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An Overview Of Acupuncture

May 1993



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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Division of Life Sciences
C. David Lytle, Ph.D.



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Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

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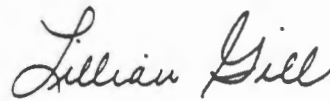
A handwritten signature in black ink, appearing to read "D.B. Burlington". The signature is fluid and cursive, with a long horizontal stroke at the end.

D. Bruce Burlington, M.D.
Director
Center for Devices
and Radiological Health

PREFACE

The Office of Science and Technology provides scientific support in response to the program needs of the Center for Devices and Radiological Health. The Division of Life Sciences within the Office of Science and Technology is responsible for evaluation of biological information relevant to medical devices and radiological health.

As part of the medical device effort, The Health Sciences Branch of the Division of Life Sciences has undertaken an overview of acupuncture. Acupuncture is a health care practice which originated in China and has been offered in the U.S. for more than a century and a half. However, only since the 1970's has it been brought to the attention of the general public. While few carefully-controlled clinical trials have been done which might substantiate claims of efficacy, the understanding of mechanism in Western scientific terms has progressed in recent years. The purpose of this document is (1) to briefly describe the practice of acupuncture, (2) to present an overview of laboratory research results regarding physiological processes underlying acupuncture effects, (3) to present information on clinical trials of acupuncture efficacy, and (4) to describe other aspects of the practice of acupuncture in the U.S.



Lillian Gill
Interim Director
Office of Science and Technology

ABSTRACT

Lytle, C.D. Ph.D., Health Sciences Branch, Division of Life Sciences, Office of Science and Technology, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland 20857 (April 1993) (34 pp.)

After a brief description of the practice of acupuncture, this document provides an overview of acupuncture, including the following: (1) Acupuncture is based on traditional Chinese medicine (the Qi paradigm), which has no direct correlate in Western physiology. (2) Acupuncture is practiced by physicians and non-physicians; more than half the states accept and regulate non-physician acupuncturists. (3) Acupuncture needles are specialized devices, and must be labeled investigational. (4) Most experimental scientific research has focused on analgesia produced by needle stimulation of the nervous system (which increases endorphin and monoamine productions). (5) Conducting human clinical trials for evaluating efficacy is difficult, and such trials have not yielded compelling results. However, clinical trial data favors efficacy for control of pain of different etiologies and for reduction of alcohol recidivism. (6) The annual number of patient visits may be ten million, enough to support the practice of acupuncture at an estimated annual level of half billion dollars. (7) Part of the health care community has accepted acupuncture: (i) the American Osteopathic Association endorses acupuncture, (ii) many health insurance companies, including Medicaid in some states, cover acupuncture treatments, (iii) a few medical schools teach acupuncture, and (iv) the World Health Organization recognizes the utility of acupuncture. (8) The justice system uses acupuncture in the treatment of certain parolees.

As with all therapeutic procedures, acupuncture is not without risk, including infection transmission, punctured organs, and imbedded needle fragments. Those risks can be minimized with adequately trained practitioners and appropriate quality control in the manufacture of acupuncture needles.

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AN OVERVIEW OF ACUPUNCTURE

INTRODUCTION

Acupuncture became a part of the American health care scene when physicians trained in France came to the North American continent in the 1700's and when Oriental practitioners began entering the United States in the mid 1800's. It was accepted by some Western-trained physicians and became part of classical medical textbooks: H. Gray's Anatomy, Descriptive and Surgical states "The sciatic nerve ... has been acupunctured for the relief of sciatica." (1901 edition, page 798) and W. Osler's The Principles and Practice of Medicine states "For lumbago acupuncture is, in acute cases, the most efficient treatment" and for sciatica "Acupuncture may be used" (included in the first edition, 1892, and continued in subsequent editions through the sixteenth edition, 1947). However, only since relations with China reopened in the early 1970's has acupuncture come to the attention of the general American public. Wolpe (1985) has written an evaluation of the response of the U.S. medical community to the introduction of acupuncture during and following that period. Today, acupuncture is practiced by some physicians and, in many states, by non-physicians as well.

In 1973, the Commissioner of the Food and Drug Administration announced that the devices used in acupuncture, e.g., the specialized needles, electrical stimulators and associated paraphernalia, were considered investigational (Gardner, 1973; Davis and Yin, 1973). At that time "the safety and effectiveness of acupuncture devices [had] not yet been established by adequate scientific studies to support the many and varied uses for which such devices are being promoted, including uses for analgesia and anesthesia" (Gardner, 1973). In the Food and Drug Administration today, acupuncture devices, including needles, remain as investigational medical devices; no scientifically-convincing data have been presented to the FDA's Center for Devices and Radiological Health (or to the former Bureau of Medical Devices) demonstrating efficacy for any acupuncture device for any medical indication. As a result, all domestic and imported acupuncture devices must be labeled as investigational and may not be advertised or in any way promoted. Domestic manufacturers and importers of acupuncture devices are "responsible for assuring that the distribution of such devices is to a sponsor or investigator or other person involved in a lawful investigation" (FDA Compliance Policy Guide #7124.11, 9/24/87).

Despite the investigational status of the devices, acupuncture is becoming increasingly more evident in health care practice in the United States. For example, nearly half the states have governing bodies which regulate acupuncture within those states, and many health insurance companies cover acupuncture treatments. An increasing number of research articles are being published in scientific and medical journals. There are now several acupuncture schools in the United States, plus courses at several medical schools.

WHAT CONSTITUTES THE PRACTICE OF ACUPUNCTURE

To establish a common background from which to discuss acupuncture, the practice of acupuncture will be briefly described. Acupuncture is practiced with many variations throughout the world. The emphasis in this document will be on the variations most commonly found in the U.S.

Acupuncture is the insertion of acupuncture needles at specific points on the body to correct/balance physiological processes. The points of insertion are called acupuncture points. Acupuncture literature identifies hundreds of such points on the skin, which the practitioner locates by anatomical reference and palpation.

Acupuncture Needles

Acupuncture needles are typically thin and solid (i.e., not hollow as are hypodermic needles). They are made of several materials, with the needle portion being of various lengths and thicknesses. The most common material for the needle is 18-8 stainless steel, which is essentially comparable mechanically to the ASTM 316L surgical stainless steel. The needle portion may be 0.5-3 inches (15-75 mm) long and 0.16-0.35 mm thick (# 00-# 10 Japanese gauge or 36-28 Chinese/English gauge). The handle portion may be solid metal, wound wire, or plastic tube. Other, special-use needles include the Press Needle (shaped somewhat like a thumbtack, with a needle length of 1.3-1.8 mm and a top diameter of 2.8 mm) and the Intradermal Needle (for horizontal needle placement with a 1-1.5 mm flat, circular head). These special needles are made from one piece of metal and are commonly held in place with surgical-type tape. Other special-use needles include ones made of precious metals, e.g. gold or silver. Although most needles are sold as disposable and are packaged individually, only the type with the plastic handle cannot be resterilized (by steam heat).

Disposable needles are packaged either individually or in bulk packages of 2, 5, 10 or 50 needles per package. Bulk packaging may be desirable to the practitioner, since 5-10 or more needles may be used in quick succession during a single patient treatment. When sold, most types have been sterilized with ethylene oxide (EtO); some with 2.5 Mrad gamma rays.

The following information from one distributor¹ of acupuncture needles (OMS Medical Supplies, Inc., Weymouth, MA) may be representative of the market for these devices in the U.S. Most of the acupuncture needles (99%) they sell are made of 18-8 surgical grade stainless steel. Disposable needles are marketed at \$0.05-0.14 each. The three major sources are Japan, China and Korea. Other countries that manufacture acupuncture needles are Taiwan, France and Germany. This distributor estimates that 90% of the U.S. market consists of disposable needles, with some (30- 40%) of those "disposable" needles being reused for subsequent visits by the same patients. A poll taken at the 1990 meeting of the American Association for Acupuncture and Oriental Medicine (AAAOM) indicates that 80-85% of the attending acupuncturists use disposable needles, while 25-30% use reuseable needles (AAAOM, 1990).

Three qualities are important for acupuncture needles. (1) They must be strong enough to withstand proper use. If they are reused, they must be able to withstand (without significant material fatigue) many cleaning and reesterilization procedures. (2) They must not elicit toxicity reactions. (3) If disposable, they should be sterile packaged.

The Qi Paradigm

Acupuncture is included in the traditional Chinese system of diagnosis and treatment and has been described in a medical classic "Huang Di Nei Jing Su Wen", which has been dated to circa 200-300 B.C. and which describes a rather complete medical system that had probably been in use for hundreds of years (Veith, 1966; Unschuld, 1987). Traditionally, the practice of acupuncture has been based on a paradigm of the body unlike that used in Western medicine (for brief discussions on similarities and differences between the medical systems see Unschuld [1987] and Patel [1987a, 1987b]). This paradigm is based on the flow of Qi (pronounced "chee", meaning "internal energy"; Qi is the modern Chinese pinyin term, Ki is the term in Japanese and Korean) in channels through the body and its relation to the different physiological processes; states of health were described in terms of Qi. A brief overview of the Qi paradigm is presented in Appendix 1. An important aspect of Oriental medicine is the intent to diagnose and treat conditions before clinical symptoms manifest, thus affording early intervention and prevention of the progression of the disease process. This is not dissimilar to the approach currently being taken to prevent cardiovascular disease in Western medicine. At present Qi has no well-defined single counterpart in Western science and medicine. Research with animals and with human volunteers has focused primarily on neural effects and has shown that acupuncture procedures affect the nervous system.

