Assembly HEALTH & WELFARE COMMITTEE MINUTES

APRIL 4, 1973

MEMBERS PRESENT: BENNETT, WITTENBERG, CRADDOCK, MCNEEL, HICKEY, GETTO & FRY

MEMBERS ABSENT: NONE

GUESTS: See Exhibit A attached

The meeting was called to order by Chairman Bennett at 7:20 a.m. and he stated the first discussion would be a continuation of SB 448.

Dr. John P. Sande, President of the Nevada Medical Association, was the first speaker. He wanted to reply to some of the statements made by Mr. Steinberg and Mr. Armstrong on April 2nd. Mr. Armstrong had stated his case was diagnosed by taking of six pulses. Dr. Sande referred to a letter to the New York Legislature from the Commissioner of Education in which it was stated "..Until fairly recently, its use in the Orient followed a diagnosis based upon an analysis of the "twelve pulses." At the present time, this oriental diagnostic technique has been discarded, even in the Peoples Republic of China, for a "Western-style" medical diagnosis prior to the administration of acupuncture". A complete copy of the brief from Ewald B. Nyquist is marked <u>Exhibit B</u> and attached hereto.

Dr. Sande said Mr. Steinberg had said he knew of no MDs qualified to practice acupuncture, and he named a Dr. Jane Lee, teacher of acupuncture at University of California, San Francisco; Dr. Fong, a dentist who teaches acupuncture to physicians; and Dr. Moss, working on research acupuncture at UCLA. An article from "Medical World News" of March 23, 1973, is marked <u>Exhibit C</u>, and made a part of these minutes.

Regarding the cost of acupuncture - it is not a poor man's dream. In Washington, D.C. first visit is \$50 and second visit is \$25. In Sacramento it is \$25 a visit.

Dr. Sande also feels there is a problem on licensing as it would be difficult to check backgrounds in a foreign country - not like in United States. He sent cablegrams to China regarding Professor Lok Yee-Kung.

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A copy of his reply from the Hong Kong Medical Assn. is attached hereto marked <u>Exhibit D</u> and made a part of these minutes. No reply has been received from the Kowlown Chinese Medical Society in Hong Kong. Dr. Sande had also inquired about the credentials of Stephen Rosenblatt and Chim Shek Ju who appeared before the Senate and was unable to find anyone who knew them. A copy of Dr. Sande's remarks are attached hereto marked <u>Exhibit E</u>.

Dr. Sande questioned whether or not Medicare and Medicade would cover acupuncture and also discussed the position of the Food and Drug Administration as to the safety and effectiveness of acupuncture devices. (See <u>exhibits F</u> and <u>G</u> attached.)

Hank H. Pesner, Chiropractic Assn. of Nevada, said it was their contention that it was a grave injustice to exclude chiropractors from the practice of acupuncture. For years they have been doing the same thing except for the use of needles. Chiropractors and all healing arts should be included.

Dr. E. M. Scrivner, State Board of Examiners for Chiropractors, said that Mr. Steinberg had stated he did not feel chiropractors had sufficient knowledge of the vital organs of the body, and evidently Mr. Steinberg has no idea of the qualifications necessary to become a member of the healing arts. They must have 60 unit credits in an acredited college before entering Chiropractic College. Then 4 years of Chiropractic College consisting of 4000 hours before they can be examined. They have to attend a seminar yearly by statute. They are highly skilled and have an interest in acupuncture and the well-being of patients in State of Nevada.

Dr. Larry Bridges, Nevada Chiropractic Assn., a licensed chiropractor and licensed to practice acupuncture in Michigan, described the theory of acupuncture and the importance of chiropractors being included.

Dr. Joseph M. Kadans, President of Bernadean University in Las Vegas, was very much in favor of the bill, but suggested the following amendment:

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HEALTH & WELFARE COMM. MIN.

Under Section 25 add another exemption such as "any herbalist or college of acupuncture already in operation in the State of Nevada for at least 60 days prior to the date of passage of this act".

Stephen Rosenblatt appeared before the Committee in reply to Dr. Sande's statements and submitted a registration card showing his enrollment in UCLA. He left such card with Mr. McNeel. He stated he was studying psycho-physiology and also on the staff of anesthetialogy.

