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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	WHCCAMP Roster (partial) (2 pages)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Commissioner Binder, Day 3, May 16, 2001 [5]

2011-0568-S
kc814

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: Chase

#57

American Institute *of* **Homeopathy** 801 N. Fairfax St., #306, Alexandria, VA 22314

Good afternoon. I am Dr. Sandra M. Chase, the immediate past President of the American Institute of Homeopathy, the nation's oldest national medical association, and a former President of the National Center for Homeopathy, the nation's largest public organization representing the interests of Classical Homeopathy. I am a family physician in the private practice of classical homeopathy in Fairfax, Virginia. I am here to share with you our concerns for reimbursement, in general, and via Medicare, in particular.

Homeopathy is unique in its regulatory status among CAM modalities in the US. Specifically, homeopathy is included in the 1965 Medicare Act [H.R. 6675, Part II, *Drugs and Biologicals* (t),(1)]. Additionally, the *Homœopathic Pharmacopœia of the United States* is recognized in the 1938 Food, Drug, and Cosmetic Act (21 U.S.C.§ 321 *et seq.*). This places homeopathic drug products under the ultimate regulatory authority of the FDA, which, in 1988, promulgated the Compliance Policy Guide 7132.15 for the regulation of their marketing.

Homeopathic physician visits, which range from a few minutes for a simple acute case up to 2 hours in length for a complicated chronic case, may be billed under current E&M codes, using the time component where more than 50% of the visit involves consultation, rather than physical examination. Codes for additional time may be added where the visit exceeds 60 minutes, or, alternatively, some physicians ask that the patient return for a second visit in order to complete the homeopathic case-taking process.

A keyword search for *homeopathy* on the website for Local Medical Review Policies (www.lmrp.net) referenced by Dr. John Whyte of HCFA earlier this week, reveals that only New York policy M-95-3 bans homeopathy, along with other alternative medicine, from Medicare coverage. This suggests that homeopathy is covered by Medicare everywhere else in the United States. (Incidentally, the language of the New York policy inaccurately describes homeopathy as including "therapies using such products as antioxidants, oxidizing agents, cellular and chelation therapies and hydrogen peroxide.")

Nonetheless, physicians employing homeopathy have been harrassed by HCFA in several states. The threat of that occurrence, along with the increasing complexity of E&M coding and the potential for severe punishments for mis-coding, have caused many homeopathic physicians to opt out of Medicare participation. The end result is limited access to homeopathic medical care among the elderly and the disabled, the very populations in which pharmaceutical costs are skyrocketing and the most potential cost savings could be achieved, as homeopathic medicines are only pennies a dose.

We recommend two actions:
First, the Medicare statute should be enforced as national policy, allowing physicians to practice homeopathy without fear of reprisal throughout the 50 states.
Second, when that is accomplished, we recommend the addition of a two-digit suffix to the E&M CPT code, indicating that homeopathy has been used. This simple mechanism would facilitate tracking of the utilization and cost-effectiveness of homeopathic medical care throughout the healthcare system. Thank you.

1938 FD Cosmetic Act

#57

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

CHAPTER I—SHORT TITLE

SEC. 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. [321] For the purposes of this Act—

(a) (1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) [1] The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the U.S. Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) * The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article.

(g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the

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[1] Subsec. 201(a)(2) amended by sec. 4(a) of P.L. 90-639 and by Sec. 701 of P.L. 91-513.

NOTE—References in brackets [ ] are to title 21 U.S. Code.

*The following additional definitions for food are provided for in other acts:

Sec. 201a [321a]. Butter. The Act of March 4, 1923 (42 Stat. 1500), defines butter as "For the purposes of this chapter 'butter' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."

Sec. 201b [321b]. Package. The Act of July 24, 1919 (41 Stat. 271), declares "The word 'package' where it occurs in this chapter shall include and shall be construed to include wrapped meats enclosed in papers or other materials as prepared by the manufacturers thereof for sale."

Sec. 201c [321c]. Nonfat Dry Milk. The Act of July 2, 1956 (70 Stat. 486), defines nonfat dry milk as follows: "* * * for the purposes of the Federal Food, Drug, and Cosmetic Act of June 25 [sic, 1938 (ch. 675, sec. 1, 52 Stat. 1040), nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated."

"The term 'milk', when used herein, means fresh milk of cows."

The definition of oleomargarine appears preceding sec. 407a.

diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) [1] The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, offical Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also

[1] Sec. 201(h) [illegible] by sec. 3(a)(1) of P.L. 94-295.

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. [351] A drug or device shall be deemed to be adulterated—

(a)[1] (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 706(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity

[1] Sec. 501(a) amended by sec. 101(a) of P.L. 90-399, and sec. 9(b) of P.L. 94-295.

from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e) [12] If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

(f)(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which does not have such an application in effect; or

(C) which was classified under section 520(1) into class III, which under such section is required to have in effect an approved application under section 515, and which does not have such an application in effect.

(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

[12] Secs. 501(e), (f), (g), (h), (i) added by sec. 3(d) of P.L. 94-295.

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

(ii) on the ninetieth day after the date of the promulgation of such regulation, whichever occurs later.

(g) If it is a banned device.

(h) If it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

MISBRANDED DRUGS AND DEVICES

SEC. 502. [352] A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: and *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) [11] If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in paragraph (1) the term "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

[11] Subsec. 502(e)(2) amended by sec. 5(a) of P.L. 94-295.

(4) [14] As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia: *Provided further*, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

[14] Subsec. 502(e)(4) amended by sec. 3(a)(4) of P.L. 94-295.

#57

WYRTH POST BAKER, M.D., M.H.D., F.A.C.P.
4974 QUEBEC STREET, N.W.
WASHINGTON, D.C. 20016

202-362-8942

September 25, 1995.

Dear Mrs. Caffi:

The requested information is being faxed to-day

The original 6675, establishing the MEDICARE system omitted the Homeopathic Pharmacopoeia. During the extensive hearings I testified and was able to convince the committee that it should be included in the final amendment

REPORT

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

TO ACCOMPANY

H.R. 6675

TO PROVIDE A HOSPITAL INSURANCE PROGRAM FOR THE AGED UNDER THE SOCIAL SECURITY ACT WITH A SUPPLEMENTARY HEALTH BENEFITS PROGRAM AND AN EXPANDED PROGRAM OF MEDICAL ASSISTANCE, TO INCREASE BENEFITS UNDER THE OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE SYSTEM, TO IMPROVE THE FEDERAL-STATE PUBLIC ASSISTANCE PROGRAMS, AND FOR OTHER PURPOSES

PART II

Drugs and Biologicals

(t) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) of this section, include only (1) such drugs and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homoeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or (2) combinations of drugs or biologicals if the principal ingredient or ingredients of the combinations meet the conditions specified in clause (1), or (3) such drugs or biologicals as are approved, by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals, for use in such hospital.

Provider of Services

(u) The term "privider of services" means a hospital, extended care facility, or home health agency.

