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Submission to the Senate Community Affairs References Committee

Inquiry into Services and Treatment Options for Persons with Cancer

March 2005

As an Executive Director and Board member of the National Herbalists Association of Australia I am writing on behalf of Herbal Medicine Practitioner members who interact daily with clients seeking help after a diagnosis of cancer or the experience of cancer treatments.

I wish to address the following items noted in the Terms of Reference for this Inquiry:

(b) 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.

Shauna Ashewood BSc, Dip Ed, ND, Dip Hlth Couns, MPH.
Executive Director on behalf of the
Board of the National Herbalists Association of Australia
C/o PO Box 154, Semaphore.
South Australia. 5019
Ph: **08 8242 2083**
email: ashewood@cobweb.com.au

Summary
The National Herbalists Association is a peak body representing Herbal Medicine and Naturopathic practitioners.

- We believe that practitioners who work with people with cancer need to be well qualified and have high educational standards, such as is accepted by the NHAA.
- We are concerned about the misinformation in the medical community about CAM, particularly herb-drug interactions, and advocate the education of Oncologists and General Practitioners about CAM
- The NHAA advocates the presence of experts in the practice of herbal medicine on government committees investigating the use of herbal medicines.

The extent of research

- We see traditional evidence of herbal medicine use as valued and important component of knowledge about herbs. We prefer to have a "mosaic" model of research that incorporates different research methodologies that address different aspects of CAM.
- We are concerned about the misinformation about herb drug interactions, and would like to see this clarified by consultation with herbal medicine experts.
- There are many obstacles to CAM Research, including the lack of earmarked funding and CAM specific research institutions and infrastructures.
- Support and education is needed to involve CAM practitioners in research.

Scientific evidence about the efficacy of herbal medicines
We highlight three herbal medicines as examples of different herbal medicine use and the development of knowledge and evidence about their use.

- Astragalus (*Astragalus membranaceus*) is a herb with emerging evidence about it effectiveness in supporting the immune system and decreasing the side effects of chemotherapy treatments.
- Mistletoe (*Viscum album*) extract (Iscador) is an Anthroposophical preparation that is used as an adjunct cancer treatment in Europe. There is level II scientific evidence from Cohort Studies of the positive effect of Iscador on reducing the side effects of conventional cancer therapies and improving survival in a number of cancers.
- Essiac is a herbal formula from North America that has persisted in popular use. There is much anecdotal information but no scientific evidence about its efficacy from clinical trials. Investigations into the constituents of the herbs and Essiac's traditional use suggest it has a potentially potent effect in degenerative diseases.

We support the need for more research, especially into the value and effectiveness of herbs in reducing the side effects of conventional cancer treatments and improving long term recovery. We also support research on the influence of herbal medicines and CAM on survival of persons with cancer.

Background

The National Herbalists Association of Australia (NHAA) is a peak Professional Association for Medical Herbalists and Naturopaths who primarily use herbal medicines. It was founded in 1920, making it the oldest complementary medicine association in Australia, and has a current membership of 1200.

The NHAA's primary role is to support practitioners of herbal medicine through

- promoting herbal medicine within the community as a safe and effective treatment option
- disseminating knowledge of herbal medicine
- encouraging high standards of education in herbal medicine
- supporting and protecting the practice of herbal medicine by qualified practitioners
- encouraging the highest ideals of professional and ethical standards in the practice of herbal medicine

Since its inception, the NHAA and its Members have been at the forefront of herbal medicine, and have been influential in areas ranging from education and practice standards, to government regulation and industry. The NHAA has a strong commitment to achieving high educational standards in herbal medicine practice and supports regulation within the CAM industry.

The membership are mainly practitioners of “Western Herbal Medicine”, as distinct from Traditional Chinese Medicine, which has different principles and philosophy, although in practice there is considerable overlap between the systems, particularly with regard to the specific plants employed.

The use of Complementary and Alternative Medicines (CAM) in the general population in Australia is substantial, and people with cancer have been reported using CAM at rates of between 22% and 48%.[1] In Correa-Velez’s study in 2003, 48% of people with advanced cancer used CAM, and of these, 44% used herbal medicines.[2] Worldwide, CAM use in cancer figures vary from 15 to 73%, most likely because some definitions of CAM are broader, and in some countries, traditional use of CAM therapies is high.[3], [4] Herbal medicine is consistently, among the most commonly used therapies.

