

RECOMMENDATIONS
ON THE
DESIGNATION OF
TRADITIONAL
CHINESE
MEDICINE

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Applications by the
Traditional Chinese Medicine Association of British Columbia,
Canadian SinoBiology Practitioners Association of Canada
and Pacific Region TCM Practitioner and Acupuncturist Society

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FOREWORD

This report is in response to applications by the Traditional Chinese Medicine Association of British Columbia, the Canadian SinoBiology Practitioners Association and the Pacific Region TCM Practitioner and Acupuncturist Society for designation under the Health Professions Act (R.S.B.C. 1996, c. 183). Under the Health Professions Act, the Health Professions Council (the Council) is a six-person advisory body appointed by the Government of British Columbia to make recommendations to the Minister of Health about the regulation of health professions. This report is the result of an investigation of the practice of traditional Chinese medicine by a three member panel of the Council.

EXECUTIVE SUMMARY

In its review of the three applications for designation of TCM, the Council applied the Public Interest Criteria as directed by the Act. The Council reviewed the information provided by each of the three applicants and information gathered during the research, written consultation and public hearing phases of its investigation.

The Council first determined that the practice of TCM meets the definition of "health profession" set out in the Act.

The Council then reviewed the services provided by TCM practitioners. After examining the four primary therapies which form the basis of TCM practice and the technologies, procedures and therapies utilized, the Council concluded that the practice of TCM met the basic risk of harm criteria which must be satisfied in order to designate a health profession under the Act.

The Council then considered the supporting criteria listed in s.5(2) of the Regulation. The Council found that there was a public interest in ensuring the availability of regulated services provided by TCM practitioners and that those services provided a benefit to the health and well-being of the public. The Council noted the long history of the practice of TCM throughout the world and the unique body of knowledge forming the basis of the practice. The Council was advised that there are currently eleven educational institutions in British Columbia offering programs in TCM and many practitioners trained in the practice of TCM in China or in a family tradition. The Council's review of the foregoing criteria lead it to conclude that it is in the public interest to designate the profession of TCM as a health profession under the HPA.

The Council then considered whether any of the activities or services provided by TCM practitioners were activities which presented a significant risk of harm such that those activities were encompassed within the Council's reserved act list. The Council recommended that TCM diagnosis and insertion of acupuncture needles be reserved acts for members of the College of TCM.

The Council examined prescription of Chinese medicinal formulas within the practice of TCM. The Council concluded that some of the substances used in TCM formulas may be toxic in certain combinations and could thus cause adverse effects in patients. The Council found that precise determination of these substances was beyond its competence and recommended that the Minister of Health strike an expert multidisciplinary panel to finalize the list of substances used in TCM formulas which carry a high potential for adverse consequences.

The Council further recommended that upon the determination by the multidisciplinary panel of the list of substances, that the reserved act of prescription according to TCM principles of TCM formulas that include those substances be included as a

reserved act on the Council's list of reserved acts and that this reserved act be recommended for members of a college of TCM.

The Council considered the role of College of Acupuncturists in regulation of practitioners of TCM and recommended that one college govern practitioners of acupuncture and traditional Chinese medicine.

I. APPLICATION AND PROCESS OF INVESTIGATION

In Canada, there are no statutes that recognize the practice of traditional Chinese medicine (TCM) as a self-regulating profession. In British Columbia, the practice of acupuncture, one aspect of the practice of TCM, is regulated by the College of Acupuncturists. Acupuncture was designated as a self-regulating profession under the Health Professions Act (the HPA) in April 1996.

Acupuncture is also regulated in Alberta and Quebec. In Ontario, the Health Professions Regulatory Advisory Council conducted public hearings in June 1996 to determine if acupuncture and TCM should be regulated separately or whether acupuncture should be regulated as a part of TCM. The final report has not been released to date.

This investigation was undertaken because the Traditional Chinese Medicine Association of British Columbia (TCMABC) submitted an application for designation of TCM as a self-regulating health profession under the HPA. This application was received on February 3, 1992.

A notice of investigation was published in the British Columbia Gazette on January 18, 1996.

A second application was submitted by the Canadian SinoBiology Practitioners Association (CSPA) on April 25, 1996. A third application was submitted by the Pacific Region TCM Practitioner and Acupuncturist Society (PRTCMPAS) on June 10, 1996.

All three applicants are incorporated under the Society Act (R.S.B.C. 1996, c.433).

Because of similarities in the applications and the goals of the three applicants, each seeking to have TCM designated, the applications were joined procedurally by the Ministry of Health and the required fee was shared amongst the three groups.

The Council met with representatives of each of the three applicant societies on April 23 and 24, 1997. During discussions with each of the applicants, the CSPA and the PRTCMPAS stated that they regarded their applications as supplementary and supportive to the application of the TCMABC. Each applicant indicated a willingness to work cooperatively in the event that TCM was designated under the HPA.

For the purposes of this report the Council has chosen representative excerpts from each of the applications for discussion of the criteria which have been applied in this investigation.

The Council's investigation of TCM included an extensive consultation process with related professions and other interested agencies and parties. As well, the Council conducted research on the practice of TCM and herbology and its regulation in

other jurisdictions. The role of Health Canada, Health Protection Branch, Therapeutic Products Directorate, in the regulation of herbal and animal products, as well as foods and drugs, was also investigated.

The Council corresponded with a large number of organizations during the consultation phase of its investigation. A synopsis of positions taken by respondents to the consultation process is found in Appendix A.

The Council examined the education and training available in British Columbia for the practice of traditional Chinese medicine and made a site visit to the International College of Traditional Chinese Medicine of Vancouver on May 27, 1997. The Council has examined curricula and calendars from seven other TCM educational programs.

A public hearing was held on October 9 and 10, 1997. The participants are listed in Appendix B.

II. STATEMENT OF ISSUES

The Council identified three issues involving the regulation of traditional Chinese medicine. In assessing the public interest in the regulation of this profession, the Council considered:

- (1) the extent to which the practice of TCM may involve a risk of physical, mental or emotional harm to the health, safety, or well-being of the public according to s.5(1) of the Health Professions Regulation under the HPA (the Regulation);
- (2) whether regulation of TCM falls within the mandate of the College of Acupuncturists of British Columbia, and if not;
- (3) whether designation of a college of TCM would be in the public interest having regard to the criteria of sections 5(1) and 5(2) of the Regulation.
- (4) in the event a college of TCM was designated;
 - a) whether members of the college of TCM perform any reserved acts as listed in the Council's January 1998 Shared Scope of Practice Model Working Paper; and
 - b) do any other acts or activities performed by members of the college of TCM present such a serious risk of harm that consideration must be given to establishing a new reserved act.

III. RECOMMENDATIONS

The Council recommends to the Minister of Health that:

1. traditional Chinese medicine (TCM) be designated as a health profession under the Health Professions Act.
2. the services which may be performed by registrants are the practice of TCM, as defined in the following scope of practice statement:

the practice of TCM is the promotion, maintenance and restoration of health and prevention of disease by utilization of the four primary therapies:

- *Chinese acupuncture and moxibustion (Zhen Jiu),*
 - *Chinese manipulative therapy (Tui Na) and Chinese rehabilitation exercises (Lian Gong or Dao Yin),*
 - *Chinese energy control therapy (Qi Gong) and Chinese shadow boxing (Tai Ji Quan), and*
 - *prescribing Chinese medicinal formulas (Zhong Yao Chu Fang) and Chinese food cure recipes (Shi Liao).*
3. the reserved acts recommended for members of the College are:
 - TCM diagnosis, and
 - the insertion of acupuncture needles below the dermis.
 4. in addition,
 - an expert multidisciplinary panel including practitioners who utilize TCM formulas, be appointed by the Minister of Health to finalize the list of substances used in TCM formulas which carry a high potential for adverse consequences; and

- upon finalizing the list of substances, prescription according to TCM principles of TCM formulas that include those substances be included as a reserved act on the Council's list of reserved acts and subsequently be granted to members of a college of TCM.
- 5. a single college govern both practitioners of acupuncture and practitioners of TCM.
- 6. the college established for the health profession be named the "College of Traditional Chinese Medicine Practitioners".
- 7. the title "Traditional Chinese Medicine Practitioner" be reserved for the exclusive use of registrants of the College of Traditional Chinese Medicine Practitioners. The title "Acupuncturist" be reserved for those members of the college who are not qualified to use "TCM Practitioner" as their training is only in acupuncture.

IV. RATIONALE FOR THE RECOMMENDATIONS

A. DESIGNATION, SCOPE OF PRACTICE AND RESERVED ACTS

In order to proceed under s.7 of the HPA to recommend the designation of traditional Chinese medicine, the Council must determine (1) whether the applicant's profession comes within the definition of "health profession" as set out in s.1 of the Act; and (2) that designation is in the public interest pursuant to s.5 of the Regulation.

1. Definition of "Health Profession":

The HPA s.1 defines a health profession as "... 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."

A review of the three applications submitted indicates that a TCM practitioner provides treatment and advice to persons who have a wide variety of health conditions. According to the applicants, this includes TCM diagnosis, the use of acupuncture, prescription of TCM formulas according to TCM principles, and recommendation of other TCM treatments or exercises which are described later in this report. The Council recognizes the use of skill and judgment required of a TCM practitioner in the care and treatment of persons who are seeking either preventative health care or treatment of existing illness or infirmity and concludes that the practice of TCM falls within the definition of "health profession" set out in the HPA.