AB 491, continued from March 30th, was the next bill to be discussed.

Judy Monk of the Welfare Coalition repeated that the bill would allow families to stay together by giving aid when fathers were unemployed. Mr. Tomlinson's figures of 15% were much too high. Not a large amount of people would be affected by this bill. California's figures for unemployed fathers are 10%, Oregon 7% and the National figures about 7%. The rules are rigid as to whom would be eligible under this bill and people cannot take advantage of it.

Eddie Scott, NAACP, cited various cases where a father mould be unemployed when it was not his fault - if he were incarcerated, handicapped, physically or mentally ill, etc.

Ruby Duncan said this bill would cover the "new poor" which they are called when the father suddenly looses his job. Often the fathers must leave home so the family may obtain welfare. Judy Monk thought the fiscal note would be \$727,000 for the biennium. Father Louis Vitale felt very strongly this bill should be passed since it involves a moral issue - many people come to him with this problem. He called it the "intact bill" because it would keep family intact.

J. Duarte of the Welfare Division said they estimated the fiscal note to be 1,500,000 for the state portion only. They have based their figures on a 14% increase. The medical portion would be \$508,441.

AB 492 was next for discussion. Sister Carole Hurray, explained that she felt this was really more of a health bill as it allowed more individuals to qualify for aid when medically indigent. The counties have been trying

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to assist these people and it has cost them over a million dollars, while if the State assumes the responsibility the Federal Government will match the funds. She thinks the cost would be about 1.9 million. Mr. LaBodie of Welfare said their figures were higher.

AB 493 was the next bill discussed. Ruby Duncan stated there is no provision for welfare aid in case of an emergency such as home burning down, check being lost or stolen, and many other cases. Many other states have this type of legislation. For 1973-74 the State would pay 46% and the Federal Government 50%. Mr. LaBodie supplied their figures as approximately \$116,000 per year. Sister Marilyn Ingram, Franciscan Center, said that often the Catholic Church was beseiged with requests in case of an emergency and often they could not meet the demand. She urged support of the bill.

Father Louis Vitale asked that he be allowed to present his testimony on <u>AB 714</u> even though it was not on the agenda. He did not think he would be able to return when it was up for hearing. This bill provides a method of computing grant for aid to dependent children. He described the method of computation and said he understood it was recommended by the Health & Welfare Department. He urged the Committee to take a careful look at this improved method because of the medical aid too.

This concluded the general discussion, and the Committee turned to its discussion of the various bills.

Mr. Fry_had a suggested amendment for <u>SB_448</u> which he presented to the members.

COMMITTEE ACTION:

- <u>SB 192</u> Do Pass moved by Mr. Wittenberg, Seconded by Mr. Bennett. Unanimously approved.
- <u>SB 448</u> Amend and Do Pass moved by Mr. Wittenberg, Seconded by Mr. Fry. Unanimous "yes" vote except Mr. McNeel not voting.
- <u>AB 491</u> Mr. Wittenberg moved "indefinitely postpone", second by Mr. Fry. Yes votes: Craddock, Wittenberg, Fry & Getto No votes: Bennett, Hickey and McNeel. Motion carried.

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- <u>AB 492</u> Mr. Fry moved "do pass and refer to Committee on Ways and Means". Second by Mr. Craddock. Yes votes: Bennett, Craddock, Hickey, Fry, Getto, McNeel No votes: Wittenberg. Motion carried.
- AB 493 Mr. Wittenberg moved "indefinitely postpone". Second by Mr. McNeel. Yes votes: Craddock, Wittenberg, Getto, McNeel No. votes: Bennett, Hickey & Fry Motion carried.

Meeting adjourned at 9:30 a.m.

Respectfully submitted,

Jane Dunne, Secretary

ASSEMBLY

AGENDA FOR COMMITTEE ON HEALTH & WELFARE Wednesday Date April 4, 1973 Time 8:00 a.m. Room 240

Date April 4, 1973 Time 8:00 a.m. Room 240

Bills or Resolutions to be considered

Subject

Counsel requested*

THIS AGENDA SUPERSEDES AND CANCELS PREVIOUSLY

PUBLISHED AGENDA FOR WEDNESDAY, APRIL 4, 1973

AB 491 Enlarges eligibility for aid to dependent children.