Discussions with our association’s members indicate that the majority of persons with cancer who consult professional herbalists and naturopaths are usually looking to combine conventional and herbal medicines and CAM. Occasionally people will come who have not been offered further conventional treatment or have been unable to tolerate the treatments, and will use CAM alone.

Only rarely are we also working with someone who has refused conventional treatment on principle. In these cases, under their duty of care, most practitioners would counsel that person to also pursue the conventional

treatment being offered, and may or may not agree to treat them if orthodox medical advice is consistently refused.

Practitioners are also aware that a missed diagnosis or delay in appropriate treatment may be critical to outcomes for persons with cancer, and our membership is educated about referral in these cases. Legally, we do not treat the cancer per se but we give support to the person who has cancer through herbal and naturopathic interventions while they experience conventional treatments.

Currently, most Herbal Medicine practitioners work mainly to support the person during their conventional treatments. Very generally that would involve using herbal medicines to support immunity, the nervous system, digestion, blood, skin and wound recovery. Where possible, herbalists work as part of a healthcare team, where treatments can be coordinated with orthodox interventions, ensuring that the aim of herbal treatment and the aim of medical treatment are compatible. This may mean changing or ceasing interventions when a patient is undergoing chemotherapy or surgery. Herbal medicine also has an important and perhaps overlooked role in the long term recovery after cancer and cancer treatments, and there is along history of use of herbs that support the body after stress, trauma and chemical toxicity.

Legitimate role of government in the field of less conventional cancer treatment

Qualifications and educational standards of CM practitioners who work with people with cancer

The NHAA has long advocated raising educational standards for practitioners of Herbal Medicine and Naturopathy. It is now anticipated that future practitioners will require a degree level of education to practice herbal medicine. We are committed to practitioners having a high level of education about the safety, efficacy, actions and applicability of herbal medicines. We also require that our members undertake Continuing Professional Education.

The NHAA is concerned about possible dangers that may face the public from unqualified or poorly educated practitioners, and prefers to see a legislated system of regulation of Herbal Medicine and Naturopathic practitioners similar to the model adopted in Victoria for Traditional Chinese Medicine practitioners. We believe that these standards qualify us to work with persons with cancer in an educated, safe and ethical manner and in conjunction with other health professionals in a multidisciplinary team.

We have strong concerns about the self prescription of CAM “Over the Counter” medicines (OTC’s), especially herbal medicines, by seriously ill persons. Whereas some CAM remedies carry little risk of side effects or interactions, people who are undergoing complex chemotherapy regimes need professional guidance and supervision. Educated practitioners are

aware of the cautions and potential interactions of some herbs, and also aware of those that are safe and able to be used. We also hold concerns about the quality of herbal products, and acutely so in the post Pan Pharmaceutical's era. We continue to work with government and other professional associations to address these concerns

OTC herbal products are sold in health shops, pharmacies and by some network marketing schemes. There is no guarantee that those selling OTC's are qualified to comment on their appropriate use for persons with cancer and those undergoing chemotherapy treatments. We believe there should be a limit to the advice that can be offered in these settings, and that qualified Herbalists and Naturopaths are those best placed to advise on these medicines, especially herbal medicines.

A Canadian study into advice given to persons with cancer by health food store employees has raised concerns about the advice given. For example, one employee advised to stop a current medication, others considered their products to be curative. More positively, 44% of employees recommended that the person see a health professional.[5] With better education about these issues, we would hope that most of the seriously ill people who seek help from a health shop would be referred to a qualified practitioner. Advice then can be offered that is only appropriate to the setting.

The education of oncologists about CAM

The knowledge and opinion of oncologists about the helpfulness or harmfulness of CAM remedies as reported in the study by Newell and Sanson-Fischer is not always consistent with the known information about the particular therapy. [6] In practice, Herbalists and Naturopaths find vastly different opinions from oncologists about their clients using CAM. Whilst some oncologists are positive, some are overtly negative and discourage people from taking any other medications during their conventional therapies.

In the main there is an attitude of support for psychological therapies such as meditation, relaxation and mental imagery, which has been supported by evidence in the scientific literature. However, for other therapies, including herbal medicines, there is often a patronising attitude of "its ok since it probably does no harm", or the converse opinion of "stop taking all CAM in case they do cause harm".