2. Public Interest Criteria

Section 5 of the Regulation Part II Public Interest Criteria states:

5.(1) For the purposes of s.10(1) of the Act, the Council must consider the extent to which the practice of a health profession may involve a risk of physical, mental or emotional harm to the health, safety or well being of the public, having regard to

(a) the services performed by practitioners of the health profession,

(b) the technology, including instruments and materials, used by practitioners,

- (c) *the invasiveness of the procedure or mode of treatment used by practitioners, and*
- (d) *the degree to which the health profession is*
 - (i) *practised under the supervision of another person who is qualified to practise as a member of a different health profession, or*
 - (ii) *practised in a currently regulated environment.*

(2) *The Council may also consider the following criteria:*

- (a) *the extent to which the health profession has demonstrated that there is a public interest in ensuring the availability of regulated services provided by the health profession;*
- (b) *the extent to which the services of the health profession provide a recognized and demonstrated benefit to the health, safety or well being of the public;*
- (c) *the extent to which there exists a body of knowledge that forms the basis of the standards of practice of the health profession;*
- (d) *whether members of the profession are awarded a certificate or degree from a recognized post-secondary educational institution;*
- (e) *whether it is important that continuing competence of the practitioner be monitored;*
- (f) *the extent to which there exists within the health profession recognized leadership which has expressed a commitment to regulate the profession in the public interest;*
- (g) *the likelihood that a college established under the Act would be capable of carrying out the duties imposed by the Act, having regard to factors which in the view of the council may affect the viable operation of the College;*
- (h) *whether designation of the health profession is likely to limit the availability of services contrary to the public interest.*

Introduction:

Prior to discussing the applications and criteria the Council will first discuss concepts relevant to reviewing an application for designation, including scope of practice statements, "exclusive scope of practice" and reserved acts.

A scope of practice statement describes what the profession does, the methods it uses, and the purposes for which it does it. The statement itself does not grant the profession an exclusive scope of practice. Nonetheless, the statement is important because it defines the area of practice in relation to which the governing body must establish registration requirements and standards of practice; it defines the parameters of the profession for members of the profession, employers, courts and educators; and it informs consumers about the services practitioners are qualified to perform.

The Council notes that the use of the term "exclusive scope of practice" was included in the Council's terminology at the time of the applicant's initial submission in 1992. In its 1993 Report on the Designation of Acupuncture, at page 18, the Council clarified its terminology:

In previous reports, the Council has used the terms "controlled act" or "exclusive scope of practice" to refer to specific tasks and services which should only be performed by members of one or more regulated health professions with the necessary training, qualifications, and abilities to perform them safely. The Council has now adopted the term "reserved act" for those tasks and services involving a significant risk of harm which should only be performed by those health professions authorized to perform them under their governing legislation.

The Council's 1994 Terms of Reference for the review of scopes of practice of regulated health professions direct the Council to define scopes of practice and to encourage shared scopes of practice among qualified health practitioners. These same principles apply to the Council's mandate to define scopes of practice for health

professions for which designation is recommended. The term "reserved act" has now been adopted by the Council. The term "exclusive scope of practice" is no longer used.

The Public Interest Criteria contained in s. 5(1) of the Regulation provide the context in which the Council will analyze the risk of harm in the applicants' practice. While the Council may also consider the s.5(2) criteria in making its designation decision, these criteria do not address risk of harm. If the Council decides that the profession should be designated, the Council will determine an appropriate scope of practice statement for the profession. The Council will then determine which aspects of the scope of practice have been shown to present a significant risk of harm. These will be defined as reserved acts, as directed in s.10(3)(b)(v) of the HPA and the Council's Terms of Reference. Any other aspects of the scope of practice of a health profession are considered to be capable of being shared with other health practitioners and the general public.

There is a distinction between analyzing risk of harm for the purposes of s.5(1) and for reserved acts. The s.5(1) analysis is broadly based and looks at the extent of the risk of physical, mental or emotional harm to the health, safety or well being of the public in the practice of the profession. This analysis looks generally at the services performed by practitioners, the technology used, the invasiveness of procedures or treatments and the degree of regulation or supervision of practitioners, as directed in s.5(1)(a), (b), (c) and (d). The Council will make its determination of whether the profession should be designated on the basis of this analysis together with the analysis of the criteria contained in s.5(2) of the Regulation.

After it is determined that the profession should be designated, a more narrowly focused risk of harm analysis is conducted to determine whether the health profession will be granted one or more reserved acts. The Council emphasizes that it is not necessary for a health profession to be granted any reserved acts in order to be designated. However, once the decision to designate is made, the Council will look at whether there are acts or activities within the profession's scope of practice which present such a significant risk of harm that they must be designated reserved acts, as directed in s.10(3)(b)(v) of the HPA. In the Shared Scope of Practice Working Paper issued by the Council in January 1998, reserved acts have been restricted primarily to physical acts which carry a significant risk of harm.

These distinctions between the two risk of harm analyses are valid and important; however, they are often misunderstood by applicants. Additionally, there is significant overlap between the two, particularly when discussing the services performed by practitioners, the technology utilized and invasiveness of procedures employed. In the following analysis of TCM practice, the Council looks generally at the services performed by TCM practitioners in order to analyze the risk of harm for purposes of designation, using the s. 5(1) criteria. When discussing the areas of services performed, technologies employed or invasive procedures, the Council will discuss the general risk of harm for purposes of the s.5(1) analysis, but will also address specifically whether any acts or activities present the significant risk of harm required of a reserved act, as directed under s.10(3)(b)(v) of the HPA and the Council's Terms of Reference.

The Council's Shared Scope of Practice Working Paper will form the basis of the reserved act analysis. Where an act or activity is currently listed as a reserved act, the Council will determine whether members of the applicant profession are trained and qualified to perform such act. Where the applicant requests a reserved act which is not included on the current reserved act list incorporated in the Working Paper, the Council will conduct a risk of harm analysis to determine if a new reserved act is warranted or a current reserved act could be expanded or adapted to include that which is requested by the applicant should it present a significant risk of harm.

a. Section 5(1): Risk of Harm Criteria

The risk of harm criteria are contained in s.5(1) of the Regulation. When examining the services of the health profession being considered for designation under the HPA the Council must consider these criteria. The Council may also consider the s.5(2) criteria. While the s.5(2) criteria are not mandatory, the practice of the Council has been to consider them in all previous applications.

According to information provided by the applicants, TCM is composed of four primary therapies operated according to shared philosophical principles and based upon diagnostic techniques unique to TCM. The four primary therapies are:

- (1) Chinese acupuncture and moxibustion (Zhen Jiu)
- (2) Chinese manipulative therapy (Tui Na) and Chinese rehabilitation exercises (Lian Gong or Dao Yin),
- (3) Chinese energy control therapy (Qi Gong) and Chinese shadow boxing (Tai Ji Quan), and
- (4) prescribing Chinese medicinal formulas (Zhong Yao Chu Fang) and Chinese food cure recipes (Shi Liao)

These therapies can be used alone or together for the promotion, maintenance and restoration of health and prevention of disease.

The applicant proposed that these four branches of TCM should form an exclusive scope of practice for members of a college of TCM. The Council has analyzed the four branches of TCM in the following pages and found there is a general risk of harm involved in these therapies. While these four elements form the scope of practice of TCM, the reserved acts which are part of this scope are the only parts of the scope which could be considered "exclusive" in the sense that they will be reserved to

properly trained and qualified TCM practitioners and members of other health professions who are so qualified. The reserved acts will be discussed in the following pages.

RECOMMENDATION 1:

traditional Chinese medicine be designated as a health profession under the Health Professions Act.

Based upon the application of TCMABC and information provided by respondents during the consultation process, the Council has determined that the above scope of practice statement outlined in Recommendation 2 accurately reflects current TCM

RECOMMENDATION 2:

the services which may be performed by registrants are the practice of TCM, as defined in the following scope of practice statement: the practice of TCM is the promotion, maintenance and restoration of health and prevention of disease by utilization of the four primary therapies:

- Chinese acupuncture and moxibustion (Zhen Jiu),

- Chinese manipulative therapy (Tui Na) and Chinese rehabilitation exercises (Lian Gong or Dao Yin),

- Chinese energy control therapy (Qi Gong) and Chinese shadow boxing (Tai Ji Quan), and

- prescribing Chinese medicinal formulas (Zhong Yao Chu Fang) and Chinese food cure recipes (Shi Liao).

practice in British Columbia.

s.5(1)(a): the services performed by practitioners of the health profession

Before discussing the four primary therapies of TCM, the Council will consider the issue of TCM diagnosis. The applicant in its initial application in 1992 did not address the issue of TCM diagnosis directly. However, in subsequent communications it was made clear that the clinical decisions made by TCM practitioners are based upon TCM diagnosis. The Council recognizes that, at the time of the initial application, the applicant had not had benefit of the Council's Shared Scope of Practice Working Paper in which the Council lists "diagnosis" as a reserved act.

TCM diagnosis is involved in all TCM primary therapies. Risk to the public may arise both from the clinical judgment of TCM practitioners in arriving at a diagnosis and in the application of the therapies based upon that diagnosis. The applicant submitted that all TCM practitioners are trained in TCM diagnosis and provided clarification of the nature of TCM diagnosis in a May 1, 1997 letter to the Council. In the letter the applicant made reference to two texts to clarify the unique nature of TCM diagnosis and to differentiate it from other types of diagnosis. The texts cited are Diagnostics of Traditional Chinese Medicine and Clinic of Traditional Chinese Medicine from a series of books entitled *A Practical English-Chinese Library of Traditional Chinese Medicine*, Editor in Chief Dr. Zhang Enqin, Publishing House of Shanghai College of Traditional Chinese Medicine.

The letter of May 1 states:

Diagnostics of TCM emphasises the "differentiation of syndromes" (Bian Zheng) in combination with the simpler technique of naming disease after the causes (Bian Bing) . . .

On page 14, it states "the whole course of pathological changes and the law of the progress of a disease cannot be grasped if only the syndrome, but not the disease itself is differentiated. On the contrary, if we merely make diagnosis of the disease, but not the syndrome, we cannot undertake our treatment."

In effective TCM practice, what Western medicine describes as disease is considered as a symptom in a larger pattern.

In Clinics of TCM is a sample of this process in practice in a hospital setting. Note that a diagnosis in a western sense is done, but then the diagnosis is further differentiated to be able to supply a treatment. [For example] "Chronic Gastritis" is differentiated into 4 types. Each type dictates a different therapeutic principle leading to a particular formula to be used for treatment. In Western treatment, all four would probably receive the same prescription, and each would probably experience different side-effects due to the differing origins of the symptom (chronic gastritis).