AB 492 Allows certain additional individuals to qualify for state aid to medically indigent.

AB 493 Requires welfare division to provide emergency assistance to dependent children in certain cases.

*Please do not ask for counsel unless necessary.

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HEALTH AND WELFARE COMMITTEE LEGISLATION ACTION

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Exhibit A

HEALTH & WELFARE COMMITTEE

GUEST REGISTER

DATE april 4, 1973 WISH TO SPEAK (Specify Bill) NAME REPRESENTING YES NO le Mo Neurla, State med ann C, ANED . n/ Heintere leup 01 Welfare Division 491-3 Tomlinson 1 YALLIKE TA 1: 1. 11 ь). Duarte 440 adams n h Rom ail Oa 0 714 Jobson Franciscon 714 us lita VQ. concerned nive de citing Marilyn Ing n.

E UNIVERSITY OF THE STATE OF NEW YOR THE STATE FOUCATION DEPARTMENT OFFICE OF THE PPESIDENT OF THE UNIVERSITY AND COMMISSIONER OF EDUCATION ALBANY NEW YORK 12224 Friday December 29 19 72

TO:

Executive Branch Officials, Members of the State Legislature and Members of the New York Congressional Delegation

FROM: Ewald B. Nyquist, Commissioner of Education

SUBJECT: Acupuncture

This memorandum has been prepared to assist you in answering inquiries concerning the present status of the practice of acupuncture in New York State.

The Education Department's policy with regard to acupuncture is stated in the attached statements of the New York State Board for Medicine of July, 1972 (Attachment I) and November, 1972 (Attachment II).

GENERAL COMMENT

Acupuncture, an ancient oriental method for treatment of pain and production of anesthesia, has been used for centuries without any basic scientific explanation of how the procedure actually produces its effect. Until fairly recently, its use in the Orient followed a diagnosis based upon an analysis of the "twelve pulses." At the present time, this oriental diagnostic technique has been discarded, even in the Peoples Republic of China, for a "Western-style" medical diagnosis prior to the administration of acupuncture.

Acupuncture has produced beneficial results in many well documented cases; its use has been totally without benefit in other patients. If the procedure is not performed properly, it can produce side-effects by altering functions of the internal organs, the levels of blood pressure, etc. Some of these undeaired side-effects may be harmful in certain patients. Almost nothing is known about this aspect of reactions to acupuncture. If the needles are not aterilized and properly inserted, local infections at the puncture sites may result or infectious diseases, such as hepatitis, may be tradisticted.

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Perhaps the greatest danger is the possibility that acupuncture treatment of resurrent or chronic pain may mask the development of serious inflammatory disease or even the growth of a benign or malignant tumor, thus delaying established medical or surgical treatments which would combat the cause of the underlying disease process, perhaps save the patient's life, and not simply treat the symptom of pain. For these reasons it is especially important that patients should be examined thoroughly first by a physician, before selection and referral for acupuncture administration.

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To date the Education Department has received information from California, Iowa, Wisconsin, Kansas, Pennsylvania, Florida, Delaware and the District of Columbia to the effect that, in their jurisdictions, acupuncture has been declared to be within the practice of medicine and surgery, and that its use without restriction must await the development of adequate information regarding its safety and efficacy. A news release on acupuncture by the American Society of Anesthesiologists in June, 1972 reports a similar opinion by that organization (Attachment III).

PROJECTS IN NEW YORK STATE

The New York State Board for Medicine has requested the medical schools in the State to consider seriously the establishment of research projects which would foster the development of knowledge of acupuncture, based on treatment of patients under the necessary and proper conditions. Acupuncture programs are either under way or beginning in several locations, primarily in the New York City metropolitan area. The following projects are reported to date:

- (A) The College of Physicians & Surgeons of Columbia University is sponsoring projects at
 - Columbia-Presbyterian Medical Center, where

 a small group of patients is treated primarily
 for teaching acupuncture techniques, by a qualified
 acupuncturist who is also a licensed physician,
 to a group of physicians chiefly from the fields
 of neurology, rehabilitation medicine and
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A basic scientific research project is being conducted also in animals by neuro-physiologists.