A copy of my testimony appears on page 781 of HEARINGS BEFORE THE COMMITTEE ON FINANCE OF THE U.S. SENATE ON H. R. 6675 Part 2

With my regards,

Wyrth. Post Baker

WYRTH POST BAKER, M.D., M.H.D., F.A.C.P.
4974 QUEBEC STREET, N.W.
WASHINGTON, D.C 20016

202-362-8942

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89TH CONGRESS } SENATE { REPT. 404
1st Session } { Part II

SOCIAL SECURITY AMENDMENTS OF 1965

REPORT

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

TO ACCOMPANY

H.R. 6675

TO PROVIDE A HOSPITAL INSURANCE PROGRAM FOR THE AGED UNDER THE SOCIAL SECURITY ACT WITH A SUPPLEMENTARY HEALTH BENEFITS PROGRAM AND AN EXPANDED PROGRAM OF MEDICAL ASSISTANCE, TO INCREASE BENEFITS UNDER THE OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE SYSTEM, TO IMPROVE THE FEDERAL-STATE PUBLIC ASSISTANCE PROGRAMS, AND FOR OTHER PURPOSES

PART II

JUNE 30 (legislative day, JUNE 29), 1965.—Ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE
49-648 O WASHINGTON : 1965

#57

Homoeopathic Pharmacopoeia Convention
of the
United States

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HPUS

THE LEGAL STATUS OF HOMEOPATHIC DRUG PRODUCTS SINCE 1897

The initials "HPUS" on the label of a drug product assure that legal standards of strength quality, purity, and packaging exist for the drug product within the package. The active ingredients are official Homeopathic Drug Products and are found in the current *Homœopathic Pharmacopœa of the United States*. The standards which must be met in order to append *HPUS* to a substance or a product are established by the Homœopathic Pharmacopœia Convention of the United States, a non-governmental, non-profit scientific organization composed of experts in the fields of medicine, arts, biology, botany, chemistry and pharmacy who have had appropriate training and experience and have demonstrated additional knowledge and interest in the principles of homœopathy. The Convention is an autonomous body which works closely with the Food and Drug Administration and homœopathic organizations notably the American Institute of Homœopathy and the American Association of Homeopathic Pharmacists. Guidelines are published for the prescription or over-the-counter status of homeopathic drug products.

The *HPUS* is declared a legal source of information on drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C § 301. Section 201(g)(1) of the Act. 21 U.S.C. § 321 defines the term "drug" as "articles recognized in the official *United States Pharmacopeia*, official *Homeopathic Pharmacopoeia of the United States*, or official *National Formulary* or any supplement to any of them.
Section 201(j) of the Act (221U.S.C. § 321) defines the term "official compendium" as the "official *United States Pharmacopeia*, official *Homeopathic Pharmacopeia of the United States*, official *National Formulary* or any supplement to them".

The *Homœopathic Pharmacopœia of the United States* is included in 42 U.S.C. § 801 the Medicaire-Medicaid statute and 21 U.S.C § 801 the Controlled substances Act. The FDA Compliance Policy Guide 7132.15 treats the subject of "Conditions Under Which Homeopathic Drugs May Be Marketed".

The Convention is responsible for the production and constant updating of the *HPUS*. The Board appoints a Monograph review Committee, a Pharmacopœia Revision Committee and a Council on Pharmacy to contribute to assist in the discharge of its ongoing responsibility. The Convention has a panel of experts which assists the Convention as required.

The *HPUS* is published as "Homoeopathic Pharmacopœia of the United States Revision Service" thus it can be kept current without delays implicit in a permanently bound form.

The HPUS has been in continuous publication since 1897, but was preceded by unofficial homoeopathic pharmacopoeiae since 1841, a total period of 150 years.

This information provided as a service by
The Homœopathic Pharmacopœa Convention of the United States

Similia Similibus Curentur

#57

American Institute *of* Homeopathy
801 N Fairfax Street, Suite 306, Alexandria, VA 22314
Telephone (703) 246-9501

Office of the President
10418 Whitehead Street
Fairfax, VA 22030
FAX (703) 273-1235 email: smchase@erols.com

Instituted April 10, 1844.

LEGAL STATUS OF HOMŒOPATHY IN THE USA

In regard to your questions about the recognition of homœopathy, I offer you the following information in that regard for the USA. It really involves two separate issues: pharmaceutical products and clinical practice.

Pharmaceutical products, whether conventional or homœopathic, are regulated by the federal government, specifically, by the US Food and Drug Administration(FDA). Homœopathic medicines were included in the 1938 Food, Drug, and Cosmetic Act which created the FDA, which was established to protect the public. Therefore, homœopathic medicines are officially recognized by the United States government. However, since homœopathic drugs predate the existence of the FDA, for many years they were considered over-the-counter drugs, meaning available without a prescription. The U.S. government recognizes two official pharmacopœiae in this country, the *United States Pharmacopœia* and the *Homœopathic Pharmacopœia of the United States*. In May,1988, the FDA published for the first time a written Compliance Policy Guideline as to how it would deal with homœopathic drugs. In recent years, some homœopathic drugs have now come under prescription, either because of their remedy source, such as *Opium*, or because of their clinical use, such as *Crataegus*.

Clinical practice, whether medical, osteopathic, etc., is regulated by each of the fifty states. Nevertheless, homœopathy was included in the 1965 Medicare Act which is a federal law that created the tax-funded healthcare system for the elderly and the disabled. In most of the states, homœopathic medical physicians are practicing under their conventional medical license. There are a few states, such as Arizona, Connecticut, and Nevada, in which there is a separate licensing board for homœopathic medical physicians. Additionally, there are a few states, such as Alaska and North Carolina, in which there are state laws which prohibit the revocation of a physician's license just because he or she practices an alternative form of medicine. Some other states are working towards a similar law.

As to your question about public use of homœopathic medicine, the sale of homœopathic drug products has grown geometrically in this country, which explains both the FDA's new keen interest in it and the dramatic increase in numbers of new homœopathic manufacturers, both domestic and foreign, here. Additionally, a sort of a bombshell, I think, went off within establishment medicine when, in Jan.,1993, the *New England Journal of Medicine* published an article by D.M. Eisenberg, M.D., et.al., of Harvard Medical School, which was a telephone survey of the public that revealed that a 34% of them were consulting alternative practitioners of various disciplines, even at their own out-of-pocket expense, since their insurance would not cover it, most often without telling their orthodox physicians. *Homœopathy in Europe* (7/94) contains a table on p.5 that shows in the USA 34% use non-conventional medicine, 3% using homœopathy (~7,500,000 people).

