

Majority Report
of the
Special Commission on Complementary
and
Alternative Medical Practitioners

A Report to the Legislature
January, 2002

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EXECUTIVE SUMMARY

In 2000, the Massachusetts Legislature established a special commission to study the use of and need for licensing complementary and alternative medical practitioners in Massachusetts. This study was to identify the various forms of complementary alternative medical practices that exist in Massachusetts, estimate the level of usage and availability of third party reimbursement, and identify those types of practices that are appropriate for state regulation and/or licensure. The study was also to include recommendations on possible regulation and/or licensure specifically for naturopathic doctors.

Due to time constraints, the Commission focused its deliberations solely on naturopathic medicine. This report provides a review of naturopathic medicine, describes the therapies involved, and outlines issues related to education and training standards, scope of practice and regulation. The report outlines regulatory approaches, and makes recommendations on some general principles for licensing naturopathic doctors in the Commonwealth.

Summary of Recommendations for Regulation of Naturopathic Doctors

After careful consideration of all of the information and evidence presented, the majority of the Commission has concluded that state licensure of practitioners of naturopathic medicine is both appropriate and necessary for the protection of the public health, safety and welfare.

Based upon the evidence presented, the majority has found (1) at least some of the diagnostic and therapeutic modalities currently employed in the practice of naturopathy may result in direct patient harm if they are not used safely and prudently, and (2) safe use of the modalities in naturopathy requires learned skills and/or systematic training. The Commission also found that clinical evidence to support efficacy of naturopathic treatment is very limited. However, a majority of Commission members are persuaded that at least some forms of treatment—such as the use of ginkgo, saw palmetto, St. John’s wort, horse chestnut, kava kava, and cranberry juice—have merit in treating certain medical conditions. At the same time, a minority of members is not convinced that current evidence supports the efficacy of naturopathic medicine.

Finally, it was also clear to Commission members that consumers would benefit from government clarification of minimum standards of professional qualifications and practice in this field. While the number of practitioners in this field is currently relatively small, it is evident that public interest in various forms of complementary or alternative health care is growing rapidly. Given this and the historical precedent of medical research institutions to become interested in certain “natural” remedies, the majority believes that the number of practitioners can be expected to grow to meet increasing market demand for these services.

In developing its recommendations, the Commission was mindful of the principle that, unless it can be shown that a particular form of health care service poses a demonstrable and unacceptable risk of injury or harm, a consumer should be free to make informed choices about his or her health care services. Currently, naturopaths are able to receive their education through various means such as naturopathic universities, correspondence programs, and in-the-field apprenticeships. The Commission thought it appropriate to distinguish between the different levels of education and of obtaining status as a naturopathic doctor by recommending specific requirements for licensure while not prohibiting the general practice of naturopathy by those who do not hold a license. A consumer will be more informed knowing that a person calling him/herself a naturopathic doctor has met the Commonwealth's requirements for licensure, and therefore has been compelled to demonstrate that he or she possesses a certain basic level of knowledge and skill in the field. At the same time, he or she still has the freedom to choose naturopathic services provided by an unlicensed practitioner. Hence, the recommendations presented below have attempted to recognize the diversity of philosophy and practice that exists among practitioners of naturopathic health care while ensuring a minimum level of protection of the public interest.

Following are the summary recommendations for regulating naturopathic doctors. Part IV of this report provides a more thorough discussion of each recommendation.

1. Enact licensing legislation for naturopathic doctors that vests the power to license and regulate such practitioners in a board to be comprised of nine members, including four naturopathic medical doctors, professionals from other health care fields and a public member.

2. Licensing legislation for naturopathic practitioners should take the form of a "title protection" statute, as opposed to a so-called "practice" act. Title protection ensures that those individuals who are licensed abide by the practice standards established by the act and would allow the board to suspend, revoke or otherwise discipline a licensee who violates those standards or regulations.

3. Licensing legislation for naturopathic doctors should contain specific provisions which prohibit unlicensed individuals from using any of the following terms or titles: "naturopathic physician", "naturopathic doctor", "doctor of naturopathy", "N.D.", "naturopathic medicine", "naturopath", or any term that indicates or implies that he or she has been licensed or otherwise approved to practice any form of naturopathic health care by any governmental body. The Commission further recommends that the term "physician" and "primary care" be reserved for medical doctors and that licensed naturopathic doctors be prohibited from using those terms.

4. The definition of the scope of practice of naturopathic medicine should include many of the practices and treatments being taught at naturopathic medical schools yet exclude certain

practices—such as surgery and the prescribing of controlled substances—as beyond the scope of naturopathic medicine (see Part IV for more detail).

5. The naturopathic licensing board, in consultation with the Department of Public Health and the Board of Registration in Medicine, should promulgate regulations to establish standards for required collaboration between naturopathic doctors and conventional medical doctors.

6. The naturopathic licensing board should promulgate ethics regulations that would reduce the potential for conflict-of-interest, prohibit false and misleading claims, and provide for adequate disclosure of a patient treatment plan and obtain informed consent before treatment (see Part IV for more detail.)

7. Applicants for licensure as naturopathic practitioners shall possess a baccalaureate degree or its equivalent, as determined by the board, and shall have attended and graduated from a four-year doctoral program that is accredited or is a candidate for accreditation by an accrediting agency recognized by the U.S. Department of Education. The naturopathic doctoral program shall further be accredited or be a candidate for accreditation by the Council on Naturopathic Medical Education, or its successor. The naturopathic licensing board shall also have the authority to approve candidates for licensure who are graduates of naturopathic medical schools in countries or territories outside of the United States that offer equivalent training and education.

8. The naturopathic licensing board should establish a minimum 1,200 hours clinical training requirement, prior to graduation from a doctoral program, as a prerequisite for licensure. The clinical training may take place in both outpatient and inpatient settings, and may include components from conventional medicine as well as naturopathic medicine.

