Minister.
- deal with it under the inspection part of the CRA.
- deal with it under the immediate suspension part.

Immediate Suspension Provisions. If the board is of the view that a registrant poses an imminent threat to vulnerable persons and immediate action is necessary the board can suspend or impose conditions on the registrant's registration.¹³²³

Health Assessment

The board can order a health assessment of a registrant if the board is conducting an investigation and it reasonably believes that it is necessary for the registrant to undergo a health assessment.¹³²⁴

1319 HPPSA s 51.

1320 HPPSA Part 5.

1321 HPPSA s 118.

1322 HPPSA s 122-s 265.

A disciplinary matter can be heard by¹³²⁵:

- a hearing by the board.
- a hearing by a disciplinary committee of the board.
- a professional conduct review panel.
- the Health Practitioners Tribunal.

Disciplinary Action

The grounds for disciplinary action include:¹³²⁶

- the registrant has acted in a way that constitutes unsatisfactory professional conduct.
- failure to comply with a condition of practice.
- the registrant no longer meets the criteria under the relevant health registration act.
- the registrant is convicted of an offence against a statute related to the practice including the *Fair Trading Act*.
- The registrant is convicted of an indictable offence.

Section 124 provides that one ground for disciplinary action is ‘unsatisfactory conduct.’ This term is defined in the Schedule to the HPPSA to include ‘professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgment or care, in the practice of the registrant’s profession.’ This means that negligent treatment and not only unethical treatment can attract penalty.¹³²⁷

1323 HPPSA s 59.

1324 HPPSA s 107.

1325 HPPSA s 130, 126.

1326 HPPSA s 124.

*Board disciplinary proceedings procedure*¹³²⁸

In a disciplinary proceeding by a Board the following provisions apply:

- It requires notice to registrant of the grounds of the disciplinary action, the facts and circumstances.
- A registrant can be represented at a hearing.
- The board or an appointed disciplinary committee must comply with natural justice.
- The board must act as quickly and with little formality as is consistent with fair and proper consideration of the issues.
- The board is not bound by the rules of evidence.
- Proceedings can be by correspondence.¹³²⁹
- The board can determine that a practitioner be advised, cautioned, reprimanded or be required to enter an undertaking.¹³³⁰

*Professional Conduct Review Panel*¹³³¹

This is a panel constituted by professional and general public representatives. The panel deals with matters only that permit advice, caution, reprimand or imposing conditions on the registrant's registration.¹³³²

Panel Procedures

In its proceedings the Panel:¹³³³

- Must comply with natural justice.
- Must act quickly with minimum of formality and technicality.

1328 HPPSA Part 6 Division 4.

1329 HPPSA s 152-157.

1330 HPPSA s 165.

1331 HPPSA s 171.

1332 HPPSA s 201 and s 14.

1333 HPPSA s 179.

- Is not bound by rules of evidence.
- The complainant and the board may be accompanied by a lawyer but they do not represent the party.

A panel may refer matters to the tribunal that may require suspension or deregistration.¹³³⁴

Health Practitioners Tribunal

The tribunal can deal with more serious matters such as where suspension or deregistration is possible and in relation to impaired practitioners.¹³³⁵ The jurisdiction of the tribunal includes¹³³⁶ disciplinary matters under s 126 referred by a health practitioner board; hearing appeals under part 9 of the HPPSA and reviews of reviewable decisions of other bodies. The tribunal is constituted by a District Court judge assisted by 2 professional review panel members and one public review panel member.

Procedures of Tribunal

These are the same as described above for a professional conduct review panel except a party can be represented by a lawyer and the proceedings may be subject to rules or directions as to proceedings.¹³³⁷ The tribunal is able to suspend and/or deregister a practitioner as well as applying the other disciplinary measures such as a caution, reprimand and imposing conditions.¹³³⁸ If the board or disciplinary committee considers the matter may justify the suspension or deregistration of a practitioner the matter should be referred to the tribunal.¹³³⁹

Appeal to Tribunal

1334 HPPSA s 178.

1335 HPPSA s 211.

1336 HPPSA s 211.

1337 HPPSA s 225.

1338 HPPSA s 241.

1339 HPPSA ss 134 -135.

There are appeals against decisions of a panel and board by way of re-hearing to the Tribunal.¹³⁴⁰ There is also an appeal to the Court of Appeal from decisions of the Tribunal on a question of law only.¹³⁴¹

Assessment of Disciplinary Provisions

These provisions are complex but do provide some objectivity in the review of the performance of registered practitioners. This review is made within a context where natural justice is observed but with the aim being the speedy resolution of charges, complaints and issues. This process is important in providing complainants with a resolution of their complaints while respecting the practitioner's entitlement to a fair hearing.¹³⁴² Importantly, the statutory process provides effective enforcement that can allow deregistration or suspension to stop an unethical or incompetent practitioner from causing further harm. It also provides an open and transparent process that provides some control over practitioner behaviour while providing the public with some insight into that process. The input by a public representative on a Professional Conduct Review Panel or Tribunal permits public input into decision-making to reflect community attitudes and to avoid the implication that decisions are made by practitioners based on self interest.

This type of disciplinary process has as its aim the protection of the public. Certainly there is a public benefit in disciplining unethical or incompetent practitioners. Mendelson notes that authority suggests that the outcome of disciplinary proceedings may be punitive for the practitioner but punishment is not considered to be the purpose of these provisions.¹³⁴³

1340 HPPSA s 325.

1341 HPPSA ss 346, 348.

1342 Stone, above n 1233, 200.

Mendelson does not argue with the application of a penalty but with the fact that the proceedings can have a substantial impact on a practitioner's personal and professional life when the standard of proof applied to such proceedings is higher than the civil standard but not as high as the criminal standard of proof.¹³⁴⁴ Where the matter relates to a minor issue this is not problematic but may be a concern where serious matters are raised, such as in the case of a claim of serious sexual misconduct. This concern is compounded as these tribunals do not apply the rules of evidence.¹³⁴⁵ That may permit the use of hearsay evidence not permitted in a criminal trial. The admissibility of hearsay evidence could result in injustice.¹³⁴⁶ The application of a higher onus of proof and the strict application of the rules of evidence to these tribunals could avoid injustice in some cases but may create more delays and more expensive justice. This may not be in the interests of complainants or practitioners. The aim of providing accessible, informal quick and efficient enforcement of justice may be lost.

Application to CAM practitioners

Any regulatory system that is suggested below will need to incorporate professional misconduct provisions that incorporate ethical rules; practice criteria, referral procedures and protocols that relate to the modality in question. The regulation of chiropractic is somewhat easily incorporated into the normal medical regulation structure as chiropractic has many similarities in training and professional outlook. Any statutory structure must relate to the

1343 *New South Wales Bar Association v Evatt* (1968) 117 CLR 177, 183 ; Dunuta Mendelson, 'Disciplinary Powers of Medical Practice Boards and the Rule of Law' (2000) 8 *Journal of Law and Medicine* 142-152.

1344 *Brigginshaw v Brigginshaw* (1938) 60 CLR 336; *Purnell v Medical Board of Queensland* (1999) 1 Qd R 362, 368.

1345 For example HPPSA s 225.

1346 Mendelson above n 1343, 151. An example of injustice is *CD v Medical Practitioners Board* (Unreported, MF McNamara Administrative Appeals Tribunal no 1997/58363 March 1998) where a doctor was found to have sexually assaulted a patient but subsequently the accusations were shown to have been untrue.

type of modality being regulated. For example, in regulating herbalists it would be necessary that there would be an ethical protocol to ensure the purity of prescribed herbs or requirements on the handling of poisons for homoeopaths.

Codes of Ethics and their Implication For Unregistered CAM practitioners

For the majority of CAM practitioners who are not subject to specific statutory control professional ethics are found in codes of ethics that have been promulgated by most professional associations.

Codes of ethics vary greatly. Codes of ethics may be aspirational indicating general virtues or aims such as caring, communication and competent practice. Codes of Ethics may be prescriptive and indicate specific duties of practitioners or rules of professional conduct, such as, practitioners should not guarantee results of treatment.¹³⁴⁷ Codes of ethics do have an appropriate role in encouraging ethical practice even though their legal status is somewhat uncertain.¹³⁴⁸

- a code of ethics might provide some indication for determining what is or is not negligence. The relevance of codes of ethics has been rejected in some cases dealing with appropriate behaviour of nurses.¹³⁴⁹
- a code of ethics can provide a public statement of how a profession can be expected to behave and for which they can be accountable.¹³⁵⁰
- it provides a standard to be attained by any person entering the profession.

1347 Johnstone above n 1238, 51.

1348 Loane Skene, *Law and Medical Practice: Rights, Duties, Claims and Defences* (1998) 34.

1349 Johnstone, above n 1238, 53.

1350 Ibid; Stone, above n 1233, 65.

- It can assist in cultivating a moral character by increasing the chance that a practitioner will act in moral ways for the right reasons.

There are numerous associations, federations and councils in Australia relating to non-registered and registered CAM modalities.¹³⁵¹ Most associations have a code of ethics or code of practice that attempts to regulate the activities of practitioners. Members are obliged to comply with the terms of the code or risk losing their membership or being made the subject of disciplinary action.

Unlike registered professions, non-registered professions have little statutory backing to their codes of ethics. Although some conduct may also have civil and criminal consequences, the direct professional impact is limited to disciplinary proceedings. Exclusion will have little or no impact on the ability to practice.

In most states, a breach of professional ethics, if accompanied by a formal complaint to a health complaints authority,¹³⁵² may result in the practitioner being subject to investigation by that body.

Typical Points Covered by Codes of Ethics

A review of the Codes of Ethics of a number of major CAM professional associations¹³⁵³ reveals the most common provisions in Codes of Ethics are:

1351 In Bensoussan and Myers there were 23 identified associated with TCM and acupuncture, above n 77, 136.

1352 Refer to pp 263-275 above.

1353 Including Australian Traditional Medicine Society; Australian Acupuncture and Chinese Medicine Association; Australian Natural Therapists Association.

- Practitioners should not criticise other practitioners. Perhaps a patient based approach would encourage a practitioner to act quickly if he or she thinks another practitioner is acting unprofessionally.¹³⁵⁴
- The necessity for professional development and continuing education.
- The primary concern for practitioners is that the health of the client comes first.
- Practitioners should practice while being non-discriminatory on the basis of race; impairment etc.
- Practitioners should ensure they practice from safe, hygienic premises.
- Current Professional Indemnity Insurance should be obtained.
- Practitioners exhibit both physical and mental fitness for practice.
- Practitioners should practice only within the discipline for which they are trained.
- Sexual Relationships with Clients should be avoided.
- Practitioners should not indecently exposure themselves or their patient.
- A practitioner should avoid a conflict between their interest and that of their client.
- Advertising of the practice should be honest and not misleading.
- Practitioners should not use titles suggesting medical qualifications.
- Claims of Cures should be avoided
- Claims of Secret Methods should be avoided.

Critique of Codes of Ethics

Codes of ethics are documents that are designed to achieve a number of goals. They are directed to inculcating ethical behaviour in association members for the benefit of patients and for the profession. Codes of ethics also exhibit less laudatory intentions or 'enlightened

¹³⁵⁴ Stone, above n 1233, 66.

self interest' that focus on attempts to limit competition in the profession for the benefit of maintaining higher fees and market share for members.¹³⁵⁵ The purposes of codes of ethics are:

Professional profile

It is in the interests of all members of a profession that the members be aware of their ethical and legal obligations to their clients, other professionals and the general public. The inculcation of a positive image of the profession as caring, professional and competent will engender demand for the services in the community. In this way a code of ethics expresses publicly the commitment of a profession to moral behaviour in a professional capacity.¹³⁵⁶

Government lobbying and public opinion

An association that represents a large proportion of practitioners and enforces professional standards will be in a better position to lobby government bodies, inquiries and government ministers in relation to the formulation of government policy. A professional body may use them to obtain conformity and to assist in the administrative control of professionals.¹³⁵⁷

Creating awareness amongst the profession

An important purpose of a code of ethics is that professionals are aware of and are thinking of ethics, and thereby have particular responsibilities to a client. Codes of ethics systematise the ethical rules of a profession, to clarify what are the requirements for ethical practice. A properly drafted and well thought out document can provide helpful guidance to a professional as to who and what they are.¹³⁵⁸

1355 Milburn, above n 176, 37.

1356 M. Coady and S. Bloch, *Codes of Ethics and the Professions* (1996) 27.

1357 Ibid 7.

1358 Ibid, 83.

The existence of a code can increase the chance that practitioners will act in the interests of their client and the profession and not purely in self-interest by providing sanctions for non-compliance.¹³⁵⁹

The extent to which a code of ethics achieves its purpose will depend very much on the level of shared commitment to the principles at the basis of the expressed rules. Codes of ethics have been criticized for not being explicit in basing their guidance upon fundamental ethical principles. For example, many state the need to obtain consent for treatment but do not clearly ground that upon the principle of autonomy.¹³⁶⁰

A code of ethics may state that it is unethical to become sexually involved with a client but do not refer to the principle of non-maleficence. Codes of ethics are made by professionals for professionals and often don't deal adequately with the principle of justice, such as describing why a patient is entitled to compensation if they are the subject of negligent treatment and the need to deal sensitively with complaints.¹³⁶¹ They will often not deal with the distributive justice issue that relates to provision of pro bono services.¹³⁶² Codes of ethics tend to be couched in negative terms that emphasise what a practitioner should not do rather than what they should aspire to achieve in their practice.¹³⁶³

Complaint Mechanisms

1359 Ibid, 27.

1360 Matthews and Stone, above n 32, 194; J Stone, above n 233, 69.

1361 Matthews and Stone, *ibid* 195.

1362 Stone, above n 237, 67.

1363 *Ibid* 69.

Few codes provide clear instructions about how to complain about a practitioner and how this relates to the disciplinary procedures. Most codes do not indicate:

- how and to whom a complaint could be made and whether a complaint can be made orally or only in writing.
- who can make a complaint. Can the association; another practitioner; government body; patient; health professional or third party commence it?
- the procedure for investigation of a claim made against a member.
- the procedures for giving notification of the complaint to the practitioner.
- provisions to ensure procedural fairness for a practitioner is preserved. This would include provision for the practitioner to be given notice of the charge or complaint; the potential consequences if the charge is proven; that sufficient time is provided to prepare a defence and an indication that a properly constituted and fair tribunal will be convened to hear the charge with an indication of any possible appeal provisions.
- Provision for alternative dispute resolution to resolve a dispute between a complainant and a member.

