Submission

to the

Senate Community Affairs References Committee Inquiry Into Services and Treatment Options for Persons with Cancer

by the

Australian Traditional-Medicine Society

March 2005

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

Contents

Executive Summary3
A. Contact Details4
B. About the Australian Traditional-Medicine Society6
C. ATMS Policies
D. Extension of Time Granted10
E. Response to the Senate Inquiry11
1. Use of the Term 'Complementary Medicine'1
2. The Extent to Which Less Conventional and Complementary Treatments are Researched, or are Supported by Research
3. The Efficacy of Common but less Conventional Approaches Either as Primary Treatments or as Adjuvant/Complementary Therapies
4. The Legitimate Role of Government in the Field of Less Conventional Cancer Treatment

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

Executive Summary

The Australian Traditional-Medicine Society (ATMS) is Australia's largest professional association of complementary medicine practitioners, representing approximately 65% of the total complementary medicine profession.

The Society suggests to the Inquiry that the term 'complementary medicine' be used in place of 'less conventional and complementary treatments'. The term complementary medicine was adopted by the Commonwealth Department of Health and Family Services at the Alternative Medicines Summit on 16 October 1996. The term 'complementary medicine' refers to the practice of complementary medicine disciplines by its practitioners, and the term 'complementary medicines' refers to its medicines.

All of the research into complementary medicine is undertaken overseas. The results of the research are frequently reported in prestigious biomedical journals. However, support for research into complementary medicines in Australia is lacking. Research grants are not made available by the National Health and Medical Research Council (NHMRC). Since 2001, of the \$1,000 million allocated to research on pharmaceutical drugs, no more than \$0.85 million has been made available for research into complementary medicines¹. Unlike the Australian Government, the United States Government allocated \$14 million in 2003 to the Office of Alternative Medicine.

The Health and Medical Research Strategic Review Discussion Document noted that the rapid growth and economic impact of complementary medicines justified the need for research². The paper emphasised that for complementary medicines to be integrated into mainstream medicine, research into complementary medicines requires collaboration between complementary medicine practitioners and mainstream medicine researchers.

To date, there has been inertia on part of the Government to make funds available for research into complementary medicine, in spite of recommendations from high level Government committees. The Society hopes that this unwillingness to support complementary medicine by the Government research will be addressed by the Senate Inquiry.

There can be no doubt, based on the plethora of scientific studies, of the efficacy of complementary medicines in a large number of conditions. However complementary medicine should not be used as primary treatment in the management of cancer, but in conjunction with mainstream medical treatments.

The view of the Society is that complementary medicine practitioners must never engage in the primary treatment of cancer, but rather complementary medicine practitioners, using complementary medicines and practices, can contribute in a significant manner as part of a healthcare cancer management team.

¹ Bensoussan A, Lewith GT. Complementary medicine research in Australia: a strategy for the future. Medical Journal of Australia 2004;181(6):331-333.

² Wills PJ (Chairman). The Virtuous Cycle. Working Together for Health and Medical Research. Canberra: Commonwealth of Australia, December 1998.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

Complementary medicines are adequately regulated by the Therapeutic Goods Administration of the Commonwealth Department of Health and Ageing, and no further regulatory controls are necessary.

The role of the Commonwealth Government should be in providing adequate research funding for complementary medicine research, and ensuring that complementary medicines are manufactured in accordance with the Code of Good Manufacturing Practice and advertised according to the requirements of the Therapeutic Goods Advertising Code.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

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Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

B. About the Australian Traditional-Medicine Society

The Australian Traditional-Medicine Society (ATMS) is Australia's largest professional association of complementary medicine practitioners, representing approximately 65% of the total complementary medicine profession. At March 2005, the membership of ATMS was 9,983 practitioners.

ATMS was founded in 1984 and is a non-profit company incorporated with the Australian Securities and Investments Commission (ABN 046 002 844 233).

1. Executive and Administration

ATMS is governed by the Executive Board of Directors. The ATMS Secretary is appointed by the Executive Board. The Society's administration consists of full-time and part-time staff. Five Departments have been established within ATMS to address the specific needs of massage therapy, traditional Chinese medicine, naturopathic nutrition, naturopathy and western herbal medicine practitioners.