SANDRA M. CHASE, M.D., ..D.Ht. *22 April 1998*

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Owens

Divider Title: _____

White House Commission on Complementary and Alternative Medicine Policy Meeting Topic II. Complementary and Alternative Medicine: Research Challenges May 15-16, 2001

Testimony by Edward F. Owens, Jr. MS, DC
Director of Research
Sherman College of Straight Chiropractic

Thank you for allowing me to address you today. I am here to discuss some of the challenges we face in the chiropractic research community and reiterate what some of the other speakers for chiropractic have said. I am the research director at Sherman College of Straight Chiropractic in Spartanburg, SC and have been involved in chiropractic as an educator, researcher and practitioner for almost 20 years.

Sherman College Interim President, Dr. Brian McAulay, spoke to this body on February 23rd of this year. He raised three very important points that not only apply to chiropractic research, but to CAM in general.

- There is a huge disparity between the research funding to medical schools and that to alternative schools. The NIH alone granted some $6.5 billion dollars to the top 50 medical schools in 1999. The entire budget of the NCCAM, which funds most CAM research, is on the order of $70 million - about 1 percent of the NIH budget.

- We need to formally recognize the value and appropriateness of the meta-therapeutic health care paradigm that focuses on enhancing performance and function rather than treating disease. This would put more emphasis on the "complementary" in CAM, and recognize that there is a fundamental difference in the approaches between allopathic care and complementary care. Complementary care is more often aimed at improving the health of the whole person, rather than treating a particular symptom.

- More federal funding should be directed to research efforts in the wellness and preventive health paradigm that explores ways to help people avoid serious health problems and enjoy greater function and performance. This emphasis is a natural outgrowth of an increased awareness of the potential of meta-therapeutic methods to help forestall disease.

Two other chiropractic researchers spoke to this body on October 5th last year, Dr. Tony Rosner and Dr. Bill Meeker. Both of them had suggestions on how to accomplish some of the tasks Dr. McAulay suggested.

Dr. Rosner had a similar comment about the preventive aspect of chiropractic care, in particular the notion that regular chiropractic care over the long term can have benefit. At this point the evidence for his statement is largely anecdotal. There have been a few cross-sectional studies that showed how elderly patients under long-term chiropractic care tend to be more active, use fewer medical services and have better general health.

An emphasis on randomized clinical trials to test the efficacy of any therapy on a particular condition would not be effective in supporting or refuting the preventive benefits of long-term care. As Dr. Rosner pointed out, we need to relax the dependence on RCTs and open research funds to long-term descriptive studies, such as cohort designs and case series.

In our experience at Sherman College, federal funding for this kind of research is very difficult to obtain, even from the profession's own Consortial Center for Chiropractic Research. A suggestion from Dr. Rosner to provide properly balanced and enlightened study sections to review grant applications should help lower some of the barriers to the conduct of CAM research. We might also take this advice to heart in how we construct review sections in the CCCR.

In his presentation, Dr. Meeker went further to suggest that chiropractors and other CAM professionals be routinely appointed and otherwise included in research policymaking efforts (to include hiring chiropractors at the same level as other doctors in the Department of Health and Human Services as administrators and investigators). Certainly this initiative would provide a more knowledgeable and balanced staff, sensitive to the unique challenges of CAM research.

As an addendum to this presentation, I have enclosed a list of the research publications and presentations that Sherman College faculty members have produced in the past two years. The titles will give you an idea of the kinds of research we are interested in doing in chiropractic.

Thank you.

Peer Reviewed Publications by Sherman College Faculty, 1999

Owens E., Koch, D, & Moore, L (1999) Hypothesis Formulation for Scientific Investigation of Vertebral Subluxation. Journal of Vertebral Subluxation Research. 1999; 3(3).

Hoiriis K., Burd D., & Owens E.(1999) Changes in general health status during upper cervical chiropractic care: A practice-based research project update. Chiropractic Research Journal; 6(2):65-70.

Zhang J. (1999) The Correlation of Students' Entry-Level GPA, Academic Performance, and the National Board Examination in All Basic Science Subjects. Journal of Chiropractic Education; 13(2):91-99.

Owens E. (1999) Vertebral Subluxation-Centered Straight Chiropractic Research. Chiropractic Research Journal; 6(1);12-13.

Zeitz G., McAulay, B., & Mittal, V. (1999) Differentiating adoption from entrenchment: A Theoretical framework. Organizational Studies; 20(5); 742-776.

McAulay B. (1999) Negative push, positive pull: Differentiated work commitment in a turbulent career environment. Academy of Management annual conference in Chicago, August.

McAulay B., Zeitz, G., & Mittal, V. (1999) The Transition from Scientific Management to the New Management Model in Manufacturing: New Paradigm or Evolutionary Refinement? Association for Business History Conference, London, England, September.

Clusserath MT. Vertebral subluxation and a professional objective for chiropractic. Journal of Chiropractic Humanities 1999; 9(1):1-12.

Publications by Sherman College Faculty, 2000

Hart J & Boone WR. Pattern Analysis of Paraspinal Temperatures: A Descriptive Report. Journal of Vertebral Subluxation Research 2000; 3(4).

Owens EF. Theoretical Constructs of Vertebral Subluxation as Applied by Chiropractic Practitioners and Researchers. Topics in Clinical Chiropractic 2000; 7(1):74-79.

Owens EF, Stein T. Computer-aided Analysis of Paraspinal Thermographic Patterns: A Technical Report. Chiropractic Research Journal 2000; 8(2). In press

Owens EF, Pennacchio VA. Operational Definitions of Vertebral Subluxation: A Case Study. Topics in Clinical Chiropractic 2001; 8(1). In press

Senzon S. An Integral Approach to Unifying the Philosophy of Chiropractic: B.J. Palmer's Model of Consciousness. Journal of Integral Studies 2000 1(0). Online journal.

Owens EF. Philosophically driven scientific Investigation of Vertebral Subluxation. Proceedings Lisbon 2000 - ICA/FACTS conference.

McAulay B. Attitudes toward Chiropractic Philosophy: A Principle Components Analysis. Proceedings Lisbon 2000 - ICA/FACTS conference

McAulay B, Lemberger D, Owens EF. Success in chiropractic practice: a practitioner-based content analysis. Proceedings Lisbon 2000 - ICA/FACTS conference

Peer Reviewed Presentations and Posters by Sherman College Faculty, 1999

Zhang J. (1999) The effects of chiropractic care on short-term power spectrum analysis of heart rate variability. Association of Chiropractic Colleges Sixth Annual Conference. Orlando, FL, March.

Owens E, Donofrio J, & Guest T. (1999) Vertebral Subluxation Assessment in Clinical Research. Proceedings World Federation of Chiropractic, 5th Biennial Congress, Auckland, NZ, May.

Hoiriis K, Burd D, & Owens E. (1999) Changes in General Health Status During Upper Cervical Chiropractic Care. Proceedings World Federation of Chiropractic, 5th Biennial Congress, Auckland, NZ, May.

Owens E. (1999) Vertebral Subluxation Hypothesis Tree. Research Agenda Conference IV, Chicago, IL. July.

Hart J. (1999) Comparison of Upper Cervical X-Ray Listings to Upper Cervical Palpation Listings. National Subluxation Conference. Spartanburg, SC, October.