Acupuncture Treatment

Since acupuncture came to the U.S. as a part of Oriental medicine, it has been traditionally combined with Oriental diagnostic techniques, herbal remedies and exercise programs. It is now also being combined with Western diagnostic and therapeutic techniques. A typical acupuncture treatment (after appropriate diagnosis) may consist of (1) several needles being inserted a few millimeters to a centimeter or more into acupuncture points at specific locations over the body (depth and direction of needle insertion is important), (2) one (or more) of the needles being manually twirled to increase its effect (called manual stimulation), and (3) the needles being left in place for a few seconds to tens of minutes. In some instances one (or more) of the needles may be connected to a low-voltage electrical source for electroacupuncture, which is done to replace manual twirling and may be used to increase the stimulation of an acupuncture point beyond that normally done with manual twirling. Other means of affecting acupuncture points include heat (moxibustion) and massage (acupressure). A course of therapy with acupuncture usually includes several treatments over several days or weeks.

The choice of acupuncture points to be used in a treatment varies, depending on the diagnosis and on the training and experience of the acupuncturist. The 'formula' (or recipe) approach uses a fixed set of points for a specific symptom. The traditional

(Chinese medicine) approach may use different points from patient to patient and from treatment to treatment, depending on the assessment of Qi balance at the time.

Many different conditions are treated by acupuncture (see Appendix 2 for the commonly treated conditions listed by the AAAOM and Appendix 3 for the categories listed by the World Health Organization [WHO]).

Training of Acupuncturists

Practicing acupuncturists in the U.S. have differing types of training. A poll taken at the 1990 meeting of the AAAOM indicated that about 46% of the attendees were trained solely in the U.S., while 25-30% were trained solely outside the U.S. (AAAOM, 1990). The traditional Oriental training typically consists of 3-4 years of specialized classroom and clinical experience, where diagnosis, treatment, etc., are described in terms of Qi flow. Western acupuncture schools usually use the Oriental approach, using Qi as the basic mode of description. There are 35 such schools and colleges in the U.S. Apprenticeships with qualified acupuncturists have also been used to train student acupuncturists.

Physicians who practice acupuncture learn most aspects of medicine in Western terms in medical school and add acupuncture later, by attending an acupuncture school, studying acupuncture through a continuing education program of a medical school (available through at least three major universities), or taking special acupuncture courses elsewhere. (See section below on Acupuncture in Medical Schools.)

Acupuncture Organizations

There are several national organizations which serve different aspects of the acupuncture community. The membership organization for physician acupuncturists (American Academy of Medical Acupuncture, AAMA) is restricted to physicians. The other major membership organization, American Association for Acupuncture and Oriental Medicine (AAAOM), consists primarily of non-physicians but is open to physicians as well. The founders of AAAOM have also been instrumental in developing a national certification commission (NCCA, see Appendix 4) for qualified acupuncturists and a national accreditation commission (NACSCAOM, see Appendix 4) for qualified acupuncture schools. The certification process has been adopted by several states for licensing acupuncturists at the state level. In summary, the physician and non-physician acupuncture community in the U.S. has organized and developed institutions through which practitioners can be certified.

SCIENTIFIC BASES OF ACUPUNCTURE

There is laboratory evidence that acupuncture has many effects, including effects through more than one neural pathway. Most studies have focused on nociception and pain control. Scientific research on the mechanisms of acupuncture effects has advanced substantially since the discovery of endorphins (early 1970's). The following is a brief overview of acupuncture mechanism(s).

There are thousands of published papers on mechanisms and clinical results of acupuncture. By Western scientific standards, most of those papers do not provide convincing data. However, a number of investigators have done carefully-designed and controlled studies which now constitute the current state of scientific knowledge in acupuncture research. Fortunately, a book "Scientific Bases of Acupuncture" (Pomeranz and Stux, 1989) has been published recently which presents reviews by several leading researchers of their investigations and the implications for understanding mechanisms. This book serves as an excellent source of up-to-date information, with references to most of the important published studies. The following briefly summarizes the major points of the reviews:

1. Several neurotransmitters and neuropeptides are involved in acupuncture analgesia in rabbits, mice, rats, cats and humans. Endogenous opioids play a major role, with β -endorphin and two enkephalins having primary functions. Evidence that endorphins mediate acupuncture analgesia: i.) 4 different endorphin blocking agents (including naloxone) block acupuncture analgesia (naloxone does not block hypnotic analgesia), ii.) a stereoisomer of naloxone was much less effective, indicating endorphin receptor involvement, iii.) naloxone blocked acupuncture analgesia at the spinal cord (as well as in the brain, i.e., the midbrain and the pituitary), iv.) a strain of mouse genetically deficient in endorphin receptors was less capable of expressing acupuncture analgesia (although endorphin levels were normal), further indicating endorphin receptor involvement, v.) acupuncture analgesia could be augmented by agents which block enzymes which degrade endorphin peptides, and vi.) interference with the pituitary indicates that pituitary endorphins are important. Kinetic and inhibition experiments provide evidence that enkephalins are also important, including the fact that electroacupuncture elicits enhanced production of mRNA coding for proenkephalin in rat brain for at least 48 hours. (Han, 1989; Pomeranz, 1989; Cheng, 1989; Tsou, 1989)

The location of endorphin-mediated acupuncture analgesic action within the central nervous system has been partially characterized by microinjections of specific inhibitory compounds (e.g., naloxone) or specific antibodies. Rather detailed "maps" of the neural pathways responsible for acupuncture analgesia have been developed. (Han, 1989; Pomeranz, 1989)

With electroacupuncture, the frequency of stimulation determines which analgesic process is activated. Low frequencies (2-15 Hz) activate the endorphin pathway which is blocked by low doses of naloxone (1 mg/kg); high frequency (100 Hz) analgesia is blocked only by higher doses of naloxone (10-20 mg/kg), suggesting possible non-endorphin opioid involvement. Data from experiments on blocking and enhancing properties of neurohormones indicate that monoamines (i.e., serotonin and/or norepinephrine) may mediate high frequency acupuncture analgesia. Acupuncture analgesia mediated by 5-hydroxytryptamine, a classical neurotransmitter, is frequency independent. (Han, 1989; Pomeranz, 1989; Cheng, 1989)

2. Release of endorphins by acupuncture may be useful in suppressing certain drug withdrawal symptoms. Electroacupuncture has been shown to relieve morphine withdrawal symptoms in rats and mice. (Pomeranz, 1989)

3. Most research on acupuncture mechanism in animals uses stimulation of peripheral acupuncture points. In the mouse, it has been shown that acupuncture analgesia can not be produced when muscle nerve impulses are absent from the needle site, and that type II and III muscle afferent nerves were required. Skin nerves are apparently unimportant. For non-naloxone-reversible analgesia A δ nerves are important. (Pomeranz, 1989; Takeshige, 1989; Chung, 1989)

4. Acupuncture-induced peripheral sympathetic effects were detected by using thermographic scans to visualize surface temperature of the face, hands and feet. Manual or electrostimulation of two acupuncture points commonly used for analgesia (LI-4 and St. 36) each caused increased skin temperature of the face; manual stimulation also resulted in increased temperature of the hands. The temperature continued to increase for at least 15 minutes after acupuncture treatment. Some data also indicated acupuncture reduced heart rate and diastolic blood pressure. This evidence suggests that acupuncture acts to inhibit stress-induced sympathetic effects. (Lee, 1989)

In summary, the current level of scientific knowledge indicates that stimulation of the peripheral and central nervous systems is elicited by some acupuncture techniques. The effects include stimulated production of endorphins, monoamines and 5-hydroxytryptamine which can be utilized in pain control. It is evident from many studies on laboratory animals that acupuncture has analgesic effects that might be used therapeutically. In addition, other effects which may have therapeutic value (e.g., relief of drug withdrawal symptoms) have been demonstrated. Thus, it is reasonable to expect that acupuncture can affect physiological processes in the body that might also be utilized therapeutically.

Studies with experimentally-induced pain indicate that acupuncture increases the pain threshold in healthy human volunteers. Using electrical stimulation of the skin in the thyroid area, Stacher et al. (1975) found that acupuncture needling increased the pain threshold and that manual needling at classical acupuncture "pain control" points (LI-4 and EH-6) was significantly more effective than needling at a non-acupuncture point. In a different study utilizing pain evoked from electrically-stimulated tooth pulp (Chapman et al., 1977), intrasegmental electro-acupuncture significantly increased the pain threshold within 10 minutes of initiation of needling. With a painful heat stimulus to the forearm, needling at LI-4 and Jianqian (Extra.) produced a 50% average increase in pain threshold (Brockhaus and Elger, 1990). These studies (and others) demonstrate that the analgesic effects in animals extrapolate to humans, providing a further basis to expect therapeutic results with clinical pain.

CLINICAL EVIDENCE OF EFFICACY

There are many articles in the published literature claiming clinical effectiveness of acupuncture for many specific diseases; some articles claim lack of effectiveness. Relatively few articles describe what might be considered carefully-controlled clinical trials. The term "carefully-controlled" usually means utilization of a double-blind protocol, which is difficult with needle acupuncture (Richardson and Vincent, 1986). The

reasonably well-controlled clinical trials of acupuncture efficacy, which sometimes included the use of sham acupuncture, tested only a few of the many claimed uses.