9. Applicants for licensure should be required to take and pass a uniform, proctored, psychometrically sound examination in order to obtain a license to practice as a naturopathic practitioner. This examination should, in particular, test the diagnostic and therapeutic skills of the applicant. The Commission supports the adoption of a standard national examination.

10. Licensing legislation for naturopathic doctors should contain specific continuing education requirements that must be met in order to renew that license.

11. Licensing legislation for naturopathic doctors should grant broad authority to the licensing board to develop and implement any regulations necessary to protect the public health, safety and welfare.

12. Licensing legislation for naturopathic doctors should contain specific grounds for

taking disciplinary action against providers who engage in certain forms of professional misconduct and violations of regulations of the board.

13. The naturopathic licensing board should establish a list of prohibited practices and treatments where controlled clinical trials have demonstrated a lack of efficacy or a risk of harm. The Commission also recommends that the legislature establish a list of prohibited practices for those practitioners who do not fall under the terms of this proposed act. The Commission further recommends that the naturopathic licensing board, in collaboration with the Department of Public Health and the Office of Consumer Affairs and Business Regulation, review annually research reported or conducted by the National Center for Complementary and Alternative Medicine of the National Institutes of Health and other CAM centers.

PART I: THE PURPOSE OF THIS REPORT

The Massachusetts state Legislature established a special commission to study the use of and need for licensing complementary and alternative medical practitioners in Massachusetts (Section 469 of the Commonwealth of Massachusetts Fiscal Year 2001 Budget Appropriation). The Commission was comprised of the director of the Division of Professional Licensure and included representation from the Massachusetts State Senate, House of Representatives, the Acupuncture Society of Massachusetts, the Board of Registration in Medicine, the Department of Public Health, the Massachusetts Medical Society, and the Massachusetts Society of Naturopathic Physicians. (see Appendix for membership of the Commission).

The enabling legislation directed this Commission to make: a) a reasonable identification of the types of complementary and alternative medical practitioners and therapies available to the citizens of the commonwealth; b) an estimation of the usage of such types of complementary and alternative medical practitioners and therapies by Massachusetts citizens; c) an evaluation of the necessity for state licensure of certain complementary and alternative practitioners, including practitioners of naturopathic medicine, as a consumer protection measure; d) a review of naturopathic education and training standards in existence within the United States; e) a review of the scope of practice in those states that license naturopathy; f) a review of standards of conduct, restrictions, and exclusions that might apply to naturopathy, and g) a review of the availability of third party reimbursements for therapies and services delivered by complementary and alternative practitioners in the Commonwealth.

The Commission was directed to report its findings together with drafts of legislation necessary to carry out its recommendations to the state legislature.

Initially the Commission focused on identifying the various forms of alternative and complementary medicine and therapies and developing reliable estimates of the extent to which each of these modalities are currently used in Massachusetts. In subsequent discussions, that focus was narrowed to include only three practices—naturopathic medicine, homeopathy and massage therapy. Because of the short time frame and complexity of the issues involved, the Commission further restricted its focus to naturopathic medicine.

During its deliberations the Commission developed a set of evaluation criteria by which it would determine the need for regulation of naturopathic doctors. The evaluation criteria were used as a guideline that is modifiable and applicable for future study of other types of complementary and alternative medicines.

The Commission accepted or solicited testimony from the Massachusetts Society of Naturopathic Physicians, from the Massachusetts Medical Society, Massachusetts Board of

Registration of Medicine, and the Coalition for Natural Health, a grassroots organization that represents over 2,500 natural healers nationwide. The Commission also received written testimony supporting licensure from various individuals.

This report provides a review of naturopathic medicine based on the evaluation criteria, describes the therapies involved, and outlines issues related to education and training standards, scope of practice, and regulation. The report outlines regulatory approaches, and makes recommendations on some general principles for licensing naturopathic doctors in the Commonwealth.

PART II: WHAT IS NATUROPATHIC MEDICINE

The Commission looked at a broad range of definitions for complementary and alternative medicine and naturopathy. Following is a review of definitions commonly used nationwide. The Commission wishes to note, however, that its specific recommendations may include many but not all of the practices included in these definitions. The majority of Commission members found that some practices, such as acupuncture, are not taught in naturopathic medical schools in sufficient depth to warrant inclusion in naturopathic scope of practice without a separate license from the Massachusetts Commission on Acupuncture. Other practices, such as surgery and the prescription of controlled substances, are not appropriate for licensed naturopathic practice in this state.

The National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health defines complementary and alternative medicine as:

[T]hose treatments and healthcare practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies... Therapies are used alone (often referred to as alternative), in combination with other alternative therapies, or in addition to conventional therapies (sometimes referred to as complementary).¹

The NCCAM additionally describes naturopathic medicine as:

[A]n array of healing practices, including diet and clinical nutrition; homeopathy; acupuncture; herbal medicine; hydrotherapy (the use of water in a range of temperatures and methods of applications); spinal and soft-tissue manipulation; physical therapies involving electric currents, ultrasound and light therapy; therapeutic counseling; and pharmacology.²

Naturopathic medicine includes two basic approaches. Some practitioners do not employ any invasive procedures or prescribe any pharmaceuticals. This group considers themselves to be primarily educators and advocates for healthier lifestyles.

Another group of practitioners, however, has a broader scope of practice. They may perform minor invasive procedures, prescribe pharmaceuticals, and deliver primary health care

¹ <http://nccam.nih.gov/nccam/fcp/index.html#what-is>

² <http://nccam.nih.gov/nccam/fcp/classify>

to patients. This group of practitioners is supported for state licensure by the American Association of Naturopathic Physicians (AANP), a national professional society representing naturopathic doctors. They are educated in recognized schools of naturopathic medicine.

