REPORT OF THE
BOARD OF HEALTH PROFESSIONS OF THE
DEPARTMENT OF HEALTH PROFESSIONS

Review of the Regulation of Acupuncture in Virginia

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 19

COMMONWEALTH OF VIRGINIA
RICHMOND
1989

COMMONWEALTH of VIRGINIA

Department of Health Professions

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TO: The Honorable Gerald L. Baliles
Governor of the Commonwealth of Virginia

The Members of the General Assembly of Virginia

It is my privilege to present the report constituting the response of the Board of Health Professions to the request contained in Senate Joint Resolution No. 16 of the 1988 Session of the General Assembly of Virginia.

This report provides findings of the Board regarding the regulation of acupuncture in Virginia.

Bernard L. Henderson, Jr.

BLHjr/rbt
Enclosure

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

BOARD OF HEALTH PROFESSIONS

REVIEW OF THE REGULATION OF ACUPUNCTURE IN VIRGINIA

In Response To

Senate Joint Resolution Number 16

of the

1988 Session of the General Assembly of Virginia

January 1989
Richmond, Virginia

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SENATE JOINT RESOLUTION NO. 16

Requesting the Council on Health Regulatory Boards to study the feasibility of authorizing the practice of acupuncture by professionals other than physicians in the Commonwealth.

Agreed to by the Senate, February 2, 1988
Agreed to by the House of Delegates, March 9, 1988

WHEREAS, under the law of Virginia, acupuncture is considered "an experimental therapeutic modality" and its practice is restricted within the Commonwealth pursuant to regulations of the Board of Medicine; and

WHEREAS, other jurisdictions have come to accept the practice of acupuncture as a valid treatment; and

WHEREAS, many states, including some that adjoin this Commonwealth, license nonphysician professionals to practice acupuncture; and

WHEREAS, many citizens of the Commonwealth find it necessary to travel to an adjoining state to obtain acupuncture treatment; and

WHEREAS, access to this treatment should be provided to those Virginians who desire it; and

WHEREAS, § 54-955.1 of the Code of Virginia requires the Council on Health Regulatory Boards to evaluate each health care profession and occupation in the Commonwealth to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Council on Health Regulatory Boards is requested to conduct a special study, within its authority granted by § 54-955.1 of the Code, on the practicality and desirability of authorizing nonphysician professionals to practice acupuncture and, if such practice is found to be appropriate, the means of regulation for such practice.

Upon completion of this study the Council shall report its findings to the Governor and the General Assembly as provided in procedures of the Division of Legislative Automated Systems for processing legislative documents.

VIRGINIA BOARD OF HEALTH PROFESSIONS
REVIEW OF THE REGULATION OF ACUPUNCTURE IN VIRGINIA
In Response to
Senate Joint Resolution Number 16
1988 Legislative Session of the Virginia General Assembly

I. INTRODUCTION

Senate Joint Resolution Number 16 of the 1988 Session of the Virginia Legislature requested the Council on Health Regulatory Boards (renamed Board of Health Professions effective January 1, 1989) to "conduct a special study...on the practicality and desirability of authorizing nonphysician professionals to practice acupuncture and, if such practice is found to be appropriate, the means of regulation for such practice."

The Board of Health Professions is authorized to evaluate the need to regulate health professions and occupations and the appropriate methods for regulation, as well as to examine scope of practice conflicts involving regulated and unregulated professions, and to "advise the health regulatory boards and the General Assembly of the nature and degree of such conflicts" (Code of Virginia, § 54.2510.2. and 12.).

Because acupuncture is licensed by the Board of Medicine, the Board of Health Professions did not interpret the request to include assessment of whether the practice should be regulated. Rather, Senate Joint Resolution No. 16 makes clear that conflict exists between those who support the current system for regulation and those practitioners who believe themselves to be competent and qualified to provide acupuncture services but are prevented by existing statutes and regulations from doing so. As a consequence, this review was assigned to and conducted by the Board of Health Professions' Committee on Scopes and Standards of Practice. The report and recommendations have been approved by the full Board of Health Professions.

The Current Regulation of Acupuncture in Virginia.

Acupuncture in defined by statute in Virginia as "an experimental therapeutic modality, used in the practice of the healing arts, intended to alleviate pain, and involving the selective stimulation of the human body's neurological mechanisms by the insertion of needles" (Code § 54.1-2900).

The healing arts are further defined as "the arts or sciences dealing with the prevention, diagnosis, treatment and cure or alleviation of human physical or mental ailments, conditions, diseases, pain or infirmities" (Code § 54.1-2900). Except as they are exempted from such governance by law, the

healing arts practiced in the Commonwealth are regulated by the Board of Medicine. The health professions and occupations regulated currently by the Board of Medicine are:

- o Medicine (M.D.) and Osteopathic Medicine (D.O.)
- o Chiropractic (D.C.)
- o Podiatry (D.P.M.)
- o Physical Therapy (and Physical Therapist Assistant)
- o Clinical Psychology
- o Respiratory Therapy
- o Physician's Assistant
- o Correctional Health Assistant
- o Acupuncture

The Board of Medicine defines and restricts the practice of acupuncture in Virginia by regulation (Regulation 1.1) as follows:

> Acupuncture is an experimental therapeutic procedure, used primarily for the relief of pain, which involves the insertion of needles at various points in the human body. There are many acupuncture points, and these points are located on most portions of the human body. Insufficient information is available regarding its general usefulness and the risks attendant. Among the risks that are attended upon it are the possibilities of prolonged and inappropriate therapy. It is clear that the administration of acupuncture is accompanied by the possibility of serious side effects and injuries and there are reported cases of such injuries. Possible complications and injuries included peritonitis, damage from broken needles, infections, serum hepatitis, acquired immunity deficiency syndrome, pneumothorax, cerebral vascular accident (stroke), damage to the eye and/or damage to the external or middle ear, and the inducement of cardiac arrhythmia.
>
> In the judgment of the Board, acupuncture should be performed only by those practitioners of the healing arts who are trained and experienced in medicine, since only such a practitioner has (1) skill and equipment to determine the underlying cause of the pain, and (2) the capability of administering acupuncture in the context of a complete patient medical program in which other methods of therapeutics and relief of pain, including the use of drugs and other medicines, are considered and coordinated with the acupuncture treatment, and (3) skill and training which will minimize the risks attendant with its use.
>
> No person shall practice acupuncture in this State without being registered by the Board to do so.
>
> Based on the foregoing considerations, the Board will register only doctors of medicine (M.D.), osteopathy

(O.D.), and podiatry (D.P.M.) since only these practitioners have demonstrated competence in medicine by passing Parts I, II and III of the medicine/osteopathy, and podiatry licensure examination. Podiatrists shall use acupuncture for treatment of pain syndrome originating in the human foot. One hundred (100) hours of postgraduate training in a school of acupuncture approved by the Board shall be prerequisite to registration as an acupuncturist. Records of the diagnosis, treatment and patient response to acupunture shall be maintained an submitted on request to the Board.

. . .Acupuncture is interpreted strictly by the Board as the insertion of needles.

In regulations proposed by the Board of Medicine to become effective in January 1989, the substance of existing regulations is continued, but prerequisites for acupuncture are increased to include (1) "at least 100 hours of instruction in general and basic aspects, specific uses and techniques of acupuncture and indications and contraindications for acupuncture and (2) at least 100 hours of supervised clinical experience approved by the Board of Medicine and under the supervision of a currently licensed physician in acupuncture" (Proposed Regulation 4.2.A.1 and 2). The level of regulation of acupuncture is also changed from registration to licensure.

Senate Joint Resolution No. 16 implies that statutes and regulations governing acupuncture may be more restrictive than required for the protection of the public health, safety and welfare, observing that:

- other jurisdictions have come to accept the practice of acupuncture as a valid treatment;
- many states, including some that adjoin Virginia, license nonphysician professionals to practice acupuncture;
- many citizens of the Commonwealth find it necessary to travel to an adjoining state to obtain acupuncture treatment; and
- access to this treatment should be provided to those Virginians who desire it.

Currently, there are 50 individuals registered by the Board of Medicine to perform acupuncture, compared to 28 registered in 1985 (although only 38 current registrants have paid renewal fees now due). Thirteen of the current number reside in states or countries distant from Virginia. Thirteen are located in the Greater Metropolitan Washington area, ten are in the Richmond area, eight are in the Tidewater/Peninsula region, and the balance are dispersed throughout the Commonwealth. Two are osteopathic physicians and 48 are M.D.s.

Process of the Review.

The Committee on Scopes and Standards of Practice devoted three work sessions to this issue, and an informational hearing was conducted in August 1988 in Richmond. In addition, a review of the literature relevant to the issue was conducted by the Chairman. The status of the regulation of acupuncture in other states was reviewed, and the Committee attempted to determine whether harm related to the practice of acupuncture has been documented.

Organization of the Report.

This report is organized in the following sequence. First, the patterns of regulation of acupuncture among the states are reviewed. This review is followed by an analysis of issues raised in testimony presented at the informational hearing and in subsequent written comments. A review of the literature is then provided, and the report concludes with an executive summary of findings and recommendations. Additional material of interest is appended.

II. REGULATION OF ACUPUNCTURE AMONG THE STATES

Types and Levels of Regulation.

According to the Clearinghouse on Licensure, Enforcement and Regulation of the Council of State Governments (CLEAR, 1986), twenty-two states regulated independent practitioners of acupuncture in 1984. According to CLEAR's interpretation of state law, 12 states licensed acupuncturists, two certified these providers, and three states regulated independent acupuncturists by registration. The type of regulation is not always self-apparent. For example, while the Virginia program is titled "registration," in current (1988) regulations, CLEAR argues that the Virginia program is more accurately "licensure" since only specifically designated groups may engage in the practice of acupuncture. This confusion is clarified in the revised regulations of the Board, effective January 1989, in which the term "license" is used. The regulation of acupuncture among the states, as reported by CLEAR, is summarized in Table 1.

The balance of states--representing a small majority--reserve the practice of acupuncture to physicians, but impose no separate requirements for physicians practicing acupuncture. In one state--Georgia--acupuncture may be performed only by licensed physicians following approval by the Board of Medical Examiners "to investigate and experiment with acupuncture in accordance with requirements of the Board and the U. S. Food and Drug Administration (FDA)."

The restriction of acupuncture to physicians and the characterization of acupuncture as an "experimental procedure" have been subject to legal challenge (Havighurst, 1988).

In Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980), the court invalidated a move by the Texas Medical Licensing Board to treat acupuncture as the practice of medicine and as an experimental procedure requiring special safeguards. In this case, two physicians were disciplined for allowing nonphysicians to practice acupuncture under their supervision. Because no physician in Texas was trained in acupuncture, the practical effect of the board's action was to make the service unavailable. The court ruled in favor of the consumer plaintiffs, stating:

> The plaintiffs have a constitutional right, encompassed by the right of privacy to obtain acupuncture treatment. The challenged articles and rules effectively deprive them of that right, and are not necessary to serve the State's interest in protecting the patient's health.

In Virginia, the practice of acupuncture is classified as "experimental" by statute. The Board of Medicine has been encouraged by the Board of Health Professions to include in the language of its regulations only those provisions that place a

TABLE 1

REGULATION OF ACUPUNCTURE AMONG THE STATES IN 1984
According to The Council of State Governments

STATE	TYPE OF REGULATION
Alaska	Licensure
Arizona	Certification
California	Certification*
Florida	Certification*
Georgia	Approval (a)
Hawaii	Licensure
Louisiana	Certification
Maryland	Registration
Montana	Licensure
Nevada	Licensure
New Mexico	Licensure
New Jersey	Certification*
New York	Licensure
	Certification
	Registration
Oregon	Registration*
Rhode Island	Licensure
South Carolina	(b)
South Dakota	Registration
Texas	(c)
Utah	Licensure
Virginia	Registration*
West Virginia	Registration (d)
Washington	Licensure (e)

KEY:

* Although designated in law as certification or registration, according to CLEAR's definition, the program is in effect licensure.

(a) Licensed physicians must get approval from the Board of Medical Examiners to "investigate and experiment with acupuncture." (See text)

(b) Licensed M.D.s and D.D.S.s may practice acupuncture with approval of State Board of Medical Examiners.

(c) A physician must apply to the State Board of Medical examiners for approval to supervise services of acupuncturist.

(d) A licensed M.D. must register with Board of Medicine to practice acupuncture. There are no other requirements.

(e) Licensed as an acupuncture physicians assistant who shall perform only under direct supervision of a licensed physician.

Source: Council of State Governments' Clearinghouse on Licensure, Enforcement and Regulation (CLEAR). State Credentialing of the Health Occupations and Professions. 1986, p. 34, Lexington, KY.

substantive requirement on regulated practitioners and to avoid terms and phrases that are philosophical in nature or that may be legally indefensible. The Board of Medicine has retained the challenged language, arguing that this language is needed for clarity.

Scope of Practice.

Licensure as a form of occupational regulation implies a statutorily defined scope of practices that may be provided only by members of a specific group. In this sense, licensure confers a monopoly for the provision of a given service upon one or more professions or occupations.

Among the 12 states that license acupuncturists independently, three types of practice are defined in state law. The most common (8 states) defines acupuncture to mean "the insertion of needles into the human body by piercing the skin for the purpose of controlling and regulating the flow and balance of energy in the body." The second type includes needle insertion and also specifies other forms and applications of acupuncture. For example, four states, including California, define acupuncture to mean "the stimulation of a certain point or points on or near he surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain diseases and dysfunctions of the body and includes the techniques of electroacupuncture, cupping, and moxibustion(CLEAR, 1986).

A single state, New Mexico, has adopted the practice definition proposed as a model by the Traditional Acupuncture Institute. This definition includes the use of other traditional Asian methods such as pulse and tongue evaluation, as well as needle insertion and the use of thermal or electrical stimulation of acupuncture points.

Licensure Requirements.

CLEAR reports that the initial requirements for licensure, certification or registration to provide acupuncture services are diverse and that major trends are not discernible. Evidence for this diversity is present in the summary of requirements appearing in Table 2. This summary, it must be noted, pertains only to those states regulating acupuncture independent of the regulation of physicians and other health provider. In the majority of states, in which only licensed physicians may provide acupuncture services, no separate qualification beyond that required of all physicians licensed is imposed.

In Virginia, candidates for acupuncture privileges must complete a specific number of hours of training approved by the Board of Medicine to qualify. For this purpose, the Board currently recognizes schools of acupuncture approved by the New

TABLE 2

ACUPUNCTURE
INITIAL REQUIREMENTS FOR LANGUAGE/LICENSE

STATE	EDUC.	INTERN[1]	MORALS	AGE	CIT.	RES.	WORK EXP.	EXAM
Alaska	a+b	1 yr.			yes			w/o
Arizona	s							w/o/p
California	c			18			yes	w/o/p
Florida	d			18	yes*		yes	w/p
Georgia	e							none
Hawaii	d+v	1 yr.						w
Louisiana	t							
Acupuncturists' Assistant	u							none
Maryland	b		r	21				w
Montana	f or g		q	18				w/p
Nevada	c+h		r				yes	w/o/p
New Jersey	(Bach+d) or g or i		q	21			yes	w/o/p
New Mexico	g	500 hrs.	q			yes		w/p
New York								May
Licensure	j		q,r					
Certification	k	100 hrs.	q,r					
Registration	l	100 hrs.	q,r					
Oregon	f	1 yr.	q,r					w/o/p
Rhode Island	m			21				
Acupuncture Assistant	n			21				w/p
South Dakota	o							w/p
Texas	d	2 yrs.	q,r	18		yes		none
Utah	d	500 hrs.		21		yes		w/p
Virginia	p							none
Washington	w+d	350 hrs.	r					w/p

KEY

1 An internship is defined as supervised work experience.
* Or a permanent resident of the U.S. or a legal alien who has resided in the U.S. for six months immediately prior to qualifying for the exam.
a Graduate of an accredited medical school.
b Meet educational and/or experiential requirements of the Board.
c Completion of an approved education and training or tutorial program
d Completion of a Board-approved two-year program.
e Board approval of 100 hours of training.
f Graduate of an approved school of acupuncture.
g Completion of a course approved by the Board.
h Six years of training.
i At least three years' experience practicing acupuncture, which is Board recognized, or is licensed to practice medicine and surgery, or registered to practice physical therapy in this state.
j Licensed as a Doctor of Acupuncture, herb physician, or doctor of traditional Chinese medicine, with ten years' experience.
k Licensed to practice medicine or dentistry, 300 hours of instruction.
l Graduate of school of medicine, acupuncture, herb medicine or traditional Chinese medicine; 200 hours of instruction and five years' experience.
m Certificate from an accredited program and ten years' experience.
n Completion of a 36-month course with three years' experience.
o Chiropractor and 200 hours of study recognized by the Council on Chiropractic E tion.

p. M.D., D.O., or D.P.M.; 100 hours post-graduate training in a school of acupuncture.
q Good moral character.
r Must be proficient in the English language.
s Licensed Chiropractor
t Physician licensed to practice in Louisiana and completion of six months' training in Traditional Chinese Acupuncture in a school or clinic approved by the Board.
u Completion of 36 months' training in a school or clinic of Traditional Chinese Acupuncture approved by the Board or an individual who has been appointed or employed at a licensed or accredited Louisiana hospital, medical school, or clinic to perform acupuncture for research purposes. The acupuncturists' assistant must be employed by and work under the physical direction, control, and supervision of a physician or an acupuncturist certified by the Board to practice acupuncture and must perform such duties at the place of employer's practice or in the physical presence of the employer.
v Diploma from an approved qualified tutor. Tutorships approved by the Board prior to December 31, 1984, shall be acceptable for examination upon their completion. Tutorships shall no longer be accepted for qualification for examination after June 30, 1987.
w Completion of two years of college in the general sciences and the humanities.

Examinations: w = written; o = oral; p = practical (National Board Examination of the National Commission for Certification of Acupuncturists required in New Jersey and Utah).

Source: Council of State Governments Clearinghouse on Licensure, Enforcement and Regulation. State Credentialing of the Health Occupations and Professions. 1984, pp. 41-42, Lexington, KY.

York Department of Education. Approval of other programs has been requested, and the Board recognizes that it has no procedure in place for evaluating these requests at this time.

Of the twenty-two states regulating acupuncturists independently, fewer than one-half require continuing education as a condition of license renewal. Reflecting the uneven requirements for initial and continuing eligibility, only seven states provide for the licensure of out-of-state candidates by endorsement of other state credentials or by reciprocity.

Organizational Arrangements for Acupuncture Regulation.

The Virginia Board of Medicine is counseled relative to acupuncture by an Advisory Committee, comprised of six physicians (M.D.s), three of whom are Board members. Three others are associated with university medical faculties, and two of these three are licensed acupuncturists.

Of the states regulating independent practitioners of acupuncture, fewer than one-half use the services of a separate acupuncture board; most states regulate the practice through the state board of medicine. In nearly every state, the functions of the regulatory board include the issuance of licenses and the promulgation of rules and regulations. In all states that regulate acupuncture independently, the regulatory board may revoke or suspend the acupuncturist's credential to practice. In four states, an administrative fine may also be imposed.