Donofrio J, Spano N, & Owens E. (1999) Reliability and Validity of Muscle Palpation as an indicator of Subluxation in the Upper Cervical Spine. National Subluxation Conference. Spartanburg, SC, October.

Owens E. (1999) Time-Series Analysis: A Research Method for Field Practitioners. National Subluxation Conference. Spartanburg, SC, October.

Owens E, Penrod M, & Stein T. (1999) Thermographic Pattern Analysis Using Objective Numeric Methods. Upper Cervical Conference, Marietta, GA November.

Hart J. (1999) Pattern Work in Chiropractic Practice. Upper Cervical Conference, Marietta, GA November.

Research Platform and Poster Presentations by Sherman College Faculty, 2000
Association of Chiropractic Colleges 2000 Educational Conference, March 15-18, San Antonio, TX (Presentations also published in the Journal of Chiropractic Education)

Owens EF, Hoiriis KT. The relationship between chronicity of complaints and changes in general health in a practice-based study.

McAulay B, Owens EF, Moore L, Hartley A. Clinical curriculum validation as a chiropractic college: a participant observation case study of an alternating bifocal model of work team effectiveness.

Brown S, Hinson R, Owens EF. Comparison of radiographic analysis and clinical outcome for two upper cervical specific techniques.

Owens EF. Thermographic pattern analysis using objective numeric methods.

Sherman College Lyceum, Spartanburg, SC.
Owens EF. Research in the Office Environment

Eighth Annual Vertebral Subluxation Research Conference, October 2000, Spartanburg, SC
(Presentations also published in the Journal of Vertebral Subluxation Research)

Owens EF. The Relationship Between Science, Philosophy, and Art in Chiropractic Research

Senzon SA. The Theory of Chiropractic Pattern Analysis Based on the New Biology

Hartley A, Charley L. Dissecting the Prone Leg Check

Clusserath M. Rationale for Multiple Common Indicators of Vertebral Subluxation

Hart J. Comparison of X-ray Listings and Palpation Listings of the Upper Cervical Spine

Clusserath M. The VSC Model and the Philosophy of Chiropractic

Chiropractic Philosophy Conference, October 2000, Spartanburg, SC
(Presentations also published in the Journal of Vertebral Subluxation Research)

Koch D. Force vs. Energy

McAulay B. Innate Intelligence and Universal Intelligence: Unnecessary Distractions in Chiropractic Philosophy?

Senzon S. Mental Impulse: Theoretical Construct or Scientific Reality?

Clusserath M. When is there Pain Associated with a Vertebral Subluxation?

Clusserath M. Philosophical Similarities between the Historically Opposed Groups in Chiropractic.

Senzon S. An Integral Approach to Unifying the Philosophy of Chiropractic: B.J. Palmer's Model of Consciousness

McAulay B. From 33 Principles to Coherent Concepts: Parsimony in Chiropractic Philosophy

Koch D. Chiropractic Philosophy: Where the Profession Needs to go to Advance.

World Federation of Chiropractic Conference on Education, November 2000, Ft. Lauderdale, FL

McAulay B, Naylor G. Philosophy Curricula in Chiropractic Colleges: A Content Analysis

International Chiropractors Association/Federation for the Advancement of Chiropractic Tenets Conference, November, 2000, Lisbon, Portugal

McAulay B, Lemberger D, Owens EF. Success in chiropractic practice: a practitioner-based content analysis.

Owens EF. Philosophically driven scientific investigation of vertebral subluxation.

McAulay B. Attitudes toward Chiropractic Philosophy: A Principle Components Analysis.

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NIMC
National Integrative
Medicine Council

Statement of

Matt Russell
Executive Director
National Integrative Medicine Council

Before the

White House Commission on Complementary and Alternative Medicine Policy

May 16, 2001

5151 East Broadway, Suite 1095 • Tucson, AZ 85711 • 520-571-1110 Fax 520-571-1177 • www.nimc.org

Matt Russell
National Integrative Medicine Council

Chairman Gordon and members of the Commission, good afternoon. My name is Matt Russell and I am the Executive Director of the National Integrative Medicine Council (NIMC). The NIMC was created as a membership and advocacy organization to leverage the widespread demand for a new kind of medicine, one that appreciates the full range of resources to prevent disease and promote healing - from the best of allopathic medicine to the best of complementary and alternative medicine. However, the integrative approach does not simply add a handful of alternative therapies to the conventional physician's regimen, nor does it in any way deny the many strengths of allopathic medicine. Integrative medicine seeks to restore the focus of medicine on health and healing, emphasizing the centrality of the doctor-patient relationship and the human body's innate capacity for self healing and repair. It values lifestyle influences on health (such as diet, stress management, and exercise) and insists that physicians recognize their patients as more than just physical bodies.

Mr. Chairman, there are many important issues about which I could testify today. Just a little over a week ago, the Integrative Medicine Industry Leadership Summit convened in Arizona to address issues concerning reimbursement, clinics, employer strategies, CAM integration, and national policy. It was heartening to see such positive communications across stakeholder lines. While we honor all of the good work coming out of this summit, and expect to play an integral role in advancing issues of importance to the CAM professions, my testimony today focuses on specific public policy recommendations for physician education. This is an area where we believe an immediate opportunity exists.

Not surprisingly, the current structure of education and training of physicians in this country is inadequately preparing our physician workforce to meet the needs of patients. I believe it was Hippocrates who was often quoted as saying, "Cure sometimes, heal often, comfort always." Unfortunately, today's physicians are encouraged to cure always, heal if they have the time, and leave the comforting to someone else. Physicians are entering practice with frustrations about not being able to spend more than just a few minutes with their patients,

and are forced to rely too heavily on costly and impersonal technologies. Ironically, the shift toward high tech medicine over the past few decades is a dramatic departure from what our patients are saying loud and clear is important to them. Patients are looking for doctors who are sensitive about complementary and alternative therapies, and can knowledgeably guide their patients through the confusing maze of treatment options.

What, then, can be done to respond to this appeal for a healing-oriented health care system without neglecting the significant role that conventional medicine plays? There have been many, many solutions proposed. We have heard that our case needs to be made to the insurance industry, once issues of cost-effectiveness and quality can be ascertained. We have heard that the case needs to be made to employers, that if our nation's workforce unites behind this message, third-party payers will respond. We have heard that the solution lies in more appropriate research, moving away from the randomized controlled trial and towards clinical outcomes research. We have heard that consumers and health care providers alike need access to reliable information about choices in health care. These are all very important issues, each playing a significant role in this new system of care. However, if we do not have an appropriately educated physician workforce, no amount of research or reimbursement will ever find its way to our patients.