Following are the definitions of naturopathic medicine and its scope of practice as supported by the AANP:

Naturopathic medicine is a distinct system of primary health care - an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic medicine is distinguished by the principles which underlie and determine its practice. These principles are based upon the objective observation of the nature of health and disease, and are continually reexamined in the light of scientific advances. Methods used are consistent with these principles and are chosen upon the basis of patient individuality. Naturopathic doctors are primary health care practitioners, whose diverse techniques include modern and traditional, scientific and empirical methods (American Association of Naturopathic Physicians).³

The following principles are the foundation for the practice of naturopathic medicine as reported by the AANP:

The Healing Power of Nature (Vis Medicatrix Naturae)

The healing power of nature is the inherent self-organizing and healing process of living systems which establishes, maintains and restores health. Naturopathic medicine recognizes this healing process to be ordered and intelligent. It is the naturopathic doctor's role to support, facilitate and augment this process by identifying and removing obstacles to health and recovery, and by supporting the creation of a healthy internal and external environment.

Identify and Treat the Causes (Tolle Causam)

Illness does not occur without cause. Causes may originate in many areas. Underlying causes of illness and disease must be identified and removed before complete recovery can occur. Symptoms can be expressions of the body's attempt to defend itself, to adapt and recover, to heal itself, or may be results of the causes of disease. The naturopathic doctor seeks to treat the causes of disease, rather than to merely eliminate or suppress symptoms.

First Do No Harm (Primum Non Nocere)

Naturopathic doctors follow three precepts to avoid harming the patient:

³ <http://www.naturopathic.org/about/definitions.htm>

- Naturopathic doctors utilize methods and medicinal substances which minimize the risk of harmful effects, and apply the least possible force or intervention necessary to diagnose illness and restore health.
- Whenever possible the suppression of symptoms is avoided as suppression generally interferes with the healing process.
- Naturopathic doctors respect and work with the healing power of nature in diagnosis, treatment and counseling, for if this self-healing process is not respected the patient may be harmed.

Doctor As Teacher (Docere)

The original meaning of the word "doctor" is teacher. A principal objective of naturopathic medicine is to educate the patient and emphasize self-responsibility for health. Naturopathic doctors also recognize and employ the therapeutic potential of the doctor-patient relationship.

Treat the Whole Person

Health and disease result from a complex of physical, mental, emotional, genetic, environmental, social and other factors. Since total health also includes spiritual health, naturopathic doctors encourage individuals to pursue their personal spiritual development. Naturopathic medicine recognizes the harmonious functioning of all aspects of the individual as being essential to health. The multifactorial nature of health and disease requires a personalized and comprehensive approach to diagnosis and treatment. Naturopathic doctors treat the whole person taking all of these factors into account.

Prevention

Naturopathic medical colleges emphasize the study of health as well as disease. The prevention of disease and the attainment of optimal patient health are primary objectives of naturopathic medicine. In practice, these objectives are accomplished through education and the promotion of healthy ways of living. Naturopathic doctors assess risk factors, heredity and susceptibility to disease, and make appropriate interventions in partnership with their patients to prevent illness. Naturopathic medicine asserts that one cannot be healthy in an unhealthy environment and is committed to the creation of a world in which humanity may thrive.

PART III: CRITERIA THAT SUGGEST THE NEED FOR LICENSURE

A guiding principle for evaluating requests for new regulation is whether an unregulated profession or occupation presents a clear and present danger to the public's health, safety and welfare. Reasons for regulating health care professions are to prevent misdiagnosis, non-treatment and mistreatment by unlicensed medical providers; and to ensure the safety of those patients who seek services from licensed practitioners.

Based on these concepts, the Commission deliberated over several meetings and developed a set of evaluation criteria to evaluate the extent to which naturopathic medicine was ready and appropriate for state licensure and regulation. The evaluation criteria are a guideline, modifiable and applicable for future study of other types of complementary and alternative medicines.

Following are those criteria and the Commission's findings relative to naturopathic medicine:

- Evidence that misuse of some or all of the modalities in naturopathic medicine could lead to patient harm, and the nature and probability of that risk of harm is substantial enough to warrant government intervention.**

Naturopathic medicine has a wide-ranging scope of practice, including nutritional medicine and the dispensing of botanicals, to counseling, to physical medicine such as naturopathic manipulative therapies. Misuse of any of these modalities, misapplication of botanicals and herbals, or misdiagnosis could lead to unsafe practice and patient harm. The Commission agrees that both the degree to which a patient could be harmed and the possibility that such harm could occur from misdiagnosis or misuse of the therapies is sufficient to warrant some form of government intervention.

- A learned skill or training is necessary to safely use the modalities within naturopathic medicine**

After review of the testimony it has received, the Commission finds that the safe practice of naturopathic medicine requires learned skills and comprehensive training. The Commission found that standardized training is available to practitioners of naturopathic medicine. Formal naturopathic medical education is based on a particular theory of health and disease, and prepares its graduates to use medicines and therapeutic devices produced by the field's own material support system.

❑ Prevalence of the practice, the number of practitioners in Massachusetts and their caseloads

There are approximately 30 naturopathic doctors currently practicing in the Commonwealth who would be eligible to apply for licensure under the requirements recommended by this report. Several other naturopathic doctors who reside in the state practice in neighboring states that grant licensure. While this number may be relatively small, the Commission believes that public interest in various forms of complementary or alternative health care is growing, and that the number of practitioners can therefore be expected to grow to meet increasing market demand for these services. The Commission also believes that if naturopathic doctors become licensed in Massachusetts, more of them will open practices in Massachusetts, drawing more patients.