Virginia is one of four of the 22 states regulating acupuncture independently that do not require successful completion of an examination. In two states (New Jersey and Utah), the law specifically requires the National Board Certification Examination administered by the National Commission for Certification of Acupuncturists (CLEAR 1986).

Private Credentialing Mechanisms.

As with many other health occupations and practices, private credentialing programs have arisen to promote voluntary standards. In 1985, a Certification Examination for Acupuncturists was inaugurated by the National Commission for the Certification of Acupuncturists (NCCA), a joint commission of representatives of the National Council of Acupuncture Schools and Colleges (NCASC), and the American Association of Acupuncture and Oriental Medicine (AAAOM). The Commission also includes one consumer representative selected by the eight organizational representatives.

Any acupuncturist licensed by any state is eligible to sit for the Commission's voluntary certification examination. For others, requirements include four years of acupuncture practice and a minimum of two years' full time acupuncture schooling or four years of apprenticeship. The educational requirement must

include a minimum of 1000 hours of entry level acupuncture training consisting of at least 300 clinical and 700 didactic hours (NCCA, 1988a).

In response to public concerns about potential AIDS transmission by acupuncture practices, the Commission also publishes guidelines and standards for the clean and safe clinical practice of acupuncture. The current certification examination tests for knowledge of these clean needle techniques (NCCA 1988b).

According to the Commission, more than 2,000 individuals now hold certification as a result of successful completion of the examination. More than 700 individuals were examined in 1987. In contrast to the CLEAR report that two states were required the NCCA examination in 1984, the Commission reports that in 1988 twelve states (FL, HI, ME, MD, MA, MO, NJ, NM, NY, OR, PA, and UT) now accept or require the examination as a basis for state credentialing, and two additional governments (DC and RI) are developing regulations based on NCCA standards.

Summary.

The credentialing and regulation of acupuncture in the United States is uneven and in flux. Little unequivocal guidance is afforded for decision-making from this review of state regulatory mechanisms and private credentialing programs.

As evidence of the lack of conformity in the public sector, the Acupuncture Examining Committee of the California Board of Medical Quality Assurance will convene a National Conference on the Licensing and Regulation of Acupuncture/Oriental Medicine for state government staff and board members in February, 1989. The agenda for this conference includes:

- minimum standards for acupuncture training and education, including standards for the approval of schools;
- enforcement and disciplinary issues, including advertising and scope of practice;
- written and practical examination standards and development;
- evaluation of foreign credentials, and;
- review of national standards, issues and organizations,

The Virginia Board of Medicine and the Board of Health Professions will be represented at this national conference, the first to be held on acupuncture regulation in the United States.

III. PUBLIC POLICY ISSUES IN ACUPUNCTURE REGULATION

Significant public policy issues inherent in the regulation of acupuncture were drawn into sharp focus during the informational hearing conducted as part of this review and in comments submitted following that hearing. The strength and substance of the conflict between those who support existing provisions and those who wish to practice acupuncture but cannot be credentialed under these provisions is central to this review.

To control for unintended bias in the exposition that follows, a summary will be provided with no attempt to assess the validity of the opposing positions. Once this presentation is complete, the report will turn to the published literature to validate or refute these positions insofar as relevant issues are addressed authoritatively in reported studies and analyses.

Arguments Supporting the Current Regulatory Arrangement.

Support for maintaining the current system for restricting the provision of acupuncture to physicians, osteopathic physicians and podiatrists rests on statements of the Board of Medicine and the Medical Society of Virginia. In addition, the American Academy of Medical Acupuncturists, while agreeing that acupuncture lies clearly within the bounds of medical practice, argued for increasing the training for physicians licensed to perform acupuncture as well as for the licensure of certain nonphysicians who possess this training.

The position of the Board of Medicine's Advisory Committee on Acupuncture was presented in written comments of a member of that Committee, later ratified by the full Board:

> While acupuncture is accepted as an alternative form of therapy in the Peoples Republic of China its efficacy in the treatment of disease is not recognized. Its primary use in this country has been for the treatment of pain. Although claims of its benefits are widespread, yet most reports are anecdotal and lack scientific verification. The few controlled studies in the literature suggest that random needling is as effective as traditional acupuncture, indicating that the effect is largely that of a placebo.
>
> Animal studies indicate that there may be a diminution in response to painful stimuli with acupuncture, but comparative studies in humans are inconclusive. Experimental studies suggest that there may be an endorphinergic response to acupuncture which produces pain modulation. Further studies may elucidate the mechanism by which modulation is achieved.
>
> In the Commonwealth of Virginia, acupuncture as a therapeutic tool has been wisely restricted to physicians who can diagnose disease states and prescribe

appropriate therapy. Nonphysicians utilizing acupuncture cannot make a medical diagnosis, and, in treating symptoms of pain, may cause delay in diagnosis and treatment of severe disease states.

Of greater concern at this time is the possibility of transmission of hepatitis, and, more importantly AIDS through improper needle sterilization techniques. Physicians receive considerable training in asepsis and communicable disease, whereas lay individuals and other practitioners denied the performance of invasive procedures lack such training.

Further, current regulations should be strengthened rather than liberalized. It is impossible to become proficient in a 'science' with just 100-200 hours in attendance at weekend seminars or workshops as is currently the requirement for licensure. A medical education requires years of training in anatomy, physiology, neurology, disease states and clinical therapeutics. To apply a single modality of therapy to all pain patients regardless of etiology is irrational.

Since institution of the current acupuncture regulations, exploitation of patients with acupuncture has been minimal in the Commonwealth of Virginia. If licensure is extended to those other than physicians, not only is there the possibility of exploitation of patients for profit, but a substantial public health hazard could be created. There are already sufficient physicians licensed to perform acupuncture in Virginia to provide an adequate geographic distribution of such services. Review of records of those so licensed fails to suggest a shortage of availability of acupuncture for the population of Virginia (Carron, 1988).

A statement of essentially the same regulatory philosophy was also presented by the Medical Society of Virginia:

Research indicates that acupuncture provides some degree of analgesia to relieve chronic pain in certain circumstances. Pain management, however, requires a multi-disciplinary approach using numerous modalities (i.e. physical therapy, nerve block, TENS [transcutaneous electrical nerve stimulation] and pharmacological treatment) of which acupuncture can be used as an additional modality by physicians certified to use acupuncture for the treatment of chronic pain.

Until more scientific research can be done on the effectiveness of acupuncture in the treatment of chronic pain, its use needs to be restricted to those physician acupuncturists certified in accordance with current Virginia statutes. With 38 Virginia physicians currently certified in acupuncture, consumer demand is

being adequately filled and the need for non-M.D. practitioners is not indicated (Rafii, 1988).

Arguments Favoring Acupuncture Practice by Nonphysicians.

A relatively small number of special interest organizations and nearly 100 individuals supported the credentialing of trained nonphysicians to practice acupuncture. The majority were consumers wishing to commence or continue acupuncture treatments without the need to travel to adjoining jurisdictions (notably the the District of Columbia and Maryland).

In most instances, current recipients of acupuncture were aware that these services could be provided by Virginia licensees in their area; they nonetheless favored nonphysicians as providers, citing cost, "humanism," and superior training in the theory and practice of acupuncture as reasons for this preference. A number had sought acupuncture only after a persistent problem failed to respond to traditional medical, surgical and pharmaceutical intervention.

A surprising number of conditions were cited by these consumers as having been effectively treated by acupuncture. Among these were arthritis, tendonitis, allergies, digestive problems, chronic pain (especially back pain), rapid mood swings, depression, fatigue, pre-menstrual syndrome (PMS), dysmenorrhea, rashes, bladder infections, gall bladder pain, loss of hair, and plantar warts.

Among those presenting arguments for reform were a number of health professionals: physicians (4); chiropractors (2); a nurse, a pharmacist, a dentist, and three "registered acupuncturists". Chiropractors commenting on acupuncture favored extending licensure to any licensed health profession, noting that chiropractic and acupuncture often focus on musculoskeletal pain. Other health professionals were annoyed by the inconvenience of referring patients who could benefit from or wished to receive acupuncture treatments to the few currently licensed acupuncturists.

The extension of acupuncture license eligibility to dentists with proper post-professional training was advocated by the Virginia Dental Association. Dentists are trained in conscious sedation and many have additional training in general anesthesia. Since one of the more prevalent uses for acupuncture is to manage pain, this organization believes dentists with proper training should be permitted, along with physicians, osteopaths, and podiatrists, to perform acupuncture.

While most of those favoring liberalization of requirements reside in Northern Virginia, a smaller number are dispersed throughout the Commonwealth. Consumers noted frequently that traditional medical practices and acupuncture should be viewed as complementary services, each effective for treatment of certain aspects of specific health problems or syndromes.

Virtually all those favoring the licensure of nonphysicians cited the disparity of training between Board-licensed acupuncturists and nonphysicians licensed elsewhere. Training requirements for nonphysician acupuncturists in Maryland, for example, total more than 1,000 hours while Virginia (until January 1989) requires only 100 hours of postprofessional training for physicians, osteopathic physicians, and podiatrists.

A number of interest group organizations also supported liberalization of policy to include nonphysician acupuncturists: The American Association for Acupuncture and Oriental Medicine; The National Commission for the Certification of Acupuncturists; The American Academy of Medical Acupuncturists; The Traditional Acupuncture Foundation; and The Korean Acupuncture Association. These organizations favored a system in Virginia identical or analogous to that in Maryland where trained nonphysicians can be credentialed so long as patients are referred by a physician or seen by a physician who certifies that acupuncture is not contraindicated for the patient or condition. The level of supervision of nonphysicians by physicians advocated by these organizations varied from general to direct supervision.

A common focus of advocates for nonphysician practice privileges was upon the statement in Virginia law that acupuncture is "an experimental therapeutic modality." Those objecting to these terms do not deny that the efficacy of acupuncture has not in all cases been subjected to or validated by Western scientific methods (including controlled experiments with double-blind methodologies). Rather, they assert that acupuncture relies on several thousands of years of experience as its basis for validation. They also note that the World Health Organization recognizes acupuncture, as does the American Veterinary Medical Association, American Osteopathic Association, and other national professional societies in the United States. While acknowledging that the U.S. Food and Drug Administration (FDA) considers acupuncture devices as "investigational," they allege that FDA has not sought to limit the use of acupuncture in either regulated or unregulated states. Food and Drug Administration policy relative to acupuncture devices is appended (C-1).

A central tenet in these arguments is the unsuitability of Western paradigms for evaluating Oriental practices. It is summarized in an argument quoted from the earlier-cited proceedings of the U.S. District Court for the Southern District of Texas:

> Acupuncture 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.

Summary.

The arguments favoring continuation of the current system for the regulation of acupuncture rest on the authority and

collective wisdom of the Board of Medicine and the organized medical profession. This Board asserts that acupuncture is an alternative treatment method, the effectiveness and/or safety of which is subject to question. So long as knowledge remains rudimentary with respect to the scientific basis for acupuncture, these authorities believe it is best reserved for use by practitioners demonstrably competent in Western diagnostic and treatment regimens who are held accountable for their practices, primarily through their licensure as physicians or other practitioners of the healing arts.

Arguments favoring extension of regulation to nonphysicians rest primarily on testimony by citizens and advocacy organizations that acupuncture is safe, cost effective and efficacious, validated by a long history of use, and essentially complementary to Western medical practice. Under these conditions, nonphysicians with proper training should be credentialed by the State to practice, and consumers should have freedom of choice with respect to their personal health care.

Neither set of arguments has been authoritatively documented. In this regard, the Board of Health Professions encourages the Board of Medicine in its current attempt to place issues related to the medical and scientific validity of acupuncture on the agenda for consensus-building of the National Institutes of Health (NIH).

In August 1988, the Board of Medicine recommended that a national consensus development conference be convened by NIH on the topic of acupuncture. In response, NIH clarified that consensus development conferences are scheduled on topics that (1) have public health importance; (2) are surrounded by controversy as to the use or implementation of a practice and its efficacy; and (3) are the subject of published scientific data sufficient to resolve the controversy. The Board of Medicine has, in turn, responded that the topic of acupuncture meets these guidelines. The Board of Health Professions joins the Board of Medicine in the hope that a national scientific conference can be convened on this subject of interest to many state-level decision-makers. In tandem with the forthcoming national conference on regulatory issues, this examination of the scientific merit of acupuncture will provide useful guidance.

In the interim, this review must rely on the public record and on any contribution to understanding that can be provided by a review of the published literature.

IV. REVIEWS OF THE LITERATURE

It is not surprising that literature reviews published by advocates of acupuncture and those appearing in the archives of the Western medical establishment reach different conclusions. It is of greater interest to policy makers to examine those areas in which the two bodies of literature are in agreement.

The Chairman of the Board of Health Professions' Committee on Scopes and Standards of Practice provides a balanced overview of the literature in which it is concluded that acupuncture remains an experimental procedure that should continue to be reserved for use by physicians and others licensed by the Board of Medicine, except in the instance of university or hospital research endeavor governed by Human Subjects Review Committees.

This review (Altizer 1988), which is reprinted in the Appendix, includes literature published prior to and including 1987. Because it excludes more recent information of interest, a supplemental discussion is warranted.

Literature Advocating Practice by Nonphysicians

In Spring 1988, the Journal of Traditional Acupuncture published a historical overview (pp. 21-25; 52-54) and discussion of acupuncture in America and a review of basic research (Duggan, pp. 9-14). While both articles have distinct political overtones, they merit attention as illustrations of the difficulty of evaluating Oriental theory and practice with Western scientific methods. Because the articles frame the controversy surrounding acupuncture in terms acceptable to advocates of the practice, these references are also included in the Appendix (A-1).

Duggan in his referenced review of selected research concludes that:

- acupuncture has a distinct theoretical base;
- the "objective reality to acupuncture's theoretical base is the meridian system;"
- stimulation of the meridian system affects the physiology of living beings;
- acupuncture is clinically effective by Western research standards, and;
- acupuncture is evolving its own place in the health care system.

The second article, a historical overview and discussion, was prepared for the Council on Postsecondary Accreditation (COPA), an agency responsible for evaluating and recognizing accrediting agencies for postsecondary education. As such, the article argues the need for a reliable method for recognizing

acupuncturists who have the the education and skills requisite to engage safely in practice and supports the use of the National Council of Acupuncture Schools as the appropriate agency for the accreditation of acupuncture education in the United States.

Reviews favoring the liberalization of regulatory policies relative to acupuncture frequently assert that the practice is effective for the treatment of many conditions, and cite a World Health Organization list of diseases and conditions "that lend themselves to acupuncture treatment." That listing is reprinted in Table 3 with the strong caveat that any reputed effectiveness is based on "clinical experience and not necessarily on controlled research." Quite simply, research of acceptable quality has not focused on the effectiveness of acupuncture in the treatment of most of these conditions.

Reviews of Recent Western Scientific Literature.

Within the archives of Western medicine are several recent publications of interest. Richardson and Vincent have explored the appropriate concepts and methods for the evaluation of therapeutic acupuncture (1986a), and subsequently used these concepts and methods to review the literature on the use of acupuncture for the treatment of pain (1986b) and other common disorders (1987).

In terms of the treatment of pain, the researchers conclude that there is good evidence from reliable research for the short-term effectiveness of acupuncture in relieving pain, specifically headache and back pain. Also reviewed were the treatment of phantom limb pain, sore throat, dental postoperative pain, cancer pain, peripheral polyneuritis, rheumatoid arthritis, osteoarthritis, sciatica, cervical syndrome, bursitis, and tendonitis. The authors conclude that evidence is insufficient to confirm the effectiveness of acupuncture in the treatment of these latter conditions, either because so few studies are reported or because the quality of the reported research is not acceptable. In addition, the article reports that evidence of the effectiveness of acupuncture in relieving chronic pain, or in producing longer-term effects is weaker than that for short-term relief of acute pain.

In summarizing their findings, the authors alert general medical practitioner to expect both short- and long-term benefits from the use of acupuncture in the treatment of back pain. The efficacy of acupuncture for headache, cervical pain and arthritis is less well supported, but there are some encouraging results; at least some number of patients may obtain relief. Modest benefits, they report, have also been obtained for asthma. In addition, acupuncture seems as effective as other methods for the the treatment of smoking addiction. Its use for many other afflictions, including sensorineural deafness "is a waste of time" (1987:80).

TABLE 3

World Health Organization List of Diseases and Conditions that Lend Themselves to Acupuncture Treatment

Neurologic and Musculoskeletal Disorders

Headache
Migraine
Trigeminal neuralgia
Facial palsy (within 3-6 months of occurrence)
Paresis following stroke
Peripheral neuropathies
Sequelae of poliomyelitis (within 6 months)
Meniere's disease
Neurogenic bladder dysfunction
Nocturnal enuresis
Intercostal neuralgia
Cervicobrachial syndrome
"Frozen shoulder"
"Tennis elbow"
Sciatica
Low back pain
Osteoarthritis

Upper Respiratory Tract

Acute sinusitis
Acute rhinitis
Common cold
Acute tonsillitis

Respiratory System

Acute bronchitis
Bronchial asthma (most effective in children and patients without complicating diseases)

Gastrointestinal Disorders

Spasms of esophagus 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

Disorders of the Mouth

Toothache
Postextraction pain
Gingivitis
Acute and chronic pharyngitis

Disorders of the Eye

Acute conjunctivitis
Central retinitis
Myopia (in children)
Cataract (without complications)

*NOTE: This information is based on clinical experience and not necessarily on controlled research. The inclusion of specific diseases is not meant to indicate the extent of acupuncture's efficacy in treating them.

Source: Bannerman, R. "Acupuncture: The WHO Review," World Health, December 1979, pp. 163-97, as reported in The Acupuncture Society of Virginia (Durana, Herdrich, et al). "Acupuncture Recognition and Regulation," a statement submitted to the Committee on Scopes and Standards of Practice, Virginia Council on Health Regulatory Boards, 1988.

A significant finding in this review is that acupuncture treatment effects, while ranging from study to study, are commonly in the 50-80 percent range, significantly greater than the generally accepted 30-35 percent effectiveness of placebo treatments.

Long and Chernow (1988) have reviewed the effects of acupuncture on operative pain and hormonal responses to stress. They conclude that acupuncture has been most successful as an analgesic in dental procedures and relatively superficial operations such as thyroidectomy, although it has also been used in more complex operations. They encourage further study of the effects of acupuncture since significant blood pressure and heart rate stability has been achieved when acupuncture has been used as analgesia. The possibility that acupuncture may be helpful in shock states characterized by increased stress hormone concentrations should also be explored.

In a recent textbook discussion, it is concluded that "acupuncture will probably not have a major role to play in the control of chronic pain states" because it is less satisfactory than other treatments (Miller, 1986:2105), and its use as anesthesia for vaginal delivery is not encouraged (p. 1692).