It is ambitious, if not unrealistic, to assume that we can realize the kinds of shift in medical education that we believe is important over the short-term. However, within only a few years, we can begin to see the initial effects of this model. The National Integrative Medicine Council is advocating for a small, federal demonstration project to gauge the effectiveness of building predoctoral medical education around the integrative model. The concept of providing grants to medical schools to evaluate new innovations in education is not new. Launched in 1997 under the Health Resources and Services Administration (HRSA), the federal UME-21 program has awarded grants to 18 medical schools, each of which has proposed certain curriculum innovations. We believe a similar system can be created for medical schools to build integrative curricula. Funding for medical schools for this purpose is critical, and we urge the Commission to recommend that HRSA set-aside specific funds for an integrative medicine education demonstration project. Another potential vehicle to create curricular innovations is through the reauthorization of the Public

Health Service Act, which Congress is soon expected to take up. The NIMC recommends an increase in appropriations for Title VII programs for the specific purpose of educating medical students in integrative medicine.

Mr. Chairman, we believe that many factors contribute to the development of this new system of care we collectively envision. It is about building stronger bridges between physicians and CAM providers. It is about an awareness that conventional medicine is in economic trouble. It is about providing access to reliable information. It is about empowering the consumer to make informed choices. And it is about building an infrastructure to bring the education of our nation's physicians back...to the future. This opportunity is before us today.

Thank you for the opportunity to share issues of importance to the NIMC. I would be glad to answer any questions.

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Divider Title: Sabatini

Carolyn Jones Sabatini, B.A., M.B.A.
Pharmavite Corp.

Pharmavite manufactures dietary supplements and markets these products under the Nature Made and Nature's Resource brand names.

Pharmavite shares reliable information on its products with health care providers in several ways. We employ registered dieticians who give accredited lectures on dietary supplements to health care providers nationwide.

We also distribute a comprehensive, heavily-referenced product manual to pharmacists which outlines usage, recommended dosage, safety, side effects and adverse reactions, if any, with conventional medicines. We call it our Vitamin & Herb University and are pleased that the Purdue School of Pharmacy includes this manual as part of its curriculum.

Pharmavite also operates several toll-free information lines for trained professionals and the public to address any questions about our products' safety, usage, and stated benefits. We clearly note warning labels on our products, if needed, and identify those groups of consumers who should
consult with a health care provider before taking our products.

What are the obstacles/barriers and possible solutions to accomplish this goal ?

One obstacle is the industry's inability to effectively communicate product quality to the public.

One solution is for this Commission to urge FDA approval of the Good Manufacturing Practices (GMPs) covering our industry that were first published as proposed rulings in 1997. Pharmavite has supported, endorsed and long awaited thse guidelines to complement our own efforts to build public confidence in the quality and safety of our products. GMPs will help us achieve that goal.

Christina Walker
The Shenk Human Energetic Institute

PHARMAVITE

DISSEMINATION OF RELIABLE INFORMATION ON CAM TO HEALTH CARE PROVIDERS AND THE GENERAL PUBLIC: A DIETARY SUPPLEMENT MANUFACTURER'S PERSPECTIVE

Statement of Carolyn Sabatini
Government and Regulatory Affairs Manager
Pharmavite Corporation
before the
White House Commission
on Complementary and Alternative Medicine Policy
May 14-16, 2001

Pharmavite manufactures dietary supplements and markets these products under the Nature Made and Nature's Resource brand names.

Since 1971, Pharmavite has been committed to providing consumers with quality dietary supplements that make a positive difference in people's lives.

We are pleased to offer suggestions on the dissemination of reliable information on CAM to health care providers and the general public.

Our response is tied to specific questions posed in the letter of invitation to participate in this forum.

How reliable information on CAM can be disseminated to health care providers and the general public:

I will share with the Commission some of Pharmavite's routine information-sharing practices. We encourage other dietary supplement manufacturers to continue or adopt similar communication approaches because information exchange benefits everyone.

Pharmavite regularly shares reliable information on its products with health care providers. We employ a team of registered dietitians who travel the country giving accredited, continuing education courses for pharmacists as well as science-based lectures on dietary supplements to other health care providers, professional associations and interested consumer groups.

Pharmavite Corporation • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/221-6200 • 800/423-2405
Deliveries Only: 8510 Balboa Blvd., Northridge, CA 91325

We have developed a comprehensive, heavily-referenced product manual that outlines usage, recommended dosage, safety, side effects and adverse reactions, if any, with conventional medicines. We call it our Vitamin & Herb University and are pleased that the Purdue School of Pharmacy includes this manual as part of its curriculum. We also have distributed this manual to retail pharmacists, nutritionists and others nationwide.

Pharmavite also operates several toll-free information lines for trained professionals as well as the general public to address any questions about our products' safety, usage and stated benefits. We clearly note warnings on our product labels, if needed, and identify those groups of consumers -- such as pregnant women and those currently taking prescription medication -- who should consult with a health care provider before taking our products. In addition, our Web sites contain detailed product information, suggested dosage, drug-nutrient interactions and an information forum we call "Ask Our Nutritionist".

The second topic we'd like to address is:

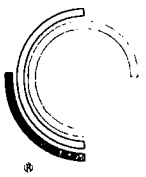
Obstacles/barriers and possible solutions to accomplishing this goal:

One obstacle is the industry's inability to effectively communicate product quality to the public. While Pharmavite and other dietary supplement manufacturers follow strict quality assurance programs, the public and media perceive that we are not regulated. This misperception may in part exist because FDA has not fulfilled the Dietary Supplement Health and Education Act (DSHEA). Seven years ago, Congress passed DSHEA to give FDA the authority to among other things, set good manufacturing practices or GMPs for our industry that were "modeled after current GMPs for food".

Working closely with the Council for Responsible Nutrition, an industry trade association, Pharmavite helped draft GMPs appropriate for dietary supplements that go beyond GMPs for food. The draft was submitted to FDA in November 1995 and published by the agency in February 1997 as an advance Notice of Proposed Rulemaking. After comments were received, FDA modified and finalized a GMP proposal, which was at the Office of Management and Budget awaiting review when the new administration took office in January 2001. The proposal was withdrawn in February 2001, along with numerous other pending regulations, to permit the new administration to review all actions.

Pharmavite has supported, endorsed and long awaited formal GMPs to complement our own efforts to build public confidence in the quality and safety of our products. We believe the Office of Management and Budget has an obligation to give FDA the ability to set the GMPs that we have been waiting for, for seven years. Our industry's ability to disseminate reliable information would be improved if people had a better understanding of how closely we are regulated.

Thank you.



About PHARMAVITE

Nature Made and Nature's Resource brands are made by Northridge, Calif.-based PHARMAVITE. For more than 30 years, PHARMAVITE has offered high-quality vitamins, minerals, herbs and other nutritional supplements that promote wellness and help maintain good health. Pharmavite was also an instrumental force in developing the supplement industry's manufacturing standards recommended by the United States Pharmacopoeia (USP). For more information, call PHARMAVITE at 818-221-6200.

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#61

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In this testimony I will present a case study and interweave recommendations concerning research.