❑ Evidence of effective treatment of conditions if treated by well-trained naturopathic medical practitioners

Based on the testimony presented to it, the Commission found that clinical evidence to support efficacy of naturopathic treatment is very limited. However, a majority of Commission members are persuaded that at least some forms of treatment—such as the use of ginkgo, saw palmetto, St. John’s wort, horse chestnut, kava kava, and cranberry juice—have merit in treating certain medical conditions.

Naturopathic medicine, like other complementary, alternative and conventional medical practices, faces many challenges to conducting safety and efficacy studies. These include a lack of funding and the relative newness of naturopathic medicine as a health care choice for consumers. While conventional medicine has had the ability to raise government, industry and privately donated monies to conduct research over the last several decades, naturopathic medicine has been unable to attain that same level of resources in order to conduct more thorough studies.

❑ The need for consumer access to information that will help consumers determine which naturopathic medicine practitioners meet certain standards that will increase the quality and safety of treatments, prescriptions and referrals

Since naturopathic doctors are able to receive their education through various means (naturopathic universities, correspondence programs, in-the-field apprenticeships), there is a need to distinguish the different levels of education and of obtaining status as a naturopathic doctor. The consumer will be more informed knowing that a person calling him/herself a naturopathic doctor has met the commonwealth’s requirements for licensure, and therefore has been compelled to demonstrate that he or she possesses a certain basic level of knowledge and

skill in the field.

Governmental clarification of the scope of practice and/or standards of professional practice for naturopathic medicine would enhance informed decision-making by health care consumers

The aim of government intervention in the practice of a profession via licensure is to protect the public from the dangers of incompetent, negligent or unethical practitioners by establishing minimum standards for licensure, practice and conduct, and by enforcing those standards if a licensed professional engages in misconduct. The Commission agrees that at least some of the modalities currently employed in the practice of naturopathy may result in direct patient harm if they are not used safely and prudently, and that safe use of the modalities in naturopathy requires learned skills and/or systematic training. Government clarification would help consumers identify the qualifications of practitioners and would help to prevent non-diagnosis, misdiagnosis, non-treatment and mistreatment by unqualified practitioners.

The existence of discernible and consistent educational and clinical training standards for naturopathic medicine

Training in naturopathic medicine is currently obtained from several different sources including formal education in a naturopathic accredited institution of a required duration, correspondence courses, or apprenticeships, all of which have differing educational standards. The Commission found that graduates of a four-year doctoral level program accredited by the Council on Naturopathic Medical Education are required to complete standardized training that includes clinical nutrition, homeopathic medicine, botanical medicine, psychology, and counseling.

In its deliberations, the Commission agreed that licensed practitioners should meet minimum education and training standards, including graduation from an accredited school that provides clinical training and should pass a standardized national exam.

The existence and nature of a proctored, psychometrically sound national certification examination

Naturopathic doctors graduating from an accredited college are required to pass the NPLEX (Naturopathic Physicians Licensing Examination). This standardized national exam is used consistently by other state naturopathic licensing boards, and is similar to the examination process established by other professions such as acupuncture, physical therapy, and chiropractic.

Evidence of an orderly licensure process of the naturopathic medicine profession in other states

Currently naturopathic doctors are licensed/registered in 11 states including Alaska, Arizona, Connecticut, Hawaii, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, and Washington, as well as Puerto Rico.

The existence of professional associations with established policies and ethical standards for naturopathic medicine exist

There are two national associations, the American Association of Naturopathic Physicians (AANP) which represents providers of "naturopathic medicine" and the Coalition for Natural Health, a national group of "traditional naturopaths." Additionally, within the Commonwealth there is the Massachusetts Society of Naturopathic Physicians. At a minimum, the AANP and its Massachusetts Society have published a code of ethics and have established operating by-laws.

The existence of published materials, including textbooks and journals, regarding naturopathic medicine and the standards used in developing such materials are sufficient to support licensure

A list of journals and textbooks for naturopathic medicine were presented to the Commission. However, the Commission was not able to determine the quality or reliability of these books or the standards used in developing them.

The presence of federally recognized regional and/or national accreditation bodies for naturopathic medicine education and training programs

Naturopathic medical colleges must have accreditation from the government agency responsible for regulating post-secondary education in the state in which the college is located. Bastyr University in Kenmore, WA, the National College of Naturopathic Medicine in Portland, OR, and the University of Bridgeport College of Naturopathic Medicine in Bridgeport, CT have regional accreditation by a federally recognized accrediting body. The Southwest College of Naturopathic Medicine in Scottsdale, AZ is a candidate for accreditation by a regional body. These programs are also accredited by the Council on Naturopathic Medical Education (CNME). CNME, like the accrediting body for conventional medical schools, is a private accrediting body not recognized by the federal government.

Evidence of available clinical research in the field and a system for informing practitioners of developments

As previously stated, the amount of clinical research in naturopathic medicine is much less than for

conventional medicine. The evidence presented to the Commission suggests that the present system for informing naturopathic practitioners of new developments in the field could be improved. Requiring continuing education as a condition for renewal and the establishment of an annual report on state-of-the-art research to the Joint Committee on Health Care may promote the development of better mechanisms for disseminating such information.

☐ A balance between the administrative, economic and social benefits and costs to the state, insurers, public and naturopathic medicine practitioners associated with regulation or licensure

Administrative costs for licensing naturopathic doctors would be partially offset by licensing fees. Public safety and welfare will be protected as consumers will have access to qualified practitioners and have a means to formally file complaints against unqualified practitioners. Government would then have the ability to discipline these practitioners. Insurance coverage will be at the discretion of the insurer.

☐ Licensure will legitimize effective naturopathic medicine practices, promote consumer access to them, and increase the likelihood of insurance coverage

Naturopathic medicine is an emerging profession. Licensure would promote consumer access to naturopathic doctors and increase usage because more naturopathic doctors will begin to practice in the state. As in other professions, licensure will increase the potential for insurance coverage of licensed naturopaths. However, insurance coverage will be at the discretion of the insurer.