An overly vague complaint mechanism does not support patients who make complaint nor does it provide members with well defined rights to ensure they are appropriately and fairly dealt with in the process.

Features of regulation focussed on ethical practice

One feature of the current professional ethics structure for both registered and unregistered practitioners is the reliance on retrospective enforcement of ethics. Only after a breach of ethics has occurred such as through gross negligence; sexually inappropriate behaviour or

exploitation of a client does professional ethics enforcement become relevant. This retrospective mechanism may encourage compliance through the application of sanctions but does not guarantee that a client will be protected from unethical practice.¹³⁶⁴

The optimal model of professional ethics combines the retrospective application of sanctions with prospective encouragement for ethical practice from the internal concepts and thought processes of a practitioner. Achieving this goal would involve attention to the production of ethical health professionals at the very beginning of a professional career.

The dissemination of ethical principles of practice can involve a discussion of complex and erudite philosophies that are said to provide the intellectual background to moral decision-making. This is probably of greatest importance in the medical profession or allied professions such as nursing which deal with life and death decisions on a daily basis. For these professions decisions might relate to whether life support should be continued for a comatose individual; what are appropriate steps to take in counselling parties to fertility procedures; decisions on the provision of potentially dangerous pharmaceutical or surgical procedures. This type of activity requires either a well informed understanding of the ethical obligations of a practitioner or a well developed set of protocols or standard procedures to provide guidance in making appropriate decisions. It is arguable that training in fundamental ethical philosophy and theory will make a valid contribution to the capability to make such decisions and to resolve the inconsistent ethical principles at play in those situations.

For the practice of CAM it is unlikely that life and death decisions or fundamentally complex ethical decisions will commonly arise. It is suggested that for CAM practitioners the

¹³⁶⁴ Stone and Matthews, above n 32, 211.

emphasis in education for ethical practice should be in real life situations that arise on a daily basis and particularly aimed at the unique position of CAM in the health sector.

A broad education on ethics and philosophy will no doubt produce a well-rounded and educated practitioner. This might produce a better practitioner but the placement of much CAM education within private colleges, TAFE and in diploma courses does not always allow the time and resources for this approach. Even in degree courses the amount of time available for such tuition is limited.

Matters of primary specific concern for a CAM practitioner should be:

- Understanding the legal and ethical limitations of CAM practice.
- When to refer a client to a medical practitioner or other CAM practitioner.
- Identifying inappropriate activity with clients based upon the closeness of the therapeutic relationship; how to avoid such a situation and how to deal with that behaviour.
- The ethical issues relating to statements about the efficacy of treatment; likely prognosis and risks of treatment.
- Ethical issues relating to the marketing of services generally.
- Ethical issues relating to the safety of therapies.
- Ethical issues relating to confidentiality of the therapeutic relationship.

Education

Education of CAM practitioners is important as it will be one basis upon which a modality will be assessed by government and other regulatory authorities. It is also one

potential area of weakness for some CAM modalities that until recent years relied for intellectual structure upon traditional knowledge derived from ancient practice and the writings and words of the originators of the modality.¹³⁶⁵ This type of knowledge base does not easily translate into the well-formulated knowledge base that modern regulators may seek when considering statutory regulation.

An understanding of professional ethics derives from a number of sources namely:

- Societal values.
- Models of professional practice provided by professional associations in a code of ethics or conduct.
- Models of professional practice from supervisors; mentors, employers or employees.
- Principles derived from educational practice.
- Legislative models ie registration statutes and regulations and health complaints legislation.

Formal education provides a means to maximise the theoretical underpinning for professional ethics. Where should this education be placed in the course?

Should it be integrated at various places in the curriculum as issues arise for consideration? or; should it be incorporated through a discrete subject on professional ethics or law and ethics subject?¹³⁶⁶

Critique of educational model

¹³⁶⁵ Stone, above n 1233, 16-18.

If the purpose is to provide a well-focused model of ethical practice the integrated model relies upon there being a properly coordinated framework for that training where the goals of the program are reinforced at each stage. By being integrated the training is situated and embedded in practical examples of ethical dilemmas or concerns. The danger for the integrated model is that it may rely upon the uncoordinated efforts of individual teachers. Some teachers may not have the appropriate understanding in fundamental ethical issues to provide the appropriate guidance. Currently much CAM education relies upon the input of part time teachers who may lack the appropriate vision of integrated ethical skills education or exhibit appropriate practice habits that should be propagated. Training in professional ethics may be swamped by the demands of the substantive subject matter of the relevant course. The use of integrated ethics education, if attempted, should be within a framework of an integrated ethics skills program with clearly articulated goals that are policed for compliance.

The use of a distinct subject model has its advantages over the integrated model in that students (hopefully near the end of their degree) in one subject are asked to focus on the ethical and practical issues that will apply for their practice of CAM.¹³⁶⁷ This approach provides the focus and time to achieve considerable progress in the understanding of ethical obligations of practitioners. The challenge for this style of education is to provide a practical understanding of how to deal with specific situations that occur in practice. This suggests the need for a focus on case studies and practical examples to anchor the knowledge in a practical reality. It is hope that even if a distinct subject model is followed that ethical practice is inculcated by example during the other subjects taught in the degree or diploma.

1366 Stone and Matthews, above n 32, 279.

Content of education

The content of ethics education provided to a practitioner can encompass the broad range of professional tasks. Potentially most tasks performed by a professional health practitioner can be considered in the context of one or more of the four basic ethical principles. For example, note the ethical implications of hygiene precautions; competent record keeping and expert technical advice. Stone and Matthews suggest a number of parameters for practitioner education for ethical practice that are:¹³⁶⁸

Assessment of competence in modality.

Without basic competence in the modality a practitioner cannot claim the status of a professional or satisfy the obligation to provide the services sought by the health consumer. This encompasses ensuring techniques used will provide the benefits that are claimed and will not injure the client or be to their detriment.

Assessment of human skills.

It goes to the heart of CAM that practitioners are able to deal with the emotional and spiritual aspects of their profession. This is a skill that may be difficult to teach and to assess though communication can be taught and practiced as a skill. For a CAM practitioner the ability to communicate, empathise and to create an environment of trust is fundamental to the healing process. Stone and Matthews suggest that:

The problem for complementary medicine is one of credibility. It is all very well to pay lip-service to treating emotional needs and spiritual needs, but are most complementary therapists equipped to do this? Even if they have some training in counselling skills, which would seem to be a prerequisite if attempting to work on an emotional level, what training is given, or can be given, to respond to a patient's spiritual dimension? The issue goes to the heart of orthodox

1367 Johnstone, above n 1238, 434; Exemplified by subject Clinic Law and Ethics at Australian College of Natural Medicine Brisbane.

1368 Stone and Matthews, above n 32, 271-279.

scepticism of complementary therapy, and is a matter which sooner or later, will have to be addressed on a collective level.¹³⁶⁹

Without being able to demonstrate some competence in human skills the professional status of CAM professions is put at risk.

Selection of candidates.

The historical development of the hegemony of OM was to some extent based upon the high educational, financial and social standards of the candidates for medical education. History suggests the raising of the status of CAM will depend to some extent on the ability of CAM to raise the status of its candidates. Stone and Matthews indicate that educational establishments have a responsibility to reject candidates who may be unsuitable practitioners. This unsuitability they state may be because candidates have ulterior motives or an unhealthy desire to dominate or care for people.¹³⁷⁰ In a perfect world tight and enlightened selection of candidates would be preferable but it is not practical to firstly identify these people and then exclude them from education. People afflicted in this way may choose not to practice or can change their approach or attitude. The identification of these individuals during training could assist in the provision of counselling or rehabilitation for persons identified as having problems in this area. Much of the training of CAM practitioners is via private colleges and TAFE and it is unlikely that those institutions would have the interest in or resources to properly address this issue. This is not an issue adequately dealt with by any other profession.

Agreed core competencies.

This process is continuing in the ANTA training packages for homoeopathy, naturopathy, shiatsu, remedial therapies (including remedial massage), TCM and Western Herbal

¹³⁶⁹ Ibid 273; Stone, above n 1237, 6.
¹³⁷⁰ Stone and Matthews, Ibid 274.

Medicine recently finalized.¹³⁷¹ If these competencies are determined then a standard set of performance criteria can be applied to determine a basic level of competence.

Strong research base

The ability to point to scientific proof of efficacy of a therapy aligns CAM with scientific medicine. If the rhetoric of OM is taken at its word then there is no such thing as alternative and orthodox medicine just proven and unproven medicine. If a treatment is scientifically proven to be effective then it is no longer alternative.¹³⁷² The obtaining of a strong research base for CAM is problematic owing to the cost of obtaining that evidence but is important to forge a secure place for this industry in the health sector.¹³⁷³

Inclusion of orthodox medical knowledge

A constant refrain from OM is the perceived danger of a CAM practitioner not recognising conditions that may require medical intervention. For many clients the choice of a CAM practitioner does not exclude attending a MD if necessary. It is part of a CAM practitioner's responsibility to be able to advise when a malady is outside their scope of practice or to react appropriately if the client has not responded to treatment. Although some CAM practitioners would argue that they should be entitled to practice within the terms of their modality that eschews standard bio-medical concepts the legal and regulatory context suggests this dimension cannot be ignored. The inability in most cases to incorporate medical standard training in CAM owing to its expense and sophistication suggests the need for closer connections with OM practitioners to encourage referral. Registration status and integration

¹³⁷¹ Australian National Training Authority, *Health Training Package, HLT 02 Version 1.0*, January 2002.

¹³⁷² The Medical Council of New Zealand, *Guidelines on Complementary, Alternative or Unconventional Medicine* April (2000); The Medical Board of Queensland has adapted these guidelines for their Board Policy on *Complementary, Alternative and Unconventional Medicine*

http://www.medicalboard.qld.gov.au/files/policies_alternative.html.

¹³⁷³ Bensoussan and Myers, above n 77, 12.

into the health care sector would encourage the practice of cross referral and may deliver better health care outcomes.

Post qualification education and mentoring

Post qualification education or continuing education will ensure that practitioners keep up to date with the developments in their profession and the regulatory environment. Most CAM practitioners are in private practice. This means there is limited access to the advice and mentoring available to inexperienced medical doctors. This access would improve the professionalism of CAM. Currently most major professional associations provide a compulsory continuing education program.¹³⁷⁴

Conclusion

This chapter suggests a new model of professional ethics for CAM practitioners that acknowledges standard ethical precepts but within the unique context of CAM practice. Once it is appreciated that OM ethics derives from its own therapeutic context then the need to differentiate CAM ethics is easily understood. The suggested model emphasises modality specific ethical decision making drawing upon concepts of autonomy that requires an information rich environment to function adequately. Ethical CAM practice based on legal reality and attention to the concepts of beneficence suggests a well developed understanding of the need for referral to MD's when necessary and the promotion of well informed decision making by clients. These concepts should also be incorporated into any statutory disciplinary structure that may be contemplated for CAM practitioners.

¹³⁷⁴ Based on telephone conversation with ATMS officer.

Chapter 7

A model for Professional Regulation of CAM

Introduction

This chapter will investigate the history of professional statutory regulation and its aims. This reveals that the form of regulation currently preferred does not always serve the public interest. From this discussion will be derived a suggested model for the regulation of CAM in Australia that deals with the limitations of statutory regulation to permit regulation where the public interest is preserved.

History of regulation

The modern regime of professional regulation derives from 19th and early 20th century conceptions of the appropriate role for the professions in society.¹³⁷⁵ Emile Durkheim proposed that professions had a role based on a conception of structured functionalism. From the Durkheim perspective the professions were said to provide a significant foil to the materialist self-interested motivations of much of society.¹³⁷⁶ Durkheim saw the professions as the major avenue for subjugating individual motives of self-interest to the needs of the community in a manner functional for society.¹³⁷⁷ This approach both legitimised and mystified professional knowledge.¹³⁷⁸

1375 Manitoba Law Reform Commission, *Regulating Professions and Occupations*, Report 84 (1994) 2-4.

1376 R L Abel, *American Lawyers* (1989) 16.

1377 Alec Pemberton and Paul Boreham, 'Towards a Reorientation of Sociological Studies of the Professions' in Paul Boreham, Alec Pemberton and Paul Wilson (eds), *The Professions in Australia* (1976) 17.

1378 Willis, above n 129, 10.

During this period it was thought that science and the application of rational thought wielded by noble men of higher education and scholarship would be the source of solutions to the blights on the human condition.¹³⁷⁹ This higher education was to be provided by universities where the principles at the basis of law; science; medicine and engineering could be studied, researched and progressed.¹³⁸⁰ This scholarship was derived with an eye to the practical application of immutable laws for the benefit of the world. The professional's services were to be provided by gentlemen for whom the receipt of monetary reward was a secondary consideration to serving society. This selfless aim was said to be the vital distinction between the professions and non-professional trades and occupations. Pemberton and Boreham have expressed doubts about the validity of the altruism said to be part of a professional's outlook. They suggest that self-interest is important to many professional ideals.¹³⁸¹

The commitment of the professions to the public interest was reflected in and buttressed by the enforcement of written codes of ethics that applied professional discipline to both the private and professional life of the professional. The learned professions were expected to shoulder considerable responsibility in undertaking their professional duties. Professional activity involved respecting the confidential information of a client and undertaking tasks where the expert knowledge of the professional created a power discrepancy and dependence by the client.¹³⁸²

These professional burdens and responsibilities were said to justify the statutory force given to statutory schemes for the regulation of a wide range of professions. Statutory self-regulation as distinct from government regulation was said to be preferable as only members

1379 Starr, above n 6, 3.

1380 Cant and Sharma, above n 616, 579-588.

1381 Pemberton, above n 1377, 25.

1382 Wardwell, above n 124, 221; Manitoba Report, above n 1375, 4; Abel, above n 1376, 37.

of the profession could assess the competence of prospective members of the profession. This view could be seen as disingenuous as the profession created the monopoly for that expert knowledge and government could access its own independent advice.¹³⁸³

Self-regulation delegates professional controls to members of the profession by statute. This form of regulation is reflected in the early professional regulation statutes like the *Medical Act 1858* (UK), in medical practice legislation in all states and the recently enacted *Chinese Medicine Registration Act 2000* (Vic). Typically, most important decisions of a professional nature such as educational or admission standards and determinations of professional misconduct are addressed by members of the profession regulated, although the administrative functions are performed by public servants.