Here in British Columbia, without access to hospital equipment, a Doctor of TCM uses the diagnosis supplied by a patient's M.D. as a symptom, and then differential diagnosis is used to complete the picture.

In its investigation, the Council has benefited from the report, commissioned by the 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 (the Australian Report). The following was included, at page 92, in its summary of the risks associated with the practice of TCM:

Risks to the public may arise from the clinical judgment of the TCM practitioners. These may be either risks of commission or omission. These types of risks exist in all health care practices...

The Australian Report states, at page 55:

Misdiagnosis is often associated with failure to refer a patient to an appropriate health care practitioner, and may be further compounded by incorrect prescribing.

According to information provided by the applicant, TCM is often used as a form of primary health care. Therefore, risk involved in misdiagnosis can be significant. The Council determined that TCM diagnosis falls within the scope of practice of TCM and further that the risks related to TCM diagnosis include a general risk that some patients may delay seeking treatment by other practitioners and a specific and significant risk of harm if advised or treated inappropriately by a TCM practitioner.

The Council recommends that "TCM diagnosis" be included in Recommendation 3 as a reserved act for members of the college.

In considering the extent to which the practice of TCM may involve a risk of physical, mental or emotional harm, the Council's investigation examined each of the four primary therapies of TCM listed in the introduction at page ten .

(1) Chinese Acupuncture and Moxibustion (Zhen Jiu):

TCMABC submitted the following with regard to the risk of harm in the performance of the first primary therapy of TCM:

The risks involved to the patient for the insertion of acupuncture needles have been documented in the November 1993 report of the Health Professions Council entitled Recommendations on the Designation of Acupuncture. These include possibility of infection or hemorrhage and the transmission of disease and puncturing an internal organ from improper insertion of the needle.

Risks involved in moxibustion therapy involve an incompetent practitioner ignoring or being unaware of conditions contraindicated for moxibustion, such as excess syndromes and heat syndromes, and use on patients with a feeble and rapid pulse, due to possibility of aggravating a condition. Moxibustion is also not allowed on the abdominal or lumbosacral regions of pregnant women.

Cupping is similarly prohibited on pregnant women in the same areas. Cupping on skin ulcers, areas with edema or areas overlying large blood vessels is also not advisable, due to possibility of aggravating a preexisting condition.

(a) Acupuncture:

The risk of harm associated with the use of acupuncture needles was thoroughly discussed in the Council's 1993 Report on the Designation of Acupuncture. At this time, the Council sees no need to elaborate on that discussion and concurs with the conclusions made in the 1993 Report. In that report, at page 18, the Council said, "The insertion of needles below the dermis causes a risk of harm of infection and hemorrhage and the transmission of certain diseases. There is also a risk of puncturing an internal organ."

The Council recommends that "the insertion of acupuncture needles below the dermis" be included in Recommendation 3 as a reserved act for members of the college.

In its application, TCMABC has stated that there is an independent risk involved in the insertion of acupuncture needles if a proper TCM diagnosis is not made prior to treatment. This aspect of the risk of harm was not discussed in detail in the 1993 Report on the Designation of Acupuncture. The risks of improper application of acupuncture have been stated by the applicant as exacerbation of the condition or failure to improve the condition. The Council is not in a position to resolve the

issue of whether there is an independent risk of harm in acupuncture therapy without a proper TCM diagnosis as no evidence was provided to document this statement.

(b) Moxibustion and Cupping:

From information provided by the applicant, the Council determined that, for centuries, moxibustion, cupping and acupuncture have been combined in clinical practice and are usually termed together in Chinese. The Council in the Report on the Designation of Acupuncture did not discuss the risk of harm in moxibustion in detail. Therefore, the Council requested further clarification regarding moxibustion and cupping from the applicant TCMABC.

As presented in TCMABC's application, moxibustion and cupping are considered to be adjunctive therapies to acupuncture. Moxibustion is the use of heat generated by burning dry moxa leaves (*Artemisia Vulgaris*). Moxibustion includes heating the acupuncture needle with moxa herbal sticks or use of moxa sticks or cones, which are made from *artemisia vulgaris*, directly over the acu-points or close to the skin. The purpose of moxibustion is to initiate and enhance the healing process. The technique of cupping certain areas on the body may be used in conjunction with treatment by acupuncture or moxibustion. A relative vacuum is created in a glass cup or similar device and it is applied to the body to create an infusion of blood into a particular area of the body or draw out stagnated blood from injured areas.

There are a number of different moxibustion techniques. Moxibustion with cones may be used either on the skin (direct) or close to surface of the skin (indirect). Direct moxibustion involves placing a cone on the skin and igniting the cone. In some applications, direct moxibustion could result in burning or scarring. The Council understands that this form of moxibustion is not used in British Columbia. Indirect moxibustion, which the Council understands is commonly used in British Columbia, involves placing a cone on top of a piece of medicinal plant or substance, such as ginger or salt. Moxibustion with moxa sticks involves applying a lighted moxa stick over the selected point to bring a mild warmth to the local area for five to ten minutes until the area is red. Sparrow pecking moxibustion applies a lighted moxa stick rapidly to the skin over the point. In both applications, care is taken not to burn the skin. Moxibustion with warming needle involves wrapping the acupuncture needle with moxa wool and igniting it causing a mild heat sensation around the point.

Moxibustion is contraindicated for patients with certain conditions, for example those with a high fever caused by the common cold. There are certain parts of the body which are not suitable for moxibustion because they are close to vital organs or arteries. Moxibustion is contraindicated on the lumbosacral and abdominal regions of pregnant women. The applicant has discussed risks with the use of cupping on certain patients, such as those who are pregnant, in a debilitated state of health, or on an area of skin which may be affected by a preexisting condition. The Council was advised by the applicants that these situations present a risk of hemorrhage or miscarriage.

The Council recognizes that there is some risk of harm in the use of moxibustion and cupping. However, this risk is the same as with any treatment modality. All practitioners must assess a patient before beginning any treatment to determine if the treatment is suitable for the particular patient. The Council concludes that moxibustion and cupping are not inherently dangerous procedures and there is not a sufficient risk of harm to qualify moxibustion and cupping as reserved acts.

RECOMMENDATION 3:

the reserved acts recommended for members of the college are:

- TCM diagnosis, and

- the insertion of acupuncture needles below the dermis.

(2) Chinese Manipulative Therapy (Tui Na) and Chinese Rehabilitation Exercises (Lian Gong or Dao Yin):

The applicant TCMABC submitted the following with regard to the risk of harm in the performance of the second primary therapy of TCM:

Lian-Gong refers to a series of exercises to achieve health. The first division of Lian Gong is general Lian Gong, a general workout done by anyone for the purpose of developing body energy. The second division is therapeutic Lian Gong which refers to a specific workout designed by a TCM doctor for a particular patient to achieve a particular therapeutic health result.

In Lian Gong or Dao Yin (Chinese rehabilitation exercises) improper instruction to the patient may produce little or no therapeutic effect or a worsening of symptoms in some cases.

Incorrect technique can result in injury to joints and tendons, and a worsening of symptoms. Even during proper treatment, fainting can occur. The practitioner must be aware of the state of the patient to adjust the treatment accordingly.

The Council sought further clarification from the applicant, who replied:

Lian gong means "daily practice" which includes postures which aim at ensuring that joints are mobile and flexible. These are not strenuous or cardiovascular. Dao Ying is a form of breathing exercises with movements, and focuses more on the breath. Tui Na is the actual manipulation by a practitioner, described as a cross between massage and manipulation of joints.

The area of Chinese manipulative therapy, as described above in the submission of TCMABC, was considered by several of the respondents to the consultation to be vaguely defined. The Chinese Medicine and Acupuncture Association of Canada commented that "manipulation techniques must be clearly defined in the regulations if they are to become a reserved act."

Each of the three applicants provided the Council with clarification of Chinese manipulative therapy during informal meetings held in April 1997. The three agreed that the use of manipulation is part of the scope of practice of many, but not all, TCM practitioners. Information provided by the applicants satisfied the Council that Tui Na does not include "movement of the joints of the spine beyond their physiological, but within their anatomical, range of motion by means of a high velocity, low amplitude thrust" which is currently included as a reserved act in the Council's Shared Scope of Practice Working Paper.

The use of manipulation techniques and rehabilitation exercises generally requires skill and training. The Council recognizes that the provision of this service forms part of the scope of practice of TCM. However the Council has not seen evidence to indicate that the use of Chinese manipulative therapy (Tui Na) and rehabilitation exercises (Lian Gong or Dao Yin) constitutes a significant risk of harm to such a degree as to warrant a reserved act.

In its application, PRTCMPAS, whose application is supplementary to the application of TCMABC, requested Die Da as part of the scope of practice of TCM. Die Da is defined as:

traditional Chinese [osteopathy] and is supplementary TCM to cure joint-dislocation, fractured bones or soft tissue injury. The TCM practitioner detects the injury and put(s) right the disjointed bones to the correct position, sometimes ointment and/or bandaged fixation are also applied according to patients' condition.

The Chinese Canadian Acupuncture and Herbal Medicine Association of Canada also commented that "in addition to the four main categories, a fifth, Chinese orthopaedic manipulation should be added, as this is a common practice of doctors of TCM in British Columbia." The Council considered this statement to be supportive of the PRTCMPAS application.

Because the written submissions made during the consultation process were based on the TCMABC application which did not include reference to Die Da or Chinese orthopaedic manipulation, the Council recognizes that none of the respondents were able to comment on these therapies during the written consultation phase of the investigation. However, the Council raised it as an issue at the public hearing.

During the public hearing, the Council was informed that Die Da was currently being practiced in British Columbia by some practitioners who were trained in China and that the treatment of fractures was confined to "simple" fractures that could be managed with the application of external herbal preparations and bandaging. The speakers were clear that any patient who showed signs of a complication would be referred to a hospital. During the public hearing, a speaker also gave a demonstration of repositioning a dislocated jaw.