PART IV: RECOMMENDATIONS FOR NATUROPATHIC DOCTOR LICENSING LEGISLATION

After careful consideration of all of the information and evidence presented, the majority of the Commission has concluded that state licensure of practitioners of naturopathic medicine is both appropriate and necessary for the protection of the public health, safety and welfare. Before coming to this decision, Commission members engaged in considerable discussion and debate about whether or not naturopathic practitioners should be subject to licensing requirements, and what those requirements for licensure should be. In developing its recommendations, the Commission was mindful of the principle that, unless it can be shown that a particular form of health care service poses a demonstrable and unacceptable risk of injury or harm, a consumer should be free to make informed choices about what types of health care services he or she wishes to obtain.

The Commission supports the continued integration of naturopathic and conventional medical practice. Accordingly, the Commission recommends the enactment of a naturopathic licensing bill that includes specific requirements for naturopaths to have a collaborative practice agreement with a medical doctor. The Commission believes that naturopathic medicine is complementary to conventional medicine, and that both practices would benefit from an integrative approach. The Commission proposes that the naturopathic licensing board should mandate protocols that detail the nature of the practices and the patterns of collaboration and referral between naturopathic and conventional doctors.

This document frames the scope of practice for licensed naturopathic doctors in this light and is consistent with the core practices defined by eleven states that currently license naturopathic practitioners. The recommendations presented below also recognize the diversity of philosophy and practice that exists among practitioners of naturopathic health care while aiming to ensure adequate protection of the public interest.

1. Board Composition

The Commission recommends that the adoption of licensing legislation for naturopathic doctors that vests the power to license and regulate such practitioners in a board to be comprised of nine members:

- **Four licensed naturopathic medical doctors, appointed by the Governor, who have a minimum of five-years experience in the practice of naturopathic medicine, and for the initial appointments, naturopathic doctors who have a minimum of five-years experience and who are eligible for licensure under the terms of the act;**
- **One physician licensed to practice in Massachusetts, appointed by the Governor;**
- **The commissioner of Public Health or his designee;**

- **The chairman of the Board of Registration in Medicine, or his designee;**
- **One clinical pharmacologist, appointed by the Governor; and,**
- **One member of the public.**

The Commission believes that naturopathy is *complementary* to other more traditional forms of health care and recommends that the board reflect that premise. The Commission believes that, as with all other professional fields in which state licensure is required, the power and the responsibility for licensure and regulation of naturopathic health care practitioners should be placed in the hands of a licensing board within the executive branch. Most licensing boards consist of a majority of members from the professional being regulated. However, the Commission believes that further work needs to be done to link the recognition of naturopathy with the practice of health care practitioners at large. Thus, the Commission recommends that the legislature consider board membership that strikes a proper balance between naturopathic doctors, who can bring their expertise within the field to the board, other health care professionals, who can bring a wealth of traditional medical knowledge and experience to the regulation of naturopathic doctors, and a public member, who represents the voice of consumers.

2. Form of Licensing

The Commission recommends that licensing legislation for naturopathic practitioners take the form of a “title protection” statute, as opposed to a so-called “practice” act.

The evidence presented to the Commission during its deliberations clearly demonstrated that the term “naturopathy” encompasses a very wide range of diagnostic and therapeutic approaches and practices. It is evident, for example, that there are at least two “schools” of naturopathic health care practice. One “school” subscribes to a system of training and professional preparation which is relatively conventional in its approach, if not in its content, as well as a relatively narrow range of “acceptable” diagnostic and therapeutic practices. The other “school” relies on a far less formal and structured approach to preparation for practice and encompasses a potentially very broad range of therapies and modalities. Given this dichotomy and the apparently irreconcilable differences between the two “schools,” the majority of the Commission has concluded that a “title” act, as opposed to a “practice” act, will serve the best interests of the public.

A practice act establishes a regulatory board and prohibits any individual from practicing a particular profession, as defined by the licensing act, unless that person holds a license issued by the board. In contrast, a title protection act “reserves” the privilege of using certain professional titles for those who meet required education, training and examination standards and who are approved for licensure under the terms of the title act. A title act also establishes a regulatory board and defines a scope of practice for those individuals licensed by the board.

The Commission believes that a title act provides assurance to consumers that a governmental body has established minimum standards of qualification for licensure, competence and conduct for those naturopathic practitioners who wish to obtain a license. At the same time, title protection ensures that those individuals who are licensed abide by the practice standards established by the act and would allow the board to suspend, revoke or otherwise discipline a licensee who violates those standards or regulations.

The Commission further believes that a title act will provide for broad consumer choice because it will not restrict entry into the profession, so long as those practitioners who are not licensed do not hold themselves out as licensed or use a restricted title.

3. Title Protection

The Commission recommends that licensing legislation for naturopathic doctors contain specific provisions which prohibit unlicensed individuals from using any of the following terms or titles: “naturopathic physician”, “naturopathic doctor”, “doctor of naturopathy”, “N.D.”, “naturopathic medicine”, “naturopath”, or any term that indicates or implies that he or she has been licensed or otherwise approved to practice any form of naturopathic health care by any governmental body. The Commission further recommends that the term “physician” and “primary care” be reserved for medical doctors and that licensed naturopathic doctors should not hold themselves out as physicians or as primary care providers.

Consistent with its previous recommendation, the Commission believes that the right to use the titles listed above should be reserved to those who meet the education, training, and examination requirements contained elsewhere in the licensing legislation. Such a restriction is necessary to ensure that members of the general public can accurately distinguish between practitioners who meet those standards and those who do not.