The motivation for regulation is usually expressed as the desire to protect important values in society. Selznick described regulation as ‘sustained and focused control exercised by a public agency over activities that are valued by a community.’¹³⁸⁴ Regulation of a profession involves a movement away from market forces to regulate the provision of services towards a collectivist model.¹³⁸⁵ Although the professions provide important services they are also economic units. The view of the professions as selfless servants promoted by philosophers like Durkheim inhibits the mature appreciation of the role of the professions in actively establishing and maintaining their control over market forces for their benefit. If the Durkheimian view had some validity in the 19th and early 20th century the post modernist era has laid bare the role that strident self-interest plays in the professions attempts to control the provision of professional services. The involvement of the professions including OM and

1383 Manitoba Report, above n 1325, 4; Abel *ibid*, 37.

1384 P Selznick, 'Focusing Organizational Research on Regulation' in R Noll (ed), *Regulatory Policy and the Social Sciences* (1985) 363 quoted in Anthony Ogus, *Regulation: Legal Form and Economic Theory* (1994) 1.

1385 Ogus, above n 1384, 2.

CAM in seeking and maintaining professional closure must be understood to appreciate the appropriate role of regulation in the health care sector.¹³⁸⁶ Without this understanding, arguments addressed to maintenance of standards and quality may not be seen in the context of their economic impact and the profession's goals based on self-interest.¹³⁸⁷

Regulation of CAM – Is there a need?

Mills and Budd have suggested that the purpose of regulation of health-care is:

To establish a nationwide, professionally determined and independent standard of training, conduct and competence for each profession for the protection of the public and the guidance of employers. To underpin the personal accountability of practitioners for maintaining safe and effective practice and to include effective measures to deal with individuals whose continuing practice presents an unacceptable risk to the public or otherwise renders them unfit to be a registered member of the profession.¹³⁸⁸

The analysis above suggests the need to reconsider the way in which CAM is regulated in Australia based upon factors such as:

- Actual and potential dangers in CAM from the inherent risks of the therapies and the possibility of delays in obtaining potentially beneficial OM.¹³⁸⁹ Some of these delays may reflect the difficulties and suspicions that exist between OM and CAM and the lack of accepted referral protocols that could avoid some of this difficulty.
- The popularity and widespread use of CAM. This reflects partly the acceptance of a holistic healing philosophy and the rejection by many consumers of the biomedical approach to healing as being appropriate in all situations. The autonomous choice

1386 Abel, above n 1376, 20.

1387 Michael Trebilcock, 'The Professions and Public Policy: The Nature of the Agenda' in P Stayton and Michael J Trebilcock (eds), *The Professions and Public Policy* (1976) 3.

1388 House of Lords, above n 39, 5.1 quoted from S Budd and S Mills, *Regulatory Prospects for Complementary and Alternative Medicine* Information Pack (2000) from.

1389 Dimond, above n 75, 81.

made by many people to choose CAM for their health care is currently not fully supported (and is arguably discouraged) by the regulatory system.¹³⁹⁰

- The need to provide to consumers of CAM with information and quality markers for treatment and the provision of practitioners who exhibit certain minimum quality educational and ethical standards.¹³⁹¹ The provision of accurate pre-market information can avoid the costs and difficulties of seeking compensation for injury after the event.¹³⁹²
- The costs and difficulties of obtaining a remedy for incompetent practice; impropriety or fraud associated with CAM for any aggrieved patient based on generalist common law and statutory remedies.¹³⁹³

Public Benefit as a Fundamental Criteria

Any type of regulation of CAM should be based upon the delivery of a public benefit and not simply to provide the avenue to establish and maintain the income and status of the profession regulated through techniques of professional closure.¹³⁹⁴ A derived public benefit is essential to offset the social and economic cost of statutory regulation. The cost of regulation includes compliance costs; infrastructure and equipment to comply with standards and administrative costs.¹³⁹⁵

1390 Easthorpe, above n 312, 294.

1391 Ibid 291.

1392 Dimond, above n 75, 35.

1393 Ogus, above n 1384, 217.

1394 Easthorpe, above n 312, 296; Options Report, above n 642, 2; Manitoba, above n 1375, 8; House of Lords above n 39, 5.14 Walter Gellhorn, 'The Abuse of Occupational Licensing' (1976) 44 *The University of Chicago Law Review* 6, 12; Alex Maurizi, 'Occupational Licensing and the Public Interest' (1974) 82 *Journal of Political Economy* 399-413; Sherman Folland, Allen C Goodman and Miron Stano, *The Economics of Health and Health Care* (2nd ed, 1997) 371; CE Phelps, *Health Economics* (2nd ed, 1997)

540-546; Frank A Sloan, 'Does the Market Choose The Correct Incentives to get to the Desired Outcomes? Market Failure Re-examined' in Richard J Arnould (ed), *Competitive Approaches to Health Care Reform* (1993) 260; Ogus, above n 1384, 219; Treblicock, above n 1387, 12.

¹³⁹⁵ Ogus, *ibid* 156.

Based upon an overt motivation of protecting the public interest, professional or occupational regulation has been introduced through various forms of government regulation such as self-regulation and government licensing arrangements exemplified by statutory regulation of medical doctors; chiropractors; engineers; plumbers; electricians and real estate agents.

These regulation arrangements have exhibited a tendency to lapse into techniques of professional closure and have the effect of excluding of potential rivals.¹³⁹⁶ This is reflected especially in self-regulatory regimes where the profession or occupational group the subject of the regulation continues to control and limit access to the profession by ratcheting up the educational prerequisites for registration. This has the effect of effectively excluding potential entrants who would have provided economic competition to the incumbent practitioners.

Folland Goodman and Stanon suggest self-interest; the public interest and the general political environment are all-important factors in creating a momentum towards regulation of a profession.¹³⁹⁷

From the perspective of the profession the effect of statutory regulation is to:¹³⁹⁸

- improve the status of the profession.
- increase the ability to negotiate with government.
- promote the unity of the profession.
- secure profession wide professional indemnity insurance.
- maintain high entry standards and continuing practice standards.

1396 Wardwell, above n 124, 207- 221; Starr, above n 6, 23; Gellhorn, above n 1394, 6; S Ostry, 'Competition Policy and the self regulating professions' in P Slayton and MJ Trebilcock (eds), *The Professions and Public Policy* (1976) 19; Simpson, above n 154, 148.

1397 Folland, Goodman and Stano, above n 1394, 374.

374; Easthorpe, above n 312, 291.

1398 House of Lords, above n 39, 5.3.

These issues are exemplified by the economic effects of professional closure favoured by OM. In the 19th century OM used disciplined unions or medical societies to establish and maintain their economic power. This authority¹³⁹⁹:

- stimulated the market for medical services by taking healing out of the hands of the family to the expert medical doctor.
- restricted the market by engendering political support for licensing that placed a limit on the availability of medical services thereby causing an increase in return or economic rent for the medical profession.
- increased the dependence on expert medical practitioners as the use of technology in health care developed.

If a form of regulation is attempted only when its public benefits exceed its costs it could sensibly only be considered when the profession's scope of practice and entry and practice standards are resolved.¹⁴⁰⁰

The lessons from the history of OM suggest the need to scrutinise any suggestion that CAM should be regulated for the public benefit. Before acceding to this suggestion clear public benefit and a positive balance on a cost/benefit analysis of this structure should be obvious. This is a matter of some difficulty as CAM normally is happy to promote itself as a 'natural' or safe alternative to OM. This gentle, safe and natural approach to health care sows the seeds of doubt as to the necessity to regulate CAM. If it is safe what public benefit is being obtained for the costs of this regulation? For the purpose of promoting a policy of regulation

1399 Starr, above n 6, 24.

1400 Manitoba report, above n 1375, 25.

CAM paradoxically needs to argue that CAM is potentially harmful in the hands of unregulated and unqualified practitioners.

Type of Regulatory System

The type of regulatory system that could be applied can be categorised into compliance-based or deterrence based systems. Compliance based systems rely upon the setting of standards and the use of negotiation and persuasion to achieve regulatory goals. In the Australian context, this is exemplified by the health complaints legislation in most states that emphasise the education of consumers and health services providers about the values of respect for the patient and promotes codes of responsibilities and obligations. These statutes provide weak enforcement procedures. Deterrence based systems rely upon on penal responses to violations of regulation.¹⁴⁰¹ This is exemplified by the enforcement of criminal and professional sanctions for breaches of registration statutes by registered health professionals. It has been argued that the most effective form of regulation comes from a combination of a compliance-based system where recourse to sanctions is available if voluntary compliance is not effective.¹⁴⁰² In this way regulators are said to wield a benign big stick that encourages voluntary compliance.

The motivations for health practitioners to comply with the strategy promulgated by a regulatory body may be various.¹⁴⁰³ Health service providers may be motivated by deontological motivations such as ethical precepts of beneficence and autonomy. This type of practitioner will likely react positively to persuasion if it is aligned to their beliefs. Other practitioners may be motivated by a sense of responsibility to avoid injury to their patients.

1401 Russell G Smith, 'Health Care, Crime and Regulatory Control: An Introduction' in Russell G Smith (ed) *Health Care, Crime and Regulatory Control* (1998) 5.

1402 Ibid 6-8.

1403 Ibid.

For other practitioners more utilitarian concepts such as avoiding professional embarrassment and sanction that could impact on their income and social position might motivate behaviour.¹⁴⁰⁴ The motivation might also be to avoid the stigma of being required to appear before a professional body and undergo the shaming process this may involve.

The current deterrence based system of regulation of health professional incorporates a disintegrative process where there is little attempt to ease the practitioners into the professional fold. If a practitioner is deregistered any move to be reintroduced is an initiative of the practitioner. In a reintegrative model the system would assist a practitioner in being reintegrated after appropriate counseling, forgiveness and repentance.¹⁴⁰⁵ The impact of the disintegrative system is reflected by research in the UK that indicated that in the period 1858–1990 less than one half of the doctors deregistered were subsequently restored to the register.¹⁴⁰⁶

Economic Issues in the Health Care market

To identify whether statutory regulation will provide the necessary public benefit requires a consideration of its economic costs. The market for health care is not perfect as it is distorted by a number of factors.

The health care market is dominated by the influence of government. Government is fundamental to the health care market as a result of its massive funding of infrastructure for bio-medical services; its funding of many biomedical procedures through the universal Medicare system; and enforcement of the legal framework within which the market

¹⁴⁰⁴ Ibid 6.

operates.¹⁴⁰⁷ The Medicare system does not subsidise any activities by CAM practitioners other than acupuncture procedures by OM doctors. This lack of government funding may partly explain why the preponderance of users of CAM therapies come from the higher education and income bracket.¹⁴⁰⁸ The health funds 'extras cover' for CAM is normally the preserve of higher income earners.¹⁴⁰⁹ The success of Medicare has meant that health funds have lost custom to those who choose to rely upon Medicare and self-insurance. The health funds have responded by including many CAM practices as rebatable services thus making the cost of these services more affordable to those who can afford private health insurance. This blunts a patient led demand for integration of CAM into Medicare.¹⁴¹⁰

The professional barriers to CAM practitioners distort the market to the benefit of OM by denying their ability to practice specific health services. The pressure to rationalise the health system to maximise savings may support the loosening of professional statutory boundaries in the years ahead.¹⁴¹¹

Uncertainty in the Health Market

The health market is characterised by a high level of uncertainty for consumers and for practitioners.¹⁴¹² 'Consumers are, for the most part, terribly ignorant about what they are buying. Very few industries could be named where the consumer is so dependent upon the

1405 Ibid 7.

1406 Ibid 7.

1407 Easthorpe, above n 312, 291.

1408 Easthorpe, *ibid* 293; Furnham, above n 441, 73; Astin, above n 446, 1551.

1409 Easthorpe *ibid*.

1410 *Ibid*.

1411 D Coburn, 'Legitimacy at the Expense of Narrowing of Scope of Practice: Chiropractic in Canada' (1991) 14 *Journal of Manipulative and Physiological Therapeutics* 14, 21.

1412 Ira Horowitz, 'The Economic Foundations of Self Regulation in the Professions' in Roger D Blair and Stephen Rubin (eds), *Regulating the Professions: A Public-Policy Symposium* (1980) 6.

producer for information concerning the quality of the product.’¹⁴¹³ This is an inherent characteristic of most markets for professional services but may be pronounced in relation to the health care sector as it is difficult to assess the impact of health measures on well being and health.¹⁴¹⁴ This limits the ability of market forces to discipline health services providers as compared to a market where this uncertainty does not exist.¹⁴¹⁵ The reliance upon technology and science and the generally more distant nature of the therapeutic relationship in OM does not foster a connection or balance between the knowledge base of the practitioner and the consumer.¹⁴¹⁶

This uncertainty is also reflected in the random nature of illness and the difficulty in understanding how medical treatments or CAM treatments might work.¹⁴¹⁷ The nature of the therapeutic relationship between CAM practitioners and patients may reduce this uncertainty and differential.¹⁴¹⁸ This disparity in knowledge can allow a practitioner to generate demand for a service.¹⁴¹⁹ This has been a criticism of some CAM practitioners, such as chiropractors using a wellness mode, who have been accused of overservicing.¹⁴²⁰ This uncertainty is caused not only by the nature of the professional knowledge but by the fact that good outcomes have a random factor. A good outcome may not necessarily be the result of high quality services but self-healing or luck while a bad result may occur even though there was a

1413 Easthorpe, above n 312, 290; Victor R Fuchs, 'The Contribution of Health Services to the American Economy' in VR Fuchs (ed), *Essays in the Economics of Health and Medical* (1972) 5-6; Kenneth J Arrow 'Uncertainty and the Welfare Economics of Medicare' (1963) 53 *The American Economic Review* 943, 943.

1414 McMahon, above n 777, 181, 189.

1415 Ogus, above n 1384, 40; Phelps, above n 1394, 2; Sloan, above n 1394, 260; Folland, above n 1394, 373; M Trebilock above n 1387, 10;

1416 Hodgson, above n 629, 690; Jeffrey Braithwaite, 'Competition, Productivity and the Cult of 'More is Good' in the Australian Health Sector' (1997) 56 *Australian Journal of Public Administration* 37, 38.

