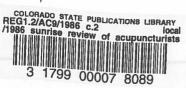
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DEPARTMENT OF REGULATORY AGENCIES Office of the Executive Director Wellington E. Webb, Executive Director

# STATE OF COLORADO

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Richard D. Lamm Governor

## **1986 SUNRISE REVIEW OF ACUPUNCTURISTS**

SUMMARY OF FINDINGS AND RECOMMENDATIONS

#### Recommendations

The Department of Regulatory Agencies has evaluated the proposal for licensure of acupuncturists. The evaluation criteria, according to 24-34-104(4)(b), C.R.S., are the following:

- (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and
- (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

The department recommends that acupuncturists be licensed. Several regulatory alternatives, along with positive and negative implications of each, are outlined in this report.

#### Findings

- 1. A 1976 opinion of the attorney general to the chiropractic board stated that acupuncture constitutes the practice of medicine, so chiropractors could not practice it.
- Most acupuncturists are not medical doctors (M.D.s) and many are practicing without the supervision of M.D.s.
- 3. Few, if any, medical schools or dental schools teach courses in acupuncture.
- 4. Chiropractors who meet chiropractic board requirements may use acupuncture.
- 5. Several kinds of physical harm can result from improper acupuncture procedures, including infection, puncturing nerves, tendons, blood vessels or organs or lungs.

- Traditional acupuncture is based upon concepts separate from Western medicine.
- 7. Requiring physician supervision is difficult as few physicians have any acupuncture training.
- 8. Cost of licensure per licensee would be high, at least initially, due to the small number of practitioners.
- 9. There appears to be no consensus on the appropriate entry level standards.

#### BACKGROUND

# Scope of Practice and Historical Perspective

According to the Acupuncture Association of Colorado (AAC) sunrise application, acupuncture is "the adjustment of body energy by the use of fine needles, heat or electrical devices to treat energetic imbalances for the maintenance of health and the relief of pain and discomfort." Its origins and underlying principles are separate from Western medicine which has resulted in significant skepticism by the U.S. medical community about its value.

One article describing acupuncture's potential for the behavioral sciences summarizes the history and underlying principles as follows:

No one knows exactly how or when acupuncture was first discovered, although there is evidence which suggests that it originated in China at least 5,000 years ago. The earliest writings about acupuncture are in the <u>Nei Ching</u> (The Yellow Emperor's Classic of Internal Medicine), the world's oldest known medical treatise. Compiled during the 2nd century B.C., it is thought to be a documentary collection of medical knowledge acquired over several hundred years. The <u>Nei Ching</u> provides a summary of the Chinese people's knowledge of anatomy, physiology, pathology, diagnosis, and treatment of various disorders at the time of compilation. It contains a detailed description of the methods of acupuncture and moxibustion, and lists nine different types of metal needles and 365 loci on the human body where acupuncture and moxibustion may be applied.

. . . According to traditional Chinese medicine, a vital force or 'Ch'i' energy circulates through the body along channels or 'meridians' on which the acupuncture loci lie. Since this energy controls the blood, nerves, and all organs, it must flow freely if health is to be maintained. If the flow of this energy is impaired . . . illness ensues. By inserting needles into the appropriate acupuncture loci, the skilled practitioner can restore the balance of this energy (according to traditional theory), thereby encouraging the body's intrinsic defenses to combat the disease.<sup>1</sup>/

<u>1</u>/Bresler, D.E., Cohen, J.S., Kroening, R., Levin, N., and Sadoff, A., "The Potential of Acupuncture for the Behavioral Sciences," <u>American</u> Psychologist, March 1975, pp. 411-412. Recent popularity in the use of acupuncture was generated beginning with the 1972 article by James Reston of the <u>New York Times</u>, reporting on his successful treatment for post-appendectomy pain by acupuncture during former President Richard Nixon's trip to China. However, acupuncture was advocated in the U.S. as early as 1836 in the <u>Southern Medical and Surgical Journal</u> and in 1897 in the <u>Journal of the American Medical Association.</u><sup>1</sup>/ The current official position of the American Medical Association (AMA), adopted in 1981, is that the practice of acupuncture in the United States is an experimental medical procedure and should be performed only in a research setting by a licensed physician or under the direct supervision and responsibility of a physician. (According to a representative of the AMA, the association's delegates may review that resolution in the near future.)

Although there are several traditions of acupuncture -- Chinese, European, Japanese, Korean and Vietnamese -- the traditional practice of acupuncture generally involves pulse diagnosis (checking 12 pulses rather than just one pulse used by Western doctors), tongue diagnosis and other observations. Traditional acupuncturists attempt to treat the system associated with a pulse, instead of treating particular symptoms as is commonly the approach of Western medicine. The treatment approach of traditional acupuncturists may also be more tailored to individual patients' needs than is the approach of other types of practitioners. (Some acupuncturists use Western diagnosis and acupuncture treatment.)

Acupuncture needles can be gold, silver or stainless steel and are approximately 1/2 to 4 or more inches in length and vary in thickness from 26 to 32 gauge. The length of the needle, the depth of the insertion and the duration of the individual treatment vary with the nature of the illness. The number of needles used and the number of patient visits needed also varies. The angle at which a needle is inserted varies from approximately 12 to 90 degrees depending upon the thickness of the underlying musculature and how near the skin surface are vital organs.