A 19-year-old female victim of a car accident in a coma for 10 days experiences multiple fractures, hypovolemic shock, R pnemothorax and a near death experience. It takes one year to heal her physical symptoms. For the next 25 years she becomes a chronic pain patient. She goes from physician to physician who cannot find a reason physically for her pain. On her journey she comes into touch with alternative medicine. She starts with acupuncture and this starts to reduce the pain, but she is told she is unable to hold the treatments. She begins her studies in Healing Touch to study the chakra system for she knows her pain lies somewhere energetically. She begins to explore her consciousness to make sense of the many different frequency bands she experienced during her near death experience. Through the search of her consciousness she finds out she still disassociates and has not fully re-entered her physical body from the trauma she experienced so long ago. With this realizations she understands how could any energetic treatment give her the full results.

Recommendation: During research we need to get a sense of where is the person's energy body. For example the person may say I am beside myself, which means the energy body is next to the physical body. This may affect results if you mix population types because the treatment is different.

With this knowledge she has now acquired she enters a state of prayer to find someone that can teach her how to re-enter her physical body. This search leads her to Austria with the teacher Christine Schenk.

During the course of her studies with Christine Schenk she is taught and experiences that some parts of the energy system are closer to the physical body and others are farther away, so which space are we really researching. What levels of space are you studying in the energy body for each space has to be studied differently

Recommendations:. You need to know where you are according to the energy body anatomy

The patient learns to re-enter her body, make peace within herself and to start to feel the regeneration of her energy system with Christine Schenk's trainings. Now grounded and clear she finds out her entire energy system was smashed in the car accident which explains why she was disassociated, in chronic pain, and energetically unable to hold any form of alternative treatment. With this information she realized she needed to take a closer look at selection criteria.

Recommendations: Researchers need to understand the energy anatomy in a more comprehensive way. They need to see the big picture not just the small area they work in because that small area affects the entire energy system.

Research is based on science and the perception of the energy body is based on feelings, therefore our study designs need to be different. Sometimes we are chosen to walk the journey personally and experience research from that place which yields a different knowing. As long as we understand where we are and how we have our patients grouped we can accurately explore the world of energy.

The client I present to you today is me and I give more in-depth recommendations in the papers attached.

Thank-you so much for giving me the opportunity to share my journey for we are all in this journey together.

CHRIS®-Technique The Schenk Human Energetic Institute LLC
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Testimony on Research issues in Energy Medicine

1) **What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?**

The following areas should be taken into consideration by the committee when address this first question.

a. **Educate about the differences between physical body research and energy body research.**
   i. **Include an understanding regarding the pitfalls and limitation of energy medicine when it comes to**
      1. **Selection criterion**
      2. **Randomization**
      3. **Control group: placebo or sham therapies in energy body medicine.**
      4. **Dosing of interventions and subgroup differences**
      5. **Better awareness of side effects of energy body medicine therapies.**

CAM therapies that affect the energy system need to be studied differently. To help understand this, we must first start with the awareness that we exist as two systems simultaneously. We have an energy body and a physical body. Many CAM therapies affect the energy body anatomy and physiology. Examples of these are Homeopathy, Acupuncture, and Hands on Healing. These approaches are commonly known as energy medicine therapies. Because these therapies are focusing on different systems and layers, the methods of studying need to also be uniquely different.

Western medicine focuses principally on the physical body. Therefore, these conventional research approaches are valid here. Some forms of CAM can be researched with this approach, since their principle focus is in the physical body space. Nutritional therapy, phytotherapy and aromatherapy are examples of these physical body focused CAM therapies.

When it comes to Energy medicine approaches however, these therapies need methods that are different due to the nature of this system. Outcomes of energy body research depend upon what area of the system is being studied. Our therapies can affect the energy body system on different levels or with in different organ systems. Error in interpretation can very easily occur if unique factors relating to the energy body system are not taken into consideration. We first need to understand how this energy body perceives, and functions to yield valid results.

The space being studied in the energy body network needs to also be well defined before initiating research. This allows us to formulate studies that hold together. We can however take the concept of western medicine rigor and structure and apply them to well-defined study groups.

SELECTION CRITERIA

One of the greatest difficulties in doing research in the Energy Medicine is population selection. We need a clear understanding if the presenting problem is physical or energetic before client selection can occur. A patient with gastritis or digestive problems can have the condition due to a purely physical disorder or due to an energetic disturbance that presents as physical system. Without a clear ability to distinguish which system is involved (and therefore which patients to group), the data will be confounded and unclear. These distinctions of symptoms in the history of the participants are critical in order to have a homogenous population to study.

Many other conditions to be studied with CAM approaches require an understanding of origin of the problem to yield the most accurate research outcome and avoid error. Within the energetic body, we need to have a clear understanding where in the system, the problem is originating. In the physical body, the problem can be heart related affecting kidney function rather than a direct kidney problem. So to, in the energetic body, one system can affect another. Knowing the origin of the energetic problem therefore will be important in doing successful and meaningful energy research. If we are not fully aware of a participant's energetic anatomy then errors can be made in participant selection.

Participants who have been involved with prior energy body therapies may affect outcome of results and need to be considered separately. This is because in most cases these therapies are medications to the energy body. Just as in western medicine research, selecting out these populations will minimize data alterations.

Examples of such patient populations with special situations are;

1) Pregnant women,
2) Mediators, and
3) People with interventions having long lasting effects on the energy body. Example of such interventions with possible long lasting effects include:
    a) Anesthesia
    b) Mind altering drug intake
    c) Breath work
    d) Psychotropic medication or
    e) Sedative medications of any kind.

Many of these groups should be studied in isolation to yield clear results.

THERAPUTIC DOSING ISSUES

Issues of dosing of energy therapies need to be quantified in order to standardized outcomes as well. Here we need to further be aware that an individual's metabolism for energy medicine therapies is different. Asian people energetic metabolism is differently that Europeans or African Americans. They may have different dosing needs and approaches. This needs to be taken into consideration when designing studies with CAM therapy to avoid outcome based errors and increased side effects.

CONTROL GROUP: PLACEBO OR SHAM THERAPIES IN ENERGY BODY MEDICINE
BLINDED STUDIES IN CAM THERAPY

Traditional research in western medicine depends as much as possible on randomizing the participants and blinding them to protocols to prevent the introduction of bias. This model has shortcomings when it comes to research in energy medicine. You cannot placebo an energy body. Energy body blinding is not possible because we have specific sensory perceptions that are present with this system. The perceptions of telepathy, clairvoyance and clairsentience, all makes it impossible to truly blind the participant if the practitioner is aware that the placebo is being applied. In this scenario an energy body will simply perceive the researcher as not truthful and possibly avoid trusting or participation. Whatever the reaction, the end result will no longer be neutral and will affect the data. That is why studies that support single blinding as a technique in this population are not effective models.