1417 Arrow, above n 1413, 964.

1418 Phelps, above n 1394, 2.

1419 Sloan, above n 1394, 260; Ogus, above n 1384, 217.

1420 Strahilevitz, above n 447, 563-656.

high standard of care provided. This makes it difficult to ascertain the quality of the health provider even where a consumer has experience of a number of encounters.¹⁴²¹

From the perspective of a practitioner there may be great divergence in what is an appropriate treatment.¹⁴²² This applies between countries where accepted medical knowledge may vary substantially.¹⁴²³ The doctor with his or her professional technical knowledge is in a position to deceive the patient. Unlike many services a consumer is not normally in a position to easily acquire sufficient general or technical knowledge to reduce the disparity.¹⁴²⁴ As particular health services may be infrequently used the opportunity to acquire the necessary expertise to assess quality may not arise. The protection that the market may provide to consumers through competition, that is, requiring competitors to inform consumers of their quality and to lower costs to compete in the marketplace does not apply as effectively in the health sector where professional restrictions and government regulation limits competitive behaviour. Advertising for MD's is very limited, price competition is not encouraged and is in any event distorted by the Medicare rebate system.¹⁴²⁵ OM argues that the statutory protection that it enjoys and the professional rules that limit competition channels competition into non-economic forms such a development of reputation; recognition and status.¹⁴²⁶ The private law remedies available for clients to protect against this lack of knowledge through tort; trade practices law and statutory complaints procedures are retrospective; expensive to implement and subject to uncertainty in result.¹⁴²⁷

1421 Phelps, above n 1394, 542.

1422 Fuchs, above n 1413, 6.

1423 Payer, above n 1250.

1424 Phelps, above n 1394, 9.

1425 Fuchs, above n 1413, 7; Arrow, above n 1413, 954.

1426 Paul A Komesaroff, 'Ethical Implications of Competition Policy in Healthcare' (1997) 170 *Medical Journal of Australia* 266, 267.

1427 Ogus, above n 1384, 217.

This uncertainty has influenced the legislatures in many jurisdictions to enact legislation that provides a balance to this power discrepancy.¹⁴²⁸ The attempts to create a power equilibrium is reflected in medical practice acts; codes of ethics; accreditation of schools and hospitals.¹⁴²⁹

In place of reliance on markets came reliance on professional norms and self-regulation by health care professionals and by institutions such as hospitals. Both buying and selling were entrusted to the sellers who, conforming to professional norms, would make the right choices for patients.¹⁴³⁰

The assumption is that there is a link between statutory regulation and the public benefit. This should not be assumed.¹⁴³¹ This stance by government has been influenced by the perception that health care is a matter of social concern and in fact a need.¹⁴³² Unlike most markets for goods and services, health care is seen as a matter of equity, associated with the moral imperative that good quality medical care should be made available to all people.¹⁴³³ This supported the exclusionary tactics of OM in suggesting the need for protection against unorthodox medicine. CAM was portrayed as superstition and unscientific and peddled by charlatans and quacks falsely diverting patients from their entitlement to government endorsed scientific medicine. These arguments have also been used by chiropractic and osteopathy to suggest they should be acknowledged in statute so as to protect clients from untrained practitioners of spinal manipulation.¹⁴³⁴

The uncertainty that prevails in regard to OM also applies to CAM but with important differences. The scientific and technical knowledge at the basis of OM is often much more

1428 James Younger, 'Competition and Self Regulating Professions' in P Slayton and MJ Trebilcock (eds), *The Professions and Public Policy* (1976) 30; S Breyer, 'Analysing Regulatory Failure Mismatches, Less Restrictive Alternatives, and Reform' in AE Ogus and C G Veljaniovski (eds), *Readings in the Economics of Law and Regulation* (1984) 235-236; Phelps, above n 1394, 7; Arrow, above n 1413, 966.

1429 Sloan, above n 1394, 259.

1430 Ibid.

1431 Manitoba report, above n 1375, 8.

1432 Johnstone, above n 1238, 203.

1433 Ogus, above n 1384, 46; Folland, Goodman and Stano, above n 1394, 371

remote from the less technical techniques preferred by CAM practitioners. This does not mean that the knowledge base for CAM is simply common knowledge or lacking in substance. Few would doubt the complexity of the principles at the basis of modalities such as homoeopathy, chiropractic or osteopathy. A CAM practitioner who encourages the self healing potential of the client creates a better equilibrium between the healers and the patient's knowledge. The patient of a CAM practitioner is asked to listen to their body. The limited reliance on diagnostic equipment in CAM requires greater reliance on feedback from the client that will limit this knowledge dissonance.

The logic that supports the use of licensing could be expressed as follows:¹⁴³⁵

- There are significant variations in the quality of services provided by health practitioners based upon training; education and ethical standards.
- A lower quality of service may impact upon poor outcomes.
- Health service providers are not sufficiently motivated to measure the quality of labour inputs.
- The potential liability in civil law may not be a sufficient incentive for maintenance of professional standards.
- There is a lack of knowledge by consumers about the quality of health services.
- The service cannot be readily exchanged. It is tailored to the individual and defective services would endanger a consumer.
- Statutory registration protection for a profession and the professional rules that limit competition channels competition into non-economic forms such as attempts to develop reputation; recognition and status.¹⁴³⁶

1434 Easthorpe, above n 312, 291.

Licensure can ensure that at one point in time a licensed practitioner was competent to pass an examination or course of study that tests their knowledge in an area of knowledge relevant to the practice.¹⁴³⁷ This does not provide evidence of competence on a continuing basis or in specialist areas of practice.¹⁴³⁸ The legislative policy objective assumes that by having basic educational and or training standards it increases the chances of a consumer receiving competent service.¹⁴³⁹ There is no necessary connection between a higher level of education and training and the quality of service provided.¹⁴⁴⁰

A 1981 study of health care regulation in California suggests that the elements which most strongly influence the quality of health care – the choice of appropriate treatment; the equipment and technology used, and the skill of practitioners may lie beyond a medical board’s power and, therefore, be unaffected by licensing requirements. While a medical board can set minimum standards of practice, non-governmental regulation of health care (for example by training institutions or peer oversight groups) may more effectively ensure quality health care because it generally results in higher standards than does official licensure.¹⁴⁴¹

The economic benefits of standards (that is the efficient provision of effective therapy) may be lost if those standards go beyond those necessary for competent practice thereby excluding services by practitioners more than adequately trained for the services sought.¹⁴⁴² Many

1435 Phelps, above n 1394, 541.

1436 Komesaroff, above n 1426, 267.

1437 Victorian Options, above n 642, 12.

1438 Ogus, above n 1384, 223; Manitoba report, above n 1375, 10.

1439 Manitoba report, *ibid* 14.

1440 Astin, above n 446, 1551; Manitoba Report, *ibid*, 9; Abel, above n 1376, 21.

1441 Ogus, above n 1384, 156.

1442 Abel, above n 1376, 21

activities of MD's (said to be 75% of adult primary care and 90% of pediatric care) could be delegated to alternative health practitioners.¹⁴⁴³

Licensure can also provide the means to collect data about the performance of a practitioner including complaints and adverse outcomes that can trigger disciplinary proceedings.¹⁴⁴⁴ The difficulty in obtaining convictions and the fact that most disciplinary proceedings occur after the fact means that this process is not pro-active but reactive.¹⁴⁴⁵

Economic effects of licensing

When considering the appropriate model for occupational licensing of CAM practitioners it is appropriate to consider its economic effect. The effect of licensing, registration or other similar control will be to impose a barrier to entry of new competitors into the market.¹⁴⁴⁶

These barriers are created by the need for specified:

- educational qualifications.
- experience in the market place.
- training.

If the licensed profession controls the licensing scheme there will be a period of rationalisation and conflict as these parameters are sorted out and determined.¹⁴⁴⁷ This struggle may be bitter, as the result will adversely affect one group to the benefit of the favoured group. Usually relevant in this struggle is the role of grand fathering provisions to

1443 Glaser, above n 328, 213.

1444 Victorian Options Report, above n 642, 12.

1445 Manitoba report, above n 1375, 10.

1446 Hodgson, above n 629, 655.

1447 This is occurring at this time in Victoria under the *Chinese Medicine Registration Act 2000* (Vic).

incorporate some non-complying practitioners deemed by long practice experience to justify registered status.¹⁴⁴⁸

In the case of the medical profession the professional controls were fixed by accreditation of colleges considered to provide the quality education desired by the controlling elite of the profession.¹⁴⁴⁹ The preferred model of education focussed on the scientific and reductionist approach to medical practice.

The effect of licensing is to reduce the number of entrants to the profession resulting, in time, in an income gain to continuing members of the profession.¹⁴⁵⁰ A substantial increase in professional incomes may result, in time, in an increase in the number of entrants to the profession. This will over a long period of time reduce incomes though the entry requirements will limit how low the incomes may fall.¹⁴⁵¹ Over the years the requirements for entry may be extended as occurred with the requirements for doctors and other professions. Maurizi suggests that the most important determinant that maintains and increases professional incomes is control over pass rates in licensing examinations. Some economists consider licensing provides economic rent to MD's thirty three percent in excess of that required to induce them to provide services.¹⁴⁵² Maurizi suggests that:

evidence tends to confirm the notion that the power of licensing boards is often used to prolong the period of higher incomes resulting from increases in excess demand for services of the occupation in question and that the instrument then used to accomplish this purpose is alteration of the pass rate on the licensing examination¹⁴⁵³

1448 *Chinese Medicine Registration Act 2000* (Vic) s 94; Ogus, above n 1384, 220.

1449 Hodgson, above n 629, 663; Refer to p 101 above.

1450 Victorian Options Report, above n 642, 12; Ostry, above n 1396, 20; Hodgson, above n 629, 672; Manitoba report, above n 1375, 9; Ira Horowitz, 'The Economic Foundations of Self-Regulation in the Professions' in Roger D Blair and Stephen Rubin (eds), *Regulating the Professions A Public-Policy Symposium* (1980) 16; A Maurizi, 'Occupational Licencing and the Public Interest' (1974) 82 *Journal of Political Economy* 399, 399; Ogus, above n 1384, 219, 224.

1451 Abel, above n 1376, 25.

1452 Folland Goodman and Stano, above n 1394, 371.

It has been argued that the effect of licensing has been to reduce the quality of medical services by:

- reducing the number of physicians.
- reducing the number of hours that physicians can devote to important tasks; and
- reducing the incentives for research and development.¹⁴⁵⁴

The effect of licensing may be anti-competitive.¹⁴⁵⁵ Queensland Health identified a number of anti-competitive effects of licensing¹⁴⁵⁶:

- It restricts consumers in choice of health care providers. Some health professionals may be able to provide the service more economically and just as effectively.¹⁴⁵⁷
- It prevents professions who might be in competition from expanding their scope of practice.
- It can stifle the establishment of new professions.
- It can inhibit the development of innovative techniques and services as it may trespass on to the statutory scope of practice of another profession.

Komesaroff suggests that competition policy challenges the norms that underlie medical practice on the basis those norms are designed to merely protect the financial interests of doctors. He argues that licensing and ethical barriers represent ‘altruistic concerns of doctors to separate personal and financial considerations from the paramount goal of doing what is best for their patients.’¹⁴⁵⁸ This would presumably be exemplified by the ethical obligations not

1453 Maurizi, above n1450, 412; Ogus, above n 1384, 225.

1454 Hodgson, above n 629, 673.

1455 Gellhorn, above n 1394, 6; For criticism of National Competition Policy in its application to the health sector refer to McMahon, above n 777, 175; Queensland Health Review, above n 862, 56.

1456 Qld Health Review, *ibid* 56; Ostry, above n 1396, 19.

1457 Note evidence re greater economy in using chiropractors in treating back complaints below 408..

1458 Komersaroff, above n 1426, 267.

to take financial advantage for a referral and avoiding competing with their colleagues directly on the price of their services.

The only appropriate justification for the licensing of professions is that it provides real public benefits. There appears to be a lack of clear evidence of benefit from the current system of regulation. While acknowledging the economic rent that medical practice legislation provides Folland Goodman and Stano suggests¹⁴⁵⁹:

- that in spite of licensure there is a substantial amount of deficient care being rendered.
- that quality of care would not be impaired if the scope of practice of secondary (non-physician/dentist) providers were increased.
- that the licensing process may not accurately assess the practice competence of applicants; and
- that there are higher fees and provider incomes in states with more restrictive licensure requirements (supporting the self-interests motive for regulation).¹⁴⁶⁰

The costs of regulation; the possibility of unforeseen results; the difficulty in ascertaining the achievement of policy goals; the tendency for regulation to be influenced by private interests; the tendency to regulate too much or to regulate not enough; differences in what needs to be regulated and how; the possibility of stifling innovation and the potential for anti-competitive activity suggests caution in the current economic environment when any proposal is being considered that may introduce further regulation into the health care sector.¹⁴⁶¹ If further regulation is suggested then the least restrictive form possible while achieving the goals of the regulation is suggested.

¹⁴⁵⁹ Folland, Goodman and Stano, above n 1394, 370-373.

Efficacy and Cost Savings

An important policy consideration is whether CAM is economically effective when compared to OM. If it can be shown that the costs of providing CAM is lower than OM (taking into account efficacy and outcomes of treatment) this would support its continuing and expanded regulation as well as integration into OM.¹⁴⁶² This requires an assessment of what procedure provides the greatest benefit to patients for the smallest possible investment.

The determination of the economic effectiveness of CAM depends on a complicated assessment of the services that might be replaced by CAM; the costs of the CAM and if it results in improvements in outcomes compared to conventional treatment.¹⁴⁶³ As documents associated with the 2002-2003 Australian Federal Budget indicate that health expenditure on pharmaceuticals and health services as a percentage of Gross Domestic Product is projected to rise considerably in the next few decades the need to consider the role CAM might play in reducing total health expenditure is timely.¹⁴⁶⁴

The issue of efficacy cannot be avoided in considering the regulatory control of CAM. If CAM has no benefit beyond placebo it is difficult to argue that it provides any real value for money.¹⁴⁶⁵ This is a significant hurdle as there is simply insufficient data to make firm conclusions though the less technology-based approach preferred by CAM though the

1460 Ibid 374.

1461 Ogus, above n 1384, 338 -339; Breyer, above n 1428, 234.

1462 Marla Jane Orth, 'Marketing Integrative Medicine' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 131.

1463 Charles A Simpson and Nancy Faass, 'Criteria for Assessing Successful Integration' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 282.