This conclusion notwithstanding, there is an explosion of interest in the management of pain. In 1986 it was reported that 500 pain management facilities were in operation in the United States. Interest in acupuncture as an adjunctive treatment can only be expected to grow as patients seek any avenue for relief from intractable pain and discomfort (p. 2107).

Acupuncture in the Treatment of Addiction.

Recent attention in the popular media has focused on acupuncture use in the treatment of drug addiction. In an article in the Washington Post (Kurtz, September 5, 1988), testimonials to the effectiveness of acupuncture in treating alcoholism and addiction to heroin, "crack," and other highly addictive street drugs are reported. Although the article indicates that the Governor of New York would shortly sign a law to permit physician's assistants to administer acupuncture, it also reports that the National Institute on Drug Abuse (NIDR) appears disinterested in research on the effectiveness of acupuncture in the treatment of addiction.

A verdict on the effectiveness of acupuncture in the treatment of addiction must await careful scientific study. It seems likely, however, that experimentation in this arena will increase as the search for cost-effective and efficacious forms of treatment for drug abuse and addiction intensifies.

Harmful Effects of Acupuncture Treatment.

While a number of harmful effects of acupuncture are imputed by those favoring the current regulatory program, virtually no documentation of these effects has been discovered in this review. No record of complaints from consumers of acupuncture services exists within the Department of Health Professions.

Although considerable anxiety surrounds the possibility of transmission of AIDS and other diseases by use of acupuncture needles, advocates of increased use of acupuncture allege that no cases of AIDS transmitted by acupuncture treatment have been reported to the Center for Disease Control of the U.S. Public Health Service. Two allegations of hepatitis transmission via acupuncture have been made in Maryland; one was determined to be unfounded. Acupuncture advocates assert more generally that the risk of transmission of disease through treatment is not confined to acupuncture (Acupuncture Society of Virginia, 1988).

The general consensus in the scientific literature is that acupuncture is benign, although at least one fatality attributed to acupuncture is reported in a review by Miller (1986: 2105). The source for this report is a somewhat dated, nonscientific publication directed to physicians (Schiff in Medical Times, 1965: 630).

Summary.

Claims for the effectiveness of acupuncture as treatment for a broad range of conditions, and of risk for substantial or widespread harm lack resulting from it, lack verification in the scientific literature. While some claims for the effectiveness of acupuncture as an analgesic appear to be indisputable, its utility for many other conditions is open to question.

The use of acupuncture is often opposed because other, more surely efficacious treatments are readily available. Anxiety about the use of acupuncture is validated by inference rather than documentation. This anxiety may be justified, nonetheless, given the invasive nature of the practice and the virulence and increasing incidence and prevalence of AIDS and other infectious and/or communicable diseases.

V. SUMMARY AND RECOMMENDATIONS

At the request of the Virginia Legislature, the Board of Health Professions reviewed the current program for the regulation of acupuncture in the Commonwealth. The objective of this review was to determine whether acupuncture should continue to be reserved for use by a limited number of health professions (physicians, osteopathic physicians and podiatrists) whose members have received a modicum of postprofessional training or extended to additional occupations and professions with appropriate training and skills.

The review has included examination of the claims of advocates for the status quo and of those who seek liberalization of current statutory and regulatory limits. The experience of other states has been analyzed, and the contemporary literature explicating the theory and practice of acupuncture--including evidence of the effectiveness of the practice and the risks attendant upon it--has been reviewed.

The review revealed that the regulation of acupuncture in the United States is in disarray, reflecting the instability of the evidence supporting either liberalization of regulatory policy.

There are encouraging signs that scientific consensus on the benefits and risks of acupuncture can be developed through activity at the national level. Similarly, a national conference on the regulation of acupuncture may lead to some resolution of existing disparities in regulatory practices among the states. Ideally, through these separate activities, regulatory practices may become aligned with the scientific knowledge base.

Whether or not acupuncture efficacy is validated by solid research in the near future, demand for its use is likely to rise, especially as an adjunctive treatment for pain and for chemical dependency and addiction. This demand will be created among consumers and professionals alike as the search for low-cost interventions for these conditions continues.

Given the lack of validation of the effectiveness of acupuncture for the treatment of many conditions and the likelihood that demand for acupuncture services will intensify, regulatory decision-making must remain an essentially political act. Risk for harm must be balanced against consumers' rights to choose, even when the choice may favor a service offering little valid hope for benefit. It is notable that (1) anxiety about potential harm is reasonable, even though it may not be based upon documentation; and (2) effective demand, although growing, is currently limited.

As a result of this review, the Board of Health Professions finds insufficient evidence to support major changes in the

current regulatory program. These changes--advocated by a relatively small number of special interest groups and consumers--would involve extension of practice privileges to currently unregulated providers under the supervision of licensed professionals.

There is, in fact, reason to support increased rigor in the current regulatory program administered by the Board of Medicine. The number of hours of postprofessional training and experience under supervision should be reexamined by the Board of Medicine to determine the adequacy of the requirements. Some standard for the approval of training and supervision programs should also be developed. The use of a validated examination to screen candidates for licensure under existing provisions should be explored. To these ends, formal recommendations directed to the Board of Medicine are presented below.

The Board of Health Profession also supports the continued classification of acupuncture devices as "investigational," in conformity with policies of the U.S. Food and Drug Administration. While conforming with federal policy, however, legitimate research institutions and organizations should be encouraged to investigate the safety, efficacy and scientific basis for acupuncture. This research must always be conducted under protocols that protect the public from unwarranted risk. The Board of Medicine should develop criteria by which requests for exemption from its provisions--if required for the scientific investigation of acupuncture--may be evaluated and approved or disapproved. Nothing in existing statute or regulation should be interpreted to discourage or prevent such legitimate research.

Finally, the role of the Board of Health Professions in monitoring regulatory and scientific activity related to acupuncture and reporting findings and recommendations to individual regulatory boards and the General Assembly should continue as authorized by statute. The role of the Board of Medicine in administering effective regulatory programs established by the General Assembly should continue as well.

The following recommendations are presented.

1. The Board of Health Professions should monitor scientific and regulatory developments related to acupuncture in order to recommend to the General Assembly and to relevant boards any changes in regulatory policy warranted by scientific findings and the regulatory experience of other states.

2. The Board of Health Professions recommends that the Board of Medicine reexamine requirements for postprofessional training and experience necessary to qualify physicians, osteopathic physicians and podiatrists to provide acupuncture services to determine if they are sufficient to ensure the public health and safety.

3. The Board of Health Professions recommends that the Board of Medicine develop and publish as regulations standards for the approval of postprofessional training and experience programs prerequisite to licensure to provide acupuncture services to the public.

4. The Board of Health Professions recommends that the Board of Medicine develop and/or procure a validated examination for use in screening candidates for licensure to provide acupuncture services to the public.

5. The Board of Health Professions recommends that the Board of Medicine encourage scientific investigation in legitimate research institutions and organizations designed to explore and discover the scientific basis, safety, and efficacy of acupuncture as a treatment for the alleviation of pain and other human health problems. The Board of Medicine is requested specifically to develop criteria for the evaluation of requests for exemption from existing restrictions made by reputable research institutions and organizations, should such exemptions be required to conduct research in the public interest.

The Virginia Board of Health Professions appreciates this opportunity to be of service to the government and the people of the Commonwealth.

APPENDICES

ACUPUNCTURE - LITERATURE REVIEW

Barbara W. B. Altizer, Ph.D.

Overview

The practice of acupuncture, especially prior to Chiang Kai-shek, has historically been bound to customs of medical practice rooted in the thought and culture of ancient China.[1] Not unlike medieval Occidental philosophy, ancient Oriental philosophy provided a coherent view of man in relationship to cosmology, nature, and society. The task of interpreting the impact of cosmic, natural, and worldly forces on the human body fell to the physician, who was morally and otherwise responsible for the outcomes of medical intervention. Hence, acupuncture developed in a context of more general medical practice focused on empirical results which were explained in terms which coinhered with broader views of the universe and the world.

Adherence to an Eastern versus Western cosmological and world view may or may not, under certain circumstances, effect the efficacy of acupuncture treatment. Aside from the moral and legal dilemma posed by forced confrontation with modern Western science, the complex differences in philosophical outlook are not relevant to the evaluation of acupuncture and its practice under the statutes of Virginia health regulatory law. They are noteworthy primarily by way of introduction to the general theory of acupuncture. This theory emerged through ancient ritual practice and ideographic writings, which lose a great deal of the horizontal meaning structure when transposed into English.

General medical practice in China, in accordance with cultural proscriptions, developed in the absence of dissection and the consequent understanding of anatomy, which structures the foundation of Western medicine. Rather, ancient Chinese physicians developed an understanding of human organs through inductive processes focused on the observation of functional interrelationships. Acupuncture was to Oriental medicine what dissection was to Occidental medicine in that the prescience of observable variations in states of health were correlated with minute changes in small points on the skin which were, in theory, ontogenetically vital to specific internal organs. Given the dramatic differences in propriety regarding physical examinations and experimental procedures, the differences in East/West understandings of anatomical structure are less surprising than their closely approximate agreement.

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[1] The first book of acupuncture was the Hungdi Neiging Suwen, written in 200 B.C. Evidence of at least parallel medical practice has been found in the papyrus Ebers of 1550 B.C., the most important of the ancient Egyptian medical treatises (Mann, 1983). Other medical treatises may be forthcoming from Korea.

Under the Kuomintang and Chiang Kai-shek, who attempted to pass legislation which would have made acupuncture illegal, Western medicine was fostered in China. The replacement of traditional medicine with modern science failed in part as a consequence of public needs and popular preference for Oriental methods of practice. More problematic, in terms of evaluating the efficacy of acupuncture and its impact on general health, Chiang Kai-shek abolished the system of examinations used to accredit physicians, leaving no system in place through which the learned could be distinguished from the utter quacks. In 1949, Mao Tse-tung, who himself had turned to Western medicine, reinstituted traditional medicine, partially in response to the "peoples choice" and partially in response to the practical matter of Western physician/population ratios. It is noteworthy that a personal medical experience softened Mao's views on acupuncture.

Since the revolution of 1949, both Western and traditional medicine have been available in varying ratios to the people of China; Duke (1972) estimated 550,000 traditional physicians compared to 120,000 Western-styled physicians. Both types of physicians received their training through six-year academic/-practice programs at institutions specific to traditional versus modern medicine. More recent data regarding the shift in physician counts are displayed below.

No. Doctors	1953	1963	1973	1985[2]
Western	133,000	382,000	565,000	1,075,000
Traditional	315,000	339,000	216,000	336,000

Following the opening of China to the West, interaction between Oriental and Occidental Medicine has increased. The highly publicized accounts of James Reston in the sixties certainly facilitated the exchange through heightening public interest. Nonetheless, at the 1973 conference sponsored by the National Institutes of Health (NIH, 1973), most accounts of practice remained anecdotal. Since then, a substantial body of research results have been accumulated regarding the efficacy of acupuncture for specific conditions and diseases. Models of underlying processes have been developed and tested in accordance with generally accepted principles of modern science as have theories regarding which conditions and diseases lend themselves to treatment by acupuncture. This review of the literature should provide a rudimentary acquaintance with the fundamentals of traditional acupuncture and with those more contemporary research findings which have aided Western physicians in evaluating the efficacy of acupuncture as a treatment model.

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[2] Table from Siven (1988).

Traditional Chinese Acupuncture

> **The superior doctor prevents illness; the mediocre doctor cures imminent illness; the inferior doctor treats acutal illness" (ancient Chinese proverb).**

The terminology of traditional Chinese medicine is grounded in the ancient ideographic language. Partially as a consequence of this ground and partially as a consequence of the underlying "world view" in which cosmological, natural, and worldly forces are linked to man in a coherent whole, the terminology of acupuncture rings to the Western analytic mind with anthropomorphism and anthropocentrism. Within practice circles, there is extensive debate regarding the degree to which the traditional theory accounts for the undisputed results of acupuncture treatment and the degree of traditional versus modern scientific mastery required for effective acupuncture practice.

For these and other reasons, traditional Chinese acupuncture is here presented in the context of commentary from Felix Mann, a British physician, who studied both the Chinese language and Chinese acupuncture for ten years prior to incorporating the treatment methods into his clinical practice and research. Because Mann has developed a theory of acupuncture which departs significantly from the ancient Chinese model to explain the efficacy of acupuncture, his comments represent only one side of a debate.

Mann is the founder of the Medical Acupuncture Society and firmly states throughout his writings that the practice of acupuncture should be restricted to licensed medical doctors. Therefore, evidence through which other practitioners have taken exception to Mann, directly or indirectly, is also introduced, when appropriate, as commentary. This brief introduction to traditional Chinese acupuncture and the contemporary debate in no way does justice to either. The technical reader is directed to specific references throughout the text to evaluate the source materials independent of this more interpretive and general document.

Acupuncture Points

Acupuncture points are tender areas on the surface of the body which appear in conjunction with the onset of disease and disappear when the illness is cured. Physicians may understand the acupuncture point best in reference to McBurney's point, which can vary in size and position but which occurs and disappears in relation to the onset and cure of appendicitis.

Specification of the number, characteristics, and validity of acupuncture points varies widely. Even amongst traditional acupuncturists, the number of acupuncture points, generally

thought to be around 1000, can vary substantially.[3] Some contemporary researchers have discovered characteristics of the skin, tissues, and muscles which are thought to identify acupuncture points. Mann (1973) in his early work describes the acupuncture point as a small nodule, like a fibrotic rheumatic nodule, or, in other cases, as a strip to tense muscle. In both cases, the acupoint may be in areas of low electrical skin resistance, which is commonly cited by acupuncture researchers. Few physicians or acupuncturists question that some practitioners become extremely adept in locating acupuncture points with the tips of their fingers as a consequence of practice.

Dung (1984) identifies ten structures in the vicinity of acupuncture points: (1) large peripheral nerves, (2) nerves emerging from a deep to a more superficial location, (3) cutaneous nerves emerging from deep fascia, (4) nerves emerging from bone foramina, (5) major points of neuromuscular attachments, (6) blood vessels in the vicinity of neuromuscular attachments, (7) along nerves composed of fibres of varying diameters, (8) point of bifurcation of a peripheral nerve, (9) ligaments rich in nerve endings, and (10) sutures in the skull.

In his more recent work, Mann (1983) indicates that acupuncture points as such do not exist. Rather, the acupuncture response results from cutaneo-visceral, viscero-cutaneous, and viscero-motor reflexes that follow both a segmental dermatome pattern and, less frequently, an intersegmental pattern.

Meridians

Within the traditional Chinese medical literature, a thousand acupuncture points have been identified. In part as a practical means for organizing information and in part as an integral component of acupuncture theory, the Chinese acupuncturists classified these points into 12 main groups: the meridians. Meridians are best understood as passageways or charted flows of energy. The 12 meridians are intrinsically related to an underlying organ with all acupuncture points along the meridian affecting the specifically related organ. The meridians were hence names for the corresponding organ: lung, large intestine, stomach, spleen heart, small intestine, bladder,

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[3] In ancient China, where communication between various geographic regions was restricted, the location and number of acupuncture points varied a great deal, with some practitioners identifying as many as 5000 points. It is noteworthy in this context that some acupoints overlap with karate knockout points and can render the patient unconscious. There is some evidence that a phenomenon similar to acupuncture is used in accordance with the ancient traditions of India for the purpose of training elephants. The Indian Chakras identify at least nine points which kill and four unknown points for the elephant.

kidney, pericardium, triple warmer, gall bladder, and liver. Two additional meridians affect the "governing vessel" and the "conception vessel."

According to Mann (1983:p.1): "...meridians do not exist." Other acupuncture researchers use dummy acupuncture points; that is, acupuncture points which are not along the appropriate meridian, to control for placebo effects in experiments testing the efficacy of acupuncture treatment for specific conditions and diseases, indicating that there is not consensus amongst Western physicians regarding meridians.

Qi

The ancient Chinese were primarily concerned with a system of forces which acted through and upon the body. Qi (pronounced chee) is "life force" or energy. In more contemporary terms, Qi is that which transforms energy into matter or matter into energy in specific or programmatic ways. It is the "heartness" of the heart, so to speak, as opposed to its anatomical structure and function as perceived analytically in Western science, that captured the attention of the ancient Chinese. "In Western medicine we have an intricate knowledge of anatomy, microscopic anatomy, the chemistry and biochemistry of the body, but little knowledge of what actually makes it 'tick'. It was this energy at the root of all life which was the primary interest of the ancient Chinese" (Mann, 1973:p.46).

Qi is an extraordinarily complex and tricky philosophical construct with undoubtedly important heuristic utility. Those familiar with karate or judo might intuitively understand the processes whereby diffuse energy becomes focused through mental and physical discipline. This notwithstanding, whether or not the concept of Qi is crucial to an evaluation of acupuncture is debatable. Mann (1983) suggests that Western physicians who practice acupuncture and researchers who investigate modes of action regarding acupuncture need not concern themselves with this more philosophical term.

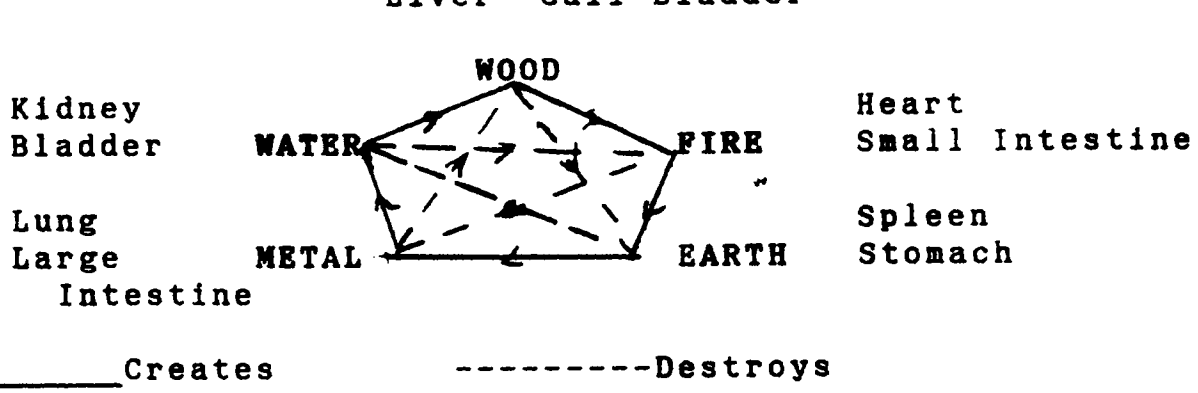
Yin/Yang

Much like ancient Western cosmology (and contemporary astrophysics), ancient Chinese philosophy describes the universe as emerging from chaos, from a formless and indivisible whole. The world as it appears to us resulted from the splitting of the universe in two. According to the wisdom of the ancient Chinese, the resulting duality--Yin and Yang, the negative and the positive, the active and the passive, the feminine and the masculine, good and evil, spirit and matter--were posited as cosmic complementary opposites at the root of all life. Again, whether or not these ideas are valid shapes a debate which can be separated from the evaluation of the efficacy of acupuncture. According to Mann (1983), they are neither tenable nor necessary to an understanding of acupuncture from a Western medical point of view. It

is noteworthy that many of the laws of acupuncture rely on at least an elementary understanding of interrelationships which refer to Yin/Yang and that these concepts are integral to the traditional understanding of acupuncture theory.