Once a needle is inserted, it may be twirled to stimulate the point. Electro-acupuncture may also be used to provide this stimulation by connecting the needles to a low-level electric current.

Moxibustion is often used along with acupuncture to stimulate a point. Moxibustion consists of the application of burning moxa (made of a dried plant called mugwort) either directly to or near the skin. When the patient feels intense heat, the moxa is removed to prevent burning or scarring of the skin.

## Research on Acupuncture

In addition to its effectiveness as an analgesic (reducing the perception of pain), a 1974 report notes it "is most effective in the disorders associated with skeletal muscle spasm, and with visceral muscle spasm such as

1/Riddle, Jackson W., "Report of the New York State Commission on Acupuncture," American Journal of Chinese Medicine, Vol.. 2, No. 3, pp. 291-292, 1974. dysmenorrhea and diarrhea. Other conditions frequently alleviated by or improved by treatment are: trigeminal neuralgia, hypertension, hypotension, chronic bronchitis, bronchial asthma, withdrawal symptoms in drug addicts, headaches (both migraine and tension), arthritis (particularly osteoarthritis), insomnia, constipation, dysmenorrhea, paralysis following cardio-vascular accidents, disorders with a significant functional component, and post-herpetic neuralgia."1/ (A discussion of research on the effectiveness of acupuncture follows this section.)

Several conditions are frequently mentioned as not suitable for treatment by acupuncture, including acute conditions, such as, cardiac infarction, congenital diseases, cancer, and fractures, among others.

## Research

How does acupuncture work? Some skeptics of the effectiveness of acupuncture contend that it is based on hypnosis or suggestion (a placebo). Another theory that has been largely discounted is the "gate theory" of Melzack and Wall "which suggests that if pain fibers were carrying impulses from an acupuncture site, other impulses could not be received from the painful organ" (from the AMA resolution on acupuncture adopted in 1981).

More recent research in the U.S., the Orient and Europe has examined its relationship to the release of endorphins (chemical substances produced in the brain) and neurotransmitters. Research has shown that acupuncture causes several changes in the body, for example, an increase in white blood cell counts lasting up to several weeks. $\frac{2}{2}$ 

With respect to the view of acupuncture affecting an energy system, as early as 1939 two Soviet scientists discovered a method of observing and photographing living substance in high frequency electrical field. This Kirlian photography technique and later experiments led a Soviet doctor to link acupuncture and energy flow in 1953. In 1968, Soviet scientists at Kirov State University stated that all living things have both a physical body and a counterpart energy body. 3/

Other studies have examined the relationship between trigger points recognized in Western medicine and acupuncture points. (A trigger point is any place on the body that, when stimulated, causes a sudden pain in a specific area.) Despite the fact that they are derived from totally different concepts of medicine. one study found a

<u>l</u>/Riddle, p. 297,299.

<u>2</u>/Skoler, Michael J., "Acupuncture: An old art coming of age in America?," Medical World News, May 14, 1984, pp. 50-51.

<u>3</u>/Worsley, J.R., Dr..Ac.(China), <u>Is Acupuncture For You?</u>, Harper and Row, Publishers, 1973, pp. 41-47. correspondence of 71 percent in terms of spatial distribution and associated pain pattern.

There is still no consensus as to the mechanism by which acupuncture operates.

Effectiveness. There have been numerous reports from China since the early 1970's regarding the effectiveness of acupuncture with a wide variety of medical conditions from deafness to schizophrenia. The documentation of such successes is often without the type of information and controls associated with formal scientific research.

However, these same weaknesses are shared by Western studies of the effectiveness of acupuncture and, in fact, controls, such as, double-blind studies cannot be used. Scientists have agreed for years that double-blind studies using randomly distributed placebos are the best approach to use with drug evaluation studies. This methodology is based on two concerns: 1) it is crucial that patients remain ignorant of whether they are getting the placebo or the real drug; and 2) the clinician giving the treatment must be equally as ignorant of this as the clinician's expectations can affect the outcome.

However, if the clinician in an acupuncture study is ignorant of whether the treatment is being given at real acupuncture points, then it is an untrained person who is not likely to treat properly. Another one of the many potential problems is that, if sham acupuncture points are used as a placebo, they may not be the best points but may still have some effect. Therefore, they would not actually be placebos. (Approximately 1,500 points outside the 12 meridians are considered effective extra-meridian odd points by modern Chinese texts. $\frac{2}{}$ )

The results of controlled and uncontrolled studies on the effectiveness of acupuncture include the following:

 In controlled studies evaluating the short-term effectiveness of acupuncture in relieving clinical pain from headaches, back pain and other chronic pain, the proportion of patients helped has varied from 50 to 80 percent, compared with the 30 to 35 percent of patients who normally benefit from placebos.<sup>3/</sup>

2) Over 90 percent of the patients properly treated in a New York

1/Melzack, Ronald, Stillwell, Dorothy M., and Fox, Elizabeth J., "Trigger Points and Acupuncture Points for Pain: Correlations and Implications," Pain, 3(1977), p. 3.

<u>2</u>/Skoler, p. 53.