1464 Commonwealth Treasury Budget, Paper no 5, *Intergenerational Report Budget* (2002-2003) 2-5.

1465 Boozang, above n 9, 571.

evidence that does exist suggests that CAM has the potential to provide cheaper health services.

Chiropractic

Amongst CAM chiropractic has the largest body of scientific evidence supportive of its efficacy and cost effectiveness. There have been numerous studies that suggest chiropractic is cheaper to provide than orthodox health services although there are different conclusions reached by other studies.¹⁴⁶⁶ The Second Report of the Medicare Benefits Review Committee acknowledged the reduced treatment costs and time off work resulting from chiropractic care.¹⁴⁶⁷ One literature search of 24 studies on the comparison of the costs of chiropractic and OM revealed that of 19 retrospective studies 15 favoured the cost effectiveness of chiropractic.¹⁴⁶⁸ Any positive research in this area is met by the claim that chiropractors tend to over-service.¹⁴⁶⁹ This may relate to a misunderstanding of what has been described as alternative chiropractic or practitioners following a ‘wellness model’ of treatment as distinct from complementary chiropractic. Alternative chiropractors if asked when they know the treatment plan is completed may reply that the client is never released, as they need maintenance care to preserve good health.¹⁴⁷⁰ Complementary chiropractic is more symptoms based and a patient is discharged when symptoms have resolved.¹⁴⁷¹

Acupuncture

There is some detailed research into the relative cost of acupuncture as against other standard OM treatments. In one study, acupuncture combined with standard stroke protocol was said

1466 Strahilevitz, above n 447, 559; For a positive perspective on this issue refer to Charles A Simpson, ‘Utilization Data: Chiropractic Utilization and Cost Effectiveness’ in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 558; Simpson, above n 154, 322.

1467 Medicare Benefits Review Committee, Second Report, 1986 151-152.

1468 Richard A Branson, ‘Cost Comparison of Chiropractic and Medical Treatment’, in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 569-581.

1469 Simpson, above n 1466, 566.

1470 Menke, above n 679, 596.

1471 Ibid 597.

to have been markedly successful resulting in a cost saving of \$26,000 per patient.¹⁴⁷² There is some evidence of cost effectiveness of acupuncture in the treatment of osteoarthritis of the knee; treatment of stroke victims; in returning workers compensation claimants to work and in avoidance of surgery and hospital visits.¹⁴⁷³ The risk of over-servicing may not be a concern in acupuncture where treatment is not particularly pleasant.¹⁴⁷⁴ The limited scientific evidence of effectiveness for acupuncture (for nausea, alleviation of pain and anaesthesia) means that the savings in the cost of medical care could be limited to a small area of practice.

Other modalities

There is evidence of cost effectiveness of CAM in relation to herbal medicine for some conditions and homoeopathy in dental care.¹⁴⁷⁵

It is likely that further scientific evidence of the cost effectiveness of the various forms of CAM will emerge in the near future. If this evidence proves positive for CAM this will provide an impetus to the role of CAM in dealing with the rapidly increasing cost of health care and will add status to any proposal to recognize, regulate and integrate this form of treatment into the provision of health services.

Options For Regulation

1472 Acupuncture and Oriental Medicine Alliance, 'Utilization Data: Acceptance of Acupuncture in the United States,' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 299.

1473 Orth, above n 1462, 132, 509; Stephen Birch and Richard Hammerschlag, 'Acupuncture Efficacy: A Summary of Controlled Clinical Trials' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 590.

1474 Ibid.

1475 Adrian R White, 'Do Complementary Therapies Offer Value for Money' in E Ernst (ed), *Complementary Medicine: An objective appraisal* (1996) Chap 6.

This thesis will discuss some of the options for regulation of CAM in Australia. This discussion will be based upon a presumption against regulation unless it is clear that the public interest is served by its introduction. Drawing on the themes discussed above there is a case for the provision of statutory regulation beyond that currently in force. The basis for this assertion is the potential for physical injury to occur through the application of some CAM therapies by unskilled practitioners. The discussion above provides ample evidence that the use of modalities such as chiropractic; osteopathy; acupuncture; TCM; herbal medicine; naturopathy and therapeutic massage can cause injury to a patient although typically at a much lower rate and at a lower level of severity than that experienced for OM procedures.¹⁴⁷⁶

This does not apply to all modalities. Even a confirmed critic of CAM would suggest some modalities are at worst harmless. The issue of harm may arise if a CAM practitioner counsels against obtaining medical advice for an affliction. Some reject this issue as a concern as most CAM modalities work in a non bio-medical model and a patient should not expect attention based upon an entirely different school of healing.¹⁴⁷⁷

For some practitioners these concerns can be addressed without any statutory registration legislation but through:

- education both as to limitations of their practice; the legal obligation to refer; education in identifying conditions that are amenable to OM; understanding those conditions that by law they cannot treat.
- Statutory provisions that specify the obligation of a health practitioner to refer on when the condition is outside their area of expertise.

¹⁴⁷⁶ Studdert, Eisenberg, Miller and Curto, above n 104, 1610.

¹⁴⁷⁷ Sloan, above n 1394, 216.

- Breaking down barriers between OM and CAM to assist in the likelihood of referrals between health professionals.
- Incentives for membership of professional organizations that have appropriate ethical standards.

The growing popularity of CAM suggests that consumers of CAM are entitled to a minimum level of quality assurance enjoyed by consumers of OM. It is not appropriate that because a consumer chooses a school of healing that is different from the dominant form of healing that they are not entitled to the admittedly imperfect protection that statutory regulation of practice may provide.

For many people the choice of their preferred healing modality is based upon cultural considerations or upon their philosophy on healing. This choice might reflect in support for holistic healing. A particular modality may be the only modality that provides relief or comfort from a malady.¹⁴⁷⁸ Without proper regulation there is little indication of quality in the marketplace and consumers are not easily able to determine where their best interests lie.

Once it is determined that some form of regulation is appropriate at least for some modalities it is necessary to consider what are the options available. With public benefit as the primary criteria the following are important issues:

- avoiding structures that involve a substantial public cost when less costly structures could suffice and ultimately the benefits outweigh the costs.¹⁴⁷⁹
- avoiding structures that incorporate anti-competitive activity unless necessary to avoid compromising health concerns.

¹⁴⁷⁸ Freckelton editorial, above n 773, 8.

- Ensuring that the regulatory structures are reflective of and consistent with the modality.
- supporting connections between different modalities to allow an integrated approach to health care.
- the importance of competent ethical practice and respect for the rights and obligations of service providers and patients.¹⁴⁸⁰
- The need to promote appropriately high entry and practice standards by practitioners.

Structural Options¹⁴⁸¹

Status Quo

There are arguments that may support the maintenance of the status quo on the basis 'why fix something that is not broken'. Reform of the law creates expense; dislocation and upsets the comparative equilibrium that currently exists. Despite the concerns about the regulatory system CAM is generally still available to clients as they desire it if they are able to afford it.

Currently there is a low level of complaints against CAM practitioners based upon the Health Complaints structures available in most jurisdictions. There are few reported cases relevant to practitioner negligence or misconduct. This point is underlined by comparison with the medical profession. This could sustain an argument that the level of injury or adverse outcome is not such that immediate attention to regulation of CAM is urgent.

1479 Manitoba report, above n 1375, 18, 22, 25.

1480 Ibid 20.

1481 AM Kleyhans, 'The Culture of Chiropractic: An Educational Perspective Chiropractic' (1998) 28 *Chiropractic Journal of Australia* 49, 60 - criteria for statutory regulation.

The advent of statutory regulation of any type will likely increase the fees of practitioners by limiting access to the profession to accredited practitioners. As CAM is currently funded privately this may make access to these services problematic for some clients.

Currently there is little public monies being expended on the administration of this very substantial sector of the health care industry. The introduction of statutory regulation would require substantial funding for the administrative structure incorporating registration; accreditation and disciplining of registrants.

Market forces determine the success of a CAM practitioner and the level of fees. Government involvement will distort this market and will introduce a level of anti-competitive activity by excluding some providers and favouring others. As the trend in recent years has been to promote deregulation in the economy the status quo would support that trend.¹⁴⁸²

Summary of Concerns about Status Quo

The thesis has discussed a number of limitations and concerns in relation to the current position. It is worthwhile to collate these issues to provide a platform for suggested reforms.

The current model of regulation lacks coherence. It has been created in a piecemeal way by augmentation and adjustment to the regulation of the orthodox medicine model. There have been few attempts in recent years to properly consider the role of CAM when approached from the perspective that CAM can provide safe and effective input into health care and has a valid role to play in the health care sector.

¹⁴⁸² Ogus, above n 1384, 10-12.

The current regulatory system is characterised by:

- A closed mind to the economic and therapeutic value of CAM and an assumption of the inferiority of its benefits and an exaggeration of its risks. This influence has been important in inhibiting statutory recognition of CAM.¹⁴⁸³
- Statutory control on practitioners is limited to chiropractors; osteopaths and TCM and acupuncture in Victoria. This affects the ability to enforce practice and ethical standards against the thousands of unregistered CAM health professionals.
- Reliance on non-statutory self-regulation for most modalities.¹⁴⁸⁴ The legislative regime for health practitioners varies between the states and lacks a national approach. This means that a procedure that is legal in one state may be illegal in another state.
- The health professional registration statutes often incorporate very broad scope of practice provisions that limit the practices of unregistered practitioners in ways that are difficult to justify in terms of protecting public health. This applies especially in the provisions in a number of states and territories which specify that only registered medical practitioners are entitled to 'practice medicine'. A satisfactory definition of the practice of medicine is not provided in any case. This leaves unregistered health professionals and other registered practitioners uncertain as to their legal position in performing uncontroversial procedures.
- CAM practitioners fall foul of overly broad scope of practice provisions in allied health registration statutes in some states. For example, somewhat surprisingly some therapeutic massage therapists in some states may be deemed to practice physiotherapy if therapeutic massage is applied.¹⁴⁸⁵ As these techniques are often practiced by well-trained practitioners and is unlikely to be a risk to a patient this regulation is unnecessary.

1483 Freckelton, above n 773, 10.

1484 Kleynhans, above n 3, 112.

1485 *Physiotherapists Registration Act 2001* (Qld) s 240(2) (b) and (c).

- The controls on CM are limited and are not uniformly enforced against CAM practitioners. Therapeutic goods legislation is not enforceable uniformly nationwide due to the constitutional limitations of the TGA and the fact that only NSW and Victoria has enacted complementary state legislation to cover intrastate transactions. CAM practitioners complain that some substances specified in state Drugs and Poisons Legislation such as comfrey and aristolochia are deemed as dangerous and are unnecessarily restricted to the therapeutic detriment of clients.
- There are few indications of quality that a consumer can rely upon in relation to CAM. An incompetent untrained and/ or unethical practitioner is subject only to the imprecise penalties provided by the criminal law, the common law and statutory provisions in certain consumer protection legislation. These avenues may not provide an effective remedy for a patient.¹⁴⁸⁶ Private remedies are directed to individual and not public health issues and are expensive, uncertain and complex options.¹⁴⁸⁷ Professional associations for unregistered professions have limited effective means to discipline and control members.
- The provisions of the various state Health Complaints statutes provide a formal avenue for complaint; investigation; conciliation and potential for referral to a registration board (if applicable) or the police in some cases. This remedy is limited in the case of a complaint made against a non-registered practitioner, as there is no registration board that can discipline a practitioner.¹⁴⁸⁸
- Most professions provide non-statutory self-regulation based on membership of a professional association. Membership is based upon specified educational and training standards; enforcement of codes of ethics and practice standards.¹⁴⁸⁹

1486 McMahon, above n 777, 193-194.

1487 Kleynhans, above n 3, 106.

1488 McMahon, above n 777, 194.

1489 Kleynhans, above n 3, 112.

- The ability of professional associations to assert disciplinary control over practitioners was formerly assisted by their ability to deny health funds provider number to a member of the association who did not comply with its professional standards for membership. The Competition Code has been interpreted by the health funds as deeming this practice as anti-competitive. This has resulted in many health funds assessing the educational standards of practitioners individually. This has made the membership of a professional association less influential and reduced the leverage available to enforce professional standards.¹⁴⁹⁰

Formal non statutory regulation – ATMS proposal

The reliance primarily on non-statutory self-regulation does not provide appropriate regulation of CAM. A possible option is a more formal form of non-statutory regulation. This was described by the major professional association the Australian Traditional Medicine Society (ATMS) as Government Sponsored Self-Regulation (GSSR). GSSR is a form of self-regulation where a government representative is actively involved, along with representatives of the profession, consumers and legal profession.¹⁴⁹¹ The inclusion of a government representative is said to assure the consumer that the self-regulatory process is credible and accountable. Under GSSR the government does not control the self-regulatory process.¹⁴⁹² ATMS suggested this form of regulation was appropriate as 'statutory regulation is an excessive form of occupational regulation for TCM in Australia.'¹⁴⁹³

The GSSR was described as involving the following features:

1490 Victorian Options report, above n 642, 103-108.

1491 McMahon, above n 777, 194.

1492 Victorian Options report, above n 642, 2-3.

1493 Ibid 2.

- A GSSR code is to be developed in consultation with all industry representatives; and government legal and consumer representatives. This code would include provision for practitioner accreditation; course accreditation; funding; an annual report; complaints mechanism and policing of quality assurance.
- The establishment of a GSSR Code Council comprised of a member representing TCM professional associations; a member representing consumer groups (seen by one critic as tokenism¹⁴⁹⁴; 4 representatives from government and a representative from the legal profession.
- An accredited practitioner will be allowed to use and display a GSSR logo to allow easy identification for the general public.

This proposal did not find support amongst those who provided input to the Human Services, *Traditional Chinese Medicine: Report on Options for Regulation of Practitioners* Victorian Ministerial Advisory Committee.¹⁴⁹⁵ This model formalises self-regulation by the inclusion of a controlling government representation in the Council to provide some perception of autonomy and objectivity. The provision for accreditation and logo can provide a consumer quality indicator if the consumer is properly aware of the significance of the logo. This proposal appears to be a comparatively low cost alternative and is not unduly anti-competitive in nature.