We are concerned that this attitude does not necessarily represent an informed opinion, especially as clients are reluctant to go against their Doctor's advice. We are also concerned about the confusion this generates.

The presence of herbal experts on committees

The NHAA advocates the presence of experts in the practice of herbal medicine on government committees investigating the use of these practices. There have been herbal medicine representatives on, for example, the Expert Committee on Complementary Medicines in the Health System, and the Complementary Medicine Evaluation Committee (TGA). However we

differentiate between those who are expert, for example in the manufacture of herbal medicine, or who are experienced researchers in the area, and those who are practitioners. We argue that herbal practitioners are the appropriate professionals to make expert comment on the practice of herbal medicine. We believe there needs to be herbal medicine practitioners as part of any government committees investigating the use of CAM and its practices by people with cancer.

The extent to which less conventional and complementary treatments are researched, or are supported by research

The history of herbal medicine use by both lay people and practitioners is thousands of years old. The accumulated knowledge of such use, based on an understanding of the herbs actions and effects on the body, has led to the body of empirical knowledge that we refer to as traditional evidence of use. This knowledge is recorded in respected Pharmacopoeias and texts such as the German Commission E Monographs, the British and European Pharmacopeias and Grieves' "A Modern Herbal", amongst others.

Bone and Burgess suggest that: "Real traditional knowledge exists in the context of a traditional medical system which has evolved over thousands of years, or it may be part of a smaller, more primitive system. The important point is that valid traditional use is the refined knowledge of many generations, carefully evaluated and re-evaluated by many of the practitioners of the craft." [7]

We challenge the notion that scientific evidence in the form of the randomised clinical trial is required as evidence for the effectiveness of CAM's, including herbal medicines. We do not dispute the high level of evidence that a randomised controlled clinical trial represents, but we challenge any notion that RCT's should be only form of *acceptable* evidence. The long history of use of herbal medicines and the possibility that other forms of scientific evidence represent valid data need acknowledgment.

I have previously proposed a mosaic model of evidence about Complementary and Alternative Medicines that takes into account the appropriate research methodology for the question being asked. Questions of outcome and benefit are different from questions of safety and efficacy, and questions of meaning and quality also require the application of different research methodologies.[8]

Mills and Bone support the idea of a mosaic of evidence about herbal medicine that includes observational studies, pharmacological and clinical research, in vitro research, clinical trials using the N-of-1 design, and make suggestions about the development of new measures for the subtle effects of CAM's. [9] There is also much scope for studies into Quality of Life using Qualitative methods as well as Quantitative methods. This builds a body of evidence that has a broad scope and is inclusive of the many dimensions of CAM.

Herb-drug interactions

One of the current frustrations of practitioners is the issue of herb drug interactions with chemotherapeutic agents. There have been recent publications suggesting caution about potential interactions of herbs with chemotherapies. As a result of these, which cite theoretic and potential, not proven interactions, medical practitioners have taken the view that **no** herbal preparation is safe to be taken during chemotherapy.

The only proven drug interaction with chemotherapy is St John's Wort. St John's Wort is a powerful inducer of the Cytochrome p-450 enzyme detoxification system, and it has been found to cause the increased clearance of irinotecan chemotherapy.[10] The potential for this to also be a problem with other chemotherapy agents has led to the current situation where best practice indicates that St John's Wort is contraindicated for administration to patients who are undergoing chemotherapy. This is well-accepted by herbalists, who are aware of the interactions of St Johns Wort with transplant rejection drugs and antiviral drugs used in HIV/AIDS, and are cautious when using it with any potent and dose sensitive drugs.

Herbalists and researchers have also considered the possibility that other herbs, especially those with an effect on the liver, may also induce Cytochrome p-450 activity. St Mary's Thistle is an important liver herb that can protect the liver against drug-induced damage. Researchers investigated its potential for changing the metabolism of indinavir, an antiviral used in HIV. The study, on human subjects, found no apparent effect of St Mary's Thistle on Indinavir plasma concentrations.[11] Indeed, the protective effect of St Mary's Thistle has been suggested as an appropriate indication for persons undergoing chemotherapies that have such toxic effects on the liver.[12] Herbal medicines' capacity to restore function in overloaded organs such as the liver and kidneys make it an advantageous therapy for persons undergoing chemotherapy.