The Five Elements

The Chinese thought of the world as divided into five elements: wood, fire, earth, metal, and water. Again, the ideographic nature of the Chinese language creates a communication obstacle in that these are not literal terms but rather archetypal categories of matter. The five elements correspond to organs and to relational principles as alluded to in the diagram below.



Again, whether or not the complex interrelationships stemming from the Chinese pentagram are essential to an evaluation of acupuncture remains a debated prinicple. According to Mann, "The frequently occurring connections can in most instances be more easily explained in Western terms than via the Chinese pentagram" (Mann, 1983:p.39). Contemporary research in medical acupuncture generally does not refer to the pentagram but rather focuses on a specific application and treatment results. It is unlikely that the pentagram will find acceptance in Western analytic circles in its current linguistic format. To focus here or on the "Five elements" detracts from the central questions pertinent to the evaluation of acupuncture treatment.

Laws of Acupuncture

The Laws of Acupuncture, derived from the long history of acupuncture treatment, identify a complex set of interrelationships which describe both direct and indirect effects of acupuncture treatment. Mastery of these laws is clearly essential to a comprehensive understanding of acupuncture as practiced by the ancients. How critical this mastery is to contemporary research and practice is less clear. According to Mann (1983:p.1), "...most of the laws of acupuncture are laws about nonexistent entities."

Western Medicine and Acupuncture.

If the West assisted in delivering China from the "Dark Ages" through technological and other advancements which improved the life conditions for most Chinese people, acupuncture stands alone as the Chinese contribution to world health and health science. Medical researchers do not understand exactly how or under what circumstances acupuncture works, but that it works as well or better than any known treatment for specific physiological reversible conditions is not disputed. Researchers do not agree on the value of importing wholesale the ancient tradition of Oriental medicine, although at least an elementary mastery is essential for evaluative purposes. But most who have examined the evidence agree that to discard the only living link to ancient Chinese thought regarding man and cosmos would be premature.

Since 1973, a great deal of medical research on acupuncture has resulted in explanations of the underlying processes which can be more easily digested by those trained in Western medicine and the analytical methods of science. This section examines the evidence presented by contemporary research as reported in standard journals of United States and European medical research science.

The review of the research literature follows a principle of strict reporting. No interpretations or suggestions are introduced. In instances where renowned researchers have arrived at different models to interpret available data, such as is the case with the micro-level analgesic model set forth by Stux and Pomeranz and the more macro-level model set forth by Felix Mann, no attempt has been made to evaluate either the relative validity or the degree to which these models offer complementary, rather than competitive, explanations.

Research reviewed includes the complete works of Felix Mann, the introductory chapter of Acupuncture: Textbook and Atlas (Stux and Pomeranz, 1987), which incorporates information in 228 studies reported in journals through 1986 and all articles published in standard American and European medical journals between 1986 and 1987, as these are listed in Index Medicus.[4] For organizational purposes, the material is divided into two sections: Analgesia and Other Health Effects.

Analgesia

Until 1973, most evidence for acupuncture analgesia was anecdotal. Since then, numerous studies have demonstrated the efficacy of acupuncture over a placebo. In the context of the

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[4] Only those journals which are standard references were included. Not included were articles published in the Chinese language or, with one exception, articles published in the American Journal of Chinese Medicine.

research reported by Stux and Pomeranz (1987), analgesic acupuncture is regarded as a possible treatment for chronic pain and as less practical for acute conditions or surgical anesthesia. Much of the research employs transcutaneous electrical nerve stimulation (TENS), a method which combines tradition acupuncture with electrical charges.

In a series of detailed diagrams with extensive text, Stux and Pomeranz (1987) describe the mechanisms through which pain messages are relayed from the skin to the cerebral cortex. This transmission of pain, and any inhibition, is contingent upon specific excitatory terminals at the synapses of neural axons and specific inhibitory synapses along the same pathways. Different types of nerves (classified according to size and their origination in skin or muscle) carry messages of touch, pain, and proprioception. These messages are carried from cutaneous nerves to synapses in the spinal cord or from sensory receptors inside a muscle to the spinal cord. From there, the message may be relayed forward to the mid-brain, the thalamus, and to the cerebral cortex.

Acupuncture at an appropriate point produces the release of endorphins. Three families of endorphins, which are probably site specific, are released. Certain endorphins block or inhibit the transmission of pain signals at the level of the spinal cord. Others block pain transmission at the mid-brain and pituitary hypothalamic level. Other peptides are thought to play a role in this process, but which ones and what specific role is not clearly understood.

> ...acupuncture activates nerve fibers in the muscle, which send impulses to the spinal cord and activate three centers (spinal cord, midbrain, and hypothalamus-pituitary) to cause analgesia. The spinal side uses enkephalin and dynorphin to block incoming messages with stimulation at low (electrical) frequency, and other transmitters (perhaps GABA) with high-frequency stimulation. The midbrain uses enkephalin to activate the raphe descending system, which inhibits spinal cord pain transmission by a synergistic effect of the monomamines, serotonin and norephinephrine. The midbrain also has a circuit which bypasses the endorphinergic links at high frequency stimulation. Finally, at the third center, the hypothalamus-pituitary, the pituitary releases beta endorphin into the blood and CSF to cause analgesia at a distance (Stux and Pomeranz, 1987: p.6).

Evidence regarding the above-described processes has been introduced through experiments demonstrating the inhibiting effects of endorphin antagonists such as naloxone and naltrexone. Nine lines of such research are reported by Stux and Pomeranz:

(1) four different opiate antagonists block AA (acupuncture analgesia). (2) naloxone has a sterospecific effect. (3) microinjection of naloxone blocks AA only if given into analgesic sties. (4) mice genetically deficient in opiate receptors show poor AA. (5) rats deficient in endorphin show poor AA. (6) endorphin levels rise in blood and CSF during AA and fall in specific brain regions during AA. (7) AA is enhanced by protecting endorphins from enzyme degradation. (8) AA can be transmitted to a second animal by CSF transfer or by cross-circulation, and this effect if blocked by naloxone. (9) reduction of puritans endorphins suppresses AA (1987: p.10).

Stux and Pomeranz report additional research results which implicate midbrain monoamines in acupuncture analgesia and more speculative work regarding the role of beta endorphins in the pituitary (hormonal) in the modulation of pain. On the basis of these speculations and on the evidence regarding the role of endorphins and other, more specifically applied research, the authors conclude that "AA is very effective in treating chronic pain, helping from 55% to 85% of patients, which compares favorably with the effects of potent drugs (e.g., morphine helps in 70% of cases). Secondly, we conclude that AA is more effective than placebo, indicating a real physical effect" (Stux and Pomeranz, 1987: p.17).

The preceding reports the research summary and model depicted by Stux and Pomeranz for the general reader interested in evaluating specific information pertaining to the evidence regarding the efficacy of acupuncture treatment. The reader interested in a more technical discussion should refer directly to the text and the 228 references cited by the authors in their introductory chapter.

Other Healing Effects

According to Mann (1983), the healing effects of acupuncture result from the fact that skin stimulation affects internal organs through a relatively simple set of reflexes. Mann presents primarily animal data, which corroborate a theory connecting skin stimulation with visceral organ responses on a dermatome basis. The data evidencing viscero-cutaneous, viscero-motor, and viscero-visceral reflexes are more sparse than those presented as evidence for the cutaneo-visceral reflex but, nonetheless, begin to provide an overall framework within which the results of acupuncture practice can be postured. Most of the evidence presented by Mann is drawn from basic research and may raise more questions than answers.

Studies cited by Mann demonstrate the stimulation of the skin on the backs of rabbits or rats results in changes in the duodenum or other parts of the intestine that correspond to the stimulated dermatome. More interesting, perhaps, is that research which specifies the effects of stimulation on amphibians

subjected to varying degrees of nervous system destruction. Wernoe, in 1925, showed that stimulation of the skin of a pithed eel with silver nitrate resulted in vasoconstriction of the dermatome appropriate section of the intestine, followed by concentric contraction of the intestinal segment and, finally, peristalsis.

In other experiments, eels with destroyed brains were subjected to the following experimental conditions: (1) destruction of the entire spinal cord, (2) destruction of the distal half of the spinal cord, and (3) intact spinal cord. The skin of the eels was stimulated with silver nitrate. Group one showed vasoconstriction, group three showed vasodilation, and group two showed vasodilation in the proximal half and vasoconstriction in the distal half. From these experiments, Wernoe concluded that vasodilation was mediated by a spinal reflex, whereas vasoconstriction was mediated by a post-ganglionic sympathetic reflex.

More recent studies, reported by Mann (1983), have evidenced variations in measured pyloric pressure in response to abdominal wall stimulation under the following experimental conditions in rats: (1) decerebrate and nonanesthetized, (2) intact CNs with anesthetic, and (3) spinal preparations with the cord divided and nonanesthetized. Through experimental controls, both blood pressure and adrenalectomy were eliminated as explanatory factors. Precise measurement of electrical responses enabled these experimenters to identify the exact locus of pyloric response inhibition. Mann submits this experimental data as evidence of the cutaneo-visceral reflex and concludes from the findings that the gastric inhibitory reflex is initiated by the appropriate spinal segment or any segment below it. He further indicates that the data fit with some responses a physician may see in clinical practice.

The cutaneo-visceral reflex is central to an understanding of acupuncture because this reflex marks the path of mediation presumed by the application of the needle at a specific point. The viscero-cutaneous reflex, the evidence for which hinges entirely upon the Wernoe eel studies and inferences drawn from phenomena such as McBurney's point, is the path which is presumed when the acupuncturist diagnoses an organ on the basis of tenderness at certain points on the skin. Viscero-motor and viscero-visceral reflexes, for which precision data are even more rare, explain phenomena such as muscle contractions in the expected dermatome in response to visceral stimulation and interrelationships between organs which are referred to in more poetic terms under the Laws of Acupuncture as described in the ancient Chinese tradition.

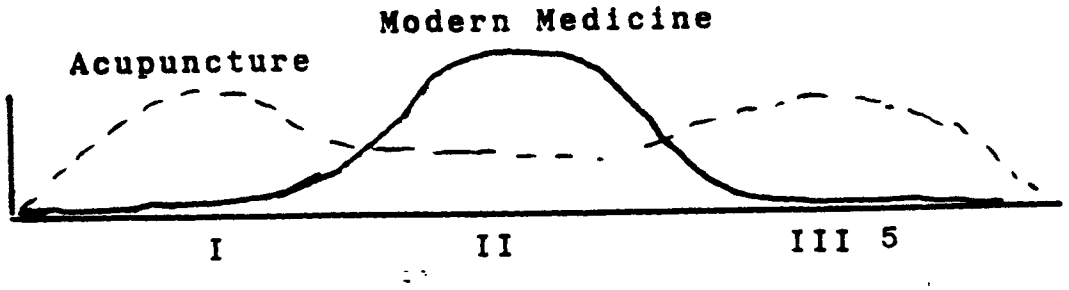
In addition to the above-cited reflexes, Mann, relying heavily on the work of Sherrington, identifies long reflexes (Sherrington long reflexes) which may partially explain why stimulation of an inappropriate dermatome might result in a

visceral response. These are referred to as intersegmental reflexes. Evidence for acupuncture points on the head and the corresponding reflexes is, at best, preliminary.

In drawing together the evidence from basic research, Mann (1983: p.28) states:

> Some years ago David Sinclair, professor of anatomy at Aberdeen University, wrote an as yet unpublished paper, which he has kindly let me read, concerning the reflexes between the skin and viscera defined as viscera-somatic, somatic-somato-somatic, viscero-visceral, and somato-visceral. In this article Sinclair quotes a hundred papers...concerning these reflexes which are the presumed mechanism of acupuncture--though most of the authors know nothing or little of acupuncture. At the time of the writing and in other papers, Sinclair advanced a branched axion theory partially to explain the observed phenomena, but since then he thinks the more conventional nerve pathways are the mediator.

If basic research on the mechanisms of acupuncture offers less than a satisfactory explanation of how acupuncture might work, the applied research has begun to offer much more systematic evidence of the conditions which lend themselves to acupuncture treatment. Generally, physicians knowledgeable in Oriental medicine regard acupuncture as an alternative for diseases and conditions which result from easily reversible physiological processes. Acupuncture, according to some, produces superior results over modern medicine in diseases which are thought to be incurable or difficult to treat, for chronic pain, and for discomfort associated with various diseases (Matsumoto, 1974). The following table diagrams the relationship between condition and the relative efficacy of acupuncture over modern medicine as suggested by Matsumoto:



5. (I) Pain and discomfort but not classified as to disease; (II) Organic, infectious congenital disease and trauma; and (III) Incurable disease, hard to treat at present.

The most sensational research, for which current data remain anecdotal, is in the area of nerve regeneration and its effects on certain types of blindness and nerve deafness. Mao Tse-tung received overnight popular acclaim through a highly publicized program in which some 80,000 deaf children were restored to hearing through acupuncture. Systematic corroboration of these results remain forthcoming. Less exciting, but more reliable, evidence regarding the efficacy of acupuncture of specific conditions is reported below.

Bullok, et. al. (1987) performed a randomized trial of acupuncture on a group of 54 hard-core alcoholic recidivists. Patients in the treatment group received acupuncture at points specific to the treatment of substance abuse. The control group received treatment at nonspecific acupoints. Significant differences were found between the two groups at the end of a six-month period on the number of drinking episodes ($p<0.0076$), on expressed need for alcohol ($p<0.003$), and on readmissions to a Detox center ($p<0.001$).

Ballegaard, et. al. (1986) report data on the effects of acupuncture treatment for stable angina pectoris. Twenty-six patients were randomized to either active or sham acupuncture in a single-blind design. The effects were evaluated from anginal attack rate, nitroglycerine consumption, and exercise tests. Compared to sham acupuncture treatment, acupuncture patients increased cardiac work capacity ($p<0.001$). No significant differences were found on the other indicators.

Dundee (1987a) reports preliminary but significant differences between acupuncture patients and patients receiving acupuncture at sham or dummy points in peri-operative emetic effects. Similar findings are reported by Dundee (1987b) in optimizing antiemesis in cancer chemotherapy through electroacupuncture.

More subjective results of systematic experiments which failed to produce significant findings are reported by Lehmann (1986) on the efficacy of electroacupuncture in the rehabilitation of chronic low back pain patients and by List (1987) in the treatment of patients with facial pain and mandibular dysfunction. A large number of applied studies not reported here can be found in Stux and Pomeranz (1987).

CONCLUSIONS

From the information presented in this brief review of the literature, the reader should easily conclude that the practice of acupuncture, while continuing to receive serious attention from medical and other researchers, remains an experimental procedure. The precise mechanisms through which acupuncture effects results are the source of substantial disputation. There is no agreement regarding which body of knowledge should be mastered for safe and reliable use or under what circumstances

acupuncture may provide a safe and reliable form of treatment for patients and clients. These ambiguities notwithstanding, there is adequate evidence to suggest that acupuncture may offer an effective means of treatment for certain patients under specific circumstances.

In order to achieve an environment in which the health and safety of the public is protected from incompetent acupuncture use and in which acupuncture research and practice can continue under the strict evaluative standards of modern science, it is the opinion of the author of this report that the practice of acupuncture should remain classified as the practice of medicine and limited to individuals who meet the following rudiments:

1. Licensed physicians (M.D.s and D.O.s) and podiatrists (D.P.M.s) who have met the requirements set by an Acupuncture Advisory Committee under the Board of Medicine; and

2. Physicians and other qualified medical researchers, including assistants working under the direct supervision of a licensed acupuncturist, who are executing research in university or hospital settings which are governed by duly constituted Human Subjects Review Committees.

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American Acupuncture: A Review of Basic Research

by Robert M. Duggan, M.A., M.Ac.(U.K.)

Introduction

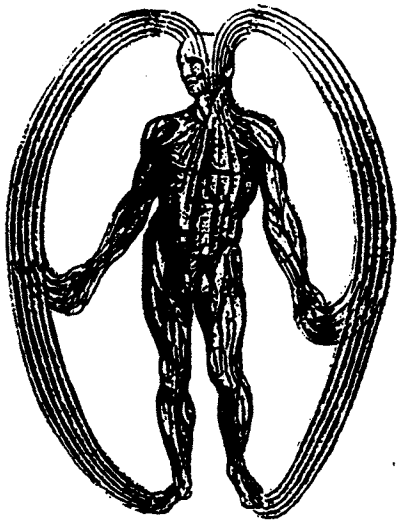
Ever since columnist James Reston's 1971 report in the *New York Times* about his experience with acupuncture analgesia in China, the practice of acupuncture in the United States, perhaps stimulated by Reston's report, has grown at an extremely rapid rate. In 1972 none of the fifty states regulated acupuncture. Fifteen years later, twenty-nine states have provided for the practice of acupuncture.[1] In 1974 seven acupuncturists practiced in the state of Maryland; currently 189 are registered to practice[2] and 68 percent of all acupuncture treatments in Maryland are covered by insurance reimbursement, an increase from 23 percent five years ago.[3] *Medical World News*, a trade journal for physicians, reported in 1984 that two thousand physicians used some acupuncture in their practice. Today an estimated four thousand non-physician acupuncture practitioners are registered in the U.S.A.[4] The teaching of acupuncture has similarly expanded. In 1971 no acupuncture courses were available in this country; now there are at least twenty-three established training programs.[5] Acupuncture has become a part of the American health care system, a small one in terms of numbers of practitioners, numbers of patients, and the economy of the system, but a part nonetheless.

The practice of acupuncture is based on the use of very fine needles to regulate flows of electro-magnetic energy. These flows influence the smooth functioning of the hormones, nerves, blood, and deep organs.[6] This system of health care, while relatively new to the United States, has been practiced for over five thousand years and is widely used by one-quarter of the world's population.

This paper makes five related points: (1) that acupuncture has a distinct theoretical base, (2) that the objective reality to acupuncture's theoretical base is the meridian system, (3) that stimulation of the meridian system affects the physiology of living beings, (4) that acupuncture is clinically effective by western research standards, and (5) that acupuncture is evolving its own place in the health care system.

A Distinct Theoretical Basis

What we in the West commonly think of as medical practice is based on the use of chemical and surgical techniques to eliminate disease and provide a better state of health. What we call "medicine" is thus really one specific type of medicine, more precisely labeled *allopathic* medicine. The major strength of allopathic medicine rests upon the science of prescribing chemicals (medicines) to provide for deficiencies in the body's functioning and using surgical techniques to correct specific mechanical difficulties. This is the dominant aspect of the health care system in the United States, which, however, also contains a variety of other therapies. For example, osteopathy, chiropractic, and physical therapy—all elements in the health care system—mainly work on skeletal structure and the muscular functioning of the body. Nutrition deals with diet. Other therapies use exercise to enhance well-being and to bring about bodily corrections after injury. The largest health profession in the United States, nursing, assists in caring within virtually all the therapies.