2. Committees

ATMS has four main national committees:

- Academic Review Committee: reviews current standards for all disciplines, conducts college inspections and assesses individual membership applications.
- Complaints Committee: handles complaints made by consumers against members and colleges
- Executive Management Committee: handles day-to-day operational matters and makes recommendations to the Executive Board
- ATMS Accreditation Board: assesses course curriculum.

3. Commonwealth Statutory Bodies

ATMS is the only complementary medicine professional association represented on two Commonwealth statutory bodies ie the Therapeutic Goods Advertising Code Council and the Complaints Resolution Panel which have their legal authority underpinned in the *Therapeutic Goods Regulations 1990*.

4. Publications

ATMS publishes the:

- Journal of the Australian Traditional-Medicine Society (ISSN 1326-3390), a quarterly peer reviewed publication. The Journal is indexed in the following international bibliographic indexes: Alt Healthwatch (USA), Cumulative Index of Nursing and Allied Health (CINAHL) (USA) and CAB International (UK).
- Qualified Natural Therapists' Membership Directory which lists practitioner members and accredited colleges. Fifteen thousand copies are distributed nationally to consumers free-of-charge.
- *ATMS Natural Therapies Leaflet* which explains to the consumer the different complementary medicine disciplines

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

- ATMS Members Handbook
- ATMS Annual Report.

5. Continuing Professional Education Seminars

ATMS is committed to a high quality Continuing Professional Education (CPE) program. The ATMS CPE program draws upon accomplished practitioners and other experts to share recent clinical, theoretical and philosophical developments.

6. Website

The ATMS website address is www.atms.com.au.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

C. ATMS Policies

1. Code of Ethics and Practice

The Code of Ethics and Practice lists the requirements for adequate professional conduct. The Code deals with duty of care, professional conduct, confidentiality, patients records, advertising and stationery. It is ATMS policy that members adhere to the Code, and a serious breach of the Code renders a member liable to removal from the Society.

2. Breast Massage

It is the ATMS policy that members do not massage the mammary glands of patients, and that only professional techniques be applied to surrounding tissue.

3. Health Fund Receipts

It is ATMS policy that under no circumstances may a student or staff member use someone else's membership number for purposes of issuing receipts for health fund rebate.

4. Use of the Title 'Doctor'

It is ATMS policy that members do not use the title of 'Dr' unless a registered medical practitioner.

5. Internal Examinations

As the practice of complementary medicine does not in any of its forms require an internal examination, any internal examination by a member, even if the patient submits, is not regarded as being made with the patient's consent and the member could be guilty of indecent assault.

6. Continuing Professional Education Program

ATMS conducts a Continuing Professional Education (CPE) program to give its practitioner members the opportunity to update their clinical skills and knowledge. The CPE program is committed to quality education. It is ATMS policy that practising members must participate in the CPE program.

7. Patient Confidentiality

Patient confidentiality is an essential requirement of the practice of complementary medicine. The ATMS Executive considers that the wrongful disclosure of personal information in respect to a patient by a member of the Society, or a member of his or her staff to a third party, to be a breach of the Society's Code of Ethics and its Articles of Association. The Executive will give serious consideration to the termination of the membership of the Society of any member who directly or indirectly wrongly discloses such information.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

8. Students Practising

It is ATMS policy that Student members do not practise. As they are not fully qualified nor completely trained, they pose a risk to the public and therefore to the interests of the profession and the Society.

9. Telephone and Internet Consultations

The prescribing of medicines following a telephone or Internet consultation, without having at least an initial face-to-face contact with the patient, is non-professional and unethical. A correct diagnosis would not always be possible and inappropriate medicine could be prescribed resulting in harm to the patient. Consequently the practitioner would be held liable for professional negligence effecting not only the individual but the profession at large. Therefore, the ATMS policy is that telephone or Internet consultation, without a prior face-to-face consultation, is not keeping the practitioner's standard of professional work as high as possible and is in breach of the Society's Code of Ethics and is prejudicial to the interests of the profession and the Society.