The success of this type of regulation would depend upon the extent to which the logo was seen and accepted as a sign of quality for the consumer.¹⁴⁹⁶ If the logo did provide a recognisable sign of quality then the impact of not being entitled to use that logo based upon the quality assurance and disciplinary procedures in the Code may have a significant impact

¹⁴⁹⁴ Ibid 20.

upon practitioner behaviour and effect the likelihood of consumers consulting the practitioner.¹⁴⁹⁷ As this proposal did not involve any limitation on the use of titles or scope of practice it would not stop any person using a title such as 'naturopath' or 'TCM practitioner' even though they may have little or no training.¹⁴⁹⁸ The proposal did not provide for an appeal apparatus if a person was unhappy with a decision of council although presumably this could be incorporated into the structure.¹⁴⁹⁹

GSSR may have merit in some of the modalities where there is little prospect in the near future for government regulation as it is one step removed from profession only self-regulation.

Government Statutory regulation

Although the use of statute-based self-regulation is common in Australia one option is the use of government regulation with little if any professional involvement. This option overcomes the suspicions that may arise about the self-serving nature of self-regulation.¹⁵⁰⁰ The inherent advantage of government regulation is that it avoids the conflict of interest that can arise when a group of professionals are making decisions based upon rules set by themselves which may be to their own benefit.

If regulatory rule-making remains with the legislature or an independent agency, groups representing such firms have the task of exerting influence on those institutions and diverting them away from public interest goals or other, competing private interest claims. Of course, delegation of the regulatory powers to SRAs relieves the groups of this task and the relative absence of accountability and external constraints maximises the possibilities of rent-seeking-with self regulation, regulatory capture is there from the outset.¹⁵⁰¹

1495 Ibid 15.

1496 Ibid 20.

1497 Ibid 15.

1498 Ibid 20.

1499 Ibid 120.

1500 Abel, above n 1376, 38.

1501 Ogus, above n 1384, 98.

Self-regulation is an example of corporatism where professional groups acquire power over themselves with very little real accountability to the government or consumers. The relevant group can use its powers to make rules about its profession that can be enforced not only against the members of the profession but also third parties.¹⁵⁰² This can raise the potential for abuse that could involve self-serving decision-making and policy development and inadequate enforcement of these rules against the profession. The common criticism is that these powers have been used to pass and support practice standards; fee regulation and advertising requirements that serve more the profession's interest than the public interest. These activities are out of step with an economic environment that now seeks to avoid anti-competitive behaviour.¹⁵⁰³

The most significant disadvantages to government regulation can be the greater cost involved and the potential for a lack of recognition and understanding of professional issues by the administrators. Many would doubt the ability of government to effectively regulate large-scale professions.¹⁵⁰⁴ A self-regulation model usually involves administration by members of a profession, perhaps without charge or by employees funded by the profession through registration fees. A government-administered regime requires the government to employ its own experts.¹⁵⁰⁵ The justifications for statutory self-regulation are described as:

- access to expertise and knowledge at a lower cost.
- lower cost of monitoring and enforcement.
- less formalised rules make the regulation cheaper to administer.
- administrative costs are internalised and less costly for taxpayers.¹⁵⁰⁶

1502 Ibid 98-99.

1503 Ibid 99.

1504 Trebilock, above n 1387, 9.

1505 Manitoba Report, above n 1375, 48; Peter Cane, 'Self Regulation and Judicial Review' (1987) *Justice Quarterly* 324-347; Ogus, above n 1384, 107.

1506 Cane, *ibid*, 328.

Self-regulation can continue the connection between the members of the institution who may have been or are still in practice. This can promote more practice sensitive administration. The advantages of self-regulation in allowing a connection between the profession and the goals of the statute can also result in a reticence to discipline practitioners who have breached professional standards even if this reticence may be subconscious.¹⁵⁰⁷ There is also a tendency for self-governing bodies to be driven to ever higher educational requirements which may raise the standards of the profession but result in reduced competition and more expensive professional services.¹⁵⁰⁸

The conclusion reached by many governments, no doubt to reduce costs and to minimise excessive government control over the economy is to prefer the self-regulation statute model. This is probably on balance an acceptable solution if there are sufficient safeguards to protect against the potential pitfalls discussed above.

The self-regulation model is the preferred model for the regulation of OM in Australia. It is not suggested that all modalities of CAM should or could be satisfactorily dealt with under a statutory scheme of regulation. CAM modalities cover a broad continuum of philosophies and approaches. Some modalities rely on a knowledge base that is highly technical and biomedical in orientation exemplified by osteopathy and chiropractic. At the other end of the spectrum are modalities that rely on intuitive and vibrational therapies such as spiritual healing.¹⁵⁰⁹ Some of these modalities lack the features that are likely to be fundamental to

1507 Manitoba, above n 1375, 49.

1508 Ibid 50.

1509 Matthews and Stone, above n 32, 215; Note differing views on this KD Phillips, 'Statutory Regulation is Essential' (1996) 313 *British Medical Journal* 882, 882.

successful statutory regulation. There are a number of possible types of statutory regulation that can be introduced each with their advantages and disadvantages.

Basic requirements of a modality before statutory regulation is considered worthwhile?

Stone proposes some features that they suggest are appropriate basic requirements for a modality before statutory regulation is appropriate.¹⁵¹⁰

Risk of harm

Reference is made to the discussion above as to the potential for harm from CAM. Ironically the concerns expressed by OM about the dangers of CAM actually provide support for greater regulation of these modalities. It should not be assumed that statutory regulation guarantees protection from harm or adverse results as is shown in the case of medical doctors and other currently registered professionals. Statutory regulation permits the enforcement of legal and ethical obligations, if imperfectly, in a way not possible under non-statutory self-regulation. The use of enforceable disciplinary measures such as suspension and deregistration can exclude practitioners from practice or the use of particular titles. If the risk of harm from a modality is small does this mean that statutory regulation is not justified? Based upon the discussion above the economic costs of regulation may not justify the comparatively small benefits that may accrue from that regulation. The risk of harm does not necessarily have to involve direct risks such as incorrect prescription of herbs; injury from manipulation or massage; or adverse reactions. Injury could include being exposed to sexually inappropriate techniques; being convinced to avoid appropriate medical procedures in favour of techniques that have no proven benefit.

Reliance on specialised knowledge

It would be difficult to design an effective means of statutory regulation if there is no substantial body of knowledge that a practitioner applies to his or her practice. Without this body of knowledge the inequality in power between a client and a practitioner that raise the ethical and legal need for regulation may not properly arise. Put simply, a client not at a substantial disadvantage in relation to their understanding of treatment may not be at such a disadvantage as to require statutory protection.

Others have indicated that a fundamental requirement for statutory regulation is that a modalities' 'scope of practice and entry and practice standards are known.'¹⁵¹¹ This is logical as without those criteria determined it is difficult to determine a statutory scope of practice (if this was desired) or to determine who is entitled to be registered as a professional under that legislation. It is likely that any modality that is at the stage of being able to successfully lobby government for registration status requires these types of issues to be resolved or settled.

What type of statutory regulation?

Once it is determined that the use of statutory regulation is possible the question is what type of regulation should be used.

There are two types of statutory regulation that are usually described namely licensing and certification:

1510 J Stone, 'Regulating Complementary Medicine' (1996) 312 *British Medical Journal* 1492-1493; Refer also

Licensing

This is a much more intrusive form of regulation that involves the creation of a scope of practice for a profession and its enforcement under statute. The principles at the heart of the Competition Code would suggest that this form of regulation can potentially affect competition and limit consumer access to health services and thereby raise the cost of those services. The potential economic cost of licensing indicates it should be reserved for situations where there is potential of serious harm if particular activities were attempted by non-registrants.¹⁵¹² The type of services that could be contemplated by that type of provision might be surgery; prescribing drugs; spinal manipulation and certain types of physiotherapy treatments. These types of provisions are not easily enforced for evidentiary reasons, are expensive to enforce and provide fertile grounds for pedantic, technical and nice questions of law on what does or does not constitute a particular practice.

It is a paradox that in Queensland the practice of medicine, that involves the most dangerous practices, is not limited by statute to registered medical practitioners while chiropractic; osteopathy; dentistry; physiotherapy; optometry; podiatry and pharmacy is defined and limited to registrants. This paradox may be explained by the fact that legislative policy reflects:¹⁵¹³

- There is an understanding by consumers and other health professionals of the role played by medical practitioners in health care.
- The perceived effectiveness of controls over prescribing of drugs.
- That there are controls on employment of non-registered practitioners in medical officer positions in medical institutions.

to AHMAC Guidelines Benssoussan and Myers, above n 77, 212.

1511 Manitoba report, above n 1375, 25.

1512 Ibid 25.

1513 Qld Health, above n 862, 55.

- the legislative difficulty of defining the practice of medicine so it does not prohibit the legitimate activities of other professions and private citizens. Many people undertake activities that might come within a definition of the practice of ‘medicine’, (for example, ‘diagnosing’ an illness).¹⁵¹⁴

In the USA the very broad definition of the practice of medicine in their state medical practice acts would deem many CAM treatments as ‘the practice of medicine’. These uncertainties in the definition of the practice of medicine are reflected by the fact that the ‘holding out’ provisions are favoured for enforcement by the relevant professional boards even in those states where a scope of practice provision exists. There are considerable difficulties in proving, to the satisfaction of a Court, that someone has ‘practiced a profession, particularly if the individual has not attempted to use a protected professional title.’¹⁵¹⁵

If the legislative objective is the least restrictive level of regulation capable of addressing the potential for harm and if scope of practice provisions are deemed appropriate these provisions should not apply to a profession but to specific acts.¹⁵¹⁶ For example, if the concern in relation to chiropractic relates to the manipulation of the spine then the scope of practice could limit that practice to registered chiropractors and other trained health professionals rather than relying upon a broad definition of chiropractic. If the concern about medical practice is the practice of surgery (as defined) then ‘surgery’ should be delineated as the controlled act rather than relying on a vague definition of the practice of medicine. To prohibit the entire activities of a profession by anyone other than a registered practitioner speaks of a scatter-gun approach to regulation that raises suspicions that the covert intention is to protect the profession not the public interest.

¹⁵¹⁴ Ibid.

An “occupational” approach to designing scopes of practice will almost inevitably result in over-regulation for some services but can also result in less regulation than is necessary for others. If every service performed by an occupation is licensed, services which require only certification or no regulation at all will be over-regulated. In this case, the public will pay more for the service but will not receive a commensurate benefit by way of additional protection. If every service performed by an occupation is certified or left unregulated, the public may be inadequately protected from those services which should be licensed. The “occupational” approach therefore tends to cost the public more than is necessary or protect it less than is needed.¹⁵¹⁷

This suggests that the most competitive but protective means to regulate the professions is to limit the use of specific tasks or procedures that qualify as requiring regulation on the minimum regulation/ protection model. This task-based regulation requires the procedures employed to be separated into those with serious health implications and those without serious or nil health implications. This process requires a common sense assessment of how the day to day activities of a practitioner can be separated and an assessment made of the risk it offers to consumers.

This option was discussed by Queensland Health context in the period prior to the enactment of the health practitioner legislation in 2000.¹⁵¹⁸ This option described as the Ontario Model did not obtain the endorsement of government but should now be reconsidered. The Draft Policy Paper stated:

Rather than using a statutory definition to restrict a broad scope of practice, it is proposed that certain ‘core restricted practices’ be restricted to specified professions only. It will be an offence for any person who is not a member of a specified registered profession to undertake a core practice.¹⁵¹⁹

For example, the Draft Policy Paper suggested that for ‘moving the joints of the spine beyond a person’s usual physiological range’ only chiropractors; osteopaths; physiotherapists and medical practitioners be permitted to perform this procedure while only medical practitioners

1515 Ibid 55-56.

1516 Manitoba report, above n 1375 25.

1517 Ibid 26.

1518 Queensland Health, above n 862, 56-58.

or other authorised persons could perform surgery.¹⁵²⁰ The Draft Policy Paper also suggested that the Governor in Council could make regulations restricting other practices not considered core practices but where the public interest suggests should be restricted, such as, the therapeutic use of electrical equipment.

It is proposed that a scheme similar to the Ontario model be instigated in Australia with the following modifications:

- that there not be a scope of practice for any profession which would limit the broad practice of a particular profession ie the practice of medicine or the practice of physiotherapy.
- That there would be a list of controlled acts that could only be performed by specified registrants.
- That only the currently registered professions would be provided with a registration statute or be mentioned in omnibus legislation with the addition of TCM, Acupuncture, naturopathy and homeopathy subject to the comments below.

The proposed model above suggests the use of controlled acts that only specified registered practitioners are entitled to use. This provides in a negative sense the goals of more pervasive legislation that defined and provided for enforcement of a statutory scope of practice using a broadly defined scope of practice. The suggested model will make it an offence to perform only those specified controlled acts without disrupting other activities that do not require regulation.

1519 Ibid 56.
1520 Ibid 57.

Certification

A less intrusive form of regulation is the use of legislative provisions that specify that only registered individuals are entitled to use specific titles. For example this legislation might specify that only registered practitioners can use the title ‘acupuncturist’ as provided in Victoria. This form of legislation currently applies in all states for all health practitioner registration statutes.

The protection of title provisions currently in force should continue with the currently registered professions with the addition of use of title limitations for TCM and acupuncture; homoeopathy and naturopathy.

Entry and Practice Standards

There would be little purpose to a licensing or certification process if the legislative process did not incorporate provision for controlling those entitled to apply controlled acts or to practice using the specified titles.

Entry and practice standards have the goal of excluding from the regulatory scheme a practitioner who is incapable of performing the health service in a competent and ethical manner while including those who are so capable.¹⁵²¹ If public protection is the primary aim of these standards it is necessary to align them to the type of concerns that are raised in relation to that practice. For example, in the accreditation of educational courses or the acceptance for registration of graduates the issue of the integrity of TCM herbs and the potential for interactions with pharmaceutical substances would likely be an important factor

¹⁵²¹ Manitoba report, above n 1375, 33-34.

in the accreditation of TCM courses. For homoeopaths, any registration accreditation should involve an appreciation of the role of a complete system of healing within an orthodox medicine context, that is, understanding the responsibility to refer to OM where necessary and the appropriate therapeutic boundaries of the modality.