"Acupuncture clearly is an aspect of this emerging field of energetic medicine."

Acupuncture is based on an approach to the body and to health that differs from the approaches guiding these other therapies. Acupuncture is not based on the chemistry of the body nor on its skeletal or physical structure. It is based instead on a distinct aspect of human physiology—energy, what the Chinese call the ch'i. The flow of ch'i along certain pathways, called meridians, is altered and adjusted by acupuncture needles, thereby influencing the health of the person. Energy as an aspect of physiology has no place in the West's established view of the body, but many western researchers are beginning to discuss what is called "energetic medicine."

For example, a major conference, organized by the World Research Foundation and called the Congress of Bioenergetic Medicine, was held in Los Angeles on November 7–9, 1986.[7] Researchers from all parts of the world attended this conference which "aimed to bridge the gap between medicine and the latest discoveries in physics." Included in the topics, alongside acupuncture, was magnetism, electricity, Kirlian photography, homeopathy and related subjects. Acupuncture clearly is an aspect of this emerging field of energetic medicine. This term speaks of an aspect of human functioning that is as new to many westerners today as was Harvey's discovery of the circulation of the blood in 1687.

The energetic perspective of acupuncture is so distinct from that of allopathic medicine, that although the father of allopathy, William Osler, recommended acupuncture for the treatment of lumbago,[8] eighty-one years later the curriculum data bank of the Association of American Medical Colleges indicates that no medical school in the United States yet provides acupuncture training. Some chiropractic schools do provide elective two-hundred-hour programs to familiarize students with acupuncture, but to our knowledge, no other health profession provides acupuncture training. Perhaps the early stages of interest, however, is indicated by the fact that the American Holistic Medical Association has developed a three-hundred-hour program for physicians.[9] The program is offered as a continuing education program at the Medical School of the University of California at Los Angeles. In early 1987, a small group of graduates of the program formed The American Academy of Medical Acupuncture to set standards for the practice of acupuncture by physicians and to draw together allopathic physicians with a serious long-term interest in the topic.[10]

Despite the divergence from the western medical thought, the theoretical base of acupuncture and energetic medicine has been explored by a number of western researchers over the past fifteen years. We look at that research now and start with the studies that explore the fundamentals of acupuncture—acupuncture points and the meridians.

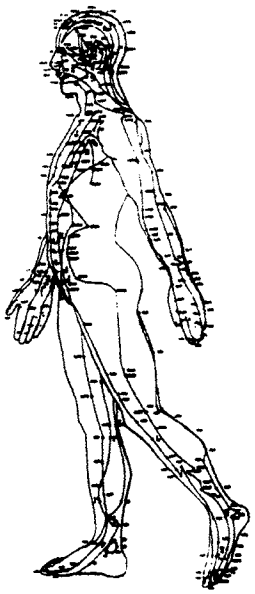
An Objective Reality

Do acupuncture points and meridians have an objective reality? Recent western studies with sophisticated equipment—for example, a Wheatstone bridge—indicate that acupuncture points do have a level of electrical conductivity distinct from surrounding skin tissue. This fact is the basis for the electrical acupuncture-point locators now widely used by acupuncture practitioners.

One study was conducted in the mid-1970s by Robert O. Becker, M.D., a pioneer in the research of electric currents in living beings, and Maria Reichmanis, a biophysicist, both at the Upstate Medical Center in Syracuse, New York. Supported by grants from the National Institutes of Health, the Veterans Adminstration, and the Johnson and Johnson Research Center, the study was reported in the *Annals of the Institute of Electrical and Electronics Engineers: Transactions in Biomedical Engineering*, November 1975. The report is entitled "Electrical Correlates of Acupuncture Points." The introduction explains the background to the study and briefly states the conclusions:

> It has been asserted that acupuncture points exhibit locally decreased DC (direct current) electrical skin resistance. Commercial devices intended for clinical application seek to exploit this property. If true, this would give the technique of acupuncture some physical basis other than hypnosis or suggestion.
>
> This assertion has recently been challenged by Noodergraaf and Silage, who reported that no resistance minima could be located on the fingers when care was taken to avoid electrode pressure artifacts. They concluded that they could find no evidence for the objective existence of any acupuncture points. This study might be considered conclusive as regards the existence of electrical resistance minima at acupuncture points, except for two factors. To establish the existence of acupuncture points, it would be sufficient to establish that they are electrical resistance minima with respect to the surrounding tissue. It is not necessary to show that these points are absolute minima in resistance. Noodergraaf and Silage reached their conclusion on the basis of the second and needlessly stronger criterion of existence. Furthermore, their study was confined to acupuncture points on the fingers and their results possibly do not apply to other anatomical areas.
>
> In view of both its importance and the scarcity of available information, we decided to re-examine the question. Our object was to determine whether the DC resistance of acupuncture points differs from that of surrounding tissue.

"Energy as an aspect of physiology has no place in the West's established view of the body, but many western researchers are beginning to discuss what is called 'energetic medicine.'"



Becker's tests showed "that at least the major parts of the acupuncture charts had . . . 'an objective basis in reality.' "

> Employing a Wheatstone bridge, skin conductance was measured over those putative acupuncture points on the large intestine and pericardium meridians lying between the metacarpophalangeal joints and the elbow. Results were compared to those from anatomically similar locations devoid of acupuncture points. At most acupuncture points on most subjects, there were greater electrical conductance maxima than at control points.
>
> In conclusion, it was found that most points on the pericardium and large intestine meridians, as defined and described by the standard charts, are points of electrical conductance maxima on most subjects. These points, therefore, have an objective existence in most subjects.[11]

In 1985, the principal author of this study, Robert O. Becker, published his book *The Body Electric*, in which he comments further on the electrical physiology of the human body and concludes:

> The biggest problem Western medicine had in accepting acupuncture was that there were no known anatomical structures corresponding to the meridians. . . . Our readings indicated that the meridians were conducting current. . . . *It was obvious by then that at least the major parts of the acupuncture charts had, as the jargon goes, "an objective basis in reality."*[12] (Italics added)

In the early 1980s, Dr. R. Prasaad Steiner, M.D., an istant professor at the School of Medicine, University of Louisville, reviewed many studies on the energetic basis of acupuncture. Writing for general practitioners in the October 1983 issue of *Postgraduate Medicine*, he draws two conclusions. He writes, first of all, that the acupuncture point is an electrically discrete entity, and that "acupuncture-induced changes in bioelectric parameters have been demonstrated at the level of peripheral nerves, spinal cord and thalamus, limbus, and cortex." He also concludes that humoral factors are involved in acupuncture therapy.

> When the blood supplies of two rabbits were connected in a cross-circulation pathway, acupuncture stimulation of one rabbit inhibited pain-related behavior in the other. Thus, a blood-borne substance must be involved in the effects of acupuncture.[13]

In separate research not connected to acupuncture, the electrical system of the human organism is being explored in new ways. Dr. Bjorn Nordenstrom, a prominent Swedish radiologist, a professor at the Karolinska Institute in Stockholm, and a member of the Nobel Prize Committee in Medicine, is one of the foremost investigators of the electrical system of the body. The August 1987 issue of *Diagnostic Imaging* offers the following journalistic report on his work:

> By applying electrical current to tumors via percutaneously implanted electrodes, a leading Swedish radiologist has successfully treated lung and breast cancer. Two patients, in fact, who were deemed terminal are alive eight years after the treatment that taps into the body's endogenous electrical pathways.
>
> Nordenstrom has applied his controversial treatment in 70 patients who failed to respond to surgery or conventional therapy. Evaluation of the first 20 patients showed that half of the 26 tumors electrically treated responded positively.
>
> These results are especially encouraging given the poor prognosis of the patients. Nordenstrom told *Diagnostic Imaging:* "You cannot compare my technique with standard techniques. I can only show that it may be possible to get control of cancers that are incurable."
>
> Nordenstrom's interest in the electrical activity of the body was triggered 30 years ago by a phenomenon he observed on x-ray studies. He noted that many tumors were surrounded by radiating streaks, which he called coronas. His search for the origin of these structures revealed that they were associated with an electrical potential between necrosis within the tumor and surrounding tissue.
>
> Nordenstrom hypothesized that his closed electrical circuit represents a third circulatory system, which together with the lymph and blood systems plays a role in tissue injury and healing. He proposed that it functions similarly to a battery. Blood vessels act as insulated cables with electrical current transported by the plasma and interstitial fluid.
>
> "In the beginning, the injured tissue is electropositive in relation to the surrounding tissue. White blood cells are negatively charged, so they accumulate in the region of

the electropositive polarity, that is, the injured tissue," he said.

The injury potential oscillates between positive and negative until it reaches an equilibrium, he added. Healing appears to be complete when polarization stops.

Nordenstrom contends that this electrical circuit is as integral to healing and homeostasis as is the flow of blood. Disturbances in this electrical network may lead to development of cancers or other diseases. Likewise, he believes the circuit can be exploited to promote healing.

Nordenstrom's most recent theories have drawn both excitement and skepticism from his radiology colleagues.

"Most of us don't begin to pretend to understand his theories, and only know a little bit of his writings," said Dr. William Murphy, professor of radiology at the Mallinckrodt Institute of Radiology, St. Louis. "But my gut feeling is that Nordenstrom has something that is going to be very important."[14]

The existence of acupuncture points and the meridians has received other scientific support. At the November 1986 Congress of Bioenergetic Medicine mentioned above, Jean-Claude Darras, M.D., and P. de Vernejoul, M.D., at the Necker Hospital outside of Paris, described their experiments using radio-active isotopes. According to a report on the conference by Brendan O'Regan of the Institute of Noetic Sciences, Darras and Vernejoul

> injected radio-active isotopes into acupuncture points and used gamma cameras to track the movement of the isotopes inside the body. This has provided the first physical evidence of the existence of the acupuncture meridian system.[15]

That acupuncture does not depend on the placebo effect, as is often charged, is demonstrated by the fact that acupuncture is widely used throughout the world in veterinary medicine and that many studies have been done on the effectiveness of acupuncture with animals. The University of Pennsylvania School of Veterinary Medicine has published numerous texts on veterinary acupuncture, including an anatomical guide to the acupuncture points in a wide variety of animal species.[16] Brief reports on some animal studies appear in the next section.

A Physiological Effect

Presuming that acupuncture points and meridians do exist, do they make anything happen? At its simplest level the question is: Does the stimulation of an acupuncture point have any effect on the physiology of the human or animal involved?

A number of scientific studies indicate that stainless steel needles, when accurately placed in known acupuncture points, do have a variety of effects on the functioning of the living body. Perhaps the most direct evidence has been produced by Bruce H. Pomeranz, Ph.D., a neurophysiologist at the University of Toronto. Dr. Pomeranz suspected that acupuncture analgesia involved a hormonal mechanism, and that it was not the result of phenomena that essentially discounted the reality of acupuncture as did the "gate control" explanation (reduction of pain sensations by stimulation of other nerve pathways) or the "hypnosis" or "psychological distraction" theory. To test his theory, he implanted electrodes in individual spinal neurons of anesthetized cats. Then, acupuncturing the cats, Dr. Pomeranz found that pain impulses but not touch—that is, the cats were not numb—were blocked after an induction period of about twenty minutes. "The results jumped out at us," Dr. Pomeranz said. "We had a very long delayed effect and a very long-lasting one, consistent with some sort of hormonal system reaction. There is no gate mechanism, or simple inhibiting mechanism that would take a half an hour to activate." The hormonal mechanism, Dr. Pomeranz believes, is linked to the release of endorphins by the brain, perhaps from the pituitary or the limbic system. The endorphins then circulate as hormones and block pathways.[17]

Researchers find it difficult to mount studies that are "both scientifically rigorous and also responsive to the complexities of acupuncture treatment."

In additional research studies, both Dr. Pomeranz and Dr. David J. Mayer of the Medical College in Richmond, Virginia, have reported that in humans the pain relief associated with acupuncture analgesia is blocked by the drug naloxone.[18] The fact that a chemical can reverse acupuncture analgesia demonstrates that acupuncture produces a chemical effect. Dr. Pomeranz has also reported that analgesic results were produced only with true acupuncture and that sham acupuncture did not yield the same effects.

The manner in which acupuncture produces physiological responses is as yet unknown. Whatever the relationship between changes in the hormonal function of the body and the classical theory of ch'i energy, the significant point of *this research* is that it *indicates clearly that proper acupuncture has a definite effect on the physiological functioning of the individual.*

Several reviews have also examined studies investigating the physiological effects of acupuncture in animals. In a relatively early review, "Therapeutic Acupuncture: A Selective Review," which appeared in the *Southern Medical Journal*, August 1977, Peter Rubin, M.D., an internist and a practicing acupuncturist, writes:

> Although the major emphasis of acupuncture research has been on pain, many workers in this area have thought that therapeutic acupuncture can affect other physiologic

"That acupuncture does not depend on the placebo effect . . . is demonstrated by the fact that acupuncture is widely used . . . in veterinary medicine . . ."

and emotional functions as well. Acupuncture-induced physiologic responses in animals have been studied by a number of groups. Electroacupuncture significantly affected the gastrointestinal motility of one group of rabbits who were vagotomized and in another group with balloon catheters placed in the large and small intestines. No changes were produced by sham electroacupuncture. Stimulation of a "stomach" acupoint on the legs of rats resulted in significantly decreased carotid artery pressure and in increased mesenteric vasodilatation. A group from Hong Kong found that manually stimulated needles at selected stomach acupoints of ten rats significantly reduced the incidence of ruminal ulceration between 30 minutes and three hours after pyloric obstruction had been surgically induced. Acupuncture was found to increase the survival rate of dogs subjected to hemorrhagic shocks. Marked increases in cardiac output and stroke volume were produced by moxibustion (a form of acupuncture treatment) at one acupoint on a group of dogs, but were abolished by previous administration of propranolol. There were no effects from stimulation of a neutral site. The results of acupuncture stimulation upon cardiovascular function in dogs recently have been reviewed. Although few of these studies have been repeated by others, they do suggest the possibility that stimulation of selective points on the skin may directly or indirectly affect the autonomic nervous system.[19]

Studies also show that stimulation of specific acupuncture points has specific effects on the functioning of the rat brain, and presumably the brain of all animals. Research in this area was compiled by Agu Pert at the National Institutes of Mental Health. "Alterations in Rat Central Nervous System Endorphins Following Transauricular Electroacupuncture," by Agu Pert, Raymond Dionne, Lorenz Ng, Evgeni Bragin, Terry W. Moody and Candace B. Pert, appeared in *Brain Research*, 244, 1981. I quote the summary here.

Auricular electro-stimulation (electroacupuncture) was found to produce naloxone-reversible analgesia in the rat. These behavioral effects were accompanied by significant increases in cerebrospinal fluid (CSF) levels of endorphins with concomitant decreases in the basomedial hypothalamus and medial thalamus of B-endorphin-like immunoreactivity as well as endorphin-like radioreceptor activity. In addition, the radioreceptor assay also revealed a decrease in endorphin-like radioreceptor activity in the periaqueductal gray (PAG) matter. These results are interpreted to imply that electroacupuncture in the rat produces at least part of its analgesic action by activating central nervous system endorphinergic circuitry which results in a release and depletion of endorphins in certain brain loci and a concomitant elevation in the CSF. Hypophyseal endorphins do not appear to be involved in mediating acupuncture-induced analgesia in the rat since plasma levels of endorphins were not altered by this manipulation.

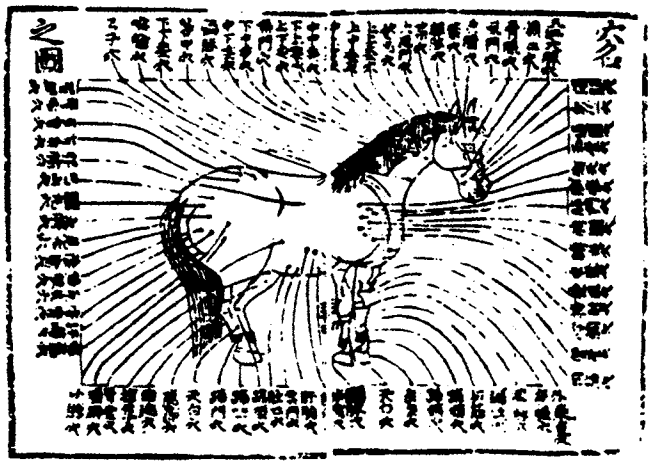
The article concludes:

Although acupuncture seems to activate the endorphin systems in the brain, this does not imply that all of the analgesic actions of acupuncture are mediated by endorphins. . . . The participation of these (other) neurohumors in acupuncture analgesia remains to be elucidated.[20]

A Clinical Effect

In terms of the health care system, questions about acupuncture cannot stop at physiological effects. The basic health care question is: Does acupuncture have any clinical effectiveness? In pragmatic terms, one might say that clinical effectiveness of acupuncture is demonstrated by the increasing demand for acupuncture throughout the United States. However, we want to look at the issue in more scientific terms.

The assessment of the clinical effectiveness of acupuncture in western research terms raises special problems. First, if one uses a western allopathic diagnosis and assesses clinical success by the disappearance of a specific disease, how can one be sure that acupuncture by itself is the specific agent of change, since acupuncturists normally suggest lifestyle changes along with their application of needles? In terms of research, how can one design controls for such a complex form of therapy? A deeper problem emerges from the fact that the aim of acupuncture (and oriental medicine in general) is not necessarily to eliminate or ameliorate a disease. The objective, rather,



Fourteenth-century drawing depicts acupuncture points on the body of a horse.

is to change functioning and the quality of life. Thus, patients receiving acupuncture treatment will often report that they feel better, are more functional, and are able to work using less medication all before they report a change in the disease process for which they have come seeking treatment. To this date, no research has been reported that seeks to measure quality-of-life change resulting from acupuncture treatment.

There are an enormous number of papers that seek to report on the clinical effectiveness of acupuncture. For example, a Med-Line print-out from the National Library of Medicine lists 2,700 titles. Yves Requena, M.D., a leading French acupuncturist, writing in *Advances: The Journal of the Institute for the Advancement of Health*,[21] estimates that more than 2,500 articles on acupuncture are published yearly worldwide. At the National Symposium of Acupuncture and Moxibustion and Acupuncture Anesthesia, held in Beijing, June 1–5, 1979, some five hundred papers were presented.[22] This major research conference, it might be noted, was an official interregional seminar of the United Nations' World Health Organization (WHO). Reporting on the conference in the *American Journal of Acupuncture* in 1980, R.H. Bannermann, M.D., of WHO, concluded, "Acupuncture is clearly not a panacea, but the sheer weight of evidence demands that acupuncture must be taken seriously as a clinical procedure of considerable stature."[23] In any event, despite the impressive number of studies, the fact is that many reports do not have the research design and control mechanisms that would satisfy a skeptical western researcher.