The Commission also believes it important to reduce confusion about the use of particular titles by the various health care professions. That is, in so far as the public identifies the provision of a particular health care service by the title of the professional delivering the service, when a particular title is used commonly by different professions it increases the likelihood that the public will be confused about the type of services provided. Hence, the Commission recommends that the title “physician” be reserved for medical doctors. The Commission also notes that while the term “doctor” is used by several professions, it is also used in conjunction with another designation such as “chiropractor,” “dentist,” “podiatrist,” or “optometrist.” In contrast, the term “physician” is generally only used in connotation with medical doctors. (An exception to this use is chiropractors; some chiropractors refer to themselves as “chiropractic physicians.”)

Finally, the Commission heard extensive testimony from both proponents of naturopathic health care and representatives of conventional medicine about primary health care services, and engaged in lengthy debate about this matter. In the course of that testimony, it was noted that the term “primary care physician” has numerous meanings in the health care field. In some contexts, it means a provider who is qualified to furnish a wide range of basic health care services, i.e., the equivalent of the old “general practitioner”. In others, it denotes a provider who serves as a “gateway” to more specialized practitioners, and to insurance reimbursement for those services. These various meanings of the term create a potential for public confusion about just what a “primary care physician” can be expected to provide. Therefore, the Commission recommends that naturopathic doctors should be prohibited from referring to themselves as primary care physicians or represent to the public that they practice primary care.

4. Scope of Practice

Naturopathic Medicine is a system of health care practices for the prevention, evaluation, and treatment of illnesses, injuries and/or conditions of the human body through the use of education, nutrition, natural medicines and therapies, and other modalities which are designed to support, stimulate or supplement the human body’s own natural self-healing processes. The Commission recommends that the naturopathic licensing bill define a scope of practice to both include the practices and treatments being taught at naturopathic medical schools yet exclude certain practices, such as surgery and the prescribing of controlled substances, as beyond the scope of naturopathic medicine.

Naturopathic medicine includes, but is not necessarily limited to:

- 1) the prevention of human illness, injury or disease through education, dietary or nutritional advice, and the promotion of healthy ways of living;
- 2) the use of physical examinations and the ordering of validated clinical, laboratory and radiological diagnostic procedures, from licensed clinics or laboratories, for the purpose of evaluating injuries, illnesses or conditions in the human body;
- 3) the counseling of a patient regarding natural medicines of mineral, animal or botanical origin, such as food products or extracts, vitamins, minerals, enzymes, digestive aids, and other natural hormones, plant substances, homeopathic preparations, natural antibiotics, topical medicines for the purpose of preventing or treating illnesses, injuries or conditions of the human body;
- 4) the use of manual mechanical manipulation of body structures or tissues, in accordance with naturopathic principles;
- 5) the therapeutic use of physical agents or modalities such as air, water, heat, cold, light, electromagnetic non-ionizing radiation, electrotherapy, diathermy, ultraviolet light, ultrasound, hydrotherapy, and therapeutic exercise for the

purpose of maintaining or restoring normal physiological functioning of the human body; and,

- 6) the mandatory tracking/documentation of immunization status of each patient under eighteen years of age and required referral to primary care or collaborative physician where evidence exists that the individual has not been immunized.

Naturopathic medicine shall not include:

- 1) the performance of surgery or invasive procedures other than those permitted in one through six above;
- 2) the prescribing, dispensing, administration of any drug classified as a controlled substance under MGL 94C;
- 3) the practice of Oriental medicine, including but not limited to acupuncture and Chinese herbal medicine; and,
- 4) the practice of emergency medicine, except as a Good Samaritan rendering gratuitous services in the case of an emergency or for the care of minor injuries.

In order to develop an appropriate scope of practice for licensed naturopathic doctors in Massachusetts, the Commission reviewed several definitions of naturopathic medicine published by various organizations, the scopes of practice adopted by states that license naturopathic doctors, and the curricula of accredited naturopathic medical programs. Based on this review, the Commission developed a scope of practice that it believe satisfies two important goals: (a) the proposed scope of practice responsibly reflects the level of training provided by the accredited programs described under #7 of this part of the report; and (b) the scope of practice provides public protection.

5. Collaboration

The Commission recommends that the naturopathic licensing board, in consultation with the Department of Public Health and the Board of Registration in Medicine, promulgate regulations to establish standards for collaboration between naturopathic doctors and conventional medical doctors.

The regulations shall establish the nature and scope of this collaboration, as well as any protocols that shall be required, and shall include at a minimum:

- 1) The name of the physician(s) who will provide medical information and consultation to the naturopathic doctor;
- 2) Provisions for managing emergencies;
- 3) A provision that the naturopathic doctor must refer a patient to an appropriately licensed

physician, or to a health care facility providing medical services, if a patient has not already seen a physician or been to a medical facility, if said patient has a health problem that requires:

- a) Emergency care
 - b) Emergency diagnostic procedures
 - c) In-patient care
 - d) Surgery
- 4) A provision for referral for any medical service that is not within the scope of practice of naturopathic doctors; and,
 - 5) A provision that the naturopathic licensing board may at any time review, either directly or indirectly, the activities of a licensee to determine whether the activities conform to the applicable guidelines.