Although pre-registration testing is important for establishing a benchmark, post registration reviews and testing is needed to ensure that a practitioner continues to exhibit competence and ethical practice.¹⁵²² The difficulties in dealing with a practitioner who has not given rise to complaint but who has failed such a review is problematic in a practical sense but is part of a pro-active approach to quality control. A current practitioner could be provided with on the job training to deal with the concerns revealed by the review. The fact that a negative review could lead to a loss of livelihood should not be a major concern as the primary aim of regulation is the protection of the public not the protection of the practitioner.¹⁵²³ These procedures would need to be balanced by appropriate provisions for procedural fairness, counselling and an appeal structure.

An important question is whether the attainment of educational and training standards can be achieved by the graduation from a specific course or institution. This type of regulation involves the assessment of the educational input of university and colleges and is common in Australia.¹⁵²⁴

The concerns about relying upon this type of evidence are:¹⁵²⁵

1522 Ibid 35.

1523 Ibid.

1524 For example *Medical Practitioners Registration Act* (Qld) s44 (a).

1525 Manitoba report, above n 1375, 38.

- This delegates the role of standard maintenance to a body outside the registration body.
- There may be dissonance between the stated aims and objectives of a course or degree and the attainment of those aims. There may be little control in what is occurring within the institution and any formal reviews may not deal with coalface issues of education.
- The educational institution may have goals that differ from the aims for the regulation. An institution may have the aim of providing a broad education that may mean skills are taught that are superfluous to the profession.
- The educational institution may emphasise knowledge without imparting the necessary skills for a competent practitioner.

The fact is that this form of regulation provides cost savings in the labour intensive process of setting and examining competence and knowledge testing. The use of the attainment of educational standards through passing an institution's requirements requires attention to reviews of the standard of those institutions on an ongoing basis.

Safeguards for self-governing bodies¹⁵²⁶

If a self-governing model is preferred some safeguards not currently provided in self government regimes in Australia should be incorporated. The focus of these safeguards relates to the need to overcome the real or perceived tendency for these bodies to act in a self-serving manner. This counsels the need for attention to matters relating to accountability and

¹⁵²⁶ Ibid 56.

openness to help ensure that the public interest is served. The measures that could assist in achieving this goal are:

- Annual reports which are freely available which detail matters such as the membership of the body; financial statements; regulations and decisions made; details of complaints made; details of disciplinary proceedings.
- Access to rules; regulations; policies and by-laws.
- Access to the register of members that should be published yearly so it is possible for consumers or other persons to establish if a practitioner remains registered.
- Access to past records of practitioner on disciplinary matters for a period of time – 3 years prior or current status ie suspended or deregistered or practice subject to conditions etc.
- Public meetings yearly to allow questioning of board by general public.

Assessment of health practitioner professions not currently regulated in Australia.

Acupuncture and TCM

For the reasons outlined by Bensoussan and Myers in the *Towards a Safer Choice* report the extension of statutory regulation to these professions is recommended across all jurisdictions in Australia based on the Victorian model. The difference from the Victorian model might be the application of controlled acts for some acts that may have public health implications such as acupuncture. In Victoria the use of controlled acts would go beyond the regulatory structure preferred in that state which normally relies on only protection of title provisions. This profession has demonstrated the most sophisticated and sustained efforts to professionalise than any other CAM modality. In recent times in response to the GST

exemption funding project AACMA, the key professional association, has been active in developing a National Professional Registration System that includes the establishment of a national education council to advise on the quality of courses and a national practitioner accreditation board to provide national accreditation standards for practitioners.¹⁵²⁷ If these initiatives are successful they should, along with the example set by the Victorian legislation, provide the impetus to state registration systems for TCM and acupuncture in all jurisdictions.

Naturopathy

The primary concern with registration of naturopaths is the ability to establish what naturopathy encompasses. Until recent years it was difficult to establish an appropriate scope of practice for naturopathy as a naturopath may be trained in a number of modalities such as massage; nutrition; homoeopathy and western herbal medicine.¹⁵²⁸ The role of a naturopath as a 'nature cure' practitioner encompasses a potentially very broad scope of practice and permits of very different ideas of what is appropriate training and education. Owing to its very broad scope, those who are not trained in any specific area often use the term 'naturopath' or 'natural therapist'. This can present some difficulties for the establishment of a professional focus for naturopathy. This vagueness in scope of practice is explained by the fact that naturopathy derived from the European nature cure movement that relied upon wide spectrum of therapies with the underlying theme being the belief in the need to deal with a vital force and the healing power of nature.¹⁵²⁹

1527 'News - 'Professional Registration and the GST' (2002-2003) 2 *Diversity* 13.

1528 S Evans, 'The Story of Naturopathic Education in Australia' (2000) 8 *Complementary Therapies* 234, 235.

1529 *Ibid* 235.

The development of naturopathy as an accepted modality in Australia has at times been chequered. Naturopaths along with other non-orthodox practitioners were a major competitor to OM in the mid to late 1800's and were probably a factor in the impetus for OM to organize and to obtain registration protection in Australia.¹⁵³⁰ In the post war years most naturopaths were essentially self-trained.¹⁵³¹ After World War Two the naturopathic profession was probably not large suggested by the fact that only 15 natural therapists were practicing in Victoria in the 1950's.¹⁵³²

Naturopathy and chiropractic were linked as professions in the immediate World War Two period divided between locally trained naturopaths who used manipulative therapy and overseas trained chiropractors. The conflict between these groups was resolved to some extent by the registration of chiropractors in most states in the 1970's that provided some naturopaths with the opportunity to obtain registration status as a chiropractor while continuing their naturopathic practice.¹⁵³³

The somewhat fractured and ephemeral nature of the profession was reflected in the criticism directed at naturopathy by the Webb Report. Naturopathy was described as 'unscientific and, at the best, of marginal efficacy' while there was criticism of naturopathic educational establishments.¹⁵³⁴ Naturopathic education was criticized for not reflecting the course descriptions; not containing a sufficient level of medical knowledge and not properly imparting naturopathic principles.¹⁵³⁵

1530 Willis, above n 129, 53.

1531 Evans, above n 1528, 234.

1532 Ibid 236.

1533 Willis, above n 129, 188, 189.

1534 Evans, above n 1528, 237; Webb Report, above n 63, 99.

1535 Ibid.

Naturopathy enjoyed a brief period of registration status in the Northern Territory under the *Health Practitioners and Allied Professions Act 1985* (NT). This legislation provided for registration based upon accreditation of the Australian Natural Therapists Association Accreditation Board. The legislation also provided for scope of practice and protection of title protection for naturopaths.¹⁵³⁶ The legislation was repealed apparently on the basis that it was deemed pointless to register naturopaths in the Northern Territory when they were not registered elsewhere.¹⁵³⁷

Since the 1990's naturopathic education has been taught in tertiary level courses; TAFE and private colleges at certificate; diploma and degree level courses. Students can obtain a bachelor degree in Naturopathy or Natural Therapies and postgraduate degrees at Southern Cross University and the Bachelor of Health Science (Naturopathy) from Southern School of Natural Therapies and University of New England. These tertiary courses provide a model of what might be the appropriate educational issues that should be dealt with in a tertiary course. The establishment of these courses suggests that the appropriate knowledge base and agreement on what it means to be trained and educated as a naturopath can be achieved. This will aid any process of assessment of those practitioners who might be entitled to registration status behind a statutory protection of title regime. In recent years naturopathy has matured as a profession with this being reflected in initiatives by Southern Cross University signing an agreement with St Vincent's Hospital Lismore to allow clinical placements for naturopathy students in the public hospital system.¹⁵³⁸

1536 *Health Practitioners and Allied Professions Act 1985* (NT) ss 64 – 65.

1537 Repealed Act no 5 of 1993; The Western Australian Department of Training and Employment, *Vocational Education and Training Opportunities within the WA Complementary Therapies Industry* (2000), 64.

1538 Paul Orrock, 'Naturopathic Medicine and Palliative Care: Complementary Partners' December 2002 *Nursing Review* 26.

For these reasons statutory registration is suggested for naturopathy. What titles would be reserved would be a matter of contention. Clearly the term 'naturopath' would be reserved for registrants as should be term 'natural therapist.' The latter term would need to be protected as the use of this term by unregistered practitioners may avoid the purposes of the statutory regulation.

Massage Therapy

Massage therapy presents some special problems for regulators for a number of reasons. There is currently no course in Australia that provides students with a tertiary degree in massage therapy. The highest level qualification available is diploma level at private colleges and at TAFE. The availability to obtain tertiary status for training and education appears to be required for all registered professions in Australia. This is presumably based upon the view that only a tertiary course can provide the teaching and learning environment that incorporates the requisite level of sophistication and connection to OM concepts ie anatomy and biological sciences to justify the costs of statutory regulation.

The physiotherapy profession that attained registration status in the 1940's and 1950's in Australia was actually an offshoot of the group of practitioners who were masseurs; naturopaths, osteopaths and natural therapists.¹⁵³⁹ Registration status for physiotherapists was only obtained when a tertiary level qualification was reached. This will probably be necessary for massage therapy to achieve full registration status. Any moves to introduce tertiary education for massage therapy may be met by the argument from physiotherapy that their course provides the relevant general medical and science training in massage and associated procedures and there is no need for a university level massage therapy course. In the light of

1539 *In Re Ward* [1953] SASR 308, 315.

the current structure and the availability of tertiary level physiotherapy courses, the aim of registration in the form of state level registration and protection of title legislation may at this time be unrealistic. This thesis endorses a middle ground of either government endorsed self regulation or local government based licensing of massage therapists as described below.

There are a myriad of forms of massage therapy including swedish; chinese; kahuna; shiatsu; sports massage; remedial and deep tissue. This may present a difficulty in ascertaining the scope of practice and practice standards for this modality. What is acceptable practice for one modality may be unacceptable to another practitioner. It will be necessary to ascertain what are the core concepts of massage therapy from which accepted educational standards can be established. Educational standards were until recent years very inconsistent however the establishment of a VTEC Training package¹⁵⁴⁰ will provide a degree of standardisation of education levels for this modality.

There is an unfortunate relationship with the practice of massage and the sex industry. This is a problem for practitioners who struggle with the need to advertise their services without being identified as a participant in the sex industry. Some practitioners respond to this issue by not advertising at all, (this reduces competition in the market place for massage services) and relying purely on person- to-person advertising or other forms of networking to develop their practice.

This reduces the ability of massage therapists to indicate to potential users that they are legitimate massage therapists demonstrated by their membership of the relevant massage association. The sex industry connotation issue has profound security issues for many

massage therapists especially for female practitioners who may choose only to have female clients, potentially in breach of anti discrimination legislation.¹⁵⁴¹ This connection is also a problem for prospective clients who may be uncertain about the nature of the training and orientation of massage therapists who advertise their services. This connection has a deleterious effect on the profession of massage therapists and the demand for their services.

The risks of therapeutic massage properly provided and within the standard scope of practice are real but are probably less than for other modalities. Although it is suggested that at this stage of development that full registration cannot be justified the issue of security and the connection to the sex industry indicates a compromise position could be taken that provides for local authority licensing. In most states hairdressers, and sometimes their premises are licenced by local authorities. Interestingly, in Queensland based upon the fact that massage therapists provide scalp massages the regulations under the *Health Act 1937* (Qld) the definition of 'hairdresser' suggests that massage therapists may need to be licensed as hairdressers.¹⁵⁴²

It is suggested that massage therapists be licensed by local authorities based upon the determined educational level and/or perhaps based on membership of prescribed professional associations that would discourage sex industry participants. This licensing would permit massage therapists to advertise their status as licensed practitioners providing some level of

1540 Eg Australian College of Natural Medicine has a Vocational Education and Training approval for courses in Massage Therapy and Remedial Massage.

1541 *Kennon – In Kind Hands – Exemption* (Unreported, Cate McKensie, [2000] Victorian Civil and Administrative Tribunal, 30 November 2000); *Fernwood Fitness Centres Pty Ltd* (Unreported, Cate McKensie and Robert Sadler [2001] Victorian Civil and Administrative Tribunal, 20 December 1995.)

1542 *Health Act Regulation 1996* (Qld) s 35. 'In this part "hairdresser" means every person who shaves, cuts, trims, dresses, waves, curls, stains or dyes or who in any other way treats the hair of any person for a fee or reward, and also any person who for fee or reward performs scalp or facial massage, manicure, pedicure, or in any other way whatsoever treats or otherwise deals with the head, scalp, face, hands, skin, fingernails, toenails, or feet.'

assurance of educational qualification and quality marker as well as permitting a differentiation from the sex industry.

Licensing could be withdrawn on conviction for a prostitution offence; for gross negligence or if they are deregistered from the relevant list of professional associations who have what is deemed to be a sufficient educational membership standard.

Homoeopathy

Despite the fact that this modality has a long and respectable history and at one time challenged the hegemony of OM there are few examples in the Western world where the lay practice of homoeopathy is protected by statutory regulation.¹⁵⁴³ If registered it is normally reserved for MD's or part of the practice of another CAM modality.¹⁵⁴⁴ This might be seen as an initiative to provide some legal protection for medical practitioners who intend to use this non OM modality. The concern that legislators have with the unlicensed practice of this modality in the USA and Canada is exemplified by the prosecution of homoeopaths for the practice of medicine without a licence.¹⁵⁴⁵

The education of homoeopaths in Australia is not reflected in any specific degree course at a university but is part of the training of naturopaths at all universities where naturopathy is taught. The Australian College of Natural Medicine offers the only bachelor degree in homoeopathy (Bachelor of Health Science (Homoeopathy)). Homoeopathy is offered in TAFE colleges and by numerous private colleges throughout Australia from certificate to advanced

1543 David Sale, Overview, above n 1022, 9-10.

1544 Ibid 9.

1545 *R v Harbakhsh Singh Sandhar*, 86 A.R.241 (1988) A.R; *Roget I Sabastier v State of Florida*, 504 So.2d 45 (1987).

diploma level. Homoeopathy has approval for National Competency Standards as a primary care giver.¹⁵⁴⁶

The risks of homoeopathy are derived from the fact that homoeopaths may use in their practice very high dilutions of poisonous substances although most practitioners will normally use professionally prepared remedies. As homoeopathy is a complete healing system homoeopaths may be consulted as a primary health professional. This raises the possibility that a client may not seek medical attention while receiving homoeopathic treatment. As discussed above the argument supporting statutory acknowledgment of any CAM modality should not be based solely on the risks of treatment but should consider the fact that persons are entitled to choose the type of health modality that best suits their philosophy and outlook. There can be no doubt about the complexity and tested nature of the remedies used by homoeopaths that rely firmly upon empirical provings and anecdotal improvement of patients while being treated.