10. ATMS Criteria for a College to Gain Recognised Status

It is ATMS policy that to be upgraded to ATMS Recognised College status, a college must have been granted provisional status for a three year period beforehand. The ATMS Criteria for Recognised College status lists the requirements required of a college including advertising, refunds policy, student information, recruitment procedures, general standards and a college inspection.

11. Professional Indemnity Insurance

Practising members must have professional indemnity insurance.

12. First Aid Certificate

Practising members must hold a current First Aid Certificate.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

D. Extension of Time Granted

On 16 March 2005, the Society telephoned the office of Mr Elton Humphrey to seek an extension of time for the submission.

The officer who answered the telephone granted an extension of time until Thursday 24 March.

In response to the request by the Society that it wished to participate in the public hearing, the officer noted and confirmed that the Society will be invited to participate in the public hearing in Sydney.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

E. Response to the Senate Inquiry

This submission by the Australian Traditional-Medicine Society (ATMS) is in response to the Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer.

This submission addresses the addresses the following terms of reference of the Inquiry:

How less conventional and complementary cancer treatments can be assessed and judged, with particular reference to:

- i. the extent to which less conventional and complementary treatments are researched, or are supported by research
- ii. the efficacy of common but less conventional approaches either as primary treatments or as adjuvant/complementary therapies, and
- iii. the legitimate role of government in the field of less conventional cancer treatment.

1. Use of the Term 'Complementary Medicine'

The Society suggests to the Inquiry that the term 'complementary medicine' be used in place of 'less conventional and complementary treatments'.

The term complementary medicine was adopted by the Commonwealth Department of Health and Family Services at the Alternative Medicines Summit on 16 October 1996. The Summit was the initiative of the Hon Dr Michael Wooldridge, Minister for Health and Family Services, and Senator Bob Woods, Parliamentary Secretary to the Minister for Health and Family Services. The term complementary medicine is used internationally by both academics and regulators.

The term 'complementary medicine' refers to the practice of complementary medicine disciplines by its practitioners, and the term 'complementary medicines' refers to its medicines. An example of the Government's adoption of these terms is the Office of Complementary Medicines, which is located within the Therapeutic Goods Administration of the Commonwealth Department of Health and Ageing.

2. The Extent to Which Less Conventional and Complementary Treatments are Researched, or are Supported by Research

All of the research into complementary medicine is undertaken overseas. The results of the research are frequently reported in prestigious biomedical journals such as Lancet, New England Journal of Medicine, Journal of the American Medical Association, British Medical Journal and the Medical Journal of Australia.

In 2004 the *Medical Journal of Australia* featured a four part series of articles on the issues facing complementary medicine.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

However, support for research into complementary medicines in Australia is lacking. Research grants are not made available by the National Health and Medical Research Council (NHMRC). Since 2001, of the \$1,000 million allocated to research on pharmaceutical drugs, no more than \$0.85 million has been made available for research into complementary medicines³.

The Health and Medical Research Strategic Review Discussion Document noted that the rapid growth and economic impact of complementary medicines justified the need for research⁴. The paper emphasised that for complementary medicines to be integrated into mainstream medicine, research into complementary medicines requires collaboration between complementary medicine practitioners and mainstream medicine researchers. The paper identified a two stage process for this to occur. Firstly that training in research methods be included in the educational curricula for complementary medicine students, and secondly that health and research funding bodies recognise the importance of complementary medicine practices and complementary medicines.

The report highlighted the work of the United States Office of Alternative Medicine which was established in 1992 within the National Institutes of Health. The Office was established to:

- facilitate the evaluation of complementary medicine treatments to determine their effectiveness
- provide a clearing house for information about clinical usefulness, scientific validity and theoretical basis, and
- provide a research training program in complementary medicine.

Unlike the Australian Government which has ignored research into complementary medicine, the United States Government allocated \$14 million in 2003 to the Office of Alternative Medicine. The Office encourages collaborations between researchers and complementary medicine practitioners, as well as providing an infrastructure for identifying and organising the scientific literature on complementary medicine practices.