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- (B) The Mt. Sinai School of Medicine is co-sponsoring projects with
 - (1) The Hospital for Joint Diseases, which is seeking foundation support for a study aimed especially at arthritis sufferers and patients to be treated through the Department of Rehabilitation Medicine.
 - (2) The New York League for the Hard of Hearing, especially for the treatment of nerve deafness in children. This project is still in the planning stage.
- (C) New York Medical College in conjunction with Grasslands Hospital, Valhalla, in Westchester County, which has a pain clinic under the responsibility of the Department of Anesthesiology.
- (D) New York University School of Medicine has projects in
 - (1) Basic research in pain control in which the Departments of Neurology, Medicine, and Psychiatry are associated.
 - (2) The Departments of Anesthesiology and Rehabilitation Medicine have research under way with patient treatment both at Goldwater Memorial Hospital and at the Rehabilitation Institute. One of these projects is related to anesthesia for application in dentistry.
- (E) Albert Einstein Medical College with its affiliated Montefiore Hospital has a pain clinic for the treatment of patients. Several research projects are now being planned.
- (F) Downstate Medical Center

A few operations (tonsillectomies) have been done under acupuncture anesthesia and some patients are being seen for the treatment of chronic pain. The Departments of Anesthesiology and Physiology are currently involved in setting up a pain treatment center.

- (G) At least two other hospitals with medical school sponsorship and affiliations are corrently planning the establishment of major treatment centers for properly medically referred patients. The exact date on which these clinics will open is not yet ready for release.
- (H) Albany Medical College has an animal research project in the Department of Neurosurgery and Physiology.

Various groups of physicians and medical organizations are also engaged in sponsoring lectures, seminars, workshops, and demonstrations in the field of acupuncture by highly qualified acupuncturists from this country and abroad. Already one of the benefits of basic studies conducted in New York City has been the finding that the several thousand acupuncture points, used by Chinese acupuncturists in the traditional oriental fashion, can be reduced in number to less than 50 such points and accomplish the same purposes. Furthermore, a great deal has already been learned about the duration of training which is necessary in order to prepare a licensed physician to become expert in the techniques of acupuncture. As additional knowledge is accumulated regarding the safety and effectiveness of acupuncture as a treatment modality, it is hoped that restrictions on its use may be liberalized and its benefits made available through properly trained physicians to the people who may benefit from its application.

We will keep you informed of progress on acupuncture in this State.

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Exhibit C

Injecting science into the acupuncture picture



The first results of American acupuncture research done under the aegis of the NIH Ad Hoc Committee on Acupuncture (MWN, Aug. 18, '72) are in, and they are a mixed bag. For one thing, at least some of the acupuncture points on the Chinese charts exist—and are found where the charts show them. But what they are in biological terms, and what acupuncture can and cannot do, are questions that haven't yet been answered.

Meeting in Bethesda, Md., for the committee's first conference, 110 researchers heard 45 papers on a variety of studies and proposals (see above). Guidelines laid down last July recommended research into acupuncture's effectiveness as a surgical anesthetic and as an analgesic in cases of chronic pain. The committee also called for basic studies of how acupuncture works and what side effects it might produce.

Validation of the traditional charts came from investigators who used a variety of instruments to measure skin resistance or potential. Dr. Louis R. Orkin, chairman of anesthesiology at New York's Albert Einstein College of Medicine, himself checked specific points with a locator that measures skin resistance, and he noted that several European researchers had found lower electrical resistance at specific points related in acupuncture theory to disease or injury.

Dr. Orkin reported that postoperative patients he had studied exhibited consistently lower electrical resistance at a number of these disease-related acupuncture points during tests in the recovery room. "But the number fell very far short of the 1,000 claimed by British and French investigators," he added. Point locations were found to be precise and generally constant from one person to another-those on the face and neck being the most consistent and easily located. "All the points we located corresponded exactly to acupuncture points described in the charts of Oriental medicine," Dr. Orkin concluded.