"Setting or casting a fracture of a bone or reducing a dislocation of a joint" is included as reserved act in the Council's Shared Scope of Practice Working Paper. The applicants stated that, in China, Die Da occurs in a hospital where both Western medicine and TCM are practiced. In the Council's view, Die Da is an activity which would fall under this reserved act.

The Council notes that at the time of the written consultation there were no educational courses in Canadian TCM schools which provided training to perform Die Da. During the public hearing, the Council was informed that the Western Canadian Institute of TCM Practitioners and the International College of TCM in Vancouver are planning to offer courses in Die Da.

The Council is not satisfied that, at this time, there is sufficient education and training in British Columbia to support granting an aspect of this reserved act to TCM practitioners. Before granting a reserved act, the Council must be satisfied that practitioners are currently trained and competent to perform it. In the future, granting TCM practitioners this reserved act could be reconsidered, however it is not appropriate to include Die Da in the scope of practice of TCM at the present time.

(3) Chinese Energy Control Therapy (Qi Gong) and Chinese Shadow Boxing (Tai Ji Quan):

The applicant TCMABC submitted the following with regard to the risk of harm in the performance of the third primary therapy of TCM:

With external Qi Gong, in which a therapist directs energy in the patient, incorrect diagnosis or technique can involve risk to the patient by worsening the condition being treated. (Improper technique can also involve risk of harm to the practitioner).

With internal Qi Gong, in which a patient directs their own energy under the supervision of a therapist, incorrect technique can result in the disorderly flow of energy (Qi), resulting in dizziness, dyspnea, fainting, or mental disturbance.

Tai Ji Quan exercises pose little risk except straining of joints or tendons from poor technique.

As noted by representatives of the Taoist Tai Chi Association during their meeting with the Council, Tai Ji and Qi Gong both represent mechanisms for movement of energy in the body. They are different forms of accomplishing the same objective, the harmonization of the flow of energy within the body. The correct flow of energy (Qi) in the body is one of the fundamental tenets of TCM practice. According to information provided by the applicants, one of the ways to correct the flow of Qi is by use of various physical exercises, postures, movements and mental exercises.

A number of respondents to the consultation process had expressed concern about the proposed inclusion of Tai Ji Quan and Qi Gong in an exclusive scope of practice for TCM. There was no dispute that these services do fall within the scope of practice of TCM practitioners, however they are also practiced by others who are not TCM practitioners.

The Chinese Tai Chi Chuan Association expressed concern about this proposed exclusive scope (reserved act) because "regulation of Tai Ji Quan is not possible . . . it is a form of exercise, similar to aerobics, and can change according to the needs of the participant . . . it has health benefits, but cannot be regulated." The medical advisor to the Taoist Tai Chi Society, Elliot Kravitz, M.D., commented at the public hearing: "It is difficult to regulate what is essentially walking", referring to the regulation of Tai Chi. The Canada Qi-Gong Research Society, Inc. submitted: "Qi-Gong exercises . . . all which are of physical and mental exercises in nature, be excluded from regulation." The Co-Dean of the Academy of Classical Oriental Sciences in Nelson, British Columbia drew to the Council's attention the similarity between Qi Gong and other forms of "Energy Work such as Reiki, Listening Hands Therapy, Healing Hands Therapy, Wai Qi, Wai Gong, Fa Qi, etc."

A reserved act must involve a significant risk of harm. When the concept of reserved act was further explored in discussion with the applicants, the applicants agreed that Qi Gong and Tai Ji Quan did not carry the significant risk of harm that they understood to be envisioned in a reserved act. Accordingly, the Council has determined that while Tai Ji Quan and Qi Gong are appropriate to be included within a scope of practice statement, they should not be considered reserved acts for TCM practitioners.

(4) Prescribing Chinese Medicinal Formulas (Zhong Yao Chu Fang) and Chinese Food Cure Recipes (Shi Liao):

The applicant TCMABC submitted the following with regard to the risk of harm in the performance of the fourth primary therapy of TCM:

Use of herbal formulas requires an understanding not only of individual herbs and foods used, but also their action in combination in a formula and recipe and the patient's physical condition as well. Some substances of the TCM materia medica have toxic effects in large doses or with extended use, and must be prescribed with care accordingly. Some substances are not harmful when used by an average adult, but can have adverse effects on children, the elderly, or when used during pregnancy. Impaired or incompetent practice could therefore result in risk to certain types of individuals. Also, medicinal prescriptions require the monitoring by the prescribing Doctor of TCM in regard to the proper use by the patient, to modify the formula if any adverse effects are observed, or to remove traditional Chinese herbs of the lower class or foods of an extreme nature when they are no longer needed.

The literature suggests that there is a risk of allergic or other adverse reactions to Chinese herbs. More than 6,000 herbs have been identified in the traditional Chinese pharmacopoeia. Among these herbs there may be potentially toxic substances and plant products which are not subject to potency standards or quality controls.

The applicant indicated that TCM formulas are delivered in a variety of ways and emphasized that in TCM food and medicine are interchangeable. There is no clear separation into the categories "food" or "drug" as in western medicine. It appears that the use of herbs in TCM occurs across a continuum of methods of delivery to the patient, food cures being one medium. The applicant said that the more toxic TCM herbs are not generally utilized in the medium of food cures, but noted, however, that may be an oversimplification. The preparation of any herb, including processing and combination with other herbs or foods affects both the individual herb's efficacy and potential toxicity.

(a) Shi Liao (Food Cures):

At the request of the Council, the applicant TCMABC provided additional materials on the subject of Shi Liao (food cures) to assist in distinguishing them from Chinese medicinal formulas (Zhong Yao Chu Fang). To further explain Chinese food cures, the applicant submitted the following excerpts from pages 2 - 24 of A Practical English-Chinese Library of Traditional Chinese Medicine published by the Publishing House of Shanghai College of Traditional Chinese Medicine:

Chinese medicated diet is not a simple combination of food and Chinese drugs, but a special highly finished diet made from Chinese drugs, food and condiments under the theoretical guidance of diet preparation based on differentiation of symptoms and signs of TCM. It has not only the efficiency of medicine but also the delicacy of food, and can be used to prevent and cure diseases, build up one's health and prolong one's life . . .

Although medicated diet is something mild, it has a notable effect on the prevention and cure of diseases, health building-up and health preserving . . . medicated diet can be prepared either from edible Chinese drugs alone, or from Chinese crude drugs and food according to certain prescription, by processing and cooking . . . Edible Chinese drugs such as fruits and vegetables are often used as ingredients of medicated tea, while drastic or extremely bitter crude drugs are usually not used . . .

The applicant, in a letter to the Council of October 23, 1997, states that the methods of Shi Liao are not just dietary recommendations, but treatments for specific diseases based on TCM diagnosis:

Medicated diet:

- a) can be used to either prevent or cure disease;*
- b) can be prepared either from edible medicinals alone or from crude medicinals plus food according to specific prescriptions;*
- c) should be used with attention paid to the nature and flavour of the medicinals just as when using herbal formulas. Dietary medicinals are a subset of the TCM Materia Medica, so the same theories of use apply.*
- d) can worsen a condition if use incorrectly;*
- e) must have attention paid to selection of quality medicinals, processing of same for desired effect, and proper cooking;*
- f) involves proper dosage and perseverance, plus correct handling of the relationship between Medicine therapy and dietary therapy;*
- g) more suitable for recovery during convalescence or recuperation from chronic disease;*

h) is not as adaptable or specific in effect as herbal prescriptions (Zhong Yao Chu Fang), but when used in coordination to supplement each other, a better effect is achieved.

(b) Zhong Yao Chu Fang (Prescription of Chinese Medicinal formulas):

The prescription of formulas using substances from the Chinese Materia Medica occurs across a spectrum which includes Shi Liao and Zhong Yao Chu Fang. Food cures, which are less toxic, milder in nature and used over a longer period, are at one end of the spectrum while toxic substances, often in a more concentrated form, are at the other. Most of these toxic substances are herbs, but may also be minerals or animal - derived substances.

In most cases, single herbs are not prescribed. Generally a TCM formula is prescribed which contains a variety of substances, some of which may be toxic. The formulas are centuries old and are contained in a number of texts. The Council was referred to the following texts as examples:

- Dan Bensky & Randall Barolet, *Chinese Herbal Medicine Formulas & Strategies*, Seattle, Washington, Eastland Press Incorporated, 1990.
- Dan Bensky & Andrew Gamble with Ted Kaptchuk, *Chinese Herbal Medicine Materia Medica*, Seattle, Washington, Eastland Press, Inc., 1986.
- Hson-Mou Change and Paul Pui-Hay But, *Pharmacology and Applications of Chinese Materia Medica, (Vol. 2)* translated by Shem Chang-Shing Yeung, Sih Cheng-Yao, Lai-Ling Wang, New Jersey, World Scientific Publishing Co., Inc., 1987.

(i) Toxicity:

According to information provided by the applicant, substances which have a high potential for adverse or toxic reactions are used in combination with other substances which lessen or neutralize the degree of toxicity. This is part of TCM diagnosis and prescription. The applicant described the practice of customizing the TCM formula for particular symptoms the patient is experiencing.

Two of the applicants and other TCM practitioners provided information that several traditional Chinese herbs and minerals, if prescribed in dosages or combinations which are inappropriate or for patients who are not appropriately diagnosed according

to TCM diagnostic principles, can cause serious, life-threatening, harm. One example given by the applicant was the use of Ban Xia. In its raw form it is toxic, but in formula it is processed with other herbs, making its effect less toxic. However, if formulated improperly or used for an extended period, harm to the patient could result.