Double blind approaches are ideal but difficult and can only apply to some CAM therapies. An example of this can be homeopathy studies. Routinely the practitioner cannot be blinded to what they are doing if they are administering the therapy on the patient. They can be blinded to the outcomes in some cases, but they sense and feel what is taking place and adjust their therapies accordingly. In short, a true double-blinded format is difficult to achieve with energy work, but can occur when there is a substance that is prescribed and taken by the participant at a later time. A study where the practitioner must do an intervention with or to a client is not possible to bind. We must study these approaches as we would when we study surgery research since the surgeons cannot be blinded in their process as well.

SIDE EFFECT AWARENESS

Any therapy that works would also mean that it must have side effects. It would be counter intuitive to believe other wise. To expand the current research environment we need to develop a clearer awareness of the side effects of our treatment modalities so that studies can be better formulated. Commonly observed side effects of energy therapy can be:

Sleeping disturbances	Constant Fatigue	Backache	Constipation
Lack of concentration	Shaking Chills	depression	Dizzy spells
Circulatory problems	Changes in eating habits		Hot Flashes
Suicidal tendencies	Headaches		

STANDARDIZATIION REQUIREMENTS FOR ENERGY RESEARCH

a. Establish a standard in terminology regarding energy body medicine.
Other confounding factors that make energy body research different than conventional research are that different subcultures and different backgrounds confabulate our understand regarding naming conventions in energy medicine. Words like energy filters, flows, and prana have different meanings in different settings. We also perceive the energy body world differently based on culture, schooling, methods, and our own individuality. This further confounds the data, and requires that we be clear on what exactly we are doing. The bottom line is that test results are not comparable unless we speak the same language using the same words and meanings, as a conventionally trained medical doctor would discuss the finds of a broken leg that needs intervention. In order to effectively proceed with research of the caliber of western physical body medicine, this terminology issues needs to be addressed.

b. Establish a clearer definition regarding energy body anatomy and physiology so that tighter population grouping is possible for future studies.
As mentioned previously, we need to have a clear definition of the population being studied. If the condition is energetic in nature, we need to be clear of the anatomy and physiology of the energy body in order to know where the condition originates and appropriately select patients with the same disorder for study.

c. Establish a clear understanding of what space each energy body modality is operating in within this terminology set.

Without knowing the space we are studying we can never really ask the correct question to appropriately design energy body studies. Each therapy needs to be understood as to what level in the energy system it is effecting. Each type of energy body practice group needs to be able to explain or formulate a theoretical position on what part of the energy body system its practices is affecting. This is critical because in the system of the energy body, space is a clear factor for successful navigation.

At this time the most successful models for studying Energy body approaches will be in an outcome based model in comparison to conventional approach. Outcome based is suggested since we do not have tools to directly measure energy changes. The issue of appropriate patient selection is still present and is directly appropriate to level of training and clear understanding of what effects

the therapy is thought to have on the system. In summery then, to expand the current research environment to adequately address the space of energy body medicine, the following need to be satisfied:

a. **Educate about the differences between physical body research and energy body research.**
    i. **Include an understanding regarding the pitfalls and limitation of energy medicine when it comes to**
        1. **Selection criterion**
        2. **Randomization**
        3. **Control group: placebo or sham therapies in energy body medicine**
        4. **Focus on questions of dosing of interventions and subgroup differences**
        5. **Encourage better awareness of side effects of energy body medicine therapies.**
b. **Establish a standard in terminology regarding energy body medicine.**
c. **Establish a clearer definition regarding energy body anatomy and physiology so that tighter population grouping is possible for future studies.**
d. **Establish a clear understanding of what space each energy body modality is operating in within this terminology guideline.**

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Testimony of Alan Dumoff, J.D., M.S.W. **#62**
Before the White House Commission on
Complementary and Alternative Medicine Policy
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I have been involved in the legal issues concerning CAM delivery for 13 years, and concerned about barriers to integrative efforts as far back as the early 1980's when, working as a psychotherapist, I became frustrated with the barriers to working collegially with nutritionists, chiropractors, and other CAM practitioners. I went to law school expressly to work on these issues. I do not speak on behalf of any one client today, but rather from the aggregate experience of representing physicians, acupuncturists, nutritionists, homeopaths, and a host of other practitioners as well as national credentialing bodies, associations and other organizations.

My topic has me scheduled out of turn; in my few minutes, I would like to highlight five items regarding reimbursement policy.

X) *Medical Necessity and Standards of Care.* The most insidious difficulty under reimbursement policy are decisions whereby Medicare or private insurers decide what constitutes appropriate, medically necessary care, ruling out payment for positive, innovative approaches because they are nonstandard. The rejection out of hand of nutritional approaches to care, despite extensive supporting literature, is but one example. While I'm sure this is clear, what I hope is also known to the Commission is the use by third-party payors of these standards to bludgeon holistic physicians about these practices. A physicians I represented was excluded from Medicare because the Health Care Financing Administration (HCFA) believed that nonstandard medicine is *per se* substandard medicine. In another case, a BlueCross BlueShield insurer complained to a state medical board because a physician was practicing nutritional medicine and innovative therapies, even though BlueCross was not being billed for noncovered therapies.

> *Recommendation*: I believe that the Commission has an obligation to directly address the value and meaning of standards of medicine in the context of holistic and integrative care.

X) *E/M Coding.* Evaluation and management (E/M) coding for office visits, especially under revised and more stringent guidelines about complexity of decisionmaking and degree of morbidity, are designed with biomedical methods in mind. Holistic approaches that take a more searching view of etiology take longer but do not easily justify higher levels of coding. This encourages rapid and incomplete assessments. One physician I represent in Maryland was charged by the Board of Physician Quality Assurance with willfully overbilling. After attending a coding course at the behest of the Board, and noting that professional billers don't agree on the application of coding guidelines, this physician raised some reasonable and pointed questions about how holistic physicians can honestly work within a billing system that the physicians it was designed for are having difficulty.

> *Recommendation*: The Commission has an opportunity to sensitize the AMA/HCFA Committee that drafts documentation and coding guidelines about the time intensive nature of holistic approaches to practice.

X) *Medicare's Same Day Rule.* Medicare routinely rejects multiple services that are done on the same day for the same purpose. This makes integrative delivery difficult. A patient seeing a physician for back pain cannot get reimbursed if she sees a chiropractor in the group the same day.

> *Recommendation*: The Commission could request that the Health Care Financing Administration review Medicare rules such as the same day rule for possible modifications that would better accommodate team, integrative practice. It is worth noting that, in working with a Florida client regarding Medicare issues, the local carrier issued the rather cryptic *non sequitur* that "team practice is dead." Support for team practice as an important principle in the new medicine by the Commission, with encouragement for regulations that support such practice, could be of great benefit.

4) *"Incident to" Billing.* As I mentioned in an article entitled "An Open Letter to the White House Commission on Complementary and Alternative Medicine: Suggestions for National Course Corrections" published in Mary Ann Liebert's *Alternative & Complementary Therapies*, one change HCFA is contemplating would effect the ability of CAM practitioners to bill under the name of a physician in a group practice.