Researchers of acupuncture in the West have sometimes found themselves unable to mount studies that were both scientifically rigorous and also responsive to the complexities of acupuncture treatment. For example, in the 1970s, researchers at the UCLA Acupuncture Research Project—a project established to look at the clinical effectiveness of acupuncture—reported success in using acupuncture for the relief of pain, but they also noted that they had to use a primitive form of acupuncture to meet the demands of the research protocol. A review of the UCLA Project's research noted several issues:

> Very few of the studies (of acupuncture in general) that have been done have "scientific value." While the technical research aspect of many studies have been well designed, a major variable has not been studied or evaluated in most research designs: The qualifications of the practitioner and the quality of the acupuncture being administered. In a very real sense almost everyone born in the Orient will be an acupuncturist in the same way that everyone born in the U.S.A. can claim to be a pharmacist.

The report noted another research difficulty:

> In good Traditional Acupuncture a great many aspects of the patient's life may be changed at one time: not only are different points used at each treatment and at times moxa substituted for needles, but also the practitioner may make recommendations for changes in life style and diet.

Despite these problems, the UCLA researchers concluded:

> Acupuncture therapy, when properly administered, is an extremely safe and effective procedure which may be indicated for the treatment of certain chronic pain problems. . . . Finally we recommend that its application for the treatment of pain be considered an accepted procedure, and no longer "experimental."[24]

But even the positive results the UCLA researchers identified did not, in their view, demonstrate the full effectiveness of acupuncture because the requirements of the research controls prevented the full proper use of acupuncture techniques.

"Acupuncture has become a part of the American health care system, a small one in terms of numbers of practitioners and the economy of the system, but a part nonetheless."

More recently, the January 1986 issue of *Pain* presented two papers that respectively survey the clinical research on using acupuncture to relieve pain and analyze the methodological problems of investigating acupuncture. The authors raise many of the issues of the UCLA study and note that these problems are

> further complicated by the fact that there are different traditions and different styles of traditional acupuncture even within China. Acupuncture clinicians from different schools recommend a very different choice of points and techniques for any particular patient.

The two papers together cite a total of sixty-three studies. The second paper focused on studies that evaluate the use of acupuncture for the relief of pain.

> This paper describes both controlled and uncontrolled therapeutic trials where the major aim of treatment has been the relief of pain. It does not consider laboratory studies of experimentally induced pain. All studies known to the authors which include at least a no-treatment control group have been included unless they are pilot studies with excessively low patient numbers or are inadequately reported. . . . Where uncontrolled trials are concerned, no attempt has been made to provide an exhaustive review. The studies which have been included generally involve either large patient numbers or other features of design or measurement which render them noteworthy.
>
> The two most commonly researched pain conditions where acupuncture is concerned have been headaches

and back pains. In addition, reports have appeared describing the treatment of a large number of other disorders, e.g. phantom limb pain, sore throat, dental postoperative pain, cancer pain, peripheral polyneuritis, rheumatoid arthritis, osteoarthritis, sciatica, cervical syndrome, bursitis and tendinitis. . . . A number of large uncontrolled studies have also looked at the effects of acupuncture on mixed groups of chronic pain patients.

The authors conclude:

> Most studies suggest that clinically significant short term pain relief is usually achieved by from 50 to 70% of patients suffering chronic pain. This is more than might be expected on the basis of placebo alone. For pain, the placebo rate is more commonly in the region of 30–35%. As far as longer-term pain relief is concerned, it is clear that a portion of patients do appear to maintain their gains at follow-up assessments. The number doing so, however, is small.[25]

The positive conclusions of the UCLA Project and the extensive review in *Pain* are echoed by a 1986 report from the National Institutes of Health. This is the first U.S. Government study in which acupuncture therapy is recommended for the treatment of pain.[26]

Given the fact that most papers on the clinical effectiveness of acupuncture do not meet adequate research standards, for the purposes of this article, we prefer to comment on this issue by noting four successful specific applications of acupuncture, each aimed at a different disorder. One application is related to breathing problems, one to menstrual problems, another to pain, and the last, the most unusual, to children with learning disabilities.

In December 1986, the British medical journal, *The Lancet*, published a clinical report demonstrating the effectiveness of acupuncture in the treatment of pulmonary disease. The study was the result of a series of meetings under the sponsorship of the Royal Society of Medicine. The abstract of the study reports:

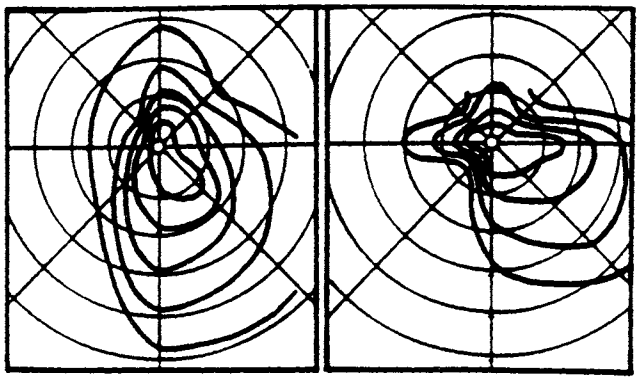
> In a randomised controlled trial, twelve matched pairs of patients with chronic obstructive pulmonary disease received traditional Chinese acupuncture or placebo acupuncture. After three weeks' treatment the traditional acupuncture group showed significantly greater benefit in terms of subjective scores of breathlessness and six-minute walking distance. Objective measures of lung function were unchanged in either group. Whether these differences are mediated by endogenous opiate and/or peptide release remains speculative.[27]

In January 1987, the professional journal *Obstetrics and Gynecology* printed its first paper on acupuncture treatment, "Acupuncture for the Management of Primary Dysmenorrhea," by Joseph Helms, M.D., an internist based in Oakland, California, and a practitioner of acupuncture since 1974. This is the abstract:

> The effectiveness of acupuncture in managing the pain of primary dysmenorrhea was investigated in a randomized and controlled prospective clinical study. Forty-three women were followed for one year in one of four groups: the Real Acupuncture group was given appropriate acupuncture and the Placebo Acupuncture group was given random point acupuncture on a weekly basis for three menstrual cycles; the Standard Control group was followed without medical or acupuncture intervention; the Visitation Control group had monthly nonacupuncture visits with the project physician for three cycles. In the Real Acupuncture group, 10 of 11 (90.9%) women showed improvement; in the Placebo Acupuncture group, 4 of 11 (36.4%); in the Standard Control group, 2 of 11 (18.2%); and in the Visitation Control group 1 of 10 (10%). There was a 41% reduction of analgesic medication used by the women in the Real Acupuncture group after their treatment series, and no change or increased use of medication seen in the other groups.[28]

For the third example, a study on the effectiveness of acupuncture in reducing back pain, I quote from a 1981 report from the AMA Council on Scientific Affairs:

> In a recent well-designed study performed by the Acupuncture Center of Washington and the Acupuncture Clinic of Maryland, authentic classical acupuncture was randomly compared with delayed or inadequate treatment of chronic low back pain in 50 American patients. The immediate treatment group of patients received 10 or more biweekly acupuncture treatments over five or six weeks and showed a 32% reduction in mean hours of pain per day, 51% reduction in pain score and a 33% reduction in pain pills per week. This contrasted with 0–2% change in these parameters during the same period in a comparable group of patients whose treatment was delayed for eight weeks. Overall improvement was reported in 83% of the treated group and only 41% of the delayed treatment group. In the delayed treatment group 52%, 40% and 62% reduction were seen in those same



These electrical conductivity maps of skin at acupuncture points appear in The Body Electric. *Author Robert Becker reports that studies showed "each point was positive compared to its environs, and each one had a field surrounding it, with its own characteristic shape."*

> pain parameters and 75% reported improvement in pain after a course of ten or more acupuncture treatments. At a late 40 week followup these same patients showed a pain score reduced by no more than 30% in any group; but, the hours of pain per day and a number of pain pills per week had reverted virtually to pretreatment levels in the delayed treatment and inadequate treatment groups.[29]

This study, conducted by Ralph Coan, M.D., and Grace Wong, O.M.D., also indicated that significant improvement was maintained by 58 percent of the sample at a ten-month follow-up.[30] Richardson and Vincent in their *Pain* article note that this study

> is the only one in which acupuncturists were given a free hand to practice as they would in ordinary day-to-day clinical work.[31]

The effectiveness of energetic medicine is demonstrated in quite another way in an intriguing educational program called PRES (Physical Response Education Systems), conducted under the auspices of the Santa Cruz County Office of Education. In looking for ways to assist slow learners, researchers discovered that stimulating specific acupuncture points through finger pressure greatly enhanced the learning capabilities of students. This project has been so successful that more than ten thousand teachers from all parts of the United States have been trained in the techniques of PRES.[32]

These, then, are examples of the quality of research and clinical applications that are beginning to emerge to reinforce the mass of anecdotal reports.

Acupuncture in the Health Care System

In the past fifteen years, the acupuncture profession has responded to the increased interest in acupuncture by opening twenty-three acupuncture schools, seventeen at the graduate level (plus seven that may not be at that level), and by establishing an acupuncture accreditation commission to monitor the quality of education in those schools. As noted in the introduction, twenty-nine states provide for the practice of acupuncture, and sixteen set standards for the licensing of acupuncturists. A national certification examination has been developed by the acupuncture profession, with more than fifteen hundred individuals taking the examination in its first four sittings. It is estimated that over four thousand individuals currently are licensed to practice acupuncture in the United States. These acupuncture schools and practitioners provide the United States with a link to a health care system widely used in the rest of the world and to a five-thousand-year legacy of written and oral tradition.

The growth of acupuncture should be set against the 1973 determination of the Food and Drug Administration that acupuncture is an "experimental procedure"[33] and also the 1981 report of the AMA's Council on Scientific Affairs[34], which concluded that "Acupuncture is an unproven modality of therapy." The F.D.A. and A.M.A. positions are echoed by a position paper of the osteopathic profession. The United States District Court for the Southern District of Texas in effect responded to all of this by stating:

> Acupuncture has been practiced for 2,000 to 5,000 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.[35]

Summary

This article indicates that acupuncture is taking its place in the American health care system, a fact demonstrated by the public's general acceptance of acupuncture, by state regulations that recognize acupuncture as part of the health care system, and by the development of essential professional organizations and standards.

In addition, a growing body of scientific research is exploring acupuncture and energetic medicine of which acupuncture is an ancient and respected form. Supplementing the positive anecdotal reports about acupuncture, major journals are beginning to publish a body of respected clinical data.

The author is grateful to Gary Arsham, M.D., Sherman Cohn, J.D., and Harris Dienstfrey for extensive guidance and editorial suggestions, and to Dianne M. Connelly, Ph.D., Susan Duggan, B.A., Charlotte Kerr, M.P.H., Donald Pachuta, M.D., Peter Rubin, M.D., Fritz Smith, M.D., William Smith, D.C., and John Sullivan, Ph.D., for their assistance and helpful comments.

Notes:

1. Legislative Information Packet. The Traditional Acupuncture Foundation, American City Building, Columbia, MD 21044.
2. Board of Medical Examiners of the State of Maryland, 201 West Preston Street, Baltimore, MD 20201.
3. *American Health*, October 1987, p. 66.
4. Over 2,000 acupuncturists are certified by the State of California alone. The seventeen major schools graduate at least three hundred new practitioners each year.
5. The National Council of Acupuncture Schools and Colleges, P.O. Box 954, Columbia, MD 21044.
6. See "American Acupuncture: A Historical Perspective," prepared by the National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine, P.O. Box 954, Columbia, MD 21044. This article can also be found in the *Journal of Traditional Acupuncture*, Spring 1988.

7. The World Research Foundation, 15300 Ventura Boulevard, Suite 405, Sherman Oaks, CA 91403.

8. William Osler. *Principles and Practice of Medicine*, 7th Edition. Appleton, New York, 1906, pp. 396–7.

9. American Holistic Medical Assocation, 2727 Fairview Avenue East, Seattle, WA 98102.

10. American Academy of Medical Acupuncture, 2520 Milvia Street, Berkeley, CA 94704.

11. Robert O. Becker, et al. "Electrical Correlates of Acupuncture Points," *Annals of the Institute of Electrical and Electronics Engineers: Transactions in Biomedical Engineering*, November 1975.

12. Robert O. Becker and Gary Selden. *The Body Electric: Electromagnetism and the Foundation of Life*. New York: William Morrow & Co., 1985, pp. 235–36.

13. R.P. Steiner. "Acupuncture Cultural Perspectives," *Postgraduate Medicine*, October 1983, Vol. 14, No. 4. pp. 61–2.

14. *Diagnostic Imaging*, August 1987, pp. 85–86.

15. Brendan O'Regan. "Healing, Remission and Miracle Cures," Special Report, May 1987, Institute of Noetic Sciences, Sausalito, CA 94966, p. 14.

16. A.M. Klide and S.H. Kung. *Veterinary Acupuncture*, University of Pennsylvania Press, 1977. Additional information is available from the International Veterinary Acupuncture Society, 3618 Middleton Avenue, Cincinnati, Ohio 45220.

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18. D.J. Mayer, D.D. Price, J. Barber, A. Rafii. "Acupuncture Analgesia: evidence for activation of a pain inhibitory system," in *Advances in Pain Research and Therapy*, edited by Bonica, New York: Raven Press, 1976, pp. 817–22.

19. Peter Rubin. "Therapeutic Acupuncture: A Selective Review," *Southern Medical Journal*, August 1977.

20. A. Pert, R. Dionne, L. Ng, E. Bragin, T. Moody, and C. Pert. "Alterations in Rat Central Nervous System Endorphins Following Transauricular Electroacupuncture," *Brain Research*, 244 (1981) pp. 83–93.

21. Y. Requena. "Acupuncture's Challenge to Western Medicine," *Advances: Journal of the Institute for the Advancement of Health*, Vol. 3, No. 2, Spring 1986, p. 46.

22. *Research on Acupuncture, Moxibustion and Acupuncture Anesthesia*. Xiangtong Zhang and Pengxun Lou, editors. Springer Verlag: New York, 1987. This is a selected summary of papers that were originally published in Beijing in 1980.

23. R.H. Bannermann. "The World Health Organization Viewpoint on Acupuncture," *American Journal of Acupuncture*, July-September 1980, p. 231.

24. David Bresler, Ronald Katz and Richard Kroening. "Review of Research Findings of the UCLA Acupuncture Research Project." Privately circulated.

25. P.H. Richardson and C.A. Vincent. "Acupuncture for the Treatment of Pain: A Review of Evaluative Research," *Pain*, Amsterdam, The Netherlands, 24 (1986), pp. 15–40.

26. National Institutes of Health. Consensus Development Conference Statement: "The Integrated Approach to the Management of Pain," May 19–21, 1986, p. 11.

27. K. Jobst, J.H. Chen, K. McPherson, J. Arrowsmith, V. Brown, J. Efthimiou, H.J. Fletcher, G. Maciocia, P. Mole, K. Shifrin, and D.J. Lane. ; "Controlled Trial of Acupuncture for Disabling Breathlessness," *The Lancet*, December 20/27, 1986.

28. J.M. Helms. "Acupuncture for the Management of Primary Dysmenonhea," *Obstetrics and Gynecology*, Vol. 69, No. 1, January 1987, pp. 51–56.

29. Report G of the Council on Scientific Affairs (A-81) of the American Medical Association. Action of the House of Delegates 1981 Annual Meeting, Report G Adopted.

30. R.M. Coan, G. Wong, S.L. Ku, Y.C. Chan, L. Wang, F.T. Ozer and P.C. Coan. "The Acupuncture Treatment of Low Back Pain: A Randomized Controlled Study," *American Journal of Chinese Medicine*, Vol. VIII, No. 2, pp. 181–189, 1980.

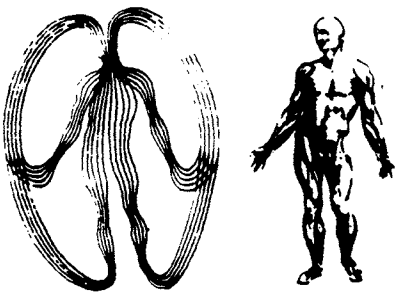
31. P.H. Richardson and C.A. Vincent. "Acupuncture for the Treatment of Pain: A Review of Evaluative Research," *Pain*, Amsterdam, The Netherlands, 24 (1986), pp. 15–40.

32. Project PRES, Santa Cruz County Office of Education, 809-H Bay Avenue, Capitola, CA 95010.

33. Food and Drug Administration. The Federal Register, Vol. 38, No. 45, Friday, March 9, 1973. This represents the only federal legislation concerning acupuncture.

34. Report G of the Council on Scientific Affairs (A-81) of the American Medical Association. Action of the House of Delegates 1981 Annual Meeting, Report G Adopted.

35. Decision of the U.S. District Court for Southern District of Texas, dated July 9, 1980. The decision appears in the *Journal of Traditional Acupuncture*, Vol. IV, No. 2, Winter 1980.



American Acupuncture: A Historical Perspective

This article was prepared by the National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine; the Commission's purpose in preparing this article was to inform the Council on Postsecondary Accreditation (COPA) about the development and status of acupuncture in the United States. The Accreditation Commission is in the pre-application phase with COPA, the national organization that evaluates and recognizes accrediting agencies for postsecondary institutions.

Acupuncture is a primary health care modality that has flourished in China for more than twenty-five centuries. What is new in the United States is actually an ancient healing art. In 1980 the United States District Court for the Southern District of Texas made the point eloquently while affirming the right of Americans to seek acupuncture treatment:

> Acupuncture has been practiced for 2,000 to 5,000 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.[1]

This report will explore the tradition acupuncture brings with it (brief historical overview); why there are difficulties when Westerners seek to understand acupuncture (the nature of acupuncture and the need for bridging between cultures and systems); and recent advances in mutual understanding. Lastly, the report will comment on the National Council of Acupuncture Schools and Colleges (NCASC) and the initiative of its accreditation commission.

A Brief Historical Overview

The origins of acupuncture are lost in prehistory. We do not know how the ancient Chinese came to see persons as constantly-moving patterns of energy, in dynamic interchange with their environment. We do not know how the ancient Chinese came to identify the location of over eight hundred acupuncture points on the human body—points that could be used to change a person's energy balance. Nor do we know when needles were first inserted into these points and manipulated to change the energy flow. We do have archeological evidence that the ancient Chinese used stone, bone and bamboo needles for medical purposes long before the advent of ceramic, gold and silver needles. We do know that around 200 B.C. the first steel needles were produced. At that time also, acupuncture received its classic formulation, and the common basic text, *The Yellow Emperor's Classic of Internal Medicine*, was written. By 200 B.C. an empirical practice of long standing was undergirded by a highly sophisticated theoretical framework.

Thus acupuncture had its classical formulation in the period before the birth of Christ, which philosopher Karl Jaspers calls an axial period of human history. The period round about 500 B.C. saw the rise of philosophy and the higher religions. Near to this date we can place the Hebrew prophets, Socrates, Zoroaster, the Buddha, Confucius and Lao Tzu. The last three founded Buddhism, Confucianism and Taoism, the three rivers of Chinese philosophy. All of this is to say that by 200 B.C. there were ample resources both practical and theoretical for the generation of a profound system of acupuncture.