The Australian Report comments generally about research into efficacy and toxicity of Chinese medicinal substances and, in Appendix 7, states:

Research into the constituents and effects of the Chinese medicinal substances began as early as 1885 when a Japanese chemist isolated ephedrine from the Chinese herb, Ma Huang. Investigations continued throughout the first part of the 20th century, especially in Japan, but only began in earnest during the 1950's in China after the formation of the People's Republic of China. During this period the government recognised that Traditional Chinese Medicine could play a significant role in national health care. The Cultural Revolution however, limited clinical research.

Judith Farquhar, medical anthropologist and historian, commenting further on the post-Cultural Revolution wrote:

It was only in the late 1970s that ethical objections to the use of control groups in clinical research were lifted by the Ministry of Health, so scientists of the 1980's who wished their clinical research with human patients to reach international standards had to consider doing a great many projects again, this time with "normal controls."

... With the increased availability of technology, scientific expertise and funding in China, the investigations into traditional medicinal substances are vigorous... The National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) produces The Pharmacopoeia of the People's Republic of China. The NICPBP maintains 40 regional offices that monitor traditional drug production, collection and identification. They set standards for the identity and use of "official" plant medicines used in TCM. Western scientific methods are used to document herbal medicine source plants in all parts of China, and identify the mineral and zoological categories of other traditional substances...

... Approximately 500 herbs are used as "official drugs" in TCM and a further 4,500 folk medicines are documented...

The cumulative result of the directed research activity into traditional medicines in China has led to the Chinese materia medica being systematically evaluated and compiled. While intensive research activity is undertaken on western medicinal plants, it lacks the direction, systematic evaluation and, most importantly, compilation of the findings, that has been developed in China . . . The most significant compilation of research in China is the Pharmacopoeia of the PRC . . . No similar text is available for western medicinal plants.

A distinct difference exists in the goals of scientific research in China and the West. In the West there is an over-riding concern for the production of synthetic pharmaceutical agents, and plant-based research is primarily focussed toward this aim . . . While this goal is not ignored in the People's Republic of China, the primary goal has been predominantly oriented towards enhancing clinical effectiveness. To the Chinese, the efficacy of these traditional materials is considered self-evident after many centuries of use with human subjects (emphasis added) . . . This orientation has begun to shift more toward an international position with increasing effort amongst Chinese researchers in validating basic efficacy . . .

Studies on Chinese medicinal substances generally begin to appear in western medical literature only after a particular substance of treatment has caught the imagination of members of the western scientific community.. One of the limitations of the current review is the extent to which the sample of the literature readily available in the West is representative of, and generalisable to, the body of literature in total. It is presumed that not all studies carried out in China are of world standard. The extent of methodological shortcomings is difficult to assess. It is clear, however, that the quality of research has improved as the technology and training available within the PRC has increased.

Included in Appendix C is material provided by the applicants which documents TCM medicinal substances which have been found to have toxic effects.

In its investigation, the Council received information concerning initiatives by Health Canada to control the use of traditional and other herbal products. An Advisory Committee to the Therapeutic Products division of Health Canada has been formed to review possible regulation issues. According to publications and communications from Health Canada, there are several traditional Chinese herbs which may be unsafe or toxic. The federal government's proposed restriction of certain Chinese herbs is further evidence of the risk of harm involved in the practice of herbology. There are some herbs the Federal Government is proposing to restrict that are used by TCM practitioners in British Columbia. The substances proposed for restriction at various times appear in Appendix D.

Detailed evaluation of basic pharmacological research into Chinese herbal medicine is not within the scope of this investigation. However, the Council has been presented with medical journals which appear to document harm associated with synergistic

effects of several herbs used together, side effects or allergic reactions which require monitoring by a health professional, and adulteration of raw herbs. These are contained in Appendix E.

In support of the risk of harm in Chinese herbology, the Council notes the findings of the Hong Kong Government's Report of the Working Party on Chinese Medicine. Following this Report, a legislative committee was established to develop a proposal for regulation. The October 1994 Report states at pages 14 and 15:

5.1 Of the 5,767 Chinese medicinal materials listed in the Chinese Herbal Medicines Dictionary, about one-third are available in Hong Kong. However, not all of them are sold in every herbal shop. Some shops are known to stock up to 900 herbs, but only some 400 are in common use.

5.2 Most Chinese medicinal material are mild in nature. Toxicity can usually be neutralised through appropriate preparation or combination with other herbs and substances. They do not normally provoke serious side-effects and can be regarded as safe for general use.

5.3 However, there are about 50 herbs which have a narrow safety margin and should be regarded as "potent" or "toxic". We consider that the sale and use of these potent or toxic herbs should be brought under control in order to protect public health.

5.4 Specifically, we recommend that a "potent herbs list" should be drawn up early in consultation with the profession. When ready, the list should be published for public reference. In due course, the statutory body should consider restricting the sales of such items only to members of the public who have prescriptions by registered TCM practitioners.

5.5 According to a survey, over 70% of TCM practitioners agreed with this recommendation. As the use of potent or toxic herbs requires specialised knowledge and skills, the profession and the public overwhelmingly supported the recommendation during the consultation for the purposes of protecting public health and provision of reference by herbalists.

5.6 To facilitate the development of a potent herbs list, we have taken reference from similar lists in force in China and Taiwan. A tentative potent herbs list is presented at Annex VI for further consideration. This encompasses those Chinese medicinal materials which are available in Hong Kong and have already been controlled in China and Taiwan, as well as some potent herbs which are available locally but are not subject to control elsewhere.

Additional evidence of risk of harm in the practice of herbology came from the Australian government. Following the initial 1996 Australian Report, the Victorian Department of Human Services on behalf of all State and Territory governments, proceeded with the second stage of a broad review of the practice of TCM. TCM: Options for Regulation of Practitioners: Discussion Paper was issued in September 1997. At page 8 the Discussion Paper indicates that:

Potential risks include:

- *inherent toxicity of the herbal substances (either alone or in combination) dispensed by practitioners;*
- *prescription of herbs that are inappropriate for the condition being treated;*
- *contaminants such as heavy metals;*
- *adulteration with western pharmaceuticals such as steroids;*
- *substitution of herbs by the dispenser without consulting the treating TCM practitioner;*
- *poor or non-existent labelling of ingredients, leaving consumers particularly at risk in the event of an adverse reaction;*
- *drug interactions in people taking herbal preparations along with prescribed pharmaceuticals.*

(ii) Jurisdiction:

During its investigation, the Council received information from the applicants and subsequent respondents that TCM practitioners in British Columbia currently prescribe, compound and advise on the use of TCM herbs both in the unprocessed (raw) form and in preformulated preparations. Many of the formulated herbal products are imported after processing outside of Canada, mostly in Asia. Some herbal products are processed and formulated in Canada. Raw herbs may be imported or of domestic origin.

Several respondents commented on the advisability of the Council making recommendations concerning the use of herbs while, concurrently, the federal government is considering regulations regarding the use of herbs. The submissions represent different and sometimes opposing views. The Canada Acupuncturists Headquarters Association - British Columbia Branch comments that "to move ahead on the application without first receiving the federal regulations concerning the use of Chinese herbs . . . would be premature." Dr Wah Jun Tze, MD, President, Tzu Chi Institute states "standards are also needed with

respect to TCM herbs and medicines to determine their safety . . . [which] is the responsibility of the Health Protection Branch, Ottawa, with the help of expertise from the qualified TCM practitioners and educators". Dr. Thomas Handley, Registrar of the College of Physicians and Surgeons of BC, in a letter to the Council of December 11, 1997, comments "With regard to prescribing Chinese medicinal formulas, if they are truly medicinal, i.e. pharmacologically active, they should be regulated along the same lines as other pharmacologically active products used for medicinal purposes". Lai Na Ho, DDTCM, Director of the International College of TCM of Vancouver cites the federal government's concern with the safety of some Chinese herbs as an argument supporting the designation of TCM as soon as possible so that only qualified individuals can practice in order to protect the public.

For the purposes of this report, the Council would like to emphasize that it can deal only with issues which are within provincial jurisdiction. The province regulates practitioners and their activities, including the use and compounding of raw herbs. However, any issue related to importation, storage, sanitation, fabrication, manufacture, testing for adulteration, packaging and labelling, distribution, sales and advertising of herbal products is within federal domain. Health Canada is currently holding hearings to determine the best way to regulate herbal products.

In response to the Council's inquiry concerning the regulation of herbs under federal jurisdiction, Dann Michols, Director General of the Therapeutics Products Directorate, Health Canada wrote:

I wish, initially, to explain the distinction between medicines that are offered for sale to the general public and those that are compounded extemporaneously by a health practitioner.

Excluding substances controlled under the Controlled Drug and Substances Act, mainly narcotic and other addictive substances or those subject to abuse, most medicines are regulated under the Food and Drugs Act. The Food and Drugs Act requires that drug products offered for sale in Canada be authorized for such sale by the Department. The authorization is given in the form of a drug identification number (DIN) which is required to appear on the product label. These requirements, however apply to products offered for sale in finished dosage form, while products prepared extemporaneously for a particular patient are exempt. The latter practice is considered to be of provincial domain. [emphasis added]

We have therefore developed a list of substances where safety concerns have been identified and for which an acceptable benefit/risk ratio, for non-prescription sale has not been demonstrated. It would be of provincial domain to determine whether such substances may be dispensed by health practitioners in compliance with provincial legislation.(emphasis added) The list of substances of concern is attached for your information.

Health Canada has circulated a number of lists identifying substances of concern at different times. Several of these lists have been included in Appendix D. Because the whole area of regulation of natural health products is under review by the federal government, these lists may not reflect the current position of the federal government on this issue. Nonetheless, the Council considers the identification of certain Chinese herbs on these lists to be some evidence of risk of harm in their use.

The use of animal products in TCM formulas is controlled under Federal legislation. These products have been characterized by two of the applicants as unnecessary for prescription of TCM formulas. The applicants do not address, nor has the Council received any information regarding, the use of animal products.