<u>3</u>/Richardson, P.H. and Vincent, C.A., "Acupuncture for the Treatment of Pain: a Review of Evaluative Research," Pain, 24(1986), p. 35. University College of Dentistry study using acupuncture analgesia were totally successful, requiring no supplementation of it. $\frac{1}{2}$ 

 Patients with post-herpetic neuralgia (pain along a nerve) were successfully treated by acupuncture in 75 percent of the test cases.<sup>2</sup>/

## Current Legal Status/Regulation

Colorado. A 1976 opinion of the attorney general concluded that acupuncture constituted the practice of medicine and it was, therefore, unlawful for it to be practiced by chiropractors. The conclusion was based upon two factors.

First, it was considered to be surgery because it involved piercing the skin and chiropractors cannot practice surgery. Second, "[u]se of acupuncture to relieve pain or alleviate pain in connection with chiropractic adjustment appears to be prohibited by the statute as the administration of an anesthetic." (Journal articles regarding acupuncture generally refer to it as an analgesic rather than an anesthetic.)

The opinion did not cover acupuncture comprehensively by specifically stating whether it could or could not be used by other health care practitioners, such as, nurses, dentists, podiatrists and veterinarians. The State Board of Nursing considers any invasive procedure, which would include acupuncture, to be part of the practice of medicine rather than an independent nursing function, so acupuncture could be practiced by a nurse trained to do so only as a delegated medical task.

Presumably, dentists could use acupuncture as an analgesic or to treat conditions they are authorized to treat, if they are trained in its use. Podiatrists, who are allowed to use local but not general anesthetics, may also be allowed to use it in specific circumstances, if trained. Veterinarians, who operate under a practice act equivalent to the medical practice act, could practice acupuncture on animals. None of these issues have been specifically addressed through an opinion of the attorney general or other formal legal means.

In addition, the relevance of the 1976 opinion is questioned given the legislation passed in 1985 to allow chiropractors to practice acupuncture if they meet training standards established by the State Board of Chiropractic Examiners. (The chiropractic board rules require chiropractors practicing acupuncture to either: 1) have a combined total of 85 hours of theoretical study and supervised clinical instruction, five years of clinical experience, and 100 cases involving acupuncture which were managed by the chiropractor; or 2)

<u>l</u>/Riddle, p. 298.

<u>2</u>/Riddle, p. 299.

have 120 hours of theoretical study, 20 hours of supervised clinical instruction, and 25 cases involving acupuncture which were managed by the chiropractor. Although the board was not authorized to require separate certification for chiropractors practicing acupuncture, it has initiated a certification process by rule. No chiropractors are yet certified but some are advertising themselves as state licensed acupuncturists.)

The Colorado State Board of Medical Examiners and its legal counsel maintain that the practice of acupuncture is the practice of medicine. So, unlicensed persons practicing acupuncture must be registered as physician extenders with particular physicians. (Physicians may supervise only two such persons without a variance from the board, according to medical board rules.) Unlicensed, unregistered acupuncturists are committing a crime, as practicing medicine without a license is a crime in Colorado.

No cases have ever been heard by any of the Colorado health care licensing boards regarding acupuncture, nor have there been Colorado court cases of which the department is aware.

Federal. Since September 1972, the federal Food and Drug Administration has maintained that acupuncture devices should be restricted to investigational use by licensed or medical and dental practitioners and that the labeling for devices must include that and other information. In March of 1973, it officially announced that the FDA regards as misbranded any acupuncture device shipped interstate which does not include the labeling information required for investigational use devices or is accompanied by claims of diagnostic or therapeutic effectiveness ("Acupuncture Device Labeling," Federal Register, Vol.. 38, March 9, 1973, p. 6419). (Although acupuncture devices are still designated as investigational, the FDA is not placing a high priority on enforcing acupuncture claims.)

Other states. According to the Traditional Acupuncture Institute which publishes updated reports on state acupuncture regulation, there are currently 22 jurisdictions licensing acupuncturists. Thirteen of them allow acupuncturists to practice independently -- California, District of Columbia, Florida, Hawaii, Massachusetts, Montana, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, and Washington. Nine of them require the supervision of a physician or a physician examination prior to acupuncture treatment -- Connecticut, Delaware, Louisiana, Maryland, Pennsylvania, Tennessee, Texas, Utah and Wisconsin.

Licensure requirements vary greatly among these 22 states.

Six of the 22 states use the National Commission for the Certification of Acupuncturists (NCCA) examination discussed on page 9. The other states have developed their own examinations. (Some state practical examinations have been the subject of lawsuits often due to their reliance on techniques not used by all acupuncture traditions.)

<u>Case law.</u> This section does not reflect an extensive search of relevant case law. The department is unaware of any Colorado cases

related to the practice of acupuncture. However, two Texas cases are of interest in identifying some of the legal issues involved in defining the practice of medicine to include the practice of acupuncture.

In 1978, in <u>Thompson v. Texas St. Bd. of Med. Examiners</u> (570 S.W. 2d 123), the Court of Civil Appeals of Texas held that it was within the power of the medical board to regulate acupuncture as the practice of medicine and the fact that acupuncture treatments may not be readily available or may be difficult to obtain was not grounds for holding that unlicensed persons may perform that procedure.