A rather complete review of the published, controlled studies (as of mid-1985) on acupuncture for the treatment of pain was published in the journal Pain (Vincent and Richardson, 1986; Richardson and Vincent, 1986). For back pain (of various origins), "taken together, the results from controlled studies with back pain patients suggest that a majority (of patients) will derive clinically significant short-term benefits from acupuncture" (Richardson and Vincent, 1986). The authors pointed out that the Coan et al (1980) study, described below, was the only one in which traditional acupuncture treatment was followed, and it showed significant improvement for 58% of the patients for long-term followup. The studies on headache treatment were inadequately done, leaving the conclusion that treatment of non-migraine headache may produce benefit and leaving no conclusion possible for treatment of migraine headache. The authors spent a great deal of attention on the value and problems of interpreting "placebo acupuncture."

Several factors add to the difficulty of producing clinical trial data which would be deemed adequate in the Western scientific community. The design of blind study protocols has particular pitfalls:

1. Keeping patients blind to their treatment when needle insertion is used is perhaps not possible.
2. Sham needling at non-acupuncture points may not be appropriate as placebo treatment. Since Qi is considered to flow everywhere in the body, some practitioners consider it unethical to insert needles at inappropriate sites. Conversely, some sham needling may produce some level of therapeutic effect (Lewith and Machin, 1983).
3. Use of adequately trained, skilled acupuncturists and use of protocols which allow traditional acupuncture treatment may optimize chances of demonstrating therapeutic efficacy. The clinical trials by Coan et al (1980), summarized below followed this idea and yielded relatively high levels of success. Formula acupuncture may be more reproducible and standardizable and therefore more acceptable to Western medicine, but may not be as efficacious (Patel et al, 1989).
4. Blind evaluators may be used, but only very carefully.

This document is not meant to be an exhaustive review, but rather is meant to show examples of studies which demonstrate the level of evidence supporting efficacy of acupuncture in treating different diseases. Three controlled clinical trials on pain are presented. Two published trials (the only two available on this subject) on acupuncture therapy for alcohol abuse are also presented. In each study a relatively low number of patients were used in each treatment group.

In an attempt to combine results of separate, but similar clinical trials, a statistical approach called meta-analysis may be used. Two groups of epidemiologists have

performed different types of meta-analyses to investigate acupuncture efficacy using published clinical trial data. Results of both of these meta-analyses are included here.

For the purposes of this document, articles were selected for presentation that included participation of (1) one or more qualified acupuncturists to assure adequate considerations of the acupuncture aspects of the study and (2) one or more physicians to assure adequate considerations of medical examinations in the study. Five studies are presented here to give the reader some indication of the factors used in a clinical trial to evaluate the efficacy of acupuncture.

Pain

Low Back Pain: Coan et al (1980) did a randomized controlled clinical study on chronic low back pain. This study was considered well-designed by the AMA (1981). An important feature of this study was the lack of restriction on number of treatments or selection of acupuncture points. Thus traditional acupuncture methodology was allowed, including the use of electroacupuncture when deemed appropriate. The 50 patients recruited for the study had low back pain for 6 months or more, no previous acupuncture treatments, not more than 2 back surgeries and no history of diabetes, infection or cancer. Physicians performed physical examinations including x rays of the lower back. Extent of medical problem was quantified by questionnaire and physical exam (e.g. straight leg raise test, exam of muscles and nerves, etc.). Relative quantitation was utilized for pain intensity (0 to 10) and range of motion (0 to 3). The patients were randomized into 2 groups by drawing lots: an Immediate Treatment Group (25 patients) and a Delayed Treatment Group (25). At the end of the study there was a third group of Inadequate Treatment, patients who had refused treatment (7) or had inadequate treatment (4). No placebo group (sham acupuncture) was used because the acupuncturists considered it unethical. Nineteen of 23 Immediate Treatment patients (83%) showed improvement when assessed about a month after the treatment regimen ended, with an overall 51% reduction in average pain score. The mean number of treatments was 11.4. In the short-term control group (Delayed Treatment) 5 of 16 patients (31%) showed improvement and 4 showed worsened condition. (This level of improvement in pain control clinical trials, 30-35%, is typical for placebos.) After this assessment, the Delayed Treatment group was then treated with acupuncture and, at about 7 weeks after treatment, 12 of those 16 patients (75%) showed improvement. That group required a mean number of 9.9 treatments. At the forty week followup, 22 of 38 treated patients (58%) continued to show improvement, although the degree of improvement had regressed somewhat (30% lower average pain score). A group of ten individuals who dropped out of the above groups served as a long-term control with inadequate or no treatment; they showed no improvement over the same 40 weeks period. Though the scale of the study was small and no rigorous statistical analysis was performed, the results appear to show that acupuncture treatment was effective on a short-term basis for chronic low back pain.

Neck Pain: Coan et al (1982) did a randomized controlled clinical study on chronic cervical spine pain. As above, an important feature of this study was the lack of restriction on number of treatments or selection of acupuncture points. Thus traditional acupuncture methodology was allowed, including the use of electroacupuncture when deemed appropriate. The 30 patients recruited for the study had neck pain and/or

radicular arm and hand pain for 6 months or more, no previous acupuncture treatments, not more than 2 neck surgeries and no history of diabetes, infection or cancer. A physician performed the physical examinations including x rays of the cervical spine. Extent of medical problem was quantified by questionnaire and physical exam. Relative quantitation was utilized for pain intensity (0 to 10) and limitation of activity (0 to 3). The patients were randomized into 2 groups by drawing lots: the Treatment Group (15 patients) and a Control Group (15). Twelve of 15 Treatment patients (80%) showed improvement when assessed 12 weeks after the treatment regimen began (mean followup time of 7.9 weeks), with an overall 40% reduction in average pain score, 68% reduction in hours of pain per day and 32% improvement in activity level. The mean number of treatments was 10.9. In the Control Group 2 of 15 patients (13%) showed some improvement and 9 showed worsened condition. Though the scale of the study was small and no rigorous statistical analysis was performed, the results appear to show that acupuncture treatment was effective on a short-term basis for chronic cervical spine pain.

Primary dysmenorrhea: Helms (1987) conducted a randomized, controlled prospective clinical study of management of primary dysmenorrhea. The diagnosis of primary dysmenorrhea was made by board-certified gynecologists according to classical criteria. Forty-three patients were followed for one year in one of four groups: Real Acupuncture, treated with 12 acupuncture needles at a standardized set of classical acupuncture points ("verified by electrical resistance measurements"); Placebo Acupuncture, treated with 12 acupuncture needles at random non-acupuncture sites; Standard Control, followed without medical or acupuncture intervention; Visitation Control, same as Standard Control, with addition of monthly office visits. The patients knew they were either in acupuncture or control groups, but not which subdivision. The acupuncture groups were treated on a weekly basis (except during menses) for three menstrual cycles. Monthly pain scores were calculated from patient records of pain intensity (range of 0 to 6) and duration. "Improvement" was arbitrarily defined as the mean monthly pain score for the nine-month period following treatment being less than half the value for the pretreatment period. By this criterion, 10 of 11 (91%) Real Acupuncture patients improved, while 4 of 11, 2 of 11 and 1 of 10 improved of the Placebo Acupuncture, Standard Control and Visitation Control groups, respectively. The Real Acupuncture patients also showed 41% long-term decreased use of analgesic medication and often reported improvement in other symptoms, e.g., nausea, headache, backache, fluid retention and breast tenderness, which began following the first treatment. Placebo Acupuncture patients showed improvement in pain score (34%) and decreased medication use (24%) during treatment, but the medication use returned to the pretreatment level in the posttreatment period. Although the number of patients in this study was small, the results demonstrate acupuncture to be effective for decreasing primary dysmenorrhea in the short-term. Information on the long-term benefit could have been obtained by comparison of the one-year followup pain scores with the pretreatment pain scores. The author suggested that for individuals who want to stop medications, acupuncture offers an additional option for prevention or control of dysmenorrhea.

Alcoholism

Alcohol abuse: Two studies on treatment of alcoholic recidivism by acupuncture were conducted by Bullock et al (1987; 1989). In the first, pilot study, 54 hardcore

alcoholic recidivists were treated to determine if sobriety could be achieved and if episodes of drinking and/or admissions to a "detox" center could be decreased. Male patients were selected according to the following criteria: ages of 25-65; at least 20 admissions to the detox center, or at least 5 admissions in the last calendar year; previous treatment failure; no identifiable support person; no full-time employment for at least 6 months. The treatment patients (27) were given acupuncture treatment specific for substance abuse; control patients (27) were given acupuncture needles at non-specific points. A qualified acupuncturist identified the point locations and placed the needles. The choice of points was fixed and, by traditional acupuncture methodology, may not have been the optimal choice for any specific patient on a given day. There was no manual or electrostimulation after needle placement. These restrictions may have provided less than optimal acupuncture therapy. The individuals who evaluated the patients' responses were blind as to the patient treatment. The statistical evaluation was quite adequate. The treatment protocol had three phases, as follows: daily for 5 days, thrice weekly for 28 days, twice weekly for 45 days. As expected with the type of patients chosen for this study, the dropout rate was high, with the control patients dropping out at a significantly higher rate (10 treatment patients completed all three phases, while 2 control patients did so). By the end of second and third phases, acupuncture treatment resulted in statistically significant reduction in (1) expressed need for alcohol, (2) drinking episodes and (3) detox admissions. The treated patients during all phases of the study stated "that acupuncture therapy had decreased their desire to drink." There seems to be validity in the authors' claim that "even if total sobriety cannot be achieved, the use of emergency rooms and detoxification centers can be reduced."