(iii) Summary

The Council accepts that the use of TCM formulas has benefits as well as risks for the public. The purpose of the prescription of TCM formulas is to produce a physiological change in the patient. This may have beneficial as well as adverse effects. For these reasons, in the Council's view, there is a general risk of harm in the use of TCM formulas.

None of the respondents disputed the risk of harm in the practice of herbology as stated by the applicant, TCMABC, whose application formed the basis of the consultation process. While there is currently insufficient data to quantify the risks, this should be a research priority. As a result of the s.5(1) risk of harm analysis the Council concludes that the use of TCM formulas carries a general risk of physical harm to the public and the practice of TCM meets the risk of harm criteria for designation as it applies to the use of food cures and TCM formulas.

As directed by s.10(3)(b)(v) of the HPA, the Council next looked at which TCM substances might represent a significant risk of harm and therefore should be restricted under a reserved act. The Council has been presented with substantial documentation that some of the substances used in TCM formulas may be toxic alone or in certain combinations and therefore present a significant potential for adverse reaction. Based on information obtained from a number of sources in the course of its investigation, the Council believes some, perhaps all, of the substances set out in appendix C,D and E would represent substances which have significant potential for adverse reactions and therefore represent a significant risk of harm to the public.

The prescription and compounding of TCM formulas is not included in the Council's Reserved Act number 5 "prescribing, compounding, dispensing or administering by any means a drug listed in Schedule A-1 or A-3.2 of the Pharmacists, Pharmacy Operations and Drug Scheduling Act". A complete and thorough analysis of the physiological and pharmacological effects of these substances is beyond the scope of this investigation. The Council believes, however, that the risk of harm to the public in the use of these substances is significant. Therefore, the Council recommends that a multidisciplinary panel should be formed by the Minister of Health to determine which substances should be restricted under a proposed reserved act. Members of this panel should include practitioners who utilize such substances in their practice, including TCM practitioners.

It is the Council's view that TCM practitioners are trained and qualified to prescribe and compound TCM formulas including these substances. The Council recommends that TCM practitioners who are trained in this area should be allowed to use these

substances, however the final determination of the substances whose use would comprise those restricted under the proposed reserved act should be left to expert determination.

In the event that the Federal Government restricts the use of certain herbs or substances which are used in TCM practice, the Council believes that properly trained and qualified TCM practitioners who are members of a college of TCM are competent to prescribe them.

RECOMMENDATION 4:

the Council recommends that:

- **an expert multidisciplinary panel, including practitioners who utilize TCM formulas, be appointed by the Minister of Health to finalize the list of substances used in TCM formulas which carry a high potential for adverse consequences; and**
- **upon finalizing the list of substances, prescription according to TCM principles of TCM formulas that include those substances be included as a reserved act on the Council's list of reserved acts and subsequently be granted to members of a college of TCM.**

Shared Reserved Acts:

Several respondents commented concerning the use of Chinese food cure recipes and the fact that the applicants did not mention the concept of sharing reserved acts with other health professions. The British Columbia Dietitians and Nutritionists Association, which generally supports designation of TCM as a self-regulating profession, commented that TCM diet therapy overlaps with the scope of dietitians and nutritionists. The British Columbia Naturopathic Association commented that the application contained no clause regarding joint reserved acts.

The Council would like to clarify that all reserved acts have the potential to be shared among members of those health professions who are qualified to perform such acts. The use of food cures has not been demonstrated to present a significant risk of harm and is not a reserved act. The Council is recommending that prescription according to TCM principles

of TCM formulas that include substances which carry a high potential for adverse consequences be a reserved act. The applicants' failure to mention sharing a reserved act would not preclude sharing any act which may be reserved with other qualified practitioners if appropriate.

s.5(1)(b) the technology, including instruments and materials, used by practitioners

TCM as practiced in British Columbia includes the use of acupuncture needles, moxibustion and cupping, which have been discussed previously, and the prescription of TCM formulas and food cures.

Apart from the traditional instruments and materials associated with acupuncture, moxibustion, cupping, and herbology, TCM, as practiced in British Columbia, does not generally utilize technology for diagnosis or treatment.

The Council has received information that some TCM practitioners may be introducing the use of laser technology in their acupuncture practice. Based upon submissions of the applicants and respondents, the Council is of the view that this practice is not widespread.

s.5(1)(c) the invasiveness of the procedure or mode of treatment used by practitioners

Acupuncture is a physically invasive procedure and as such, carries a significant risk of harm. The use of acupuncture has already been determined to carry a risk of harm and has been designated a reserved act for members of the College of Acupuncturists. TCM practitioners also utilize acupuncture. During the public hearing, the Council heard testimony that injections of substances into acupuncture points is a technique being used in other jurisdictions, such as China. The Council was told that this technique is not practiced in British Columbia.

s.5(1)(d) the degree to which the health profession is

(i) practised under the supervision of another person who is qualified to practise as a member of a different health profession, or

According to the applicants, TCM practitioners practice independently in homes, private offices or clinics. Their professional judgments and actions are generally independent and unsupervised.

(ii) practised in a currently regulated environment.

The practice of acupuncture is regulated by the College of Acupuncturists of British Columbia. All health practitioners, including TCM practitioners, who utilize acupuncture in their practices will be required to register with the College of Acupuncturists when mandatory registration begins, unless they are registrants of another college whose members are granted that reserved act. Mandatory registration with the College of Acupuncturists is expected in approximately six months.

The Council's 1993 Report on the Designation of Acupuncture does not address the regulation of herbology. The application of TCMABC was outstanding at the time of the acupuncture hearing and that application included the practice of herbology, therefore the Council chose to defer its consideration of the regulation of herbology in the context of TCM until this application could be reviewed.

The applicants state that herbology will not be regulated by the designation of the British Columbia College of Acupuncturists. The College of Acupuncturists' scope of practice statement does not include herbology, and supports this statement by the applicants. The Acupuncturists Regulation under the HPA sets out the scope of practice statement for members of the College of Acupuncturists and is included in Appendix F.

Section 5(1) Conclusion:

TCM practitioners practice independently, unsupervised by other health care practitioners and in an unregulated environment, subject to the Acupuncturists Regulation. They utilize acupuncture which is an invasive procedure. They also prescribe TCM formulas some of which have been associated with a strong possibility of serious adverse consequences. The Council finds that there is a general risk of harm to the public in the practice of TCM. The Council also finds a significant risk of harm in the use of TCM diagnosis and acupuncture, which are both activities the Council has determined to be reserved acts, and in the prescription according to TCM principles of substances used in TCM formulas which carry a high potential for adverse consequences, which the Council is recommending be given reserved act status. The Council finds the practice of TCM meets the s.5(1) risk of harm criteria for designation as a health profession under the HPA.

b. s.5(2): Other Criteria

The Council also applied the criteria in sections 5(2)(a) to (h) of the Regulation to the practice of TCM.

s.5(2)(a) the extent to which the health profession has demonstrated that there is a public interest in ensuring the availability of regulated services provided by the health profession

In October 1995, a member of the Alternative Cancer Therapy Support group met with a member of the Council and staff and stated that cancer patients have been successfully treated by TCM therapy for various types of cancer. This group actively supports the recognition and regulation of TCM in the public interest. This was subsequently supported by documentation provided by one of the applicants, CSPA.

Professor Cedric K. T. Cheung of the Chinese Medicine and Acupuncture Association of Canada, stated in his submission that a petition signed by 10,000 persons had been presented to the Ontario Health Professions Regulatory Advisory Council. The issue of regulation of either TCM, in its entirety, or acupuncture, separately, is being considered by the Ontario Council. This petition supports the regulation of TCM, in its entirety.

Very little other documentation was provided by the applicants regarding the public interest in ensuring the availability of regulated services. However it is clear to the Council that TCM has become increasingly popular throughout British Columbia in recent years. Letters and petitions have come to the Council from all areas of British Columbia. Additionally the Council's research indicates that other jurisdictions in Canada, such as Ontario, are considering regulation of TCM. In the United States, 36 states recognize and regulate the practice of herbology and acupuncture. The governments of Australia and Hong Kong are also moving toward regulation of TCM in its entirety.

s.5(2)(b) the extent to which the services of the health profession provide a recognized and demonstrated benefit to the health, safety or well being of the public

The Council accepts the view expressed by the applicants that the practice of TCM has been a recognized method of treatment for thousands of years and has provided benefit to the health, safety and well being of the persons who have used its treatments, either independently or in conjunction with western medicine.

The emerging recognition of alternative and complementary modes of therapy and their theoretical bases is illustrated in British Columbia by the establishment of the Tzu Chi Institute. The mission of the Institute to promote health through scientific evaluation of complementary and alternative approaches and integration of safe and effective therapies into mainstream health care practice. The adoption of certain parts of Chinese medicine, for example, acupuncture, by western practitioners of many disciplines, is evidence of the growing acceptance of TCM.

s.5(2)(c) the extent to which there exists a body of knowledge that forms the basis of the standards of practice of the health profession

The Council has received a great deal of information concerning the existence of a traditional body of knowledge which forms the basis of the practice of TCM. The applicants have provided information about the theory which underlies the practice of TCM and its unique philosophy on which diagnosis and treatment is based.

The Chinese Medicine and Acupuncture Association of Canada, one respondent to the consultation process, stated that "TCM theory is a completely separate and distinct core body of knowledge from Western Medicine theory . . . The terminology, pathology of disease, diagnosis and treatment are completely unique and distinct from Western medicine."

After review of textbooks and information from the applicants, the Council accepts that the practice of TCM has a unique theory and philosophical basis from which its principles, practices and techniques for diagnosis, assessment, and treatment have developed. The Council does not feel it is able to further explicate or expound on such theories, nor does it feel that it is appropriate or necessary to reconcile these theories with western medicine. The Council accepts that there is a body of knowledge which forms the basis of standards of practice.

s.5(2)(d) whether members of the profession are awarded a certificate or degree from a recognized post-secondary educational institution

The Council was provided with a list of eleven Colleges of TCM in British Columbia. In British Columbia, at present, there is no standard curricula data available, however the Council was informed at the public hearing that the schools are moving toward a more extended and standardized curriculum. In part, the impetus for standardization of curricula has come from the recognition of acupuncture as a regulated health profession.