6. Ethics and Disclosure

The Commission recommends that the naturopathic licensing board be authorized to promulgate a code of ethics to promote high ethical standards for licensed naturopaths. The code of ethics should at a minimum:

- 1) Prohibit excessive charging for any supplements or other products sold by a naturopathic doctor;**
- 2) Prohibit promotional agreements between manufacturers, wholesalers, or distributors and naturopathic doctors;**
- 3) Require disclosure of alternate sources of supplements and other products, where available;**
- 4) Prohibit unsubstantiated advertising claims as to the safety or efficacy of the treatment;**
- 5) Ensure that the label of any drug, dietary supplement, device, or food used in such treatments is not false or misleading;**
- 6) Require patient notification as to the nature of the diagnosis and treatment, including reasonably foreseeable side effects and obtain a signed consent statement from the patient at the outset of treatment indicating that he or she has been fully informed and accepts the treatment plan; and,**
- 7) Require disclosure to a patient, in the case of a treatment requiring the approval or which may be defined as needing the approval of the federal Food and Drug Administration, that the government has not declared the food, drug, dietary supplement or device to be safe and effective and that the individual uses such food, drug, dietary supplement or device at his or her own risk**
- 8) Prohibit boundary violations between a doctor and a patient**

The Commission recognizes the inherent conflict-of-interest that arises when a practitioner sells a product that he or she may prescribe. However, the Commission recognizes that many supplements recommended by naturopathic doctors are not available to consumers through retail channels. The Commission also recognizes that naturopathic doctors may assay the quality of supplements and custom-compound them for their patients. Hence, the Commission recommends that licensed naturopathic doctors be allowed to sell supplements and other naturopathic products as part of their practice, as long as they follow a strict ethical code promulgated by the naturopathic licensing board.

The Commission further believes that a licensed naturopathic doctor should be required to make full disclosure to his or her patients regarding the diagnosis and proposed treatment of their medical condition. This disclosure, in the form of a written treatment plan and signed consent form at the outset of treatment, is vital to ensuring full and accurate communication between doctor and patient. The written treatment plan may also serve as communication vehicle between a naturopathic doctor and a collaborating physician.

The Commission recommends that the licensed naturopathic doctor's ethical responsibility should also include an obligation to exercise care in any communication with a patient regarding the safety and efficacy of a supplement or product, including a product that may be under review, but not yet approved, by the Food and Drug Administration.

Finally, the Commission recommends that the code of ethics adopted by the naturopathic licensing board should clearly prohibit inappropriate contact between a doctor and patient that undermines the integrity of the professional relationship. The Commission further recommends that the naturopathic licensing board may wish to review and adopt "best practice" ethical standards from other health professions where appropriate.

7. Educational Standards

The Commission recommends that applicants for licensure as naturopathic practitioners shall possess a baccalaureate degree or its equivalent, as determined by the board, and shall have attended and graduated a four-year doctoral program that is accredited or is a candidate for accreditation by an accrediting agency recognized by the U.S. Department of Education. The naturopathic doctoral program shall further be accredited or be a candidate for accreditation by the Council on Naturopathic Medical Education, or its successor. The naturopathic licensing board shall also have the authority to approve candidates for licensure who are graduates of naturopathic medical schools in countries or territories outside of the United States that offer equivalent training and education.

In order to ensure that all naturopathic health care providers possess the same minimum

level of skill and competency, the majority of the Commission's members believe that it is essential to standardize the educational and training process by which they prepare for entry into the field. In particular, Commission members agreed that rigorous training in the basic principles of biological and chemical science which govern human anatomy, physiology and disease processes was essential for proper professional preparation and that the adequacy of such training should not be left to chance. Requiring candidates for licensure to obtain their pre-professional training through uniform, standardized programs of study at educational institutions is the only truly reliable and efficient method of ensuring that each practitioner possesses the knowledge base and practice skills needed for safe practice in the field of naturopathy. Furthermore, oversight of such programs of study by governmentally-recognized accrediting organizations which possess proper levels of expertise in evaluating the quality and adequacy of those programs and their teaching methods is necessary to ensure that the pre-professional education is both sufficient and up to date. In the view of the majority of the Commission's members, allowing licensed practitioners to prepare for entry into the field solely through hands-on "apprenticeships" in the field presents unacceptably high risks of inconsistency and inadequacy in the level of knowledge and/or skill which such practitioners might possess when they begin to care for patients.

8. Clinical Experience

The Commission recommends that the legislation should direct the naturopathic licensing board to establish a minimum 1,200 hours clinical training requirement, prior to graduation from a doctoral program, as a prerequisite for licensure. The clinical training may take place in both outpatient and inpatient settings, and may include components from conventional medicine as well as naturopathic medicine.

The majority of the Commission members believe that classroom training alone is not sufficient to ensure adequate pre-professional preparation for the independent practice of prospective naturopathic health care providers. Most licensed health care professions also require completion of "hands-on" clinical training, either prior to graduation from the college-based program of study or immediately following it, or both, as part of the licensure process. These requirements reflect the view that "learning by doing" is a vital part of becoming a skilled health care practitioner. Post-graduate clinical training is not currently available in naturopathic medicine, but the Commission encourages its use in the future.

9. Examination

The Commission recommends that applicants for licensure be required to take and pass a uniform, proctored, psychometrically sound examination in order to obtain a license to practice as a naturopathic practitioner. This examination should, in particular, test the

diagnostic and therapeutic skills of the applicant. The Commission supports the adoption of a standardized national examination such as the Naturopathic Physicians Licensing Examination or its successor as determined by the board.

The administration of a uniform, psychometrically sound licensing examination is, in the Commission's view, another essential component of ensuring that all naturopathic health care providers have a minimum level of competence and skill before they obtain licensure. Without such an examination, it is impossible to evaluate fairly and accurately the level of competence and skill an applicant actually possesses, or to obtain crucial information about how well the existing professional training processes prepare an applicant to practice naturopathy safely. The Commission recommends that the examination focus particular attention on diagnostic assessment and therapeutic procedures. Consideration was also given to the concept of requiring applicants for naturopathic licensure to take and pass some portion of the national licensing examination used for conventional medical doctors. This option, however, was rejected because the Federation of State Medical Boards has informed the Commission that the national examination for conventional medical doctors can be administered only to persons who are enrolled in a conventional medical degree program. However, the Commission encourages the further exploration of opportunities to pilot the use of portions of the conventional medical exam for applicants of naturopathic licensure.