In the second study, 80 severe recidivist alcoholics were treated to determine if the results of the pilot study could be repeated and if the results would persist for six months. Patients were selected according to similar criteria: age over 18 years; at least 10 admissions to the detox center, or at least 5 admissions in the last calendar year; previous treatment failure; no full-time employment for at least 6 months. No patients had previously received acupuncture therapy. As before, the treatment patients (40) were given acupuncture treatment specific for substance abuse; control patients (40) were given acupuncture needles at non-specific points. Two qualified acupuncturists identified the point locations and placed the needles. The individual who evaluated the patients' responses was blind as to the patient treatment. Again the statistical evaluation was quite adequate. The treatment protocol had three phases, as follows: daily from Monday through Friday for 2 weeks; Monday, Wednesday and Friday for 4 weeks; Monday and Thursday for two weeks. Followup evaluation was done at 1, 3 and 6 months after the end of treatment. Again, the dropout rate during the treatment phases was high, with the control patients dropping out at a significantly higher rate (21 treatment patients completed all three treatment phases, while 1 control patient did so). More than half the patients from both groups were located for each of the followup evaluations. At the one-month followup, the treated group expressed less need for alcohol; this success continued through the 3 and 6 month followups. During the followup periods, the patients were allowed to request and receive further treatments; 12 treatment and 1 control patients did so. The treated patients reported less than half the number of drinking episodes reported by the control group. On the other hand, abstinence from drinking was reported by 3-4 times as many treatment patients as reported by controls at each followup period. Further, at each followup, the control patients had been admitted to detox centers more than twice as often as the treated patients. It was also pointed out

that the cost of the detoxification center admissions by control patients was \$20,000 more than for the treated patients.

These two studies suggests that acupuncture might be utilized as a treatment modality for alcohol recidivism with short-term and longer-term benefits, including cost to society. The author knows of no other controlled clinical trials on treatment of alcoholism. This relatively simple technique is also being used to treat drug addiction, including within the criminal justice system (see below).

Meta-analyses of Clinical Trials

Patel et al (1989) point out several aspects of acupuncture efficacy studies which seem to be important. Their meta-analysis of pooled data from 14 studies was "based on results of all trials of acupuncture for treatment of chronic pain, published in English, listed in Index Medicus from 1970 onwards that were randomized controlled trials of chronic pain that measured outcome in terms of number of patients whose condition improved." One aspect the authors noted was that not all published studies used the standard extent of acupuncture treatment (i.e., the number of needles used, length of treatment, number of treatments was not equivalent to conventional acupuncture therapy). The meta-analysis indicated that: acupuncture compared favorably to conventional treatment of chronic pain or placebo (more favorable to conventional treatment); traditional acupuncture protocol (where treatment points vary from treatment to treatment) was more effective than formula acupuncture (fixed points); blind studies were less favorable to acupuncture than non-blind studies; trials with large numbers of patients were more favorable to acupuncture than small trials; and there may be publication bias, as evidenced by articles published in journals with the words "acupuncture" or "Chinese" being more favorable to acupuncture than those in traditional western medical journals (although articles favorable to acupuncture can be found in both categories of journals).

It should be noted that while the authors of this meta- analysis stated that the evidence was favorable toward acupuncture, they did not say that the evidence proves acupuncture is effective.

A different type of "meta-analysis," based on weighted methodological criteria, was less favorable to acupuncture clinical trials (Ter Riet et al, 1989a,b,c,d,e,f,g,i). This method compared the overall quality of the different published controlled clinical trials using specified criteria. The criteria included such study elements as randomization, blind patient, blind evaluation, number of patients per group, and adequate presentation of data, including statistical calculations. This approach to meta-analysis did not pool the results of different studies, but simply compared the qualities of the different studies that gave positive results with those that gave negative results. Ter Riet et al found that the study designs were generally poor and that the quality of the studies which gave negative results (acupuncture not effective) was slightly higher than the quality of the studies which gave positive results. These conclusions were obtained for 37 studies on chronic pain (Ter Riet et al, 1989e), for 22 studies on low back and neck pain (Ter Riet et al, 1989c), for 3 studies on rheumatoid arthritis (Ter Riet et al, 1989d), for 10 studies on migraine and tension headache (Ter Riet et al, 1989f), and for 2 studies on facial pain

(Ter Riet et al, 1989g). They concluded that acupuncture "should not be considered as proven," "remains doubtful," or "definite conclusions cannot be drawn."

When Ter Riet et al used their meta-analysis methodology on six controlled studies on treatment of alcohol and drug abuse patients, they concluded that "study design was generally poor" and "that there is no convincing evidence for the effectiveness of (electro-)acupuncture in these fields of addiction" (Ter Riet et al, 1989j). The only reports on treatment of alcoholism in their analysis were those reviewed above (i.e., there were no studies suggesting lack of efficacy).

Summary of Clinical Trials Data

Several individual controlled clinical trials indicate effectiveness of acupuncture, but in no case has the number of patients in the studies been large enough nor the protocol strict enough for the results to be unequivocal. In addition, in no case (to the author's knowledge) has there been an independent, confirmatory study using the same study protocol. The largest combined body of controlled clinical trial data has been on control of pain of different types, locations and etiologies. The weight of the combined evidence favors efficacy in pain control, but the data are not conclusive. Data for treatment of other diseases is not as extensive. All the available data (2 studies, presented here) on treatment of alcohol abusers indicate effectiveness, and this information is being applied in many clinics. The results of the meta-analyses indicate more about the quality of the clinical trials than they do about the efficacy of acupuncture.

ACUPUNCTURE IN THE UNITED STATES

Acupuncture probably first came to American medicine from France in the 18th century (Wolpe, 1985). Chinese immigrants arriving in the United States during and since the nineteenth century included individuals trained in traditional Chinese medicine, including acupuncture (Muench and Buell, 1984). Most of these individuals, trained in the Orient, served the Oriental communities in which they resided, primarily in cities. In this century acupuncturists trained in Europe (France and England) have also started practice in the U.S. Now there are several acupuncture schools in this country, and acupuncture is included in some medical school curricula.

The National Acupuncture Headquarters (AAAOM, 1991) estimates there are probably about 9,000 practicing acupuncturists (mostly non-physicians; certified and uncertified) in the U.S. today (averaging 35-40 acupuncturists per million population). This estimate comes from the number of certified practitioners in California (2,800-3,200) being estimated as about one-third of the U.S. total. There are 2,289 NCCA certified acupuncturists in the U.S. today; representing perhaps a quarter of all practicing acupuncturists (AAAOM, 1991). The AAMA estimates there are 1500 physicians trained in acupuncture, and 2,000-3,000 additional physicians who have been exposed to enough short courses, etc. to use acupuncture in their practice occasionally (AAMA, 1991). Since it is not known how much the AAMA estimate overlaps with the AAAOM estimate, it is assumed that 9,000 is a reasonable estimate for the total number of practicing physician and non-physician acupuncturists in the U.S. However, many, perhaps half, do not

practice acupuncture full-time. If a full-time practitioner treats 6-8 patients per day (250 days per year), then he or she has 1,500-2,000 patient visits per year. This range may be close to typical (personal communications with several practicing acupuncturists), although one practitioner in Rhode Island apparently had over 5,000 patient visits in one year (366 patients with a median number of 14 treatments per patient) (Kent et al, 1988). If one assumes that half the acupuncturists practice full-time and the remainder practice one-third time, these numbers extrapolate to 9-12 million patient visits per year for acupuncture treatments (or around \$500 million at \$45 per visit) nationwide.

A biostatistical profile of individuals seeking acupuncture treatment at one clinic (apparently in Texas) has been published (Dung, 1985). In a four-year period, the clinic received 3,691 new patients (5,000 patient visits per year if 5-6 treatments per new patient). Approximately 70% of the patients went for treatment of pain symptoms, 17-18% for smoking withdrawal, and 5-8% for weight reduction. Of the patients seeking acupuncture for pain relief, 97.8% had been diagnosed and treated by licensed physicians without satisfactory results.

Regulation at the State Level

Physicians are allowed to practice acupuncture in all states as a component part of the practice of medicine (AAMA, 1991). In 1973, Nevada became the first state to license the practice of acupuncture by non-physicians. Today, 27 of the 50 states, plus the District of Columbia, recognize the practice of acupuncture by non-physicians, and 22 have administrative bodies that regulate acupuncturists. The official forms of regulation are called registration, licensing or certification: 13 states license; 5 certify; 5 register. The regulations require credentialing, examination or both, except for Vermont. Ten states, plus the District of Columbia, accept the NCCA certification as evidence of adequate training and experience. Seven more states use the same criteria. Other states have their own criteria. Ten states require some sort of medical supervision. Appendix 5 lists the states that utilize different approaches to regulating non-physician acupuncturists.

Virginia, New York, New Jersey, Pennsylvania, Maryland and the District of Columbia have established requirements for a separate license for physicians to practice acupuncture as part of their profession. With the exception of Maryland, these states require 200-300 hours of documented training and clinical experience for licensure. New Mexico allows physicians to practice acupuncture without special licensing, but requires NCCA certification for them to advertise as acupuncturists. (AAMA, 1991).

Use in Criminal Justice

The Department of Justice is interested in the use of acupuncture for treating prisoners who are alcohol and/or drug addicts. Dr. Michael O. Smith, Medical Director of the Substance Abuse Division, Department of Psychiatry, Lincoln Hospital, New York City, has initiated a large scale clinical program to use acupuncture to control withdrawal symptoms and craving and to reduce the fears and hostilities that usually accompany drug abuse treatment settings. In alliance with the criminal justice system in New York City, Dr. Smith is using acupuncture in a probation program for drug abusers. One of the

conditions for remaining on probation (instead of serving time in prison) is maintaining a drug-free state, which is monitored regularly by urinalysis. The acupuncture therapy approach has been so successful that the Lincoln Hospital protocol has served as a model to set up such programs in other parts of the U.S and in several foreign countries. As an example of the success, the detox program in Portland, Oregon, reports that 85% of its patients complete their program, compared to 34% before the use of acupuncture. Dr. Smith has also given testimony before the Select Committee on Narcotics of the U.S. House of Representatives.