There are also possibilities that herbal medicines may have positive interactions by enhancing the effect of chemotherapy on cancer. Older trials in Russia in the 80's have been quoted as finding Siberian Ginseng (*Eleutherococcus senticosus*) protective against radiation and chemotherapy damage and enhancing the effect of chemotherapy. [13] This has also been raised as a possible effect of *Astragalus* in preliminary investigations in China.[14, 21]

Obstacles to CAM research

Access to research funding is the largest obstacle to developing a research base into CAM in Australia. Bensoussan notes that NHMRC funding for CAM since 2001 is just $850 000 of $1 billion in research funds. [15] This is less than 0.1%. Without a stronger commitment of research funds, sufficient preliminary research cannot be undertaken and an extended research structure cannot be developed.

Preliminary research is necessary before proceeding to the larger Randomised Controlled Clinical Trial, the gold standard of biomedical research. Without preliminary research, CAM research cannot proceed to these "higher" levels. Similarly, organisations with a research infrastructure that is well established are more likely to attract funds. Although Australia has now a number of CAM research centres, they compete with well established biomedical centres for funding.

Another problem with attracting research funds for CAM treatments for cancer is the notion that conventional medicine has scientifically proven treatments for cancer and that therefore research into CAM is not needed, nor should it be prioritised. While the advances of conventional cancer treatments are to be acknowledged, that should not exclude investigation into CAM treatments. Indeed, we know that conventional treatments for cancer have significant and sometimes long term side effects that affect quality of life, and we believe that CAM, especially herbal medicines, have much to offer to mediate these effects and improve long term recovery.

Another issue that arises on considering CAM research is the perceived problem of researching therapies that have unknown or "implausible" mechanisms of action. We would maintain that it is outcomes that matter, and that unknown mechanisms of action also exist in conventional medicine. Herbal medicines, however, are often understood in a biomedical model of research since they act at a physiological level in the body. We would also argue, of course, that they have other influences on health that appear to go beyond their constituent chemicals and physical level of action. Nevertheless, this physiological nature of herbs may make them, in the eyes of many in the scientific community, a more acceptable CAM therapy to be investigated.

As mentioned previously, we consider that the application of a range of research methods and designs will be more representative of the scope of CAM. For example, the Office of Cancer Complementary and Alternative Medicine (OCCAM) in the USA initiated a program which educated CAM practitioners in the preparation of Best Case Series and the conduct of Pilot Clinical Trials using CAM modalities. This was established to encourage the accumulation of preliminary clinical data, which may support further research. [16] The education and support of CAM practitioners, who are in touch with clinical practice, to become involved in research is a clear priority.

The efficacy of common but less conventional approaches either as primary treatments or as adjuvant/complementary therapies

It is beyond the scope of this submission to make a review or analysis of research into the efficacy of particular herbal medicines for cancer. Collating, reviewing and analysing data about specific herb is certainly an area that

could be developed with the appropriate resources. We hope academics with expertise in these specific areas have offered submissions with more detail.

As representatives of herbal medicine practice that is inclusive of traditional as well as scientific evidence for use, we would like to highlight three herbal medicines as examples of different herbal medicine use and the development of knowledge about their use.

- *Astragalus membranaceus* is a herb that is used for immune system support and has been used extensively by people with cancer. It has been systematically reviewed by the Cochrane Collaboration for its use in colorectal cancer. Astragalus is an example of a herb that is used either alone or in combination with other herbs, and is used by Western Herbal Medicine as well as Traditional Chinese Medicine practitioners.

- Iscador is a herbal (Mistletoe) extract that is commonly used in Europe and now has considerable evidence from cohort studies to suggest its efficacy and safety as an adjunct treatment in cancer. Iscador was developed within the Anthroposophical system of complementary medicine that uses a mixed system of herbal extracts and homeopathic medicines, in both oral and injectable forms. Iscador is a good example of an altered herbal extract that is still regarded by many as a herbal medicine.

- Finally, Essiac is an old Canadian herbal formula that has been popular and whose popularity and use has persisted over time by persons with cancer. There is a lack of scientific evidence about its effectiveness, but there is data to suggest the mechanisms of action of the herbs may be of benefit for people with cancer.