Finally, while the Commission encourages the use of a uniform national naturopathic licensing exam, it also recommends that the naturopathic licensing board be given sufficient latitude to develop or adopt an alternative exam should it become necessary.

10. Continuing Education

The Commission recommends that the licensing legislation for naturopathic doctors contain specific continuing education requirements that must be met in order to renew that license.

While the merits of continuing education requirements in licensure laws have sometimes been questioned, the majority of the Commission believes that the value of ensuring continuing competency and enhancing the skills of the practitioner after initial licensure has been granted applies with as much force to naturopathic health care providers as it does to other types of health care professionals. Requiring continuing education as a condition for renewal may promote the development of better mechanisms for disseminating such information.

11. Regulatory Authority

The Commission recommends that the licensing legislation for naturopathic doctors grant

broad authority to the licensing board to develop and implement any regulations necessary to protect the public health, safety and welfare.

Licensure statutes in other fields have varied in the scope of the regulatory authority granted to the licensing board. Because of the broad range of diagnostic and therapeutic approaches within naturopathy, the majority of the Commission members believe that the regulatory power granted to the licensing board should be equally expansive and flexible. A standard similar to that established for the Board of Registration in Medicine (“The board shall, after proper notice and hearing, adopt rules and regulations governing the practice of medicine in order to promote the public health, welfare, and safety ...”) would be an appropriate model.

12. Grounds for Disciplinary Action

The Commission recommends that the licensing legislation for naturopathic doctors contain specific grounds for taking disciplinary action against providers who engage in certain forms of professional misconduct and violations of regulations of the board.

As with all professional licensing legislation, the regulatory body must be given the authority to take disciplinary action against licensees who engage in certain forms of inappropriate conduct. At a minimum, the Commission believes that the regulatory authority should be empowered to take disciplinary action against licensees for: (1) fraud, deceit or misrepresentation of facts in connection with any application for licensure; (2) fraud, deceit or misrepresentation of facts in connection with the diagnosis, evaluation or treatment of any patient; (3) fraud, deceit or misrepresentation of facts with respect to the provider’s qualifications, training or certifications; (4) engaging in a sexual relationship with a patient (including attempting to induce a patient to engage in a sexual relationship with the provider by falsely representing that such behavior will be of clinical benefit to the patient); (5) failure to refer a patient to a conventional medical physician or other properly qualified health care practitioner when such a referral is warranted by accepted standards of professional naturopathic practice; (6) conviction of any criminal offense which reasonably calls into question the provider’s fitness to practice; (7) unlawful discrimination in the availability or provision of services to a patient; and (8) violation of any rule or regulation adopted by the licensing authority. In addition, the Commission believes that the licensing authority should be given broad authorization to add other grounds for disciplinary action in order to protect the public interest. The Commission also recommends that the range of disciplinary sanctions available to the regulatory authority be as broad as possible, including license revocation, suspension or denial; probation; reprimand; restitution; supervision of practice; additional continuing education; and authority to seek injunctive relief against unlicensed practitioners.

13. Practice Review/Annual Report

The Commission recommends that the naturopathic licensing board establish a list of prohibited practices and treatments where controlled clinical trials have demonstrated a lack of efficacy or a risk of harm. The Commission also recommends that the legislature establish a list of prohibited practices for those practitioners who do not fall under the terms of this proposed act. The Commission further recommends that the naturopathic licensing board, in collaboration with the Department of Public Health and the Office of Consumer Affairs and Business Regulation, review annually research reported or conducted by the National Center for Complementary and Alternative Medicine of the National Institutes of Health and other CAM centers. The findings should be reported to the Joint Committee on Health Care.

While many “natural” healing practices have a traditional basis and have demonstrated some benefit, others may be harmful—especially when taken with other substances—and may require greater regulatory scrutiny. For example, the federal Food and Drug Administration has warned that clinical studies have shown that St. John’s wort may have a negative interaction with certain prescription drugs, leading to potentially serious complications in the treatment of some illnesses. Hence, the naturopathic licensing board should prohibit a naturopathic doctor from recommending St. John’s wort and other products and remedies when their use is contraindicated.

Finally, evidence presented to the Commission shows that the science supporting naturopathic medicine is evolving and demand for treatment is increasing. Many treatments are based on the accumulated clinical experience of a broad array of complementary and conventional medical practitioners. More scientific research needs to be done to study the effectiveness of these treatments. In particular, new research conducted under the auspices of the National Center for Complementary and Alternative Medicine of the National Institute of Health and other CAM centers is vital to the broader acceptance and development of naturopathic medicine. The Commission believes that the naturopathic licensing board, in conjunction with the Office of Consumer Affairs and Business Regulation and the Department of Public Health, should conduct an annual review of the research reported or conducted by the various centers of complementary medicine in order to increase public awareness and understanding of the practice of naturopathic medicine. The review should include procedures and treatments contained within the scope of practice of naturopathic doctors as defined by the enabling act.

PART V: SUMMARY AND CONCLUSION

In its study of naturopathic medicine, the Commission draws the conclusion that naturopathic medicine is part of a growing trend of complementary and alternative health care options that are being utilized by consumers.

If delivered by well-trained practitioners, modalities employed by naturopathic doctors may be successful in treating a variety of health conditions. However, at the same time, those practitioners who are unqualified and delivering substandard care pose a threat to public safety and welfare.

Because naturopathic medicine is such a broad field and training in the practice can currently be obtained by various means, the Commission agrees that a distinction between those educated at accredited universities and those who obtain their training through correspondence courses should be made. Consumers would benefit from government clarification of minimum standards of professional qualifications and practice in this field by licensing naturopathic doctors under a title protection act.

While the Commission was able to look at naturopathic medicine, there are many other modalities that require further study and research in order to explore more fully their implications in the Massachusetts health care market. We hope that this report and the evaluation criteria developed will be useful for further study of these issues.