Two years later, in a separate case before the U.S. District Court, S.D. Texas, Houston Division, the federal district court judge held that:

(1) a decision to obtain acupuncture treatment is a constitutional right encompassed by the right of privacy, and (2) provisions of the Texas Medical Practice Act and regulations promulgated pursuant thereto, insofar as they operate to limit practice of acupuncture in Texas to licensed physicians, imposed a burden on and significantly interfered with decision of patient to obtain acupuncture treatment and, absent evidence that they were narrowly drawn to achieve a compelling state interest of protecting patient's health, were unconstitutional. (Andrews v. Ballard, 498 F.Supp.1038 (1980))

The Texas medical practice act was similar to Colorado's in that it included a broad definition of the practice of medicine that did not specifically include the practice of acupuncture. The plaintiffs in this case were 46 residents of Harris County, Texas, who sought acupuncture treatment and maintained that the medical practice act and medical board rules virtually eliminated the practice of acupuncture in Texas and were not necessary to service the state's interest in protecting the health and safety of the patient. (Excerpts from the federal court's decision explaining its basis is attached as Appendix A.)

#### Training Programs

Acupuncture schools. There is a national accreditation organization called the National Commission for the Accreditation of Schools and Colleges of Acupuncture and Oriental Medicine (NACSCAOM) which first met in 1982. There is only one acupuncture school currently certified by NACSCAOM and seven which have been accepted for candidacy for accreditation. The commission's accreditation standards include the following, among other general requirements:

- at least two academic years of general education at the baccalaureate level prerequisite for entry into the professional program;
- 2) the professional program is at least two years in length; and

3) the professional program is a residential program.

The commission points out that there are institutions or programs outside its scope, such as, technical/vocational programs with no general educational requirements, programs offering studies in acupuncture and/or oriental medicine that of themselves do not enable a student to enter the profession, and mail-order programs. In addition, NACSCAOM is in the process of revising its criteria to require a three-year master's program for accreditation.

<u>Medical and dental schools.</u> A representative of the AMA contacted by the department was not aware of any U.S. medical schools teaching acupuncture. However, a recent article stated that UCLA, Columbia, New York University, the University of Pennsylvania, and other schools have sponsored continuing education courses on acupuncture, and that that UCLA and the University of Pennsylvania offer acupuncture as an elective to medical students.<u>1</u>/ The University of Colorado School of Medicine does not offer courses in acupuncture.

The American Dental Association is not aware of any dental schools teaching acupuncture, according to the dentist responsible for accreditation review. The association's official position regarding acupuncture simply encourages further exploration of non-pharmacologic alternatives for anesthesia, including acupuncture. The University of Colorado School of Dentistry does not offer courses in acupuncture.

Chiropractic schools. The Colorado State Board of Chiropractic Examiners surveyed all approved chiropractic schools in the U.S. inquiring whether their coursework included acupuncture. According to the board staff, very few of the schools offer such training. There are no chiropractic colleges in Colorado. However, persons interviewed said that short courses designed to meet the board's standards are available in Colorado.

#### Private Credentialling

The NCCA has developed a national certification process which allows certified acupuncturists to designate themselves as "Diplomate in Acupuncture of the National Commission for the Certification of Acupuncturists," abbreviated as "Dipl. Ac.(NCCA)," or "National Board Certified (NCCA)." The only national acupuncture examination is given by the NCCA.

Persons certified by NCCA are required to pass the written examination, successfully complete the NCCA clean needle technique course (and its written and practical examination), and subscribe to the national code of ethics for acupuncturists. To be eligible to take the examination applicants must be at least 18 years of age, and either be state licensed, have four years of acupuncture practice with a minimum of 500 patient visits per year, have two years of full-time

1/Skoler, p. 61. The second should show hid the bar second second in the second sec

acupuncture schooling or have four years of apprenticeships. Other combinations of education and experience are also acceptable. (See Appendix B for specific eligibility criteria.)

The examination includes both a written test and a clinical course. The commission contracted with the Professional Examination Service (PES) to develop the written test which was first given in March 1985. In general, the test covers the following areas: information gathering (patient history), information analysis, energetic evaluation, treatment planning, treatment, treatment evaluation, and professional issues.

The examination is based upon a job analysis and the passing score for the most recent examination was set on the basis of minimal competence rather than arbitrarily set.

The clean needle technique course was designed by NCCA to be educational rather than as a test. (In fact, although there is a short written quiz and practical demonstration administered following the course, applicants may retake them in a single day until they pass which violates test security and clearly is not an accepted examination practice.)

Currently, six states -- Hawaii, Maryland, New Jersey, New York, Pennsylvania and Utah -- use the NCCA examination and clean needle technique course for licensure. New Mexico is considering using it if it is tailored to fit the New Mexico licensure requirements.

## Insurance

A 1981 report by the AMA stated that most private insurance carriers will pay for acupuncture if prescribed or performed by a physician - with the exception of Blue Cross and Blue Shield. 1/ Blue Cross and Blue Shield of Colorado confirmed that it will not pay for any acupuncture treatment. However, in some states in which a physician examination is not required, for example, New Mexico, acupuncture is covered without a physician's prescription.

Neither Medicaid nor Medicare reimburses for acupuncture treatment.

[The IRS has included acupuncture treatment as an allowable medical deduction since 1972 (IRS Rev. Rule 72-593, 1972-2CB180)].

## PUBLIC HARM

Although there appear to be few documented serious complications, there is agreement within the health care community regarding the potential for patient harm by persons practicing acupuncture. In addition to fraud that can accompany any business transaction, physical harm can result from incompetent acupuncture or from the use of needles that are not sterile.