Federal Programs that include Acupuncture for Alcohol or Drug Addiction

Two Institutes of the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) deal with addiction problems where acupuncture is expected to be useful. For the National Institute of Drug Abuse (NIDA), one completed project (at the Lincoln Hospital, New York City) evaluated acupuncture treatment for crack cocaine detoxification using the treatment protocol developed there by Dr. Michael Smith. This project used frequent urinalysis to assess drug use, but did not provide counseling or other support services. While acupuncture diminished cocaine use over the control, the difference was not statistically significant. A current extramural project is evaluating the addition of acupuncture to an existing drug abuse program in the Dade County, Florida, Criminal Justice System. This project is aimed at reducing high risk AIDS behavior (drug abuse using needles), and includes HIV education and drug counseling, in addition to acupuncture treatment and frequently monitored urine testing.

The National Institute on Alcohol Abuse and Alcoholism has a grant program aimed at developing community-based addiction treatment and rehabilitation services for the homeless. One project in New York City entitled "Outreach and Engagement for Homeless Alcoholic Women", will provide acupuncture therapy for relief of acute alcoholic symptoms as one component of the program.

Alcoholism is a serious chronic problem for the Indian Health Service, the federal agency that administers health care to Native Americans. A project on acupuncture detoxification of alcoholics is in progress at the PHS Indian Hospital in Eagle Butte, South Dakota.

Health Insurance

Many health insurance companies pay for acupuncture treatments. Some companies only pay for acupuncture performed by a physician. Other companies (including Medicaid in certain states) also cover treatment by non-physician acupuncturists. In 1989, the federal Health Care Financing Administration (HCFA) approved Oregon's request to cover acupuncture for alcohol and drug abuse patients under the State Medicaid Plan. Only acupuncture delivered by an Oregon licensed acupuncture practitioner is permitted. Other states that provide Medicaid payment for acupuncture treatment of substance abuse patients are California, Florida, Massachusetts, New York and Washington, all of which license or certify acupuncturists. In addition, there is state-mandated coverage (through enacted legislation) for acupuncture

treatments, in general, in California (since 1984), Florida (since 1987), New Mexico (since 1989) and Oregon (since 1989).

Acceptance by the American Osteopathic Association

In 1988, the American Osteopathic Association went on record as "recognizing that acupuncture may be a part of the armamentarium of qualified and licensed physicians." This position was a revision of a position taken in 1973 and reaffirmed in 1978 and 1983 to favor continuing study, evaluation, and research in the clinical application of acupuncture. The AOA revision was based partly on the recognition that acupuncture "has begun to have acceptance in the Western world."

The American Medical Association (AMA) position

In 1981, the Council on Scientific Affairs of the AMA reviewed the position on acupuncture and reaffirmed their earlier assessment that the practice of acupuncture is an experimental medical procedure. The documentation (AMA, 1981) considered primarily clinical applications in anesthesia for surgery and in pain control. For anesthesia the stated advantages included acupuncture "being quite safe," allowing the patient to cooperate, requiring little equipment, and leaving "no residual post-anesthesia morbidity or depression"; the stated disadvantages included incomplete analgesia, no muscle relaxation, and traction on viscera possibly provoking pain, nausea and vomiting. It was pointed out that the number of patients for whom acupuncture anesthesia is adequate is apparently small. (Some types of surgery are more appropriate for using acupuncture analgesia than others. Acupuncture analgesia is apparently more reliable when there is not large scale displacement of tissue or organs.) Clinical trial data was only considered for pain control. Some of the clinical studies used qualified acupuncturists, and some did not. One of the studies described as a well-designed study was the clinical trial on chronic low back pain by Coan et al mentioned above. Although substantial analgesia can be produced in some patients, concern was expressed that acupuncture may "not operate consistently or reproducibly" in most people. The Council on Scientific Affairs concluded that:

- "1. Acupuncture is an unproven modality of therapy.
2. Scientific assessment of acupuncture by an appropriately controlled clinical trial is needed to establish its clinical worth and is now proceeding under the cognizance of the National Institutes of Health.
3. Research on acupuncture may provide important clues to the understanding of pain, and perhaps of the placebo effect, as well as to an explanation of its mechanism of action."

The AMA has not reevaluated its position on acupuncture since 1981 (W. McGivney, AMA, personal communication). The American Board of Medical Specialists does not include medical acupuncturists. The Council of Medical Specialty Societies does not yet include the American Academy of Medical Acupuncture.

Acupuncture in Medical Schools

Stanford University School of Medicine presented a series of elective acupuncture lectures for medical students in 1988-1989. Jefferson Medical College included acupuncture as an elective unit in clinical training for the 1990-1991 academic year. In addition, the Departments of Anesthesiology at the University of Arizona School of Medicine and the University of Maryland School of Medicine offer acupuncture training as part of their pain management fellowship program, and include clinical demonstrations and lectures for the undergraduate programs (AAMA, 1991).

The UCLA School of Medicine, the Washington University School of Medicine and the New York University School of Dentistry include acupuncture training in their continuing education programs. Continuing education programs organized by the AAMA have been sponsored for Continuing Medical Education (CME-1) credit through the Schools of Medicine at Thomas Jefferson University, Temple University, the University of Pennsylvania, the University of Arizona, and the University of Maryland.

ACUPUNCTURE IN OTHER COUNTRIES

Acupuncture is accepted by many people in the Orient. In China, it is part of the traditional medical armamentarium and is used alongside Western medical practice. Birch (1990) has estimated the number of acupuncture practitioners in China to be about 1.5 million, which is roughly 1,500 per million population. In Japan the number is estimated to be over 42,000 (or nearly 350 per million population) (Birch, 1990). In Europe, acupuncture has been used since the seventeenth century, following substantial contact with the Orient. Today, there are physician and/or non-physician acupuncturists in many countries, including Great Britain, Germany, Austria, Belgium, Finland, Italy, Switzerland, Argentina and Brazil (Wolpe, 1985). Only physicians may practice acupuncture in France and Italy. In France, the practice of acupuncture has been accepted at one level or another for more than three centuries and currently is recognized by L'Academie de Medicine and is covered by the French National Health Insurance (Wolpe, 1985). Pain control is a major use of acupuncture everywhere. For example, in German pain clinics, 90% of the physicians use acupuncture (Stux and Pomeranz, 1988, pg. 2). In the USSR, acupuncture is used to treat drug-abuse patients (Knoth, personal communication) and several other disorders (Sitko et al, 1988).

The status of acupuncture in Canada is similar to that in the U.S.: there is no national policy, but there is regulation province by province. The Acupuncture Foundation of Canada includes approximately 2,500 physicians and physiotherapists (B. Pomeranz, personal communication). The non-physician acupuncturists (other than physiotherapists) are organized separately.

The mechanisms of acupuncture are currently being studied by many investigators in China (Kendall, 1989) and Japan (Birch, 1990), and by a number of investigators in the West as well. Research is of two types: one is oriented toward explaining acupuncture in Western physiological terms, and the other uses modern methodologies to investigate the Qi paradigm. In the USSR, other means of stimulating acupuncture points, including

millimeter-wave devices, are being investigated at the scientific and clinical levels (Sitko et al, 1988; Sitko, 1989).

It is also important to mention that two major academic institutions in Europe have developed academic programs in the study of acupuncture: the University of Heidelberg in Germany and the University of Exeter (Complementary Medicine Studies Program) in Great Britain (S. Birch, personal communication).

World Health Organization (WHO)

In 1979, the World Health Organization in its Traditional Medicine Programme recognized the utility of acupuncture to treat a broad range of medical conditions. Dr. R.H. Bannerman (1979), WHO's Programme Manager for Traditional Medicine stated: "Clearly, it (acupuncture) is not a panacea for all ills, and is certainly not without risk, but the sheer weight of evidence demands that acupuncture must be taken seriously as a clinical procedure of considerable value." The 1979 WHO Interregional Seminar on Acupuncture, Moxibustion and Acupuncture Anaesthesia provided a provisional list of diseases treatable by acupuncture (Appendix 3). Of course, acupuncture is of special value in regions where high technology medical instrumentation is less available.

In 1989, the WHO Scientific Group to Adopt a Standard International Acupuncture Nomenclature met to continue the process initiated by the WHO Regional Office for the Western Pacific during meetings in 1982, 1984 and 1985. The main features (WHO, 1990) of the recommended standard nomenclature are English and Pinyin (present-day standard phonetic Chinese) names, plus alphabetic codes and original Han character designations for the classical fourteen main meridians (channels) and eight extra meridians. In addition, 48 extra points, discovered in modern times, which were thought to have sufficiently clear anatomical locations and clinical effectivenesses, were also designated by location. Their recommendations concerning acupuncture covered nomenclature and several other important aspects:

"wide distribution of the standard international acupuncture nomenclature.

standardization of the nomenclature of auricular acupuncture and of the basic technical terms used in acupuncture.

preparation of guidelines on the following subjects:

- the regulation by health authorities of acupuncture;
- basic training in acupuncture;
- safety in acupuncture practice; and
- acupuncture research and clinical trials.

promotion of information exchange on acupuncture."

On the subject of guidelines for acupuncture training, they are particularly concerned with "how much knowledge of modern Western medical sciences is necessary for acupuncturists trained in Oriental medicine?" and "how much knowledge of Oriental

medicine (e.g., Chinese, Korean, Japanese) should graduates in modern Western medicine possess if they wish to practice acupuncture:"

Dr. Joseph M. Helms, M.D., President of the AAMA, is also Vice President of the WHO's World Federation of Acupuncture- Moxibustion Societies.