In *The Yellow Emperor's Classic*, mentioned above as the foundation text for all schools of acupuncture, acupuncture is presented as a part of a configuration of healing modalities including herbal, dietary and exercise prescriptions. All of these modalities are based upon the same underlying principles of energetics. These healing arts continued under varying conditions in China with periods of advance and periods of decline.

Through meticulous observations the ancient practitioners established the existence of meridians (energetic pathways along the surface of the body) and the relationships of those meridians with physiological functions. The application of needles was found to harmonize and regulate these functions.

Even today we have little scientific understanding of the meridians and the harmonizing of these functions, although it is known that there are distinct electrical properties to the acupuncture points. It is also known that the insertion of needles does change and balance the electrical readings associated with these points. Furthermore, it is known that the stimulation of these points with needles does affect the chemistry of the brain. More will be said later about the research in this area. Let us keep in mind the existence of such research as we examine a language that sounds strange to western ears.

Acupuncturists diagnose the balance of this energy and plan treatment configurations using a set of notions and a world view that are unfamiliar and strange to a Westerner. These include notions such as the tao, ch'i (or qi) energy, and yin-yang dynamics:

1. The Tao points to a path, a pattern, a structure. It might be thought of as a structure of natural laws, including the laws of health and healing, of growth and decline. It is perhaps close to what Gregory Bateson has referred to as "the pattern that connects." This pattern is seen to operate on the levels of body, emotion, mind and spirit. Reality, in this vision, is vast and multileveled. The laws of life, the cycles of birth and growth, of death and new life, operate on the visible bodily level. But these same laws, cycles and patterns also apply on the level of mind or heart where emotions and ideas are ordered, disordered and reordered. Finally, there is a pattern to the spiritual dimension of life as it proceeds from unawareness to awareness and from narrower to more compassionate concerns.

2. Acupuncture speaks of ch'i (or qi) energy, the energy present and flowing within the universe and within each person. Ch'i energy circulates through the body in well-defined cycles, moving in a prescribed sequence from point to point. Traditional acupuncture has mapped twelve primary (and eight secondary) pathways or meridians along which the ch'i energy travels. At times, ch'i energy flows near the surface of the body; at times, in the interior of the body. It is a dynamic force in constant movement. The healing techniques of acupuncture and oriental medicine affect the flow and intensity of ch'i energy. Like a tightrope walker, the ch'i energy must remain balanced as it moves forward.

3. The way of balance unfolds as a harmony of opposites, which are spoken of as yin-yang. In the yin-yang approach to balancing opposites, polarities exist, but they are not thought of in "either-or" fashion or judged as "negative-positive." In the eastern view, every reality contains the seeds for its reversal. In situations that we label positive, there are dangers; in situations that we label negative, there are opportunities. The Chinese ideogram for "crisis" is composed of the character for "danger" and the character for "opportunity." This approach to polarity as paradox has implications for healing. Bodily, emotional, mental and spiritual symptoms are signs of distress leading the skilled acupuncturist to the underlying factors of disease. But even the underlying imbalance is not viewed simplistically. In imbalance is an opportunity, for as energy is unblocked it becomes a powerful source of re-vision, recovery and renewal.

"Acupuncture . . . is no more experimental as a mode of medical treatment than is the Chinese language as a mode of communication."

—Decision, U.S. District Court for Southern District of Texas

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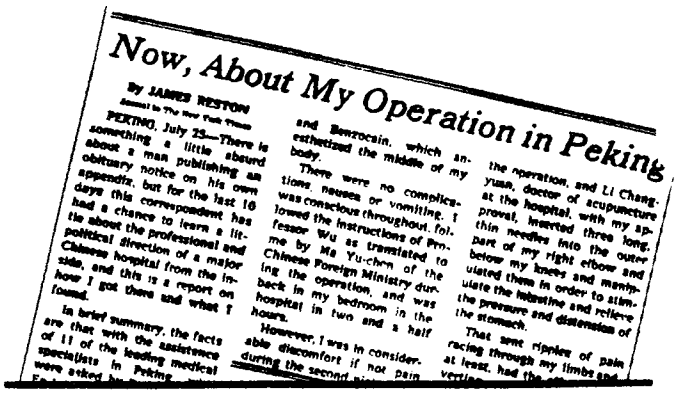

Now, About My Operation in Peking

By JAMES RESTON

PEKING, July 25—There is something a little absurd about a man publishing an obituary notice on his own appendix, but for the last 10 days this correspondent has had a chance to learn a little about the professional and political direction of a major Chinese hospital from the inside, and this is a report on how I got there and what I found.

In brief summary, the facts are that with the assistance of 11 of the leading medical specialists in Peking

and Novocain, which anesthetized the middle of my body.

There were no complications, nausea or vomiting. I was conscious throughout, followed the instructions of Professor Wu as translated to me by Ms. Yu-chen of the Chinese Foreign Ministry during the operation, and was back in my bedroom in the hospital in two and a half hours.

However, I was in considerable discomfort if not pain during the second

the operation, and Li Chang-yuan, doctor of acupuncture at the hospital, with my approval, inserted three long, thin needles into the outer part of my right elbow and below my knees and manipulated them in order to stimulate the painful area and relieve the pressure and distension of the stomach.

That sent ripples of pain racing through my limbs and at least, had the

"Astonished and grateful, James Reston reported what to him was a remarkable and unlikely therapy: slender needles placed in his hands and arms . . ."

The three notions—tao, ch'i, and yin-yang—are examples. They are but a few of the notions which together define the context of acupuncture and oriental medicine.

In addition to acupuncture, other treatment modalities were used by the practitioner of oriental medicine to restore or maintain balance—modalities such as herbal medicine, moxibustion, exercise and nutrition. Moxibustion consists of burning a processed herb, either in the form of incense-like cones or cigar-shaped sticks, held just above the skin on points chosen for application. These points are identical with those of the acupuncture system. Generally, moxa was considered more appropriate for treating chronic disease, whereas acupuncture was considered to be more valuable in cases of acute disease.

Chinese herbal pharmacology plays a unique role within Chinese medical theory. An independent system, the theory is based on the knowledge of disease and on the natural properties and therapeutic effects of herbs. The effects of the herbs are seen in changes of the ch'i energy as well as in bodily changes similar to those produced by western pharmaceuticals. Much of the theory is based on temperature (cold, cool, warm, hot) and taste (hot, bitter, salty, sour, sweet). Chinese pharmacology uses techniques of preparation that include soaking the herbs in fluids or heating herbs and fluids together. Another unique characteristic of Chinese pharmacology is that different parts of an herb are used for different therapeutic purposes. That is, the root is used for one purpose, the leaves another, and the flowers a third. In addition to herbal medicine and acupuncture, Chinese medicine uses exercise and nutritional practices to harmonize the ch'i energy. These practices are used in common life to ease stress and maintain vigor and good health.

The above outlines the basic framework of the classical traditions of oriental medicine that existed by the time c Christ. By A.D. 514, acupuncture had reached Korea. By A.D. 562, there are records of acupuncture treatment in

Japan. Word of this healing modality came to Europe only in the seventeenth century, when Jesuit missionaries returned from China with medical texts, needles and reports of treatment.

Though the first reports reached Europe in the seventeenth century, there was little or no detailed information concerning acupuncture in the West until well into the twentieth century. The first book on acupuncture in a western language was published in French in the 1930s. It was the collaborative work of a French sinologist, George Soulie de Mourant, and a Japanese physician, Yukikazu Sakurazawa.[2] By the 1950s, there were a number of schools in France, England, and Germany and several thousand practitioners in France alone. In the early 1950s, an English physician was beginning to write and publish about acupuncture, and by the end of that decade a formal school had been established in England as well as an association of practitioners. By the end of the 1960s, there were three schools in England. At this writing, there are over one thousand practitioners in that country.

Acupuncture is now also widely practiced in Germany, Italy, Switzerland and throughout Eastern Europe. The Russians not only utilize acupuncture but also have established research hospitals and published data that indicate that the life force, ch'i, can be measured and contains properties that are chemical and magnetic as well as electrical.

Only since the early 1970s has acupuncture become widely known in the United States. The decisive event was the establishment of relations between the United States and the People's Republic of China, which took place under the Nixon presidency. In July, 1971, *New York Times* senior correspondent James Reston was traveling in China in advance of the president. While there, he had appendicitis. Following an appendectomy, Reston was treated with acupuncture for post-operative pain. Astonished and grateful, he reported his experience of what to him was a remarkable and unlikely therapy: slender needles placed in his hands and arms strikingly reduced abdominal pain. Reston also wrote of acupuncture being used as an anesthetic in major surgery. Soon delegations of American doctors were touring Chinese hospitals to witness how eastern medicine and western medicine were being used in a complementary and collaborative way.

In 1971, in the United States, acupuncture was largely confined to the oriental enclaves of major American cities. Since that year, the development of acupuncture in the United States has been substantial. Many books and articles have appeared. Practitioners have come from China, Japan and Korea; theorists and teachers have also visited from Germany, France and England. Americans in greater numbers have sought to study acupuncture, and schools of acupuncture have been established in various parts of the country. Likewise, professional associations have been formed—organizations such as the American Association of Acupuncture and Oriental Medicine, the National Commission for the Certification of Acupuncturists, the National Council of Acupuncture Schools and Colleges, as well as many organizations on the state level. Many states now recognize the medical and therapeutic value of acupuncture. Research is beginning to be done at major hospitals and research centers. Americans from all walks of life now look upon acupuncture as a form of treatment that can be used in conjunction with western medical practice.

At this writing, sixteen states and the District of Columbia register or license acupuncture practitioners. Twelve states (California, Florida, Hawaii, Massachusetts, Montana, Nevada, New Mexico, New York, New Jersey, Oregon, Washington and Rhode Island) license acupuncturists for independent practice. Three other states (Maryland, Utah and Pennsylvania) and the District of Columbia license practitioners to work in collaboration with physicians. In most cases, collaboration means that a western medical diagnosis is required before the beginning of acupuncture treatment. In the great majority of states, acupuncture is not regulated by statute; however, in many of those states the practice of acupuncture under physician supervision is allowed. Many states that do not now license acupuncture practitioners, or license them restrictively, are considering legislation or administrative regulations to permit licensing or to permit more independence for those who are licensed.

Research has been done at many medical centers including the University of California at Los Angeles, the Downstate Medical Center in Brooklyn, New York, the Upstate Medical Center in Rochester, New York, and the Lemuel Shattuck Teaching Hospital in Boston. The National Institutes of Health have conducted limited studies into the use of acupuncture for pain control. In addition, researchers at the University of Virginia, the University of Toronto and many other institutions have documented the existence of the meridians through electrical measurements. Other researchers have documented the effect of acupuncture treatment on the flow of endorphins in the brain.[3]

Thus, the growth of acupuncture in the United States has been extensive. Until 1970, acupuncture was limited to practitioners largely in the oriental communities. There are now approximately four thousand practitioners in this country, with about three hundred new practitioners being certified each year.

"The western physician starts with a symptom, seeking precise cause for a specific disease. . . . The traditional Chinese physician directs attention to the complete person, looking . . . for a 'pattern of disharmony.'"

The Nature of Acupuncture and the Need for Bridging Cultures and Systems

In its original context, acupuncture and its associated healing arts are seen as preventive medicine. Persons are understood as having self-adjusting patterns of energy; sickness and disease are seen as fundamental imbalances manifesting outwardly in a variety of ways. The relatively healthy person is able to adjust and adapt to shifting inner/outer conditions. In times of transition in the cycles of human growth, and in times of personal crisis, the organism is under special stress with attendant wear and tear on the system. At such times, acupuncture can aid persons in attaining and maintaining balance in their lives.

Critics often object that acupuncture depends on belief and placebo effect. It is true that acupuncture is set in a world view that recognizes laws of health and wholeness, of growth and decline, which are unusual to our culture. However patients need not "believe" in acupuncture for the treatment to shift energy and have an effect. (In fact, acupuncture is widely used and accepted in veterinary medicine where belief plays no part.) This is not to say that persons achieve maximum functioning solely when obvious energetic impairments are corrected. Full health and wholeness demand that persons take responsibility for their own well-being. This more demanding task does indeed involve cognition and commitment, belief and behavior, on the part of patients.

Many western physicians—both the famous and the ordinary—find much to commend in this approach. Many of the greatest western diagnosticians—doctors like Sir William Osler—stand close to the classic acupuncturists in viewing a very wide range of factors as relevant to a careful diagnosis of a patient's condition.

However, western medicine, as currently practiced, is concerned primarily with isolating disease categories or agents of disease, which it then tries to change, control or destroy. This is its enormous contribution to human health. In approaching illness, the western physician starts with a symptom, then searches for the underlying mechanism, always seeking precise cause for a specific disease.

The traditional Chinese physician directs attention to the complete person, looking at the many physiological and psychological aspects of the individual seeking treatment. All relevant data, including symptoms and the patient's other general characteristics, are gathered and woven together until there emerges what oriental medicine calls a "pattern of disharmony." This pattern of disharmony identifies the imbalance in the patient's body.

Western medicine focuses on detailed analysis, exhaustive investigation, theoretical studies and clinical examinations. The identification of the disease is desirable before treatment is started. Drugs used in western medicine are composed mainly of synthetic and chemical substances. In addition, western medicine excels in the use of surgery, a principal tool of treatment. Modern medical science, fragmented and specialized, is based on experimental studies of bacteriology, physiology and pharmacology, as well as on clinical research in the treatment of disease.

Oriental medicine is intertwined with a philosophy of life and has a comprehensive approach to treatment of the whole body that issued from many thousands of empirical observations. Based on centuries of accumulated experience, oriental medicine pays special attention to the uniqueness of patients and their pains, and prescribes treatment on a subjective basis before identifying the disease by name, if it does so at all.

The skilled acupuncturist sees in disease an "opportunity, for as energy is unblocked it becomes a powerful source of re-vision, recovery and renewal."

"Acupuncture treatment enhances the ability of individuals to take responsibility for their own health and to prevent the recurrence of illness."

Differences in approach between Chinese or oriental medicine and western medicine are a result of differing viewpoints, traditions and practice. Words associated with western medicine often include the following: scientific, analytical, preventive, surgical, theoretical, bacteriological, experimental, cellular, objective and chemical. Traditional oriental medicine, reflecting another viewpoint regarding health and illness, includes these words: philosophical, balance, preventive, holistic, empirical, hygienic, experimental, energetic, subjective and natural.

There are both differences and similarities in the two approaches to health and healing. The two medical systems are practiced extensively side by side in China, complementing one another in treating illness. This is not the case in the United States, because few western physicians and researchers are familiar with the oriental system and are slow to accept traditional medical concepts. For example, the "meridian theory" of oriental medicine is still not accepted by western medicine, because the existence of meridians, which are neither blood vessels nor part of the nervous system, has not yet been verified anatomically.

Herein lies a deeper difficulty. Acupuncture brings with it and exists within one total interpretive context. To speak of an organ, say the heart, will have one sense in the

allopathic paradigm and quite another sense in the acupuncture paradigm. To speak of a symptom will have one set of implications in the allopathic paradigm and another in the acupuncture paradigm. To speak even of health itself will evoke a different path of understanding in one tradition than in the other.

Western science has had great success thinking in terms of parts that, like building blocks, can be put together to form larger wholes. From this view, processes are best understood when we can demonstrate how they work with machinelike models. In this view, the test of understanding the heart would be to build a working, physical artificial heart. Eastern thought begins with wholes, with interlocking patterns. It is both contextual and practical, judging the adequacy of a world view by the way it gives meaning and value to concrete human living. Individuals demonstrate understanding of a path or pattern by the way in which they embody it, by the way they show forth a discriminating, compassionate heart. In this view, the highest value of a teaching would be seen not in a mechanical model but in the type of physical, emotional and spiritual functioning of those who have most deeply lived it.

The first and foremost gulf to be bridged between western and eastern medicine results from disparate paradigms. A second difficulty is related to the first. Many find it difficult to keep separate (a) the fact that something works and (b) the explanation of how it works. This is not surprising. We tend to be skeptical if we cannot fit "the facts" into our explanatory scheme. Consider how our reigning scientific paradigm went from that of Aristotle to Newton to Einstein and beyond. Whatever the paradigm, features that do not fit into the explanatory scheme tend to be discounted and even ignored. Conversely, practices that "should work" according to the reigning theory tend to be retained long beyond the point where their value deserves consideration. Thus, it seems important to preserve the distinction between *that something works* and *how it works*.

When western physicians and journalists accompanied President Nixon to China in February of 1972, they witnessed surgery in which acupuncture needles were used for anesthetics. When the United States District Court for Southern Texas had to assure itself that acupuncture done by skilled practitioners was safe and effective, it relied on a mass of testimony and concluded that acupuncture does indeed work. When the same court turned to the issue of how acupuncture works, it recognized that this remains an open question within a western scientific paradigm. Interestingly, the court noted impressive documentation (including before and after photography) showing the successful use of acupuncture on animals in veterinary medicine. The court took this as evidence against the thesis that acupuncture works simply from the so-called "placebo" effect. What the court concluded is best stated in its own words:

> Whatever the best explanation is for how acupuncture works, one thing is clear: it does work. All the evidence put before the court indicates that, when administered by a skilled practitioner for certain types of pain and dysfunction, acupuncture is both safe and effective.[4]

"Acupuncturists use a set of notions and a world view that are unfamiliar and strange to a Westerner."

Of course, no court can or should settle such matters beyond the purview of its own purposes. Nonetheless, the court raised and wrestled with the central questions: How can we be assured that acupuncture is both safe and effective when administered by a skilled practitioner for certain types of pain and dysfunction? How can we recognize a skilled practitioner? With what sort of pain and dysfunction has acupuncture had success? These issues will be treated further in the next section. But before leaving this section of the report, it may not be amiss to note how we have drifted from an acupuncture paradigm back to an allopathic one.

It is not surprising that Westerners tend to narrow their attention to the insertion of needles. It is not surprising that Westerners are impressed when the needles block physical pain or cure disease in animals. However, from the perspective of classical oriental medicine, both a narrow focus on the needles and the sorts of examples cited would be considered peripheral, not central.

From an eastern perspective, the acupuncturist is not doing the healing; rather patients are being aided so that their own natural processes can do the healing. The healing is not complete until there is a restoration of balance in the whole person-in-context, a restoration of balance that extends to all levels of body-mind-spirit. Acupuncture treatment enhances the ability of individuals to take responsibility for their own health and to prevent the recurrence of illness.

Recent Advances in Mutual Understanding between Eastern and Western Medicine

In this section four issues will be discussed: 1) what can be treated; 2) how to design research on effectiveness; 3) how acupuncture works; 4) how to recognize a skilled practitioner.