By measuring electrical, thermal, and chemical characteristics, Dr. Thelma Moss of the neuropsychiatric institute at UCLA's medical school also confirmed the presence of many traditional acupuncture-point sites. And some evidence that the classical Oriental belief in an energy flow along acupuncture meridians was reinforced by her experiments with radiation-field photography. She and her associates found that gaps in the "corona" that appears around people's fingertips in such photographs filled in when the hands were rephotographed during acupuncture. "Is this a flow of energy along the meridians?" Dr. Moss wondered.

Because electrical instruments cannot locate acupuncture points on moist skin, it has been suggested that the instruments really detect aggregates of sweat glands. But sympathectomized persons cannot sweat over certain body areas, and when Dr. Moss checked five such patients she found that the acupuncture points registered—though not as strongly on the no-sweat side as well. She concluded that it wasn't just sweat-gland activity they were detecting: "We believe these points have chemical, thermal, and electrical attributes."

Xylocaine blocks were used by Dr. Moss to create a temporary sympacontinued

ACUPUNCTURE continued

ectomy in volunteers whose hands re then imaged by radiation-field notography. The hand on the *unaffected* side lost its corona during the block, but current-flow readings at acupuncture points were as high as 3,000 nanoamperes; readings taken at acupuncture points on the other hand registered only 165 nanoamperes. "This indicated to us that there was an imbalance of energy," said Dr. Moss, "that may very well correspond to a basic tenet of ancient acupuncture theory."

Acupuncture points seem to be there for rabbits, too. Dr. Teruo Matsumoto of the department of surgery at Philadelphia's Hahnemann Hospital found that they could be located, but only on skin containing sweat glands, such as the paw pads. And he was able to map zones of analgesia produced by needling various combinations of points.

During his research, Dr. Matsumoto noticed that every rabbit defecated within 15 minutes after acupuncture. Knowing that a patient's ormal bowel function is blocked for

number of days after vagotomy, he wondered whether acupuncture would help. When he vagotomized rabbits, he found that bowel sounds returned about 36 hours sooner if they were given acupuncture right after the surgery. Obtaining permission to try acupuncture on postvagotomy patients, Dr. Matsumoto got the same result in four cases.

In a controlled study of eight osteoarthritis patients, Dr. Matsumoto located their most tender spots and found that 60% of the sites showed low skin resistance and corresponded to classic acupuncture points. He used manually twirled acupuncture needles at points of high tenderness and low skin resistance in four of these patients, and applied needles at points about 2 cm. from the classic locations in the other four.

All patients in the first group felt some pain relief and two were discharged within the week. The control patients felt little or no relief for the first three days. On the fourth day, Dr. Matsumoto switched to their real acupuncture points, and they duplicated the response of the first grouptwo were discharged within days. The other two controls obtained partial but temporary relief. Duplicating the experiment with two other groups, this time with electrically stimulated needles, produced results that were virtually identical to those of the earlier test, Dr. Matsumoto reported.

At the University of Florida in Gainesville, anesthesiologist Peter K.Y. Lee reported some success with acupuncture in tests on patients with osteoarthritis, neuralgia, and musculoskeletal pain. Of 44 patients needled at accepted meridian points, 37 reported pain relief of various degrees. In a second group of 13 patients, ten reported relief of pain when needled at the correct sites. But in a second trial, needles inserted at incorrect or placebo points brought relief to only three of the 13. In the second month of the study, the investigators switched to 27-gauge disposable hypodermic needles with no change in results, said Dr. Lee.

But when a group from his department tried the placebo technique on 18 patients at the Gainesville VA hospital, about 60% of them reported at least 50% relief, even though the treatment consisted of random subcutaneous insertion of four 27-gauge disposable needles. During a 30-minute session the physician occasionally twirled the needles while he talked with the patient about his illness. "Obviously, we are not drawing any conclusions from this very small number of observations," said Dr. Thorkild W. Andersen. "We are surprised, however, that this procedure was twice as effective as other placebo treatments. This may be more than a chance observation. The patients' expectations were high because of the wide publicity given acupuncture. The individual attention of a physician, combined with the positive act of inserting the needles, is likely to leave a greater impression on the patient than the administration of a tablet or an injection."