DOCUMENTED PROBLEMS

There are several risks associated with the use of needles in acupuncture (for a dated, but comprehensive review see Peacher, 1975). However, considering the number of patients treated (estimated 9-12 million treatments per year) and the number of needles used per treatment (estimated average of 6-8), "there are, however, remarkably few serious complications" (AMA, 1981).

There is documentation of diseases being transmitted via improperly cleaned or sterilized reusable acupuncture needles (Peacher, 1975). Hepatitis B has apparently been spread by acupuncture needles when improper aseptic technique was used (Kent et al, 1988). In another case, Hepatitis B was apparently transmitted to several patients when the practitioner did not follow basic sterile procedures and reused hypodermic needles instead of the usual solid acupuncture needles (Boxall, 1978). Acupuncture needles may have been responsible for a case of osteomyelitis (Jones and Cross, 1980) and a case of transverse myelopathy (Sato et al., 1991). Prolonged placement of a short needle in the ear apparently led to a Staphylococcus aureus infection (Baltimore and Moloy, 1976), and may have been responsible for a case of bacterial endocarditis (Scheel et al., 1991; Scheel et al., 1992). There has also been a report indicating that acupuncture needles were a possible means for spreading the AIDS virus (HIV, human immunodeficiency virus) to two individuals who had no other identifiable risk factors (Castro et al, 1988). Another possible instance of HIV transmission occurred in France (Vittecoq et al, 1989). Two recent epidemiological reports indicate that acupuncture may be a risk factor for the transmission of hepatitis C virus in Japan (Michitaka et al., 1991), but not for hepatitis B virus in Brazil (Martelli et al., 1990).

Acupuncture needles may puncture organs (e.g., lung, peritoneum or urinary bladder) (Peacher, 1975). Three cases of pneumothorax were reported in Australia (Ritter and Tarala, 1978); more recently two cases were reported in Canada (Gray et al., 1991), one case in California (Wright et al., 1991), and one case in Brazil (Morrone et al., 1990). There have also been reports of self-inflicted needle punctures of the heart (Cheng, 1991), including a report where an ordinary sewing needle was used (Schiff, 1965). Proper acupuncture training includes warnings regarding careful use of needles (Peacher, 1975).

Broken needles are rare events (Peacher, 1975). A recent case was reported where a piece of acupuncture needle was found in the carpal tunnel of a patient (Southworth and Hartwig, 1990). Another possible case of a broken needle was reported where a piece of metal which resembled the tip of an acupuncture needle was removed from a patient's kidney (Keller et al, 1972). In Japan, a piece of a gold needle was removed from near the cervical vertebrae 30 years after the patient was treated with acupuncture (Murata et al., 1990); in another case, a piece of a fine acupuncture needle migrated into

the heart some years after original insertion in the neck (Hasegawa et al., 1991). There is a rarely-used technique in Japan called Okibari, where the tips of acupuncture needles are intentionally left in the subcutaneous tissue (Hollander et al., 1991); a case has been reported where one of the tips became stuck in the spinal cord (Shiraishi et al, 1979). Because of the danger associated with broken needles, a responsible acupuncturist will check each needle for intactness after removal.

Some other problems associated with acupuncture are worth mentioning:

1. Acupuncture can stimulate production of ACTH and oxytocin, which can aid in labor and delivery, but which may be hazardous to the fetus during early pregnancy (Chiu, 1984).
2. There are apparently some individuals in China who are addicted to acupuncture. This may be a form of hypochondria. (Eisenberg, 1985)
3. Some patients are allergic to acupuncture needles (Tanii et al., 1991).
4. The practitioner is at risk from contaminated acupuncture needles after use, requiring careful handling and disposal.

On the less serious side, sometimes there is transient dizziness or nausea during treatment, presumably results of anxiety or pain combined with stimulation of some acupuncture points. Transient muscle spasm or bruising is also possible, though not common.

Physicians have expressed great concern regarding inadequate diagnosis by non-physician acupuncturists (AMA, 1981). The concern is that the patient will not obtain proper diagnosis and that the undiagnosed or misdiagnosed disease may progress to an incurable stage. This issue is always important in health care and is not limited to the practice of acupuncture.

As in any scenario of health care, the level of expertise among acupuncture practitioners varies. The better trained and more experienced acupuncturist can treat a wider range of problems with a greater degree of safety. "An important element of all training of acupuncture practitioners is to help them to acquire a full understanding of their own limitations and those of acupuncture" (WHO, 1990).

In summary, there are documented risks associated with the use of acupuncture needles, similar to some of the risks associated with the use of hypodermic needles: uncleanliness and non-sterility leading to disease transmission, punctured organs, and broken needles. These issues can be minimized with adequately trained practitioners, including knowledge of anatomy and physiology, the theory and practice of acupuncture, and appropriate sterilization technique. Initial sterility of needles (direct from the manufacturer or distributor) and needle strength are a matter of adequate pre-market quality-control.

OVERALL SUMMARY

This overview of acupuncture in the U.S. included the following: (1) Acupuncture is based on traditional Chinese medicine (the Qi paradigm), which has no direct correlate in Western physiology. (2) Acupuncture is practiced by physicians and non-physicians in the U.S. (3) Acupuncture needles are specialized devices, and must be labeled investigational. (4) There is experimental scientific evidence that acupuncture produces effects on animals and humans which might have therapeutical value. (5) The present level of human clinical trial evidence favors efficacy for pain control and for treatment of alcohol recidivism, but is not compelling. (6) The annual number of patient visits may be ten million, enough to support the practice of acupuncture at an estimated annual level of half billion dollars. (7) Part of the health care community has accepted acupuncture: the American Osteopathic Association endorses acupuncture; many health insurance companies, including Medicaid in some states, cover acupuncture treatments; a few medical schools teach acupuncture; and the World Health Organization recognizes the utility of acupuncture. (8) More than half the states accept and regulate non-physician acupuncturists. (9) The justice system uses acupuncture in the treatment of certain parolees.

As with all therapeutic procedures, acupuncture is not without risk. Those risks can be minimized with adequately trained practitioners and appropriate quality control in the manufacture of acupuncture needles.

ACKNOWLEDGEMENTS

Several staff members of the CDRH Office of Science and Technology gave much appreciated assistance: Jan Scudiero for starting the process of locating organizations and individuals; Pei Sung, Ph.D., for information on medical device materials; Nelson Lao for translation of the Chinese quality standard for acupuncture needles; Teng S. Weng, Ph.D., for a statistical evaluation of the clinical trials presented here; Charlotte Silverman, M.D., for a medical evaluation of the clinical trials. Information on federal government programs using acupuncture was provided by Theo Matheny, M.D., Indian Health Service, by Robert Huebner, Ph.D., NIAAA, and by Debra Grossman, M.A. and Alan Trachtenberg, M.D., NIDA. Much information regarding various acupuncture concepts and practices were provided by officers and members of the American Academy of Medical Acupuncture and the American Association for Acupuncture and Oriental Medicine. Acknowledgement is also extended to Thomas Riihimaki, OMS Medical Supplies, Inc., for information on the acupuncture needle market. The helpful comments, preprints and reprints provided by Gerben ter Riet, M.D., Rijksuniversiteit Limburg, The Netherlands, are also appreciated.

REFERENCES

- AAMA, American Academy of Medical Acupuncture, communication on a variety of acupuncture-related subjects, 1990-1992.
- AAAOM, American Association for Acupuncture and Oriental Medicine, communication on a variety of acupuncture-related subjects, 1990-1992.
- AMA, Proceedings of the house of delegates. pg 198-202. 130th annual convention, June 7-11, 1981.
- Baltimore, R.S., and P.J. Moloy. Perichondritis of the ear as a complication of acupuncture. Arch. Otolaryngol. 102: 572-573 (1976).
- Bannerman, R.H. Acupuncture: the WHO view. World Health (English ed.) 24-29, Dec. 1979.
- Birch, S. Acupuncture in Japan: an introductory survey. Review 6: 12-13 (1989)(Part 1); 7: 16-20 (1990)(Part 2); Parts 3-5 (In press, 1990-1991).
- Boxall, E.H. Acupuncture hepatitis in the west midlands, 1977. J. Med. Virol. 2: 377-379 (1978).
- Brockhaus, A., and C.E. Elger. Hypalgesic efficacy of acupuncture on experimental pain in man. Comparison of laser acupuncture and needle acupuncture. Pain 43: 181-185 (1990).
- Bullock, M.L., P.D. Culliton and R.T. Olander. Controlled trial of acupuncture for severe recidivist alcoholism. Lancet i: 1435- 1438 (1989).
- Bullock, M.L., A. J. Umen, P.D. Culliton and R.T. Olander. Acupuncture treatment of alcoholic recidivism: a pilot study. Alcoholism: Clin. Exp Res. 11: 292-295 (1987).
- Castro, K.G., A.R. Lifson, C.R. White, T.J. Bush, M.E. Chamberland, A.M. Lekatsas and H.W. Jaffe. Investigations of AIDS patients with no previously identified risk factors. JAMA 259: 1338-1342 (1988).
- Chapman, C.R., A.C. Chen and J.J. Bonica. Effects of intrasegmental electrical acupuncture on dental pain: evaluation by threshold estimation and sensory decision theory. Pain 3: 213-227 (1977).
- Cheng, R.S.S. Neurophysiology of electroacupuncture analgesia. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 119-136, 1989.
- Cheng, T.O. Pericardial effusion from self-inserted needle in the heart. Eur. Heart J. 12: 958 (1991).