As there is at this time insufficient scientific evidence of the efficacy of homoeopathy OM continues to be particularly critical of this modality and is likely to be vehement in opposition to any statutory recognition of homoeopathy. The counter intuitive nature of the healing mechanism of homoeopathy would suggest the path to registration shall be a difficult. As the other modalities discussed above have a connection with more traditional mechanism's ie nutrition; well being and healing from massage and herbal substances it is easier for legislators to envisage some validity to their modality and to thereby resist the inevitable opposition from OM.

1546 Interim Committee for Australian Homoeopathic Standards, *National Competency Standards For*

Homoeopathy is vulnerable to claims from its critics that it does nothing and should as a result never be recognized in statute. Critics of homoeopathy will argue that legislative intervention cannot be justified because consumers should be protected from themselves in using what would be presented as a useless treatment. Homoeopathy presents itself as a comprehensive system of healing. The fact that some clients might not consult medical practitioners when they ought may not be sufficient to justify the costs of regulation.

These considerations should not override the fact that a person who seeks the services of a homoeopath as a primary care practitioner is entitled to know that if they have registered status that they have a minimal level of training; that the practitioner is obliged to observe specified ethical precepts and that any breach of those requirements may result in the practitioner being disciplined or removed from practice. Subject to agreement on required educational standards registration of homoeopaths is suggested.

Western Herbal Medicine

Western Herbal medicine is a separate modality but most practitioners do not limit their practice to that modality as it is taught and often practiced as part of the practice of naturopathy. The practice of herbal medicine has a long history in European and Anglo Saxon culture that provides some stability to its knowledge in modern times. The features of the practice of western herbal medicine that may be an issue when considering statutory regulation is whether the profession is able to point to a body of knowledge that can be used to ascertain who and what is regulated by a statutory regime. Currently there is one 3 year degree standard course in Australia through the University of Newcastle (Ourimbah campus).

As this course has only just commenced there are no graduates. Western Herbal Medicine has not been given registered status anywhere in the western world.

The fact that western herbal medicine involves the prescribing of potentially toxic substances for ingestion raises the question of whether regulation is necessary. The issues relating to the identification and quality of western herbs are not as problematic as with TCM. In addition the cultural heritage for western herbal medicine in our culture and the long-standing use of these substances for which there is good evidence of efficacy and safety means this is less problematic.

These factors do not necessarily strongly suggest the need for statutory regulation although the profession has expressed interest in this approach.¹⁵⁴⁷ This thesis does not suggest registration at this stage however it is likely it would be justified when the education for this modality becomes firmly established at the tertiary level and when the profession forges an independent stance as a modality on its own right. At this stage any regulation of naturopathy will incorporate many practitioners or western herbal medicine within the regulatory structure.

Proposed Structure

The structure that is recommended draws on both the Ontario and British Columbia model. The model assumes that each state and territory would enact its own legislation. Although national legislation would be the ideal the constitutional problems would suggest this is unlikely to eventuate.

1. Health practice legislation that specifies a list of controlled acts only permitted by specified registered professionals. The selection of these controlled acts should be based upon activities that have significant health risks. For example, the controlled acts that could be specified might include:

- piercing the skin or surgery to be performed by medical doctors subject to exceptions for acupuncture; minor procedures for podiatrists; dentists etc.
- Performing a procedure on tissue below the dermis; mucous membrane; cornea or teeth.
- Setting or casting a fracture of a bone or dislocation.
- Moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust.
- Administering a substance by injection or inhalation.
- Putting an instrument, hand or finger beyond specific orifices including external ear canal; anal verge and labia majora.
- Prescribing, dispensing, selling or compounding controlled drugs.
- Prescribing or dispensing for vision or eye problems.
- Prescribing hearing aids.
- Fitting or dispensing dental prosthesis or orthodontic appliances.
- Managing labour or conducting the delivery of a baby.
- Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.

2. That no legislation provide a specified occupational scope of practice provisions for particular practitioners such as 'the practice of medicine'; 'physiotherapy' or 'podiatry' so as to limit practice to specified registered professionals. Any activities that the legislature suggests should be limited on public safety grounds should be specified under the controlled acts provisions. This will mean unregistered health professionals will be free to practice assuming they do not perform the specified controlled acts.

3. Separate health professional statutes for currently registered professions and TCM, acupuncture and Chinese medicine dispensers; naturopaths and homoeopaths (not limited to medical practitioners). Title limitations only will apply to the use of specified titles. This would mean that only appropriately registered homoeopaths could use the title 'homoeopath' or 'registered homoeopath' and only a registered naturopath could use the term 'naturopath' or 'registered naturopath'. Sanctions would apply to the use of that title by non-registered persons.

4. The establishment of a separate registration board for naturopathy; TCM, acupuncture and homoeopathy along the lines of the medical board or one board covering all CAM modalities dealing with disciplinary and ethical matters with sub-boards for particular modalities to determine educational and admission matters. These statutes should grant power to a registration board to order reprimands; supervision; fines; suspensions and deregistration. Professional misconduct should include unreasonably convincing a client not to seek medical treatment when it was reasonably foreseeable that it was indicated.

5. statutory codes of conduct for each profession separately dealing with specific issues for modalities such as hygiene in regard to acupuncture; naturopathy – special provision re diets and ethical issues.

6. Encouragement for cross referrals. This may involve if necessary legislative provisions to clearly specify that there should be no legislative or ethical obstacles to cross referrals between registered health professionals. This would deal with the type of circumstance that arose between chiropractors and medical doctors who did not have any legislative prohibition on cross referrals but continued restrictions on ethical grounds.¹⁵⁴⁸

7. Statutory provisions requiring CAM practitioners to advise clients to continue contact with MD's . In North Carolina there is provision for acupuncturists to discuss referral with a client. If there is no improvement and in the case of significant worsening of a condition or persistent unexplained pain a referral to another health practitioner should be made.¹⁵⁴⁹

8. For massage therapists that legislation require the local authority licencing of practitioners based upon the criteria discussed above. This legislation would permit only licenced massage therapists to use the term 'licenced massage therapist' or such other appropriate title to permit a differentiation from participants in the sex industry.

9. In relation to therapeutic goods the regulatory regime requires the adjustments suggested in the conclusion to chapter 5. This requires the establishment of a national system of regulation of controls on therapeutic goods as against the disjointed system that is currently limited to constitutionally limited national controls and complementary legislation in New South Wales

¹⁵⁴⁸ Simpson, above n 154, 352.

and Victoria. The suggested reforms involves greater controls over the quality of herbs from harvesting to prescription; more prescriptive controls on the labelling and prescription of herbs and policing of the qualifications of those practitioners who are entitled to use and prescribe therapeutic goods and poisons. If the above regime is adopted the registration of practitioners will permit greater controls on the qualifications of practitioners entitled to use therapeutic goods and will allow more effective sanctions for activities that do not comply with statutory requirements. The sanctioned activities might include use of poisons or dangerous substances in circumstances where injury could occur; use of low quality herbs and inappropriate prescription procedures. This would particularly impact upon TCM practitioners and homoeopaths whose practices are currently regulated somewhat loosely.

1549 Vickie S Ina, 'Credentialing Complementary Practitioners' in Nancy Faass (ed), *Integrating Complementary Medicine into Health Systems* (2001) 206.

Conclusion

The current health care structure is dominated by orthodox medicine. The dominant and generally unacknowledged philosophy of orthodox medicine is allopathy. Overlaid with this philosophy is a scientific reductionism approach to healing which perceives the patient as a machine. Illness suggests that a part of that machine is faulty and the role of the practitioner is to fix that part.

The historical basis for this hegemony; the anchoring of it within the power structures of government, the economy and society has led to a view that it is the only valid model of healing. This has led to the position that a valid form of healing must derive from or be under the control of OM. In addition this hegemony has led to blindness to the limitations of OM and the undervaluing of the potential benefits of complementary medicine.

Medical science has provided great advances but is unable to provide relief for many chronic conditions. Medical treatment may in fact be bad for the patient's health. A considerable percentage of the health budget is directed to iatrogenic sickness. The attention given to disease states and the means to counteract the relevant symptoms has stymied research and funding for preventative medicine and the means of maintaining good health. Without a disease to cure or a drug to prescribe OM flounders. The inability or unpreparedness of orthodox medicine to acknowledge the dimensions of the human healing process beyond a physical and narrowly defined allopathic and scientific basis provides CAM with its niche.

There is a role in the health sector for those sectors of CAM that have a sufficiently developed knowledge base and practice protocols; professional regulation, ethical structure and educational standards to ensure their efficacy and safety. This thesis has identified the modalities that satisfy these criteria as chiropractic; osteopathy; homeopathy; naturopathy; acupuncture and traditional Chinese medicine. This legitimacy is based upon:

- Public acceptance of the role of these modalities in health care driven by the perceived or actual limitations of orthodox medicine.
- The traditional use and growing scientific acceptance of the validity and safety of these treatment regimes.
- The goal of providing protection for the freedom of choice to health service consumers.
- The historical and traditional place of non-orthodox medicine practitioners in western culture and that of other cultures prominent in Australia.
- The importance of the contribution of CAM to the health of the community.

There is a nascent movement amongst the medical profession towards 'integrative medicine.' This movement is reflective of consumer demand and some disillusionment with aspects of OM. This movement does not fully cater for all relevant modalities and cannot provide the type of therapy that many consumers of CAM will demand. The use of integrative medicine will be provided within an OM context and may not be applied based on the philosophy of CAM that is attractive for many consumers.

In most states and territories based upon the applicable legislation only the medical profession is entitled to practice medicine or provide medical services. This legislative position is based upon the influence that orthodox medicine has historically had over the

legislative process. This resulted in the removal of the common law entitlement for unorthodox healers to practice medicine. These provisions reflect the detritus of philosophical battles of the last century. The success of OM in influencing government policy is reflected in the legally sanctioned suppression of freedom of choice in health care even when the efficacy and professionalism of many practitioners deserves respect and support. This creates an environment where practitioners are uncertain as to what might be their legal entitlement to provide specific services to clients. Clients of CAM practitioners may not appreciate the limitations of the services being provided or the quality of the qualifications a practitioner may have. The regulatory structure is characterized by limits placed on the provision of CAM and a lack of attention to the entitlement of consumers of CAM to ascertain the quality of the practitioner and to obtain a remedy in the case of either negligence or unethical treatment.

The legislative provisions should now be reviewed in conformity with modern considerations of competition policy that emphasize the necessity to justify any anti competitive provisions by any accruing public benefit such as public safety. Based upon the level of training and expertise of medical practitioners in certain core activities it is appropriate to cede to that profession and other allied professions certain medical procedures.

Other than the need to ensure public safety by restricting core practices to medical practitioners or other specified professionals the emphasis should be on maximizing the choice to the health consumer coupled with the ability to identify those practitioners who are satisfactorily trained and qualified.

The ceding of OM territory to CAM practitioners should be based upon the following principles:

- Ensuring either by legislation or enforcement of ethical concepts that the limitations of such treatments are appreciated. This should include protocols for referrals to medical practitioners when the matter is outside the training of the practitioner. The training and educational standards of these professions need to reflect this requirement. The necessity to have the ability to understand when a malady is outside of the scope of practice of a practitioner would be integral to this approach.
- Ensuring in the case of ingestive therapies that there is training in the relationship between CM and pharmaceuticals. It is necessary to upgrade the quality of CM provided through more effective integration of complementary medicines in the TGA scheme and associated legislation.
- Minimum prescription of controlled acts that can only be performed by specified registered practitioners.
- Better adverse event recording to ensure proper supervision of practitioners.
- Targeted protection of title legislation for some CAM modalities not currently registered with provision for minimum educational and training standards enforced by a statutory board.

This approach will not dismantle the current regulatory regime but would establish a hybrid of the current structure involving both statutory regulation (including protection of title and core practice provisions), self regulation and licensing arrangements.

The aim of many complementary medicine practitioners to be part of a registered profession may be based primarily on the desire for the status accorded by that statutory acknowledgement. The costs of such a structure and the other economic negatives requires a careful assessment of the appropriate criteria for such provision based upon the need for maximizing consumer information and the protection of the public.

Registration is not justified unless there is a lack of consumer information about the modality such as to cause misrepresentation of what the modality is offering and an attendant risk of public harm by the provision of these services by untrained practitioners.

The most cost-effective method is to regulate activities not occupations ie control particular activities such as spinal manipulation not chiropractic itself.

The recommended structure if implemented will provide a structure that has as its primary objective the promotion of the public interest by the provision of safe, high quality health services that consumers demand. This structure is based not on a preexisting power structure derived from political and historical influences but from a post-modernist interpretation of the public interest. The structure permits the most limited regulation possible to achieve public protection while allowing the expression of consumer choices in health care. The structure will support a flexible and innovative approach to the provision of health care and will support rather than stymie moves to integrative medicine.

The current regulatory structure is developed from a modernist perspective that does not fit well with a post modernist environment. As many people no longer accept without question the certainties that science may offer they have begun to seek a more self-confirming form of healing. This movement finds resonance in the healing philosophy of CAM. The current

regulatory structure does not easily incorporate this approach and in fact actively discourages the role of CAM in health services. The time has come to realign the regulatory structure to reflect this fundamental change. It is difficult to justify not providing protection for the health decisions made by consumers of CAM. Although the limitations of a prescriptive regulatory structure are clear the minimalist regulation of CAM suggested here will achieve a measure of acknowledgment and protection for consumers.

Steps to upgrade the level of scientific evidence for the efficacy and safety of CAM should accompany this structure. Although there are difficulties in applying an OM scientific method to CAM a sympathetic use of scientific method can guide CAM practice to maximize its effectiveness. This will also permit more effective integration of CAM into medical practice. CAM may allow a less technological and more economic form of health care. The suggested structure provides a more client focussed and non- technological approach to healthcare with greater emphasis on disease prevention and health maintenance. It may result in cheaper health care from which the whole society will benefit.

Currently the health structure is based on a 'more is good' concept that, in accordance with OM philosophy, downplays the potentially significant role that can be played by self-healing and an alignment with CAM healing principles. The suggested model provides a balance between the need to provide protection for consumers without an overly prescriptive regulatory regime. The need for CAM modalities to upgrade their ethical controls on practitioners and educational standards is fundamental to those modalities being capable to taking a broader role in medical care in Australia.

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