The issue of research funding for complementary medicine was addressed by the Expert Committee on Complementary Medicines in the Health System⁵. The Expert Committee was established by Trish Worth in May 2003 when she was the Parliamentary Secretary to the Minister for Health and Ageing. The Committee recommended (recommendation 34) that dedicated funding be made available for complementary medicine research in Australia for a minimum of five years. Moreso, recommendation 35 went further and stated that the amount of funding available for

³ Bensoussan A, Lewith GT. Complementary medicine research in Australia: a strategy for the future. Medical Journal of Australia 2004;181(6):331-333.

⁴ Wills PJ (Chairman). The Virtuous Cycle. Working Together for Health and Medical Research. Canberra: Commonwealth of Australia, December 1998.

⁵ Expert Committee on Complementary Medicines in the Health System. Complementary Medicines in the Australian Health System. September 2003. Canberra: Commonwealth of Australia, 2003

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

complementary medicine research be determined on a per capita basis consistent with complementary medicine research funding in the USA.

The Expert Committee additionally recommended that:

- A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia (recommendation 36).
- The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication (recommendation 37).
- The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity (recommendation 40).

To date, there has been inertia on part of the Government to make funds available for research into complementary medicine, in spite of recommendations from high level Government committees.

The Society hopes that this unwillingness to support complementary medicine by the Government research will be addressed by the Senate Inquiry.

3. The Efficacy of Common but Less Conventional Approaches Either as Primary Treatments or as Adjuvant/Complementary therapies

There can be no doubt, based on the plethora of scientific studies, of the efficacy of complementary medicines in a large number of conditions. However complementary medicine should not be used as primary treatment in the management of cancer, but in conjunction with mainstream medical treatments.

The view of the Society is that complementary medicine practitioners must never engage in the primary treatment of cancer, but rather complementary medicine practitioners, using complementary medicines and practices, can contribute in a significant manner as part of a healthcare cancer management team.

For example:

- a systematic review of the literature has found that acupuncture is useful in reducing the nausea and vomiting associated with chemotherapy⁶. This results in a better quality of life for the cancer patient, allows the oncologist to maintain an adequate level of dosing for the cancer patient as well as relieving the hospital and medical system of an unnecessary financial burden.
- some degree of depression is usually experienced by cancer patients. The medicinal herb St John's wort (Hypericum perforatum) is widely used as an antidepressant for mild to moderate depression. Researchers in England in 2001 analysed 22 randomised controlled trials on St John's wort. They

⁶ Bensoussan A, Lewith GT. Complementary medicine research in Australia: a strategy for the future. Medical Journal of Australia 2004;181(6):331-333.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

found that in these studies that St John's wort was significantly more effective than a placebo, and of similar effectiveness to standard pharmaceutical antidepressants⁷.

- a recent study found that St John's wort is effective in moderate to severe depression. This was a randomised controlled double-blind trial study in 21 psychiatric clinics in Germany. 251 patients diagnosed with acute major depression took part in the trial. The patients were given 900 mg of St John's wort 3 times a day for 6 weeks, and this was compared to patients taking the pharmaceutical drug Aropax. Aropax is used in the treatment of major depression and compulsive-obsessive disorder. The researchers found that St John's wort was just as effective as Aropax, but had less adverse effects⁸.
- a cancer patient needs a robust immune system in order to accelerate the healing process after cancer treatment. The medicinal herb Echinacea (*Echinacea purpurea*) has been shown in a number of research studies to modulate the body's immune system⁹.
- research into vitamin C for cancer patients has indicated that perhaps it could be effective in increasing the life expectancy of terminal cancer patients. The results from studies are not conclusive and conflict, thus highlighting the need for research funding ¹⁰.

In summary, no complementary medicines can replace or be a substitute for primary mainstream medical treatment. However scientific research indicates that complementary medicine practitioners can contribute in a significant manner in the management of cancer patients through participation on patient management teams.

4. The Legitimate Role of Government in the Field of Less Conventional Cancer Treatment

Complementary medicines are adequately regulated by the Therapeutic Goods Administration of the Commonwealth Department of Health and Ageing, and no further regulatory controls are necessary.