Incompetent treatment can result in any of the following: 1) puncture of vital organs, such as, the heart, lung, liver, spleen, kidney,

brain or spinal cord (AAC has documentation of two Colorado cases involving puncture of a lung and kidney), 2) irreversible nerve damage, 3) bleeding from punctured blood vessels, and 4) burning from improper use of moxibustion.

The use of needles that have not been properly cleaned and sterilized can cause the spread of infections to patients or the practitioner (if a needle accidentally punctures the practitioner's skin). Many viral and bacterial infections may spread but some of the most serious are hepatitis, acquired immune deficiency syndrome (AIDS), influenza, herpes viruses, mumps, measles, streptococcus, syphilis, respiratory infections and tuberculosis. (According to the state Department of Health, there is no evidence of AIDS infection through acupuncture needles, but theoretically the potential exists.)

Although no one interviewed during this review was aware of any deaths resulting from acupuncture, a death resulting from heart damage by an acupuncture needle (cardiac tamponade) was reported in 1965.1/

COST

The cost of regulating acupuncturists is difficult to assess given the unclear legal status of acupuncture now. Some trained acupuncturists are practicing as physician extenders, while others are practicing, apparently illegally, without physician supervision.

If they were to be licensed under a newly created licensure board, given an estimated cost of over \$30,000 and a maximum of only 50 practitioners, each acupuncturists would be assessed an annual fee of \$600. Such a high fee would certainly be passed on to patients.

If a two-year education were required, it would have to be obtained outside the state. (The nearest schools are in New Mexico.) The AAC proposes the use of the NCCA requirements for education and experience.

These and other considerations are discussed in the section on Regulatory Alternatives (see page 12).

BENEFITS

Occupational regulation generally restricts rather than enhances competition. However, in the case of acupuncture in which it is currently considered to be part of the practice of medicine, yet is not being practiced by medical doctors, allowing other groups to practice could increase its availability.

In at least one state, Maryland, licensure has attracted practitioners to the state so the number of acupuncturists increased from 15 to 115 in three years.

<u>1</u>/Bonica, John J., M.D., "Therapeutic Acupuncture in the People's Republic of China - Implications for American Medicine," Journal of the American Medical Association, June 17, 1984, Vol.. 228, No. 12, pp. 1544-1551. Certainly many acupuncturists themselves would clearly benefit by state regulation allowing them to practice independently and to be designated as state-approved.

The extent to which the public would benefit also depends upon the public's demand for the service. The department has no evidence the demand of Colorado citizens for the services of acupuncturists is either increasing or decreasing.

## REGULATORY ALTERNATIVES

Several regulatory approaches to the practice of acupuncture are described below, along with the positive and negative aspects of each approach.

## Clarify Law to Specify That Acupuncture Is the Practice of Medicine

As part of the practice of medicine, other persons can practice as physician extenders registered with the board. As stated previously, some acupuncturists are currently registered and under the supervision of a physician. There are four problems with this approach:

- Traditional acupuncture is based on different principles than is Western medicine.
- Some acupuncturists have found it difficult to find physicians willing to supervise them and, therefore, allow them to register as physician extenders.
- 3) Physician extenders are allowed to do delegated medical tasks. Implicit in the law is that physicians can delegate and supervise only those tasks in which they are trained and few physicians have any training in acupuncture.
- 4) The federal district court case in Texas (see Appendix A) points out the potential for successfully challenging such a regulatory scheme on constitutional grounds.

## Licensure, Certification, or Registration

Several regulatory alternatives to current Colorado law are possible. Various components of licensure, certification or registration are discussed below. (Licensure is defined here as title protection and scope of practice protection; certification is title protection only; and registration allows anyone to practice but requires all practitioners to register.) Each of the three regulatory schemes could allow the regulating agency to take disciplinary action against an acupuncturist.

Licensure would be the most restrictive approach, which presumably, would allow only qualified acupuncturists and other qualified licensed practitioners to practice. Given the scope of practice of most acupuncturists a certain degree of competence in diagnosis and treatment appear to be necessary. Certification of acupuncturists would be less comprehensive than registration or licensure, as certification, by definition, allows uncertified persons to practice. They could not call themselves "acupuncturists," unless they were certified. So, persons without any training could legally practice acupuncture under certification.

Registration would allow anyone to practice or call themselves "acupuncturists." So, both certification and registration of acupuncturists would clearly be less restrictive.

Education/training requirements. As stated previously, state Ticensure requirements vary significantly among states currently licensing acupuncturists. For example, in addition to other requirements, Rhode Island requires that they complete an approved course and have practiced for ten years. Montana requires completion of a board approved program but has no experience requirement.

The Colorado chiropractic board requires a maximum of 120 hours of courses for chiropractors to use acupuncture as an adjunct procedure. Other state licensing boards have no standards for it.

The NCCA provides a variety of education and training alternatives. Obviously, there is no consensus as to the minimal training necessary to practice acupuncture in the United States.

Examination. If the Colorado General Assembly were to require acupuncturists to pass an examination, it would have a number of options. These include:

- Require a written exam only (the NCCA exam, a Colorado developed exam, or contract to use another state's exam)
- -- easier to validate than a practical;
- -- can demonstrate knowledge of how to diagnose and treat;
- -- does not demonstrate ability to apply knowledge as well as a practical;
- -- use of NCCA exam could facilitate licensure process as it is the only national exam.
- Require a practical exam only (Colorado developed or contract with another state)
- -- no national exam available;
- -- the difference among the various traditions of acupuncture may make practical exams more vulnerable to lawsuits;
- -- demonstrates ability to apply knowledge.
- 3) Require a written and practical exam

-- can demonstrate knowledge and ability to apply it;

-- a practical exam may be vulnerable to lawsuits.