Chiu, D.T. The use of acupuncture during pregnancy. Intern. J. Chin. Med. 1: 19-21 (1984).

Chung, J.M. Neurophysiological mechanisms of acupuncture analgesia in experimental animal models. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 137-155, 1989.

Coan, R.M., G. Wong, S.L. Ku, Y.C. Chan, L. Wang, F.T. Ozer and P.L. Coan. The acupuncture treatment of low back pain: a randomized controlled study. Amer. J. Chin. Med. 8:181-189 (1980).

Coan, R.M., G. Wong and P.L. Coan. The acupuncture treatment of neck pain: a randomized controlled study. Amer. J. Chin. Med. 9: 326-332 (1982).

Davis, J.B., and L. Yin. Acupuncture: past and present. FDA Consumer DHEW Publ. No.(FDA)74-4001, 17-23, May 1973.

Dung, H.C. Biostatistical profiles of individuals seeking acupuncture treatment in the United States. Chin. Med. J. 98: 835-840 (1985).

Eisenberg, D. Encounters with Qi. Exploring Chinese Medicine.

pg. 118-119, W.W. Norton and Co., New York (1985).

Gardner, S. Acupuncture devices labeling. Federal Register 38:

641, March 9, 1973.

Gray, H. Anatomy, Descriptive and Surgical 1901 edition (republished by Running Press, Philadelphia).

Gray, R. G.S. Maharajh and R. Hyland. Pneumothorax resulting from acupuncture. Can. Assoc. Radiol. J. 42: 139-140 (1991).

Han, J. Central neurotransmitters and acupuncture analgesia. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 7-33, 1989.

Hasegawa, J., N. Noguchi, J. Yamasaki, H. Kotake, H. Mashiba, S. Sasaki and T. Mori. Delayed cardiac tamponade and hemothorax induced by an acupuncture needle. Cardiology 78: 58-63 (1991).

Helms, J.M. Acupuncture for the management of primary dysmenorrhea. Obstet. Gynecol. 69:51-56 (1987).

Hollander, J.E., A. Dewitz and S. Bowers. Permanently imbedded subcutaneous acupuncture needles: radiographic appearance. Ann. Emerg. Med. 20: 1025-1026 (1991).

Jones, R.D., and G. Cross, III. Suspected chronic osteomyelitis secondary to acupuncture treatment. J. Am. Podiatry Assoc. 70: 149-151 (1980).

Keller, W.J., S.G. Palmer and J.P. Garvin. Possible renal complications of acupuncture. JAMA 222: 1559 (1972).

Kendall, D.E. A scientific model for acupuncture. Part I and II. Amer. J. Acupunc. 17: 251-268 (1989).

Kent, G.P., J. Brondum, R.A. Keenlyside, L.M. Lafazia and H.D. Scott. A large outbreak of acupuncture-associated hepatitis B. Am. J. Epidemiol. 127: 591-598 (1988).

Lee, M.H.M., and M. Ernst. Clinical and research observation on acupuncture analgesia and thermography. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 157-175, 1989.

Lewith, G.T., and D. Machin. On the evaluation of the clinical effects of acupuncture. Pain 16: 111-127 (1983).

Martelli, C.M., A.L. de Andrade, D. Cardoso, L.C. Sousa, S. Almeida, M.A. de Sousa and F. Zicker. Seroprevalence and risk factors for hepatitis B virus infection by AgHBs and anti-HBs markers in prisoners and prime blood donors. Rev. Saude Publica 24: 270-276 (1990).

Michitaka, K., N. Horiike and Y. Ohta. An epidemiological study of hepatitis C virus infection in a local district in Japan. Rinsho Bvori. 39: 586-591 (1991).

Morrone, N., J.A. Freire, A.K. Ferreira and A.M. Dourado. Iatrogenic pneumothorax caused by acupuncture. Rev. Paul. Med. 108: 189-191 (1990).

Muench, C.G., and P. Buell. Changes in Chinese medical practice in the United States: an historical case study from Idaho. Proceedings of the International Chinese Medicine Conference at the 65th annual meeting of the AAAS, Pacific Division, San Francisco, June 13, 1984.

Murata, K., A. Nishio, M. Nishikawa, Y. Ohinata, M. Sakaguchi and S. Nishimura. Subarachnoid hemorrhage and spinal root injury caused by acupuncture needle--case report. Neurol. Med. Chir. 30: 956-959 (1990).

Osler, W. The Principles and Practice of Medicine. Appleton, New York, 1st ed. (1892); 2nd ed. (1895); 3rd ed. (1898); 4th ed. (1901); 5th ed. (1902); 6th ed. (1906); 7th ed. (1909); 8th ed. (1916).

Osler, W., and T. McCrae. The Principles and Practice of Medicine. Appleton, New York, 9th ed. (1920), 10th ed. (1925); 11th ed. (1930); 12th ed. (1935).

Osler, W., and H.A. Christian. The Principles and Practice of Medicine. Appleton-Century, New York, 13th ed. (1938); 14th ed. (1942); 15th ed. (1944); 16th ed. (1947).

Patel, M. Evaluation of holistic medicine. Soc. Sci. Med. 24: 169-175 (1987a).

Patel, M. Problems in the evaluation of alternative medicine. Soc. Sci. Med. 25: 669-678 (1987b).

Patel, M., F. Gutzwiller, F. Paccaud and A. Marazzi. A meta- analysis of acupuncture for chronic pain. Inter. J. Epidem. 18: 900-906 (1989).

Peacher, W.G. Adverse reactions, contraindications and complication of acupuncture and moxibustion. Am. J. Chin. Med. 1:35-46 (1975).

Pomeranz, B. Acupuncture research related to pain, drug addiction and nerve regeneration. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 35-52, 1989.

Pomeranz, B., and G. Stux. Scientific Bases of Acupuncture. Springer-Verlag, Berlin, 1989.

Richardson, P.H., and C.A. Vincent. Acupuncture for the treatment of pain: a review of evaluative research. Pain 24: 15-40 (1986).

Ritter, H.G., and R. Tarala. Pneumothorax after acupuncture. Br. Med. J. 2: 602-603 (1978).

Sato, M., K. Yamane, M. Ezima, Y. Sugishita and H. Nozaki. A case of transverse myelopathy caused by acupuncture. Rinsho Shinkeigaku 31: 717-719 (1991).

Scheel, O., A. Sundsfjord and P. Lunde. Bacterial endocarditis after treatment by a natural healer. Tidsskr. Nor. Laegeforen 111: 2741-2742 (1991).

Scheel, O., A. Sundsfjord, P. Lunde and B.M. Andersen. Endocarditis after acupuncture and injection--treatment by a natural healer. JAMA 267: 56 (1992).

Schiff, A.F. A fatality due to acupuncture. Med Times 93: 630- 631 (1965).

Shiraishi, S., Y. Kuroiwa, S. Nishio and K. Kinoshita. Spinal cord injury as a complication of acupuncture. Neurology 29: 1188- 1190 (1979).

Sitko, S.P. (editor) Abstracts of the I All-Union Symposium on The Fundamental Aspects of the Application of mm-range Electromagnetic Radiation in Medicine. Kiev, May 10-13, 1989.

Sitko, S.P., E.A. Andreev and I.S. Dobronravova. The whole as a result of self-organization. J. Biol. Physics 16: 71-73 (1988).

- Southworth, S.R., and R.H. Hartwig. J. Hand Surg. 15: 111-112 (1990).
- Stacher, G. I. Wancura, P. Bauer, R. Lahoda, and D. Schulze. Effect of acupuncture on pain threshold and pain tolerance determined by electrical stimulation of the skin: a controlled study. Amer. J. Chin. Med. 3: 143-149 (1975).
- Stux, G., and B. Pomeranz. Basics of Acupuncture. Springer-Verlag, Berlin, 1988.
- Takehige, C. Mechanism of acupuncture analgesia based on animal experiments. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 53-78, 1989.
- Tanii, T., T. Kono, J. Katoh, N. Mizuno, M. Fukuda and T. Hamada. A case of prurigo pigmentosa considered to be contact allergy to chromium in an acupuncture needle. Acta Derm. Venereol. 71: 66- 67 (1991).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Oorsprong en werkings-mechanismen van acupunctuur. Huisarts Wet. 32: 170-175 (1989a).
- Ter Riet, G., J. Kleijnen and P. Knipschild. De meta-analyse als review-methode. Huisarts Wet. 32: 177-181 (1989b).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur en nekpijn/rugpijn. Huisarts Wet. 32: 223-227 (1989c).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur en reumatoïde artritis. Huisarts Wet. 32: 228-229 (1989d).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur en chronische pijn. Huisarts Wet. 32: 230-238 (1989e).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur bij migraine en spanningshoofdpijn. Huisarts Wet. 32: 258-263 (1989f).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur en aangezichtspijn. Huisarts Wet. 32: 264-266 (1989g).
- Ter Riet, G., J. Kleijnen and P. Knipschild. Acupunctuur, alcohol en drugs. Huisarts Wet. 32: 304-307 (1989j).
- Tsou, K. Activation of the enkephalinergic system by acupuncture. in Scientific Bases of Acupuncture (eds. Pomeranz and Stux), Springer-Verlag, Berlin, pg. 113-118, 1989.
- Unschuld, P.U. Traditional Chinese medicine: some historical and epistemological reflections. Soc. Sci. Med. 24: 1023-1029 (1987).

Veith, I. Huang Ti Nei Ching Su Wen. The Yellow Emperor's Classic of Internal Medicine. Univ. Cal. Press, Berkeley (1966).