In order to familiarize itself with the education for TCM practice, the Council met with representatives of the International College of TCM in Vancouver and toured the facility, examined the curriculum and met with several members of the staff. The President of the International College of TCM in Vancouver is the Vice-President of TCMABC. Graduates of this program receive either a certificate in acupuncture or a combined certificate in acupuncture and herbology.

International College of TCM in Vancouver is registered under the Private Post-Secondary Education Act, R.S.B.C. 1996, c. 375, (the PPSEA). The Council has written to the other ten institutions which are also registered under the PPSEA and claim to prepare practitioners of TCM in British Columbia. The Council has received curriculum information from the Academy of Classical Oriental Sciences, the Canadian College of Acupuncturists and Oriental Medicine, the Canadian College of Traditional

Chinese Medicine, the Western Canadian Institute of TCM Practitioners, the Royal Canadian Energy Therapy College, the Shanghai Acupuncture College of B.C. Canada and the North American Acupuncturists Examination College. The Council has not received responses from the College of Canadian Chinese TCM and Acupuncturist Education Society, the International College of Traditional Chinese Medicine of Victoria, and the Vancouver Institute of T.C.M. & Acupuncture.

Private post-secondary education is training or instruction for persons seventeen years of age and older. It covers a wide range of employment training, instruction in post-secondary education, and academic upgrading in a variety of settings. Private post-secondary institutions in British Columbia are governed by the PPSEA and are required to be registered with the Private Post-Secondary Education Commission ("the Commission"). Registration under the PPSEA is intended to provide a degree of consumer protection. The fact that a school is registered, however, does not certify the quality of the education nor the instruction provided.

Private post-secondary institutions also have the option of becoming accredited by the Commission. Through accreditation, registered institutions and their programs are evaluated and recognized for their standards of integrity and educational competence. The schools listed above are not accredited institutions under the PPSEA.

The British Columbia TCM schools vary from a two to a three year program, however some are moving toward a four year program. The prerequisites for entry also vary from two years college preparation to a grade 12 diploma.

At the public hearing, Dr. C.K.T. Cheung stated that there are programs in other parts of Canada whose curricula are similar to those in British Columbia. There are no institutions awarding a doctorate in Canada.

The Council is not in a position to appraise the doctoral programs for TCM in China, however the following excerpt from the Australia Report at p.148 describes the various forms of TCM training in China.

8.3 TCM EDUCATION IN CHINA

China has dual systems of traditional Chinese and western medical education. These are not mutually exclusive: students are trained primarily in one approach but elements of western medical sciences are incorporated in TCM programs, and western medicine students receive an overview of TCM.

During undergraduate and internship training TCM students obtain clinical experience in hospitals in both TCM and western medicine departments. Graduates from TCM university courses are able to diagnose in western medical terms, prescribe western pharmaceuticals, and undertake minor surgical procedures. In effect, they practise TCM as a specialty within the broader organisation of Chinese health care.

- *Western medical doctors undertake an introductory course in TCM (approximately 100 hours) to familiarise them to TCM treatment and theory. Practitioners trained in western medicine however, cannot practise acupuncture or Chinese herbal medicine without undertaking extensive additional training.*

There is considerable homogeneity in formal educational requirements across China. Course specifications are determined by the central government, but regional flexibility is allowed. A variety of types and levels of education is available.

There are three principal streams of TCM education that lead to formal qualifications:

- *TCM secondary schools;*
- *TCM tertiary institutions; and*
- *external courses (known as the self-study examination system).*

Each stream prepares graduates in a different manner. Graduates are then qualified to work within certain contexts and under specific limitations. This is particularly the case in differentiating secondary and tertiary TCM education. However, self-study examinations and apprenticeships are still recognised, and many mechanisms exist for further training and upgrading of qualifications.

8.3.1 Secondary Education

The principal aim of this level of TCM education is to train personnel for primary health care activities in rural areas. This stands in contrast to the level of education required at tertiary level for employment and practice rights in large urban hospitals.

After completing junior high school (the equivalent of Year 9 level in Australia), students are able to do four years of secondary education for an associate diploma in TCM, Chinese herbal pharmacy, or TCM nursing. There are 71 secondary TCM schools and 98 departments of TCM in secondary medical schools

Although the curriculum is designed by the Chinese Ministry of Health, individual schools are allowed some flexibility. Total teaching must not exceed 3200 hours. The ratio of lectures to clinical practice is 2:1.

8.3.2 Tertiary Education

Training in TCM was established at the tertiary level in 1956 with government accreditation and financial support. Currently in the People's Republic of China there are 27 universities and colleges of TCM, and 15 faculties of TCM in medical universities and colleges. Most of them offer postgraduate in addition to undergraduate studies and have the principal purpose of providing high quality education in TCM. Graduates have full practising rights within all public hospitals and are recognised by the State.

From the information received during the consultation process, the Council believes there are significant numbers of TCM practitioners practicing in British Columbia who have been trained in the Chinese system. It is also evident that there is a variety of educational resources available within the province of British Columbia and elsewhere in Canada for the training of TCM practitioners.

A new college will have as one of its objects under s.16(2)(c) of the HPA to establish, monitor and enforce standards of education and qualifications for registration of registrants. The College must deal with a variety of training programs in determining its registration criteria. There is no accrediting agency for TCM professional educational programs in Canada. Additionally there are a significant number of practitioners in the province who were trained in other jurisdictions or in a family tradition. Many do not have a degree or certificate from a recognized educational institution. It is expected that determining educational credentials of potential registrants will present a challenge to a new college during its registration process.

s.5(2)(e) whether it is important that continuing competence of the practitioner be monitored

In the Council's view, monitoring continuing competence is important in the practice of any profession which involves a risk of harm to the health, safety or well-being of the public. While the practice of TCM is based upon ancient principles, the application of those principles can result in a risk of harm to the public if not employed by a competent practitioner who is currently aware of the risks to his or her patient.

Additionally, the Council has received information that indicates patients in British Columbia are using TCM both as a primary health care system and as complementary to western medicine. There is potential for harm in combination of two distinct modes of treatment which may include both TCM formulas and pharmaceutical therapy. Because of this overlap it is even more important that regulation of the profession be established and that competence of the practitioners be monitored by a regulatory body. This should also foster interdisciplinary practice, since a college would establish and maintain standards of practice, thus enhancing the acceptance of TCM practitioners in the health care community.

s.5(2)(f) the extent to which there exists within the health profession recognized leadership which has expressed a commitment to regulate the profession in the public interest

Unfortunately, the president of CSPA, the second applicant, died in the fall of 1997. The Council has not been advised of new leadership for this society. In terms of dealing with this application, the Council considers that the remaining two applicants adequately represent the leadership of the profession.

The leadership of the remaining two applicants have a commitment to regulate the profession. They have expressed a willingness to work together.

While the Council is confident the applicants have a sincere commitment to work together toward regulation of TCM in the public interest, the Council has a general concern which relates to any new professional college board's ability to understand the intricacies of regulation of the profession in the public interest. Dealing successfully with issues related to college duties and objects, such as competency, quality assurance, education, registration requirements, and disciplinary matters, may require support over and above the inclusion of public membership on the new college Board. The new Board may need support in understanding the complex implications of regulation in the public interest. This may be a difficult goal to achieve for a new professional college with no prior experience in self-regulation.

In particular, it came to the Council's attention during the investigation that attempts by the first Board of the College of Acupuncturists to establish bylaws were frustrated by:

- lack of knowledge on the part of some members of the acupuncture practitioner community as to the meaning of governance of the profession in the public interest; and
- the difficult task of establishing a governing body due to the lack of previous experience dealing with this form of regulation.

The Council believes that a process of monitoring and assistance from the Ministry of Health in the early stages of establishment of a college would enable the college board to move through the various stages of assuming its responsibility to regulate in the public interest.

s.5(2)(g) the likelihood that a college established under the Act would be capable of carrying out the duties imposed by the Act, having regard to factors which in the view of the council may affect the viable operation of the college

The applicant organizations represent approximately 160 members of an estimated total of 200 to 300 TCM practitioners in British Columbia. The Council believes the membership of the applicant societies is sufficient to sustain the operations of a college of TCM. The precedent of other smaller colleges indicates that administration can be successfully achieved by a group the size of the applicant groups.

While no respondents disputed the risk of harm in the practice of prescribing TCM formulas, there was disagreement about whether this risk should be regulated by a separate college of TCM or should, in time, be regulated by the existing College of Acupuncturists of British Columbia. The existence of a separate College of Acupuncturists may have significant impact on the viability of a future college of TCM. Likewise, respondents to the consultation process, many of whom will be members of the College of Acupuncturists of British Columbia, are concerned that the existence of a TCM college including acupuncture practitioners would impair the functioning of the College of Acupuncturists.

Several respondents to the consultation process were of the view that TCM as a whole, including TCM formulas and herbology, should be regulated under the newly designated College of Acupuncturists of British Columbia. Others questioned the ability of the College of Acupuncturists to effectively regulate TCM, specifically the practice of herbology, since this is not clearly within the scope of practice of members of the College of Acupuncturists as defined in the Regulation. Suggestions were made that the mandate of the College of Acupuncturists be expanded to cover herbology.

If there were two separate colleges for acupuncture and TCM the applicants have indicated that there could be a significant number of acupuncturists who would join a college of TCM. However they believe that acupuncturists who primarily use only acupuncture would remain with the College of Acupuncturists.

RECOMMENDATION 5:

that a single college be established to govern both practitioners of acupuncture and practitioners of TCM.

After careful study of the submissions and the testimony at the public hearing, it is the Council's conclusion that the existence of two colleges governing TCM practitioners would not be in the public interest. TCM is the philosophical tradition from which acupuncture, herbology, and the other primary TCM therapies derive their theoretical bases and standards of practice. The

Council believes that it is more appropriate that one college, the College of TCM Practitioners, govern both practitioners of TCM and acupuncture.