The legislature could let the regulating agency decide whether to develop a new examination or contract to use one that is already developed. Test development is a very expensive process.

<u>Regulatory agency</u>. There are a number of alternative agencies to regulate acupuncturists. The four options discussed below are the most logical or most frequently mentioned options.

- Create an acupuncture board. A separate board for such a small group of practitioners is uncommon and costly. On the other hand, it would allow persons with knowledge of acupuncture to be part of the regulatory process.
- 2) Board of medical examiners. The medical board members already work approximately 26 days per year so any additional responsibility would be an undue burden. It is unlikely that any of the board members have knowledge or training in acupuncture. In addition, if an acupuncture advisory committee were established, it would create a cumbersome process with more opportunity for procedural error. All such errors allow disciplinary decisions to be overturned on technical grounds.
- 3) Division director. A process could be established similar to the new regulatory scheme for physical therapists. Giving such policy-making authority to one individual is a negative aspect of this approach. The director would definitely need to be authorized to use advisory groups of acupuncturists.
- Executive director. The major advantage of this option over the last one is that this person is one step closer to the governor in terms of public accountability.
- 5) Department of Health standards. Although most occupational regulation is within the Department of Regulatory Agencies, the state Department of Health could be responsible for developing an exam or setting standards regarding necessary needle sterilization and cleaning processes. This could be a part of any regulatory scheme.

Status: independent vs. physician referral vs. prior physician examination vs. physician consultation. Another issue in which there is no uniformity among states is whether licensed acupuncturists are totally independent practitioners or if there must be some type of involvement by physicians. That involvement could include requiring a physician's referral, requiring a patient examination by a physician prior to treatment, or requiring a physician to be consulted in certain circumstances.

Independent practice and selective consultation appear to be the most cost effective approaches for patients. The other two options would force them to pay for an examination by a physician in addition to

acupuncture treatment. Furthermore, referral would prohibit patients who wanted to see an acupuncturist from doing so unless his or her physician supported the decision and, therefore, referred them. Also, patients who use chiropractors as their primary health care practitioner would be forced to be examined by a medical doctor prior to treatment by an acupuncturist.

Scope of practice. Another area of variation among the states, at least according to the statutes if not in actual practice, is the defined scope of practice. Two examples given below exemplify those differences:

Washington -- "Acupuncture means a health care service based on a traditional Oriental system of medical theory utilizing Oriental diagnosis and treatment to promote health and treat organic or functional disorders by treating specific acupuncture points or meridians. Acupuncture includes but is not necessarily limited to the following techniques:

(a) Use of acupuncture needles to stimulate acupuncture points and meridians:

(b) Use of electrical, mechanical, or magnetic devices to stimulate acupuncture points and meridians;

- (c) Moxibustion;
- (d) Acupuncture; (e) Cupping;
- (f) Dermal friction technique (gwa has);
- (g) Infra-red;
- (h) Sonopuncture;
- (i) Laserpuncture:
- (j) Dietary advice based on traditional Chinese medical theory; and (k) Point injection therapy (acupuncture )."

Montana -- "Acupuncture means the treatment of the human body by means of mechanical, thermal, or electrical stimulation effected by the insertion of solid needles."

Exemptions. Some states specifically exempt physicians only; others do not exempt anyone; others exempt physicians and other types of practitioners. For example, Montana law states, "Nothing in this chapter shall be construed to require doctors of medicine, osteopathy, chiropractic, dentistry, and podiatry who are licensed in Montana to take further examinations in anatomy, physiology, chemistry, dermatology, diagnosis, bacteriology, material medica, or other subjects which are or may be required for licensure in their respective professions; but no doctor of medicine, osteopathy, chiropractic, dentistry , or podiatry shall practice acupuncture in this state unless and until he has completed a course and passed an examination in acupuncture as required by this chapter."

New Jersey statute states, "Nothing in this act shall be construed to prevent the practice of acupuncture by a person licensed as a physician and surgeon or dentist, provided his course of training has included acupuncture."

Disclosure of information. Mandatory disclosure of each practitioner's qualifications could be an important informational tool. Such disclosure could be especially beneficial if various groups of practitioners, such as chiropractors and acupuncturists, were practicing with very different qualifications.

## Recommendations

Acupuncturists should be licensed in Colorado to increase the availability of legal acupuncture treatment for consumers, while establishing entry requirements to ensure minimal competency. Although the department does not generally support regulation by one person, the small number of acupuncturists currently in Colorado argues for the Director of the Division of Registrations to administer the statute initially.

If licensure were adopted, whether or not passing an examination were required would be a major issue in terms of costs (especially high if the state developed its own). Entry requirements could include passing a written examination on the practice of acupuncture and either taking an approved course or an examination on proper sterilization techniques. Rather than establish additional training standards, the NCCA written examination (excluding the professional issues portion of the test and the training/education/licensure requirements used by the NCCA for certification) could be used to establish minimal competency. The state would not determine the path persons would use to become competent. It would simply require them to pass the examination.