Vincent, C.A., and P.H. Richardson. The evaluation of therapeutic acupuncture: concept and methods. Pain 24: 1-13 (1986).

Vittecoq, D., J.F. Mettetal. C. Rouzioux, J.F. Bach and J.P. Bouchon. Acute HIV infection after acupuncture treatments. New Eng. J. Med. 320: 250-251 (1989).

WHO (World Health Organization). A standard international acupuncture nomenclature: memorandum from a WHO meeting. Bull. World Health Organization 68: 165-169 (1990).

Wolpe, P.R. The maintenance of professional authority: acupuncture and the american physician. Social Prob. 32: 409-424 (1985).

Wright, R.S., J.L. Kupperman and M.I. Liehaber. Bilateral tension pneumothoraces after acupuncture. West J. Med. 154: 102- 103 (1991).

APPENDIX 1

BRIEF OVERVIEW OF Qi PARADIGM

A brief overview of the Qi paradigm follows. For this discussion Qi refers to the "internal energy" that animates the body.

1. Qi flows throughout the body. The pattern of flow includes fourteen major channels (meridians) and several minor channels interconnected throughout the body;
2. The flow of Qi through a specific major channel is associated with one of the general physiological functions (e.g., fluid exchange), although it may be called by the name of a specific organ (e.g., the urinary bladder); (Note: The traditional Chinese terminology is different from [broader than] the Western medical terminology and can lead to semantic confusion.)
3. The flow of Qi may become inhibited or accelerated, resulting in excess Qi in some areas and deficiencies of Qi in other areas;
4. Normal flow of Qi is necessary for health, i.e., abnormal flow can lead to disease or susceptibility to disease states (and diseases can further affect Qi flow);
5. The flow of Qi in the channels comes close to the skin surface at specific, anatomically identifiable locations called acupuncture points;
6. The flow of Qi can be affected with acupuncture needles, pressure, and heat at these acupuncture points;
7. A trained acupuncturist can use acupuncture needles to correct or balance the Qi flow, thereby correcting the root cause of the disease state or susceptibility to the disease and allowing the body to heal;
8. The treatment regimen includes using acupuncture points that relate to the affected physiological function and/or to abnormality along the channel (e.g. tennis elbow);
9. Appropriate diagnosis is needed on an individual basis and may differ from day to day for the same individual.

A good beginning explanation of acupuncture written by Western physicians for Westerners is "Basics of Acupuncture" by Stux and Pomeranz (1989). Discussions of differences and similarities of the paradigms underlying traditional Chinese medicine and Western medicine have been written by Unschuld (1987) and Patel (1987a,b).

APPENDIX 2

CONDITIONS COMMONLY TREATED BY ACUPUNCTURE (AAAOM)

Conditions commonly treated by acupuncture, as listed in an educational brochure from the American Association of Acupuncture and Oriental Medicine, are as follows:

| | |
|--------------------------|-----------------------------|
| Allergies/Asthma | Heart problems/Palpitations |
| Anxiety/Depression | High blood pressure |
| Arthritis/Joint problems | Immune system deficiency |
| Back pain | Infertility |
| Bladder/Kidney problems | Knee pain |
| Childhood illnesses | Neck pain/Stiffness |
| Constipation/Diarrhea | Pre-menstrual Syndrome |
| Colds/Flu | Paralysis/Numbness |
| Cough/Bronchitis | Sciatica |
| Dizziness | Sexual Dysfunction |
| Drug addiction/Smoking | Shoulder pain |
| Fatigue | Skin problems |
| Gynecological disorders | Stress/Tension |
| Headache/Migraine | Tendonitis |
| Health maintenance | Vision problems |

APPENDIX 3

CONDITIONS COMMONLY TREATED BY ACUPUNCTURE (WHO)

The WHO Interregional Seminar drew up the following provisional list of the diseases that lend themselves to acupuncture treatment (Bannerman, 1979). The list is based on clinical experience, and not necessarily on controlled clinical research; furthermore, the inclusion of specific diseases is not meant to indicate the extent of acupuncture's efficacy in treating them.

| | |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Upper Respiratory Tract | Acute sinusitis Acute rhinitis Common cold Acute tonsillitis |
| Respiratory System | Acute Bronchitis Bronchial asthma (most effective in children and in patients without complicating diseases) |
| Disorders of the Eye | Acute conjunctivitis Central retinitis Myopia (in children) Cataract (without complications) |
| Disorders of the Mouth | Toothache Post-extraction pain Gingivitis Acute and chronic pharyngitis |
| Gastro-intestinal Disorders | Spasms of oesophagus and cardia Hiccough Gastroptosis Acute and chronic gastritis Gastric hyperacidity Chronic duodenal ulcer (pain relief) Acute duodenal ulcer (without complications) Acute and chronic colitis Acute bacillary dysentery Constipation Diarrhea Paralytic ileus |
| Neurological and Musculo-skeletal Disorders | Headache Migraine Trigeminal neuralgia Facial palsy (early stage, i.e., within three to six months) Pareses following a stroke Peripheral neuropathies Sequelae of poliomyelitis (early stage, i.e., within six months) Meniere's disease Neurogenic bladder dysfunction Nocturnal enuresis Intercostal neuralgia Cervicobrachial syndrome "Frozen shoulder" "Tennis elbow" Sciatica Low back pain Osteoarthritis |

APPENDIX 4

NATIONAL PROFESSIONAL ACUPUNCTURE ORGANIZATIONS

American Association of Acupuncture and Oriental Medicine (AAAOM): Of the two major membership organizations, the one with the largest number of acupuncture practitioners in the U.S. is the AAAOM. It was founded in 1981 and consists of 1,646 members (as of 6/5/92). The membership consists of a few Western-trained physicians with training in acupuncture, with the majority of members being traditionally-trained acupuncturists. The leadership of AAAOM was instrumental in the formation of the National Council of Acupuncture Schools and Colleges (NCASC - see below), and together with the NCASC established the National Commission for the Certification of Acupuncturists (NCCA), with the purpose of standardizing acceptable levels of training and credentialing of acupuncturists. The AAAOM also has a lobbying effort for legislation that affects the practice of acupuncture.

American Academy of Medical Acupuncture (AAMA): The AAMA was formed in 1987 and is restricted to licensed physicians (M.D. or D.O.) who have received training in acupuncture. There are about 550 members (as of 6/4/92). The AAMA follows WHO's World Federation of Acupuncture-Moxibustion Societies' guidelines for physician training as requisite for full membership. Qualifications include (beyond the medical degree) a minimum of 220 hours of formal training (120 hours classroom and 100 hours clinical), or the equivalent in approved apprenticeship training, plus two years practice experience in acupuncture. The AAMA organizes and presents medical acupuncture symposia and courses accredited by the Accreditation Council for Continuing Medical Education. It is also active in educating malpractice and third party insurance companies as to standards of acupuncture practice, and has established guidelines for hospital privileges for the in-house practice of acupuncture. Its sister organization, the American Foundation of Medical Acupuncture is engaged in clinical research projects. The Review of the AAMA is published semi-annually.

National Commission for the Certification of Acupuncturists (NCCA): The NCCA was established in 1984 to set and maintain national standards for competence in acupuncture. Certification of an individual requires qualifying for the examinations (based on training and experience: two years of full-time acupuncture schooling, or a state acupuncture license, or four years of approved apprenticeship with at least 500 patient encounters per year) and passing a comprehensive written examination and a practical examination of clean needle technique. 2,999 acupuncturists have been certified, as of 6/5/92. The NCCA certification examination has been adopted by 10 states, plus the District of Columbia. Seven other states use the same criteria. The NCCA has also published a manual: "Clean Needle Technique for Acupuncturists: Guidelines and Standards for the Clean and Safe Clinical Practice of Acupuncture."

National Council of Acupuncture Schools and Colleges (NCASC): The NCASC was formed in 1982 with membership open to established three-year acupuncture training programs that provide classroom and clinical instruction. The NCASC has established the national accreditation commission (NACSCAOM - see below) to credential schools and colleges of acupuncture and oriental medicine. Together with AAAOM, NCASC

established the National Commission for the Certification of Acupuncturists (NCCA). There are presently 18 member institutions (as of June 1992) of the 35 (as of 1990) such schools and colleges in the U.S.

National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine (NACSCAOM): The NACSCAOM was established in 1982 to evaluate educational programs in acupuncture and Oriental medicine. The Commission establishes criteria for accreditation considering such factors as curriculum, training of faculty, facilities, entry requirements, organizational and financial structure. As of June 1992, 11 programs had been accredited and 7 programs had candidate status toward accreditation. NACSCAOM has achieved recognition by the U.S. Department of Education, which means that NACSCAOM-accredited schools can apply to make their students eligible for federally-funded student loans and grants. NACSCAOM also recently (April, 1990) achieved recognition by the Council on Post-secondary Accreditation (COPA), which accredits major colleges and universities.

APPENDIX 5

STATE REGULATORY SUMMARY

The following is a list of states that officially recognize the practice of acupuncture by non-physicians (as of 6/92).

| | |
|--------------------------|-------------------|
| Alaska - l | Nevada - l |
| California - c | New Jersey - c |
| Colorado - r | New Mexico - l |
| Connecticut* | New York - l |
| Delaware* | Oregon - r |
| District of Columbia - l | Pennsylvania* - r |
| Florida - l | Rhode Island - l |
| Hawaii - l | South Carolina* |
| Illinois* | Texas* |
| Maine - l | Utah* - l |
| Maryland* - r | Vermont - r & l |
| Massachusetts* - l | Virginia* - c |
| Minnesota* | Washington - c |
| Montana - l | Wisconsin - c |

l = license; c = certify; r = register; * = medical supervision required