⁷ Whiskey E, Werneke U, Taylor D. A systematic review and meta-analysis of *Hypericum perforatum* in depression: a comprehensive clinical review. International Clinical Psychopharmacology 2001; 16(5):239-252.

⁸ Szegedi R, Kohnen R, Dienel A, Kieser. Acute treatment of moderate to severe depression with hypericum extract WS5570 (St John's wort): randomised controlled double blind non-inferiority trial versus paroxetine. British Medical Journal doi:10.1136/bmj.38356.655266.82 (published 11 Feb 2005).

⁹ Wagner H. An immunostimulating active principle from *Echinacea purpurea*. A. agnew Phytotherapy 1981;2(5):166-168.

¹⁰ Cameron E, Pauling L. Supplemental ascorbate in the supportive treatment of cancer: prolongation of survival times in terminal human cancer. Proc Natl Acad Sci USA 1976;73(10):3685-3689.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

Complementary medicine practitioners operate within a self-regulatory framework, with the exception of Victoria where acupuncturists, Chinese herbalists and Chinese herb dispensers are regulated by the *Chinese Medicine Registration Act 2000*.

The role of the Commonwealth Government should be in providing adequate research funding for complementary medicine research, and ensuring that complementary medicines are manufactured in accordance with the Code of Good Manufacturing Practice and advertised according to the requirements of the Therapeutic Goods Advertising Code.

Some State and Territory Governments have expressed an interest in the statutory regulation of complementary medicine practitioners. Victoria has taken the initiative in this regard, and introduced statutory registration for acupuncturists, Chinese herbalists and Chinese herb dispensers. However the other States and Territories have not followed Victoria's lead.

The Society supports appropriate controls on practitioner practice only when there is sound evidence to support such controls. Excessive regulation serves no purpose other than to drain public funds and hinder daily practitioner activities.

In 1984 the Victorian Parliament commenced the Social Development Committee *Inquiry into Alternative Medicine and the Health Food Industry*¹¹. The terms of reference of the Inquiry were to 'inquire into, consider and report to the Parliament on the practice of alternative medicine in Victoria and on the health food industry'. Alternative medicine was defined as naturopathy, homoeopathy, herbalism, iridology and orthomolecular medicine and related practices. The terms of reference of significance to this submission included:

• whether such services, methods and therapies are effective, beneficial or harmful.'

As to whether there is potential for complementary medicine to cause harm, the Inquiry found:

'Evidence presented to the Committee indicated that there is very little public concern over the active harm caused by alternative medical practitioners at the present time. The Committee therefore does not consider that there is a case established for registration based on this aspect of public protection.'

In April 1993, the Australian Health Ministers Advisory Council (AHMAC) established a Working Group to provide advice on the criteria and process to be applied in the assessment of statutory regulation of partially regulated and unregulated health occupations. In April 1995 AHMAC released a report entitled *Working Group Advising on Criteria and Process for Assessment of Regulatory Requirements for Unregulated Health Occupations*. The report outlined the six 'criteria for assessing the need for statutory regulation of unregulated health occupations'. All six criteria must be applicable to the health occupation group for an occupation to be considered for statutory regulation.

Page 15 of 18

¹¹ Parliament of Victoria. Social Development Committee Inquiry into Alternative Medicine and the Health Food Industry. 2 Volumes. December 1986.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

The second criterion asked whether the 'activities of the occupation pose a significant risk of harm to the health and safety of the public'? The practice of complementary medicine does not pose a significant risk to either its users, the wider public or to its practitioners. In healthcare practice, an element of risk to the client is always present. However the crucial point is whether this risk is significant or not. Complementary medicine practice does not pose a significant risk of harm to the health and safety of the public for the following reasons:

- Complementary medicine practitioners do not use any equipment, materials or processes which pose a significant risk to the public.
- Complementary medicine practitioners are not permitted to use any substance which is in either Schedule 1,2, 3 or 4 of the *Standard for the Uniform Scheduling of Drugs and Poisons*.
- All therapeutic goods utilised by complementary medicine practitioners are either listed or registered on the Australian Register of Therapeutic Goods. This ensures that the quality and safety of therapeutic goods have been assessed by Commonwealth Health regulators in the pre-marketing stage.
- Equipment used by complementary medicine practitioners does not contain or emit radioactive or dangerous substances.
- Equipment used by complementary medicine practitioners must be listed on the Australian Register of Therapeutic Devices.
- No intrusive techniques are used by complementary medicine practitioners. Acupuncture, although penetrating the skin, is gentle, soft and safe when used by a qualified practitioner.
- There is no potential for the work of complementary medicine practitioners to cause damage to the environment.
- Over the last 30 years in Australia, death of consumers involving complementary medicine practitioners is rare. In comparison it is estimated that the Australian medical and hospital system are implicated with the deaths of 15,000 Australians annually.
- On an international level, death from the practice of complementary medicine practice is also rare.

In May 1998, the NSW Parliamentary Joint Committee on the Health Care Complaints Commission (HCCC) commenced an inquiry as to whether consumers have effective complaints mechanisms against unregistered health practitioners¹².

The Inquiry arose from the concerns of Health Care Complaints Commissioner that the *Health Care Complaints Act 1993* (NSW) did not allow for disciplinary action against unregistered health practitioners, even if found guilty. The Inquiry, chaired by John Mills MLA, received 27 submissions and heard evidence from 20 witnesses, including ATMS.

Page 16 of 18

¹² Khoury R. HCCC Finalises Inquiry into Unregistered Practitioners. Journal of the Australian Traditional-Medicine Society 1999;5(2):51.

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

The Committee's final report *Unregistered Health Practitioners: The Adequacy and Appropriateness of Current Mechanisms for Resolving Complaints. Final Report* arrived at seven recommendations:

- That the HCCC take a greater role in educating consumers about the Commission's ability to investigate unregistered health practitioners
- That the NSW Department of Health support this initiative by disseminating information through hospitals and Area Health Services
- That the NSW Minister of Health consider expanding the Commission's legislative power to enable it to refer matters to the Director General of Health for prosecution
- That the *Health Care Complaints Act* be amended so that health professional associations are required to establish uniform complaints handling and disciplinary mechanisms, and for the Commission to monitor these functions
- That the Minister of Health examine the feasibility of establishing umbrella legislation for unregistered health practitioners. The legislation would establish a generic form of registration, generic complaint and disciplinary mechanisms, uniform code of conduct, entry criteria into the profession and an Advisory Board to the Minister of Health
- That the Minister of Health provide the Commission with the power to publicly name an unregistered health practitioner where serious allegation has been substantiated and where publication is in the interest of the public
- That the Minister of Health consider establishing a body with the power to issue court-enforceable orders to allow consumers to obtain refunds from unregistered health practitioners where the body deems it appropriate.

The Inquiry found that the range of complaint mechanisms against unregistered health practitioners available to consumers only provided 'very limited and piecemeal protection for health consumers'. The Inquiry reached the decision that '...complaining about such practitioners can be a confusing, frustrating and ultimately fruitless task for health consumers'.

The Inquiry did not see '...that self regulation of unregistered health practitioners through their associations is particularly effective, particularly in the National Competition Policy environment'. However, the Inquiry '...strongly supports giving the Commission powers to mandatorily require unregistered practitioner associations to install uniform complaint mechanisms'.

ATMS supports the following Inquiry recommendations:

- That the NSW Minister of Health consider expanding the Commission's legislative power to enable it to refer matters to the Director General of Health for prosecution
- That the *Health Care Complaints Act* be amended so that health professional associations are required to establish uniform complaints handling and disciplinary mechanisms, and for the Commission to monitor these functions

Senate Community Affairs References Committee Inquiry into Services and Treatment Options for Persons with Cancer by the Australian Traditional-Medicine Society March 2005

- That the Minister of Health provide the Commission with the power to publicly name an unregistered health practitioner where serious allegation has been substantiated and where publication is in the interest of the public
- That the Minister of Health consider establishing a body with the power to issue court-enforceable orders to allow consumers to obtain refunds from unregistered health practitioners where the body deems it appropriate.

ATMS does not perceive there are convincing and substantive arguments for the establishment of statutory registration for complementary medicine practitioners.