> *Recommendation*: In the interest of brevity, I'll simply highlight the importance of that issue here and refer the Commission to that article and its recommendation.

5) *Getting Good Information.* Properly billing Medicare and private insurers is phenomenally complex. Every client site I visit has grave misconceptions about how to code office visits, use modifiers to bill for denial, waivers for non-covered CAM services, assign benefits . . . the list is quite lengthy. Many CAM services are delivered in small clinics with a few physicians and CAM practitioners, who do not have the resources or expertise to understand how to bill legally and successfully.

> *Recommendation*: Some form of clearinghouse or other means of providing concise and understandably information about legal and successful billing practices should be made available. The Commission could ask HCFA to provide materials on-line aimed at the usual issues that arise in integrative practices.

Lastly, I would like to urge the Commission to take greater advantage of legal expertise in this field. While it is refreshing to find a Washington institution that is not teeming with lawyers, there are a handful of attorneys in the United States who specialize in the legal concerns regarding CAM, a body of experience I believe could serve the Commission well.

Thank you for you attention, and more importantly, your efforts.

AMERICAN ASSOCIATION OF NATUROPATHIC MEDICAL COLLEGES

AND

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

TESTIMONY TO WHITE HOUSE COMMISSION ON CAM POLICY

WASHINGTON, D.C.

MAY 16, 2001

Dear Commissioners and Staff:

Thank you for the opportunity to appear before you today. While we have provided information at previous WHCCAMP meetings, we would like to make the following points:

THE HEALTH OF THE AMERICAN PEOPLE IS AT RISK

- reimbursement for CAM services and products, and coordination of CAM research, is in the American public's interest
- access to CAM services is needed by the elderly, the poor, the uninsured, and in rural areas

PLURALISM IN AMERICAN MEDICINE

- diversity, with separate but equal systems of healing
- professions in parallel, collaborative integration
- maintain the "gene pool" of ideas
- enhance creativity, critical thinking, competition of ideas, economic competition, and market forces
- each system of healing has its strengths and weaknesses; combining systems results in losses for each

"To many observers, modern medical control over the terms and process of integration has resulted in the loss of important aspects of traditional theory and practice, issues seemingly unimportant to modern medicine. [For example] Fewer

acupuncture points are taught than in the classic system and aspects of the theory of traditional Chinese medicine have been de-emphasized. The effect of "modernization" resulting in a lesser system has also occurred with traditional medical education in India." (British Medical Journal, Vol. 322, 20 Jan 2000, p.165)

- assimilation impacts public safety

  Adverse events are far more common in less-trained medical acupuncturists (tends to be MDs with less than one year of training) than in better-trained acupuncturists (36 to 43.6 months training. The adverse event rate has been reported as 2:1. (Towards a Safer Choice: The Practice of Traditional Chinese Medicine by Bensoussan and Myers, 1996, Australia)

- the various CAM professions and traditions, their history, their standards, their bodies of knowledge, represent a national resource

  - naturopathic physicians represent a separate and distinct medical system

    - distinct standards, licensing, credentials, accreditation

    - distinct body of knowledge, scope of practice

    - recognized as physician providers in eleven states

      Naturopathic medical college prepare(s) NDs "with a biological and biomedical education of the same breadth and depth that prepares an MD to be a primary care physician. Naturopathic medicine...diverges from other forms of primary medical care at that point where professionals in common possession of scientific facts conscientiously disagree on how best to use their shared knowledge in treating patients." (Oregon Office of Educational Policy and Planning Administrator David Young, April 18, 1989)

  - CAM providers are sought by the public, not for certain modalities, but for the clinical philosophy or culture or paradigm in which they are applied

  - in a pluralistic system, there should be equal access to and equal regulatory and financial support for the various systems

REIMBURSEMENT FOR CAM PRACTICES AND PRODUCTS

- public choice requires equal access to physician providers of various schools of medicine

  - one example: Connecticut requires any insurance company which covers the services of a physician to not discriminate among MDs, DOs, or NDs

- however, Connecticut's policy does not apply to federal employees and Medicare beneficiaries

- such "illusionary access" should be prohibited by federal policy by eliminating conflicting policies, regulations and laws

- public safety for providers who diagnose and treat, and are primary care or primary contact, requires access to credentialed, licensable professionals with educational standards, clinical training, board examinations, and peer review

  - credentialing is required in order to receive reimbursement for CAM services

  - to be credentialed, one must be licensed, and trained in an accredited program to a recognized scope of practice

  - licensure, credentialing, and education are linked through the reimbursement system for public safety

  - the licensed CAM professionals must be integrated throughout the health care system for safe and effective access

  - Data on access, delivery, and reimbursement for naturopathic care are available from several states (Washington, Connecticut, Montana)

    Price-per-member per month for users of CAM services (acupuncture, massage and naturopathic medicine) has been found in one study to be approximately $0.20. A large majority perceived these services to be helpful. 61% reported that the CAM treatments had resulted in diminished use of their pain medication, and 55% reported a decrease in the use of their "conventional medical team." (Utilization, Patient Satisfaction and Cost Implications of Acupuncture, Massage and Naturopathic Medicine Offered as Covered Health Benefits. Darrell Stewart, MHA, John Weeks, Stephen Bent, MD)

COORDINATION OF CAM RESEARCH

- the coordination of CAM research has been addressed by our profession's representatives in previous Commission meetings (see testimony from Traub at San Francisco Town Hall Meeting, Standish and Pizzorno at Seattle Town Hall Meeting, Kail at Dec.4-5 meeting,)

- NCCAM is coordinating CAM basic science and clinical research, and facilitating the development of infrastructure at CAM research institutions

• the proposed Office of CAM at HHS should coordinate other types of research not included in the NCCAM mandate, such as research in health services, cost effectiveness, policy, education, and practice guidelines. This Office could also collaborate with NCCAM in holding a conference on the challenges of CAM research and CAM research methodologies

• appropriations are necessary for demonstrating efficacy and cost-effectiveness of CAM services and products. The burden of funding this research should be fair and equitable compared to that which is provided for conventional care pathways and interventions.

SPECIFIC POLICY RECOMMENDATIONS

1. **Commit to medical pluralism**

• embrace the fullness of diverse health care systems

Conventional, traditional, indigenous, complementary and alternative models of care, and their bodies of knowledge, have contributions to make to the healthcare which is culturally most appropriate and effective for individuals and communities. Best practices are discovered through exploring diverse structures for integration, including parallel, collaborative, and assimilative models.

• encourage licensing all CAM providers consistent with educational standards

• require inclusion of licensed CAM providers in CAM policy making and as researchers and advisors in all federally-funded CAM studies

• establish CAM offices at and appoint naturopathic physicians and other licensed CAM professionals to the staffs of federal health care agencies, including NCCAM, NIH, DHHS, CDCP, Agency for Health Care Policy and Research, Bureau of Indian Affairs, Public Health Service, National Health Service Corps, VA, and HRSA

•appropriate funds to layer a premium on any grant at NCCAM for including a CAM