Astragalus (Astragalus membranaceus)

In Europe, China and in India, complementary medicines are routinely used side by side with conventional cancer treatments. There is a large body of research in China that evaluates the use of Traditional Chinese Medicine herbs for cancer and cancer treatment side effects. There have been questions raised about the quality of some of this research, and the systematic review of some of this evidence is underway.

For example, a recent Cochrane Collaboration review of Chinese medical herbs for chemotherapy side effects in colorectal cancer patients found that despite the included studies being of low quality, the results suggest that Huangqi compounds (Astragalus sp) may decrease side effects in patients treated with chemotherapy.[17]

Astragalus has been the subject of scientific investigations into its immune enhancing effects. Animal studies report that Astragalus stimulated immune system activity and inhibited tumour growth. Human studies also found that Astragalus decoction stimulated the immune system and prevented immunosuppression in persons undergoing chemotherapy or radiotherapy. [18]

In an open, uncontrolled study of 54 cases of small lung cell cancer, patients were prescribed a combination of Panax Ginseng and Astragalus along with a combination of conventional chemotherapies. The authors reported increased survival of 3 to 17 years compared to average survival rates.[19]

We also note a randomised clinical trial of 120 patients who received either standard chemotherapy or chemotherapy plus Astragalus. The authors found that the Astragalus injection supplemented group had demonstrated a significantly decrease in the toxic effects of chemotherapy, as well as improved immune function and decreased disease progression and increased quality of life [20]

Traditionally Astragalus is used within Traditional Chinese Medicine as a spleen tonic for fatigue and blood loss, and to increase vitality. Its modern day clinical uses include immune enhancement in chronically fatigued patients and those with post viral syndromes. These indications are completely appropriate for persons with cancer, for whom debility and fatigue are common long term consequences of cancer and chemotherapy treatments.

Mistletoe

In Europe, there is also a long history of use of traditional medicines, such as herbal medicines and homeopathic remedies, alongside of conventional treatments for cancer.

Iscador is an anthroposophical extract of the plant *Viscum album* (Mistletoe) that is used as a treatment for cancer. In Germany it is a popular and commonly prescribed adjuvant cancer therapy. Iscador has been investigated using an observational study of 622 matched pairs nested within a larger cohort study of people with cancer.[21] This was a large, well designed study over sufficient time and with sufficient numbers to yield significant data about cancer outcomes. The results were positive for Iscador, with mean survival time 40% longer in patients treated with Iscador than in the control group.

A more recent report (2004) on a cohort of 1442 breast cancer patients using Iscador was also positive for reducing the incidence of adverse drug reactions associated with the conventional medicines. Amongst the Iscador users, survival was also improved. [22]

Very recently (2005) the results of another cohort study on the effects of Iscador on Melanoma were published. This cohort study on 686 patients examined safety, side effects and survival, and found the treatment to be safe and suggested a “significant survival benefit” for those on the Mistletoe extract. The authors of this study note that in Europe, comparative epidemiological cohort studies can be accepted for the proof of efficacy and safety of “well established” and marketed drugs and are considered Level II evidence in Evidence Based Medicine (EBM) requirements. [23]

While the Iscador extract is not a herb used by traditional (Western) Herbal Medicine practitioners in Australia, (it is injectable and can only be prescribed by medical doctors), it is a Herbal Medicine accessed and used by persons with cancer in Australia.

It is worthy of note because it is a herbal extract used within CAM that has been the subject of several large cohort investigations that offer scientific evidence about its positive effects in cancer.

Essiac

A review in 1998 by Kaegi on behalf of the Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative provides much of the following information. [24]

Essiac is a herbal formula that was used by the (Ojibwa) Native Americans in Canada and passed on to a nurse Rene Caisse in the 1920's, who named the formula Essiac.

The original formula contains the herbs; Burdock Root (*Arctium lappa*), Indian Turkey Rhubarb (*Rheum palmatum*) Sheep Sorrel (*Rumex acetosella*), and Slippery Elm bark (*Ulmus fulva*). It was traditionally used as a blood purifier and balancer. There have been claims that Essiac strengthens the immune system, improves appetite and improves Quality of Life.

Its safety profile is good with no known interactions, but there may be a mild laxative effect and there have been reports of skin irritations.