It could also require licensed acupuncturists to develop a written plan for consultation, emergency transfer, and referral to other health care practitioners, along with mandatory physician consultation or referral when patients have certain disorders.

# APPENDIX A

Excerpts From Andrews v. Ballad 488 F. Supp., 1038 (1980)

Jack ANDREWS et. al., Plaintiffs, v. L. G. BALLARD, D. O., et. al., Defendants.

Proceeding was instituted on constitutional challenge to provisions of the Texas Medical Practice Act and regulations promulgated pursuant thereto. The District Court, McDonald, J., held that: (1) a decision to obtain acupuncture treatment is a constitutional right encompassed by the right of privacy, and (2) provisions of the Texas Medical Practice Act and regulations promulgated pursuant thereto, insofar as they operate to limit practice of acupuncture in Texas to licensed physicians, imposed a burden on and significantly interfered with decision of patient to obtain acupuncture treatment and, absent evidence that they were narrowly drawn to achieve a compelling state interest of protecting patient's health, were unconstitutional.

. . . The plaintiffs are 46 residents of Harris County, Texas, who seek acupuncture treatment. They maintain that the constitutional right of privacy, protected by the Due Process Clause of the Fourteenth Amendment, encompasses the decision to obtain or reject medical treatment and that Articles 4510, 4510a, 4510b, and 4505(12) and (15) and Rules 386.01.12.001-.002 impermissibly deprive them of that right because they (a) virtually eliminate the practice of acupuncture in Texas and (b) are not necessary to serve the State's interest in protecting the health and safety of the patient.

[Rules 386.01.12001-.002 of the Texas State Board of Medical Examiners read as follows:

.001(b) Acupuncture is a procedure which purports to effect cures or treatment of disease, mental or physical disorder, physical deformity or injury and is, therefore, the practice of medicine under the Texas Medical Practice Act.]

. . . Prior to 1974, the Board did not apply these articles of the Medical Practice Act, despite their seeming applicability, to the practice of acupuncture in Texas. In that year, however, according to the testimony of Dr. Max Butler, a member of the Texas State Board of Medical Examiners from 1974 through the present and currently the agency's President, the Board became concerned that the public was being exploited by individuals claiming to be acupuncturists. None of the Board's members, it should be noted, are experts on the theory or practice of acupuncture. After holding hearings at which a "fair number" of witnesses, none of whom were acupuncturists or experts on acupuncture, testified, the Board issued a policy statement on acupuncture. . . . In October, 1975, the Board disciplined two physicians, Dr. Oliver H. Thompson and Dr. Raul Baptista Mascarenhas, for allowing unlicensed individuals to practice acupuncture under their supervision. <u>Thompson v. Texas State Board of Medical Examiners</u>, supra, at 126. Ordering cancellation of the physicians' licenses to practice medicine, it stayed execution of the order and placed the doctors on probation for a period of ten years.

. . On July 27, 1978, the Texas Court of Civil Appeals issued its decision in <u>Thompson v. Texas State Board of Medical Examiners</u>, supra. It rejected the doctor's attack on the Board's December 2, 1974, policy statement and upheld the Board's disciplinary action against Doctors Thompson and Mascarenhas.

. . . The court did not, however, fully discuss all of the doctors' contentions. One argument advanced by Doctors Thompson and Mascarenhas was that the Board's action violated the "right of patients to receive medical treatment of their choosing." Id. at 126. . . That may be because the plaintiffs in <u>Thompson v. Texas State</u> Board of Medical Examiners, supra, were doctors, not patients, or it may be because the court assumed that "the Board ha[d] not precluded any patient from receiving acupuncture treatment." Id. at 129. Whatever the proper explanation, the plaintiffs in the present case are patients, not doctors. They directly challenge the court's assumption.

. . . To the extent that the Court has succeeded in that endeavor, it has done so by establishing that the decisions which will be recognized as among those "that an individual may make without unjustified government interference," <u>Carey v. Population Services</u> <u>International</u>, supra, 431 U.S. at 685, 97 S.Ct. at 2016, must meet two criteria. First, they must be "personal decisions." Id. They must primarily involve one's self or one's family. Second, they must be "important decisions." Id. at 684, 97 S.Ct. at 2015. They must profoundly affect one's development or one's life.

... [D]ecisions relating to medical treatment do not. They are, to an extraordinary degree, intrinsically personal.

. . . Second, it is impossible to discuss the decision to obtain or reject medical treatment without realizing its importance.

. . . The particular treatment decision involved in the present case, the decision to obtain acupuncture, is of equally substantial import.

. . . Thus, the decision to obtain or reject medical treatment, presented in the instant case as the decision to obtain acupuncture treatment, is both personal and important enough to be encompassed by the right of privacy.

. . . To recognize that the decision to obtain acupuncture treatment is encompassed by the right of privacy is not, of course, to end the inquiry. The Court must next determine whether the challenged articles and rules effectively deny the right of privacy by "imposing a burden on," <u>Carey v. Population Services International</u>, supra, 431 U.S. at 686, 97 S.Ct. at 2016, or "significantly interfere[ing] with," <u>Zablocki v. Redhail</u>, 434 U.S. 374, 388, 98 S.Ct. 673, 682, 54 L.Ed.2d 618 (1978), the decision in question. If they do not, then they only need be "rationally related" to a "constitutionally permissible" purpose to pass constitutional muster. Lindsey v. Normet, 405 U.S. 56, 74, 92 S.Ct. 862, 874, 31 L.Ed.2d 36 (1972). If they do, they must be "narrowly drawn" to a compelling state interest," <u>Roe v. Wade</u>, supra, 410 U.S. at 155-156, 93 S.Ct. at 727-728, and cases cited therein, in order to withstand constitutional scrutiny.