What can be treated? The very question presents a problem. It assumes an allopathic diagnostic designation. A practitioner of acupuncture would say that the balancing of the life forces helps the well-being of the individual and thereby reduces the intensity of whatever disease force afflicts the individual. Thus all individuals are seen to be aided by treatment, regardless of the allopathic

(Continued on page 52)

(Continued from page 25)

definition of the disease process. There is general agreement, however, on a list of diseases for which acupuncture is widely known to be effective. These include chronic pain problems such as migraine, back and neck pain, frozen shoulder, sports and injury-related pain, gastrointestinal problems, circulatory, menstrual and sexual problems. It is also useful for emotional depression including postpartum depression. It has been used widely for behavior and addiction-related problems such as overeating, drug and alcohol dependency. Some studies suggest that extensive acupuncture can regenerate tissue where there has been degeneration; it is clear, however, that in such situations acupuncture improves the individual's functioning and quality of life, and slows or stops the degenerative process. Some practitioners stress that acupuncture is effective for all psychosomatic functional disorders, which observers estimate are responsible for approximately 70 percent of all visits to physicians' offices.[5]

This list is a sample. Particular items may be debated. Most acupuncturists agree that there are limitations to this kind of labeling, and what should be understood by the American public is that acupuncture is most effective in restoring the body's capacity to heal itself and in restoring the individual's overall balance of energy. Persons who have had acupuncture treatment often report that they feel ready to resume work and their normal lives, using less medication, even though the technical indices such as blood samples may indicate the lingering presence of the disease entity for which they came for treatment. This particular area of discussion is of major importance to the dialogue between the eastern and western modalities which have as their common objective the improved well-being of persons who come for assistance.

How to design research on effectiveness. Acupuncture has been a part of the practice of oriental medicine for centuries. At the present time, the medical community in China accepts and utilizes both traditional oriental medicine and modern western medicine in complementary fashion. Chinese medical students are often taught both systems. While much younger, acupuncture in the United States can invoke the testimony of thousands of patients who have experienced the safety and effectiveness of acupuncture treatment. But here, the medical professional is more cautious. Though some individual doctors have become advocates of acupuncture, most wish to see western style research. In fact, formal studies are growing in number. However, just as there are important issues in specifying what can be treated, so there are significant issues concerning how to design research studies that validate the effectiveness of acupuncture.

During the 1970s, there were published in China extensive data claiming to confirm the measurable effects of acupuncture on physiological processes. These studies indicated that needles could influence, among a host of factors, the sugar, cholesterol, and triglyceride levels in the blood, the functioning of the gastrointestinal system, and the activity of the endocrine system. Most of this research failed to satisfy western standards of scientific rigor. Some research has been carried on in this country. One of the major challenges has been to design studies that respect the needs of western researchers while maintaining the integrity of a system of treatment that involves different treatments at each visit and requires that changes in diet and life-style accompany treatment. One early study at the University of California in Los Angeles[6] demonstrated a statistically significant reduction of pain, even though the researchers used a poor level of acupuncture treatment and excluded the normal practice of varying the choice of needles and giving life-style advice at each treatment in order to respect the controls demanded by the research design.

For more complete discussions on research into acupuncture's effectiveness, see especially these four sources (reference details appear in the bibliography): Robert M. Duggan, "An Overview of Completed Research"; R. Prasaad Steiner, "Acupuncture Cultural Perspectives"; Robert Becker and Gary Selden, *The Body Electric*; and Bruce Pomeranz, *Medical World News*.

How acupuncture works. The question "How does acupuncture work?" can be asked and answered out of two distinct paradigms. Within acupuncture's own paradigm, the question would be answered in terms of how ch'i energy flows within the individual as that personal energy system interacts with its environment. This explanatory scheme—developed over centuries—is subtle and complex as well as various in its articulations. It involves categories such as the following: acupuncture points, meridians, types of energy characterized by expansion of the yin-yang classifications, complex diagnostic correlations, and the laws of healing and cure expressed in various ways (as, for example, in "eight conditions" or "five element" or "twelve officials" terminology). It is along such lines that the question "How does acupuncture work?" would be answered within the acupuncture paradigm.

However, when the question is asked in the United States, most often it is asked out of a western paradigm. When this is the case, then answers are expected in categories recognized by western medical science. The attempts to give such answers have resulted in some success. Two approaches will be mentioned here.

The first approach is an attempt to explain ch'i energy as a form of electrical energy. Kotzsch makes the following comment:

> Pioneering research developed by the Nobel laureate Albert Szent-Gyorki has revealed several suggestive facts:
> • the fascial or connective tissue of the human body forms a continuous network, ensheathing muscles, bones, nerves, and blood vessels, and connecting in effect every cell in the body;
> • in the fascial tissue are embedded the ganglia or nerve cell clusters that control the autonomic nervous system;

- there are two kinds of electrons and protons in the body, those that are fixed in tissue molecules and those that flow around as electrical energy;
- all molecules are semiconductors which can either conduct or fail to conduct energetic electrons;
- the collagen which makes up the fascia is a fibrous protein with enough of a crystalline structure to conduct electricity rapidly and efficiently. In other words, it may be possible to demonstrate that meridians are pathways of low electrical resistance in the fascia which conduct and coordinate the functioning of the entire body.[7]

For a fuller treatment of the electrical energy model, consult Robert Becker and Gary Selden, *The Body Electric: Electromagnetism and the Foundation of Life.* (See bibliography.)

A second approach seeks to explain acupuncture in terms of endorphins, or, more generally, of neuropeptides. Endorphins are internally produced neurotransmitters that cause pain and also the feeling of well-being. Laboratory experiments at the National Institutes of Mental Health indicate that acupuncture stimulates the production and circulation of endorphins. This would give at least a partial account of acupuncture, namely, in its pain-killing function.

Such attempts to translate acupuncture theory into western medical terminology hold promise; but there is also a danger involved. Dr. John Machata of Cambridge, Massachusetts, observes:

> Acupuncture is an effective therapy, but it must be practiced as part of a holistic approach. The therapist must take into account the whole life of the patient, including lifestyle, diet, physical activity, and emotional and mental life. There is a danger that as acupuncture spreads it will be treated as an isolated technique. There are practitioners now who use it as a specialized therapy to remove symptoms. As such, it is just another form of symptomatic medicine.[8]

All of the above discussion leads directly to a final question—how do we identify a competent acupuncturist?

How to recognize the skilled practitioner. This section has taken as a point of departure the 1980 judgment of the United States District Court for the Southern District of Texas—namely, "All the evidence up before the court indicates that, when administered by a skilled practitioner for certain types of pain and dysfunction, acupuncture is both safe and effective." At the heart of the matter is the skilled practitioner. The patient needs to know that the practitioner is a person of competence and integrity. The researcher must also be able to identify skilled practitioners to participate in serious studies. Thus, much hinges upon the ability to identify competently trained acupuncturists.

Most often, people come to an acupuncturist on the recommendation of relatives, friends or trusted acquaintances. Where state licensing is in effect, it provides a check. Patients also use their ability to sense ethical, professional behavior: to notice, for example, the care and thoroughness of the diagnostic session, the willingness of the practitioner to explain procedures, the plan and length of treatment, the absence of extravagant claims and of sales pressure, etc. Beyond this, patients need a way to assess whether an acupuncturist has the knowledge required for competent practice. One writer suggests that, on the first contact, a prospective patient seek "proof of graduation from a respectable school of acupuncture." Herein lies a matter of prime importance.

Behind the quality of the practitioner stands the quality of his or her education. Since acupuncture demands a range of subtle diagnostic and evaluative skills, many features of the apprentice model continue in acupuncture education today. Of old, a student apprenticed to a single master; the time of training was open-ended; and the certification came at the master's discretion. Today, in the United States, most acupuncturists are trained by experienced practitioners in formally established schools offering programs of at least three academic years. As mentioned earlier, the number of Americans seeking serious and rigorous acupuncture education is growing. One also finds a growing maturity and professional concern for quality among United States acupuncturists. Several initiatives undertaken in the 1980s witness to this maturation. First, various professional associations, such as the American Association of Acupuncture and Oriental Medicine, have been formed. Second, the National Commission for the Certification of Acupuncturists has been established and has administered examinations since 1985. Third, fifteen schools of acupuncture in this country have joined to form the National Council of Acupuncture Schools and Colleges. In turn, the National Council has established an accreditation commission. The importance and timeliness of establishing such an accrediting body should now be evident.

An independent accrediting agency ensuring the quality of acupuncture education in the United States would benefit many. Patients could ask where a practitioner had been trained and whether the school was accredited. Prospective students could check a school's accreditation as an index to its quality, standards and standing in the profession. Researchers could more easily identify the quantity and quality of an acupuncturist's training as an important factor in research design.

Such an accrediting agency needs to reflect the best in the several strands of acupuncture tradition. It needs to exhibit the same healing presence that is evidenced in the mode of acupuncture treatment. This means, for example, careful diagnostic attention to the situation and special features of each school, proposal of a judicious "plan of treatment," and a mode of monitoring that encourages

"Patients need a way to assess whether an acupuncturist has the knowledge required for competent practice."

"What is sought is a complementary and cooperative relationship with western medical practice."

healing and wholeness, growth and aspirations toward excellence. Only when its own traditions are honored, deeply understood and creatively enhanced will acupuncture be a worthy conversation partner for western medicine. What is sought is a complementary and cooperative relationship with western medical practice. This is not an unrealistic goal. For at the core of both eastern and western traditions is a commitment to healing, a deep respect for persons, and a dedicated search to understand natural laws and processes.

Notes:

1. Decision of the U.S. District Court for Southern District of Texas, dated July 9, 1980. *Journal of Traditional Acupuncture*, Winter, 1980.
2. George Soulie de Mourant. *L'Acupuncture Chinoise*. Paris: Maloine, 1937.
3. Several journals report the research literature in acupuncture. Among them are: *American Journal of Chinese Medicine*, Garden City, NY; *American Journal of Acupuncture*, Felton, CA; *International Journal of Chinese Medicine*, Los Angeles, CA; *Journal of Traditional Acupuncture*, Columbia, MD; *Journal of the American College of Traditional Chinese Medicine*, San Francisco, CA. The on-line reference sources of the National Library of Medicine list over 600 titles under the heading Acupuncture/Chinese Medicine.
4. Decision of the U.S. District Court. As cited above.
5. Journals as cited above. See also "An Overview of Completed Research in Acupuncture," *Journal of Traditional Acupuncture*, Summer, 1978; and "The Evaluation of Therapeutic Acupuncture" and "Acupuncture for the Treatment of Pain," *Pain*, Vol. 24, 1986.
6. David E. Bresler, Ronald Katz and Richard Kroening. "Review of Research Findings of the UCLA Acupuncture Research Project." Privately circulated.
7. Ronald E. Kotzsch. "Acupuncture Today," *East West Journal*, January 1986.
8. John Machata, M.D., quoted in "Acupuncture Today," *East West Journal*, January 1986.

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APPENDIX B

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the indications for which the drug has been reclassified from possibly effective to lacking substantial evidence of effectiveness may on or before April 9, 1973, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulation.

The petition for issuance of said regulation should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1051-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: March 3, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-4644 Filed 3-8-73;8:45 am]

ACUPUNCTURE DEVICES LABELING

Notice to Manufacturers, Packers and Distributors

The Commissioner of Food and Drugs is aware of the current interest in the United States surrounding the use of acupuncture needles, stimulators, and other accessories for medical purposes. Acupuncture paraphernalia are being imported into this country and are also being manufactured domestically for various medical uses, including the treatment and diagnosis of serious diseases, anesthesia, and pain relief. These products are devices and must comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act.

It is the position of the Food and Drug Administration that the safety and effectiveness of acupuncture devices have 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. Although various theories have been advanced as to how medical results can be obtained through the use of acupuncture, none has been proved or generally accepted, and there is a body of scientific opinion which questions the safety and effectiveness of acupuncture in many of the uses for which it is now being applied.

Under the Federal Food, Drug, and Cosmetic Act, all devices must be properly labeled to be in compliance with the law. Devices which are not safe for use by the laity, or for which adequate directions cannot be written for safe use by the laity, must be labeled as prescription devices and must be accompanied by labeling which provides the prescribing practitioner with adequate directions for their safe and effective use. Because the safety and effectiveness of acupuncture devices have not yet been adequately demonstrated, and labeling therefore cannot be devised, which would provide adequate directions for safe and effective use, they may not be labeled in accordance with the requirements for prescription devices as stated in 21 CFR 1.106(d). Until evidence is obtained demonstrating that acupuncture is a safe and effective medical technique, acupuncture devices must be limited to investigational or research use.

Current Food and Drug Administration regulations do not contain specific provisions governing the shipment of investigational devices in interstate commerce for clinical research or experimental use. The Commissioner of Food and Drugs is aware of the need for such regulations to provide adequate guidance as to the labeling for experimental devices to be used on human beings. Therefore, the Commissioner intends to publish at a later date proposed regulations which would govern all investigational devices. In the interim, this notice will apply to all acupuncture devices.

In order to establish guidelines under which manufacturers, packers, and distributors can properly label acupuncture devices for investigational use, the Food and Drug Administration met on September 22, 1972, with individuals concerned with the use of acupuncture in the United States. These included representatives of the States of California and New York, the city of New York, the American Society of Anesthesiologists, the National Institutes of Health, the Federation of State Medical Boards, the American Medical Association, medical practitioners, and the Food and Drug Administration Medical Device Advisory Committee. It was the consensus of this group that acupuncture devices should be restricted to investigational use by licensed practitioners and that the labeling for these devices should include this restriction in addition to other information.

Accordingly, the Commissioner of Food and Drugs concludes that until substantial scientific evidence is obtained by valid research studies supporting the safety and therapeutic usefulness of acupuncture devices, the Food and Drug Administration will regard as misbranded any acupuncture device shipped in interstate commerce if the following information does not appear in the labeling:

(a) The name of the device.

(b) The name and place of business of the manufacturer, packer, or distributor.

(c) An accurate statement of the quantity of the contents.

(d) The composition of the device and whether it is sterile, nonsterile, reusable, or disposable.

(e) The dimension or other pertinent physical characteristics of the device.

(f) The following statement: "Caution: Experimental device limited to investigational use by or under the direct supervision of a licensed medical or dental practitioner. This device is to be used only with informed consent under conditions designed to protect the patient as a research subject, where the scientific protocol for investigation has been reviewed and approved by an appropriate institutional review committee, and where conditions for such use are in accordance with State law."

Instructions for the use of the device for the purpose for which it is being investigated and, to the extent such information is known, any human hazards, contraindications, precautions, or side effects associated with its use, should be provided to researchers and investigators. The Food and Drug Administration, however, will regard as misbranded any acupuncture device shipped in interstate commerce if accompanied by claims of diagnostic or therapeutic effectiveness.

Pending promulgation of separate regulations for conducting clinical investigations of investigational devices, researchers and investigators shall assure adequate informed consent and institutional committee review for such investigations, utilizing as a guideline the standards established for investigational drugs in 21 CFR 130.37 and in Division 10, unit C of form FD-1571, in 21 CFR 130.3 (a)(2).

Dated: February 21, 1973.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

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[Docket No. FDC-D-355; NDA 11-370 etc.; DESI 10722]

LAVEMA COMPOUND SOLUTION AND LAVEMA ENEMA POWDER

Final Order on Objections and Request for a Hearing Regarding Withdrawal of Approval of New Drug Application

In the FEDERAL REGISTER of September 30, 1971 (36 FR 19184), the Food and Drug Administration announced its evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on several preparations containing oxyphenisatin, including Lavema Compound Solution and Lavema Enema Powder, Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Avenue, New York, NY 10016 (NDA's 12-587 and 11-370; DESI 10722).

The announcement stated that new evidence of clinical experience, not contained in the new drug applications or evaluated together with the evidence available to the Commissioner until after the applications were approved, evaluated together with the evidence available to the Commissioner when the applications were approved, reveals that oxyphenisatin base and acetate are not shown to be safe for use under the conditions of use contained in the approved applications. The announcement further stated the conclusion of the Food and Drug Administration that in view of the hazards associated with the use of oxy-

4. The Anesthesiology Device Classification Panel recommends that acupuncture needles be classified into class II and that acupuncture point locators and electroacupuncture stimulators be classified into class III.

FDA is not publishing a proposed regulation to classify these devices because the devices have already been classified into class III by statute and such a proposal is therefore unnecessary.

FDA believes that these devices have not been shown to be safe and effective for any therapeutic or diagnostic use. In recommending that acupuncture needles be classified into class II, the Panel considered risks of infection and trauma from needle breakage, but not risks presented by lack of effective therapy or diagnosis. In the Federal Register of March 9, 1973 (38 FR 6419), FDA published a notice explaining that FDA believed that the safety and effectiveness of acupuncture devices had not yet been established by adequate scientific studies to support the many uses for which the devices were being promoted. The agency concluded that until safety and effectiveness are established, acupuncture devices would be considered misbranded if the device labeling contains any claims of therapeutic or diagnostic effectiveness, or fails to include a statement of the investigational nature of the device and certain other information. The agency has not received any information to justify a conclusion different from that announced in 1973. Thus, FDA considers acupuncture devices still to be in investigational status and not to have been in commercial distribution before the amendments, for purposes of section 513 of the act. Under section 513 (b)(1) and (f), FDA does not publish for comment proposed classification regulations for devices that were not in commercial distribution before the amendments (other than postamendments devices that are substantially equivalent to those in commercial distribution before the amendments). Proposed classification regulations are unnecessary for these devices because section 513(f) of the statute itself classifies them into class III, unless reclassified by FDA orders. Because devices classified into class III by section 513(f) of the act were not in commercial distribution before the amendments, the devices are subject immediately to the premarket approval requirements of section 515 without benefit of the statutory grace period under section 501(f)(2)(A) for preamendments class III devices and postamendments, substantially equivalent devices.

The agency will, at a later date, publish final regulations describing the statutory class III status for certain devices so classified by section 513(f) of the act, as well as the status of devices reclassified by orders under section 513(f), and those formerly considered new drugs and classified into class III by section 520(1) of the act.

Because FDA believes that acupuncture devices should remain in investigational status until safety and effectiveness have been demonstrated, sponsors and investigators of acupuncture devices will be required to comply with the final regulation governing applications for an investigational device exemption (IDE) when that regulation is promulgated and becomes effective. A proposed IDE regulation was published in the Federal Register of August 20, 1976 (41 FR 35282). Upon receipt of comments, the proposed regulation was revised, and a tentative final regulation was published in the Federal Register of May 12, 1978 (43 FR 20726). Sponsors and investigators of acupuncture devices should be prepared to comply with the final IDE regulation when it becomes effective.

FDA also has issued proposed general regulations on the responsibilities of sponsors and monitors of clinical investigations in the Federal Register of September 27, 1977 (42 FR 49612); standards for investigational review boards for clinical investigations in the Federal Register of August 8, 1978 (43 FR 31586), reproposed in the Federal Register of August 14, 1979 (44 FR 47699); obligations of clinical investigators of regulated articles in the Federal Register of August 8, 1978 (43 FR 35210); and informed consent in the Federal Register of August 14, 1978 (44 FR 47713). Sponsors and investigators should refer to these proposals for additional guidance in conducting investigational studies involving acupuncture devices.