The oft-made suggestion that acupuncture is a form of hypnosis was disputed by Dr. Kinichi Shibutani, director of anesthesiology at Grasslands Hospital in Valhalla, N.Y. A group of 59 patients referred to the hospital's pain clinic were scored on a personality profile and hypnotizability test, he said. And "patients with low hypnotizability scores responded to acupuncture just as well as those with high scores."

"I think that the evidence presented suggests that acupuncture does have effects that should be of interest to medical science," concluded the committee's chairman, Dr. John J. Bonica, professor and chairman of anesthesiology at the University of Washington. "Preliminary results indicate that it might be useful in pain problems and may be effective in producing anesthesia for some surgical procedures."



Dr. Moss uses a current-flow meter to locate acupuncture points on the arm of 'patient' Dr. Gene M. Smith of Massachusetts General.

DENT: PETER C. Y. LEE PRESIDENTI JR. KAN PUN SHUI HON. SECRETARY: DR. LEE KIN HUNG HON. TREASURER: DR. EMMANUEL CHANG LOK-PAN COUNCIL MEMBERS: DR. LING KE-DIEH DR. PAUL YUE CHEUNG-KONG DR. A. C. DA ROZA DR. RAYMOND WANG DR. H. ABDULLAH DR. VICTOR K. C. SUN SR. M. AQUINAS DR. CHIU SHIN CHAK DR. SOO HUNG NIN DR. CHRISTINA P.W. CHOW (EX-OFFICIO) HON. ADVISERS: MR. BROOK BERNACCHI Q. C. MR. PATRICK S. S. YU MR. PHILIP P. Y. YUEN HON. AUDITORI THE HON. F. S. LI

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Hong Kong, March 29, 1973.

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Dr. John P. Sande, President, Nevada State Medical Association, 3660 Baker Lane, Reno Nevada. U.S.A.

Dear Dr. Sande.

The person you enquired about, "Professor" Lok Yee-Kung, is not a registered medical practitioner in Hong Kong. He has no medical qualifications and has no standing in the local medical profession. Apparently he is a herbalist and is a self-appointed professor.

Yours sincerely,

hules

K. H. Lee. Hon. Secretary.

KHL/ymc

Commento John P Sanda, m D. H/4/73 U T. Twelve pulses - deagunsis en filit E I in accupanteure - belief desconded reference - State og new York report - from comessioner of Education. Copy eveloped TI m Steinberg's comment on 4/2/73 He did not brow anyMDID E acomputere ability. Fisted below are a few (other celso) Jane Lee, mo Chinese - teacher accupuncture at University of California, S.F. Dr Fong - brother of above - douts 1 teacher accupenture to physicians Thelme, Moss - M& - working on research accupienture at UCLA See enclosed N. I.H. report. II Cost of accepture treatment useday \$ 25/per viset See n. y times encloser of Clinic in Washington, DC. The Aroblems of lecensure - defluerilt to obtain background materal. Two Cablegroms sent to Hong Kong me March. Reply of Hong Kong med Sec. - reply enclosed No reply as yet from the Kowlown Chinese Medecal Society

Called Kenneth Kinger - gradwate og Rens Hegh Secore, Stanford, + posently a 2 first year medical steedent at UCLA to check a background of Stephen Roænblatt & Cliem Shek Ju (sp?)-acupunt These 2 appeared before the Aluste committee leaving on acuperneture. Mr. Rosenblott also appeared before the U. g necoda students this upon I spoke about acupuncture. according to the report in the Rens newspaper he was also the phi candedate in physiology as I recall this was also mentioned in the senate hearing. According to the tiger who contacted professors & second officials of the medical sciences including biology & physiology there was no read of a Stephen Rosenblatt war did anybody prow him. This check included the past 3 years. also Do Ju is unknown to the West Coast accupientivets ever and in the collowing research project. This is The acupulticist no Rosenblatt is representing (he is emable to speak english) be easy to check on mo Roundlatts semastic that he is working on a I en psycho physiology. John Pland

NEW YORK TIMES

El lil



Acupuncture Clinic, Shut Here, Opens Up Again in Washington

L Dec 27/172

By-RICHARD L. MADDEN Special to The New York Times

WASHINGTON, Dec. 27—A search to determine the medical New York City acupuncture value of acupuncture. clinic, closed last month by "The irony is that acupunc-New York State Authorities ture has been practiced in New because its Chinese praction-ers were not licensed physi-cians, reopened here today with some of its former New York store," said Charles Newmark, patients following it to Wash-administrator of the center. Ington.