There can be little doubt that the articles and rules challenged in the present case "impos[e] a burden on," <u>Carey v. Population</u> <u>Services International</u>, supra, and "significantly interfere[] with," <u>Zablocki v. Redhail</u>, supra, the decision to obtain acupuncture treatment. Plaintiff John Walter testified that he was unable to find a single licensed physician in the State of Texas who was skilled in the practice of acupuncture.

. . . Doctor Max Butler, President of the Texas State Board of Medical Examiners, the agency which promulgated Rules 386.01.12-001-.002 and is primarily responsible for the enforcement of the Medical Practice Act, see: Tex.Rev.Civ.State.Ann. art. 4495, was called by the defense to respond. . . Although fully aware that the instant case was being litigated and that he was likely to be called as a witness, Dr. Butler was unable to name one licensed physician presently practicing acupuncture in Texas. . . Texas medical schools, it should be noted, do not presently offer formal training in either the theory or practice of acupuncture.

. . . [T]he inability of the defendants to produce a single licensed physician presently practicing in Texas who either administers acupuncture or claims expertise in its theory or practice, fully supports the claims of the plaintiffs. This court can only conclude that the challenged articles and rules effectively render acupuncture treatment unavailable in the State of Texas. In practical terms, they not only "burden an individual's right to decide [to obtain acupuncture treatment] by substantially limiting access to the means of effectuating that decision," they essentially "prohibit the decision entirely." <u>Carey v. Population Services International</u>, supra, 431 U.S. at 688, 97 S.Ct. at 2018.

. . . It is not sufficient for the State to show that [the articles and rules in question] further a very substantial state interest. In pursuing that important interest, the State cannot choose means that unnecessarily burden or restrict constitutionally protected activity. . . And if there are other reasonable ways to achieve those goals with a lesser burden on constitutionally protected activity, a State may not choose the way of greater interference. If it acts at all, it must choose "less drastic means." Shelton v. Tucker, 364 U.S. 479, 488, 81 S.Ct. 247, 252, 5 L.Ed.2d 231 (1960).

Although the challenged provisions of the Medical Practice Act would, by their terms, restrict the practice of acupuncture to licensed physicians whatever its safety and effectiveness, the challenged rules, it is important to note, are presumably based upon a finding that "[a]cupuncture is an experimental procedure, the safety [and effectiveness] of which [have] not been established." Tex. St. Bd. of Med. Exam. Rule 386.01.12-001(c). There are a number of problems with this finding. To begin with, it appears to have been based on no evidence. Doctor Butler testified that the Board of Medical Examiners neither has members who are experts on the theory or practice of acupuncture nor heard testimony by or received evidence from any such experts. Moreover, acupuncture has been practiced for 2000 to 5000 years. It is no more experimental as a mode of medical treatment than is the Chinese language as a mode of communication. What is experimental is not acupuncture, but Westerners' understanding of it and their ability to utilize it properly. Finally, as has been discussed, (see p. 1044 supra), all of the evidence adduced before the Court indicates that acupuncture, when administered by a skilled practitioner for certain types of diseases and dysfunctions, is both a safe and effective form of medical treatment. This Court however, need not decide whether the Board's "finding" can be supported. Assuming arguendo that acupuncture is an experimental procedure of unproven safety and effectiveness, this Court must still determine whether the physician-only limitation is "narrowly drawn" to the State's "compelling interest" in protecting the patient's health.

. . . Moreover, it is well advised to protect that interest by assuring that both formally trained and formally untrained practitioners know what they are doing. That, however, is not what Texas has done. It has prohibited the formally trained from practicing, but has allowed the formally untrained, who it admits "are not schooled enough in acupuncture to effectively supervise acupuncturists," Defendants' Post-trial Brief, at 8, to proceed without any showing of skill or knowledge. One court has held that laws limiting the practice of acupuncture to licensed physicians are so ill-conceived that they lack, "a rational relationship to a proper legislative purpose." Wensel v. Washington, supra note 2, at 1173 n.7. This Court need not reach that issue. (See note 2 supra). Whether or not such laws are irrational, they cannot be said to be "narrowly drawn," Roe v. Wade, supra, 410 U.S. at 155, 93 S.Ct. at 728, to the State's interest in assuring that acupuncture is administered properly.

# APPENDIX B

Education/Eligibility Criteria for NCCA Examination

To be eligible for the examination you must earn forty points in any combination of the categories below:

Practice - 10 points per year

Education - (Maximum 20 points per year) Formal full time school (20 points/year)

Correspondence school - (Maximum 20 points)

Self-directed study - 10 points per year (Maximum 20 points)

Apprenticeship - 10 points per year (Maximum 40 points)

State licensure - 40 points

Total required - 40 points

Fractions of years may be claimed in 6 month units. Any length of time between 6 months and one year will be credited as the appropriate number of points for half a year. No smaller subdivisions will be accepted.

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