Essiac has persisted as an extremely popular cancer remedy, especially North America and in Australia. Whilst Caisse was alive, it is reported that much data about its use in humans was gathered, and research that was conducted in the early 70's was lost after break down of collaboration with Caisse and Memorial Sloan Kettering.

There is a report of an unpublished Canadian study in the 1970's that found subjective improvement in symptoms and wellbeing but no improvement in survival or tumour size. There is one animal study that showed increased tumour necrosis and cell degradation with oral Essiac. Since then we are not aware of any clinical studies into Essiac's effectiveness, and certainly there is no clinical trial data to suggest its efficacy.

However, data about the constituents of Essiac suggest a potentially potent effect in degenerative diseases. The constituents of the herbs (flavones, anthraquinones, polysaccharides) have been reported to have antioxidant, immunomodulating, antmutagenic and cytostatic effects.

Burdock extract causes necrosis in solid tumours and inhibits mutagens. Interestingly, one of its traditional uses is as a blood purifier and lymphatic tonic that eliminates toxins from the body. *Indian Rhubarb* contains the aloe

emodin (anthraquinone) which is known for tumour inhibition. It is also traditionally a detoxifying herb. It has been shown to be antibiotic, antimicrobial, antitumour. (Oriental Medicine Research Centre, Tokyo)

Sheep Sorrel was thought by Caisse to be the key anticancer herb. It is found in old herbals indicated for cancer and chronic disease. It is rich in antioxidants and was thought to clear blood vessels and to be detoxifying.

Slippery Elm is likely to be a synergistic element of the formula, improving digestion and healing inflammation in the digestive tract**.**

With Essiac there is an absence of clinical data, but speculation based on constituent data suggests that it may have a cytostatic and detoxifying effect. Certainly its traditional use suggests that it is supportive of actions that would antagonise the conditions in which cancer arises and proliferates. While this is insufficient to make any clinical claims, it certainly indicates that Essiac is worthy of further investigation.

Conclusion

The NHAA supports raised educational standards and qualifications of Herbal Medicine practitioners so that the best possible care can be delivered to clients, especially those with life threatening diseases such as cancer. We also support the co- operation of health professionals in multidisciplinary teams that are collaborative and open, well informed and respectful.

It seems that now the net is cast wide in the quest for more knowledge about herbal medicines, CAM and cancer. We are beginning to see a whole range of in vitro investigations documented on PubMed and Medline databases, such as whether herbs can influence resistance of cancer cell lines to chemotherapies. There are studies looking at the synergistic effects between herbs and chemotherapies. There are also many examples of investigating the effect of herbs directly on cancer cells.

What we need now is more research into clinical outcomes of herbal medicines for people with cancer.
Research needs to address such questions as:

- Can herbal medicine reduce the side effects of chemotherapy, improve efficacy of chemotherapy and improve the quality of life in persons with cancer?
- What are the long term benefits are of using herbal medicines after cancer and cancer treatments?
- Can herbal medicine and CAM, alone or in combination with conventional medicine, influence survival?

This last question needs to be addressed, despite what may appear to be ethical issues about undertaking such study.

There is clearly much knowledge “out there” that needs collation and synthesis. Books, such as Boik’s *Natural Compounds in Cancer Therapy*[25], and Lerner’s *Choices in Healing*[26] offer scientific appraisal of CAM cancer therapies. Journals, such as *Integrated Cancer Therapies* are dedicated to looking at the question of complementary medicines and cancer, and to the combination of conventional and complementary treatments in what is known as Integrated Medicine. Comprehensive Cancer Care conferences updating current knowledge of CAM in cancer care are now held regularly, especially in the USA.

However, there is also much to be investigated and we are in an era where the demand for CAM from persons with cancer now make it essential that it CAM is appropriately researched. At the same time, persons with cancer deserve and require practitioners who are well qualified to offer them care.

We hope that the information in this submission creates a positive direction on the issue of Complementary and Alternative Medicines for persons with cancer. Thank you for the opportunity of presenting our position on the matter of Herbal Medicines.

Shauna Ashewood BSc, Dip Ed, ND, Dip Hlth Couns, MPH.
Executive Director on behalf of the
Board of the National Herbalists Association of Australia

c/o
PO Box 154, Semaphore.
South Australia. 5019
Ph: **08 8242 2083**
email: ashewood@cobweb.com.au

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