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The clinic, known as the Acu- sought to bring the practice puncture Center of New York "into the open" with qualified when it operated until Nov. 10 personnel, the state "closed Irat:133 East 73d Street, resumed it up." Inc. state closed business this morning as the Mr. Newmark said that in the Acupuncture Center of Wash- capital four or five licensed ington in a fourth-floor suite physicians would be on hand in a downtown office building at the center initially to super-"that houses a number of doc-vise the work of the Chinese acupuncturists and to screen

physical ailments through the was given. ³ received permission to operate Schere earlier this month when the District of Columbia Comsimission on licensing to Practice the Healing Arts informed the tenter's officials that acupunc-tenter's officials that acupunc-terter's officials that acupunc-terter's

stressed, however, that acu- closed and that it had a waiting puncture could be practiced in list of 3,000. He said that a The District only under the "di- number of the center's former rect and immediate supervi- patients planned to continue rision" of a licensed physician treatment in Washington even fand that the physician would though it would be a financial have to bear the full responsi- hardship. for. some of them. bility for the work of the acupuncturists. 1.1.1.1

Chinatown Practice Cited

ha Officials of the center said arthritis in his knees and neck ithat licensed physicians would at the center in New York a

Work State Education Depart-flown to Washington last night timent had held that only li-tensed physicians might wield ment today and would stay in a

in New York after legal action Swas brought against it by the treatment room, the man was Istate Attorney General, Louis asked if the needle therapy had BJrithefkowitz. Since then Mr. helped. He pulled up a pants Lietkowitz has urged an accel-leg, vigorously flexed his knee, eration- in state-supported re-land said: "What can I tell you!"

"He said that when the center

any The center, which treats patients before any treatment

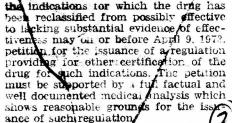
Initial Fee of \$50

The fee for the first visit. which includes a medical examination and the first treatment,

One of the center's first patients this morning was a 59-year-old Long Island man who for had begun treatments

supervise the work of the Chi-hese acupuncturists—as they did in New York. The New be identified, said that he had Recharged purysicians might wight ment today and would stay in a Recharged in the cen-ter's acupuncturists were not ficensed. The center agreed to close costs," he said.

NOTICES



The petition for issuance of said resullation should be filed preferably in quintuplicate, with the Hearing Clerk, Depertment of Heath, Education, and Welfare, Room (488, 5600 Fishers Lane, Rockville, Md. 20052. This notice is issued pursuant to pro-

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 CFF 2.120).

Dated: March 3, 1973. WILLIAM F. RANDODFH, Acting Associate Commissioner for Compliance. FR Doc.73-4544 Filed 3-8-73;8:45 am] ACUPUNCTURE DEVICES LABELING Notice to Menufacturers, 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. Acupuncting paraglaunatic age, being have ported 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 cannol 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 of 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 regulational 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 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 label ing 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 den-

Exhibit G 6419 ure tal practitioner. This device is to be used

only will informed consent under conditions designed to protect the patient as a research subject, where the scienting 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."

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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 investigators shall asresearchers 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 GARPHER, Deputy Commissioner of Food and Drugs.

[FR Doc.73-4540 Filed 8-8-78;8:46 mm]

Docket No. FDC-D-255; MEA 11-370 etc.; DESI 10732]

LAVENA COMPOUND SOLUTION AND

Final Order on Objections and Respirat for a Hearing Reporting Wilhdrawer of Approved enview-Drug Application

In the Florari Reparation ber 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 L heratories, Division of Sterling Drug, 1 c., 90 Park Avenue, New York, NY 10713 (NDA's 12-587 and 11-370; DESI 19732) The announcement stated that new

The announcement stated that new evidence of clinics 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 whet the applications were approved, reveals that oxypheniatin 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 Dung Administration that in view of the pazards associated with the use of oxy-

FEDERAL REGISTER, VOL. 38, NO. 46-FRIDAY, MARCH 9, 1973