Some practitioners have focused their professional endeavours on the promotion of acupuncture as a profession, as opposed to the promotion of TCM as a whole. These practitioners are aligned with the College of Acupuncturists. The TCM practitioners who formed the applicant groups have focused their energies and professional endeavours on the promotion of the practice of TCM as a whole. Factionalism exists along these lines and on other more personal bases as demonstrated during the consultation process and public hearing.

The Council considers the following to be the advantages and disadvantages of the three options for regulating TCM as a whole:

1) Establishment of a new College of TCM, which would encompass all of the primary therapies of TCM, and retention of the College of Acupuncturists.

The advantage of this option is that it gives the majority of the practitioners an opportunity to choose to become a registrant of one college or the other. While it is difficult to predict, this could reduce the factionalism within the TCM and acupuncture communities and its resultant effects on the operation of each individual college. The applicants favour this option. However, this option might affect the financial viability of both colleges. The number of potential registrants for each is difficult to assess. Additionally if there were two colleges, the public may be confused as to the proper college for disciplinary matters.

2) Establishment of a new College of TCM, which would encompass all of the primary therapies of TCM, and dissolution of the College of Acupuncturists.

The advantage of this approach is that it recognizes the historical and philosophical traditions of TCM practice as a health care system consisting of a number of primary therapies, including acupuncture and herbology. Any concern that some potential members of the newly designated College of Acupuncturists would be unable to qualify for membership in a college governing TCM, due to lack of qualification to practice herbology, could be addressed by establishing categories of registrants with different entitlements to reserved acts. For example, a "TCM practitioner" would be entitled to the reserved acts set out in both recommendations 3 and 4; whereas an "acupuncturist" who is a member of the College would be entitled to the reserved acts set out in Recommendation 3. A new college would have the benefit of the knowledge gained in the establishment of the College of Acupuncturists.

The Council believes the disadvantage of this option would include the possibility of perpetuation of current factionalism within the new college.

- 3) Expansion of the mandate of the College of Acupuncturists to cover the practice of TCM as a whole.

The advantage of this approach is that the College of Acupuncturists has been designated and has gained some experience in the preliminary stages of the establishment of a college. However, it has come to the attention of the Council and is a matter of public record, that there have been significant difficulties experienced in the establishment of the College of Acupuncturists. These difficulties have been of such magnitude that it appears that confidence in the ability of the College of Acupuncturists to govern in the public interest has been eroded both among members of the professions and the community at large.

A significant disadvantage of this option is that the current difficulties experienced by the College of Acupuncturists could continue in a college of TCM if the existing College of Acupuncturists were simply reconfigured to become a college of TCM. In the view of the Council it is likely that the difficulties would be exacerbated. It should also be noted that the applicants for the designation of TCM as a whole are opposed to this option.

Conclusion:

After careful study of the submissions, the testimony at the public hearing and extensive consideration of the three options, the Council concludes that it is in the public interest to recommend the second option, namely that a new college of TCM be established to govern all TCM practitioners and Acupuncturists.

s.5(2)(h) whether designation of the health profession is likely to limit the availability of services contrary to the public interest

There is no evidence that designation of the profession under the Health Professions Act would limit the availability of services provided that a grandparenting provision was allowed. Practitioners who may be grandparented are those who do not necessarily have a certificate, diploma, or degree from an educational institution, but have acquired their training through a type of apprenticeship or through the family tradition. Information provided by the applicants indicate that the goal would be to gradually require more formal training requirements. If grandparenting were not allowed, it is possible that designation of TCM could limit availability of services.

Section 5(2): Conclusion:

On the basis of the analysis of the criteria under and s.5(2), the Council finds that it is in the public interest to recommend designation of the profession of traditional Chinese medicine as a health profession under the HPA.

B. NAME OF THE COLLEGE

RECOMMENDATION 6:

the college established for the health profession be named the "College of Traditional Chinese Medicine Practitioners".

Consistent with the regulatory bodies for other health professions, the Council recommends that the College name incorporate the name of the practitioners rather than the profession. This name was requested by the one of the applicants and the Council agrees it is appropriate.

C. RESERVED TITLE

RECOMMENDATION 7:

the title "Traditional Chinese Medicine Practitioner" be reserved for the exclusive use of registrants of the College of TCM Practitioners. The title "Acupuncturist" be reserved for those members of the College who are not qualified to use "TCM Practitioner" as their training is only in acupuncture.

Consistent with the rationale of Recommendation 6, the Council recommends reserving the title "Traditional Chinese Medicine Practitioner" exclusively for registrants of the College.

The concept of "reserved title" is intended to protect the public by enabling members of the public to identify those practitioners who are trained and qualified in all aspects of the scope of TCM practice, even those aspects which do not represent reserved acts. Only those practitioners who meet the standards and have the credentials to be members of the College may use the title reserved for members of that College.

Those acupuncturists who would not be qualified as members of the College to use the title "TCM practitioner" could use the reserved title "Acupuncturist". TCM Practitioner is reserved for those members of the College who are qualified in both herbology and acupuncture.

The applicants requested the reserved title D.TCM, "Doctor of TCM", and stated that this is the equivalent of one of the levels of TCM training in China, "Zhong Yi Shi". There are several different levels of TCM training programs in China. In North America there are currently no doctoral level training programs. It is the Council's general impression that the TCM training programs in North America are equivalent to a baccalaureate level of education. Because of the diversity of educational experience of TCM practitioners in British Columbia, the Council does not believe that the title "Doctor of TCM" should be reserved. However, this would not preclude someone with educational credentials at the doctoral level from using the earned title "doctor".

APPENDIX C

SOME CHINESE MEDICINAL SUBSTANCES WHICH CARRY A HIGH POTENTIAL FOR ADVERSE CONSEQUENCES

1. "A Professional Career in TCM", International College of TCM, Vancouver course catalogue pages 24 - 36;
2. July 23, 1996 letter from Dr. Joseph Wen-Teng Wu to Director General, Drugs Directorate Health Canada;
3. "Use of Mineral Medicinals in Chinese Medicine", excerpt from a submission from J. Knights, Vice-President, Traditional Chinese Medicine Association of B.C. dated January 27, 1998.;
4. Hong Kong Government Report of the Working Party on Chinese Medicine Annex vi: "Potent or Toxic Chinese Medicinal Materials Controlled in China and Taiwan".

APPENDIX D

SUBSTANCES PROPOSED FOR RESTRICTION BY HEALTH CANADA

1. September 22, 1995, Health Canada letter, Appendix II, Part B;
2. October 1995, Policy Issues Health Canada: note: those herbs already prohibited by Food and Drug legislation are not included in this letter;
3. January 4, 1996, Letter to Trade from Health Canada of herbal preparations which pose a health hazard;
4. Schedules 705 and 624 to the Food and Drugs Act.

APPENDIX E

MEDICAL JOURNAL ARTICLES

1. Jean-Louis Vanherweghem, et al., "Rapidly progressive interstitial renal fibrosis in young women: association with slimming regimen including Chinese herbs," *The Lancet*, vol. 341, No. 8842, February 13, 1993;
2. P. Dickens, et al., "Fatal accidental aconitine poisoning following ingestion of Chinese herbal medicine: a report of two cases," *Forensic Science International*, 67, (1994);
3. Ryan J. Huxtable, PhD, "The Myth of Beneficent Nature: The Risks of Herbal Preparations," *Annals of Internal Medicine*, vol. 117, No. 2, July 15, 1992;
4. Nacim Mostefa-Kara, et al., "Fatal hepatitis after herbal tea," *The Lancet*, vol. 340, September 12, 1992, Yau-Ting Tai, et al., "Adverse effects from traditional Chinese medicine," *The Lancet*, vol 341, April 3, 1993, Robin Graham-Brown, "Toxicity of Chinese herbal remedies," *The Lancet*, vol 340, September 12, 1992;
5. R.W. Bury, PhD, et al., "Problems with herbal medicines," *The Medical Journal of Australia*, vol. 146, March 16, 1987, Peter Bowron, BSc(Hons), "Possible contamination of a herbal product with a prohibited substance," *The Medical Journal of Australia*, vol. 146, March 16, 1987, P.J. Christopher, FRSH, "Are herbal remedies safe?" *The Medical Journal of Australia*, vol. 148, January 18, 1988;
6. Bin Hsu, M.D., Ph.D., "The Use of Herbs as Anticancer Agents," *American Journal of Chinese Medicine*, vol. VIII, No. 4.

APPENDIX F

B. C. COLLEGE OF ACUPUNCTURISTS SCOPE OF PRACTICE STATEMENT

The scope of practice statement for members of the College of Acupuncturists is as follows:

Scope of Practice

4. *A registrant may practise acupuncture, based on the traditional Oriental method, including*
 - (a) *the use of diagnostic techniques,*
 - (b) *the administration of manual, mechanical, thermal and electrical stimulation of acupuncture needles, and*
 - (c) *the recommendation of dietary guidelines or therapeutic exercise.*

Reserved act

5. *Subject to section 14 of the Act, only a registrant may insert acupuncture needles under the skin for the purposes of practising acupuncture.*

Limitations on practice

6. (1) *No registrant may treat active serious medical conditions unless the client has consulted with a medical practitioner, naturopath or dentist, as appropriate.*
- (2) *A registrant may only administer acupuncture as a surgical anaesthesia if a medical practitioner or a dentist is physically present and observing the procedure.*

- (3) *A registrant must advise the client to consult a medical practitioner, naturopath or dentist if there is no improvement in the condition for which the client is being treated within 2 months of receiving acupuncture treatment.*
- (4) *In the event a client does not consult with a medical practitioner, naturopath or dentist, a registrant must discontinue treatment if*
- (a) *there is no improvement in the condition for which the client is being treated after 4 months from the date treatment commenced,*
 - (b) *the condition for which the client is being treated worsens, or*
 - (c) *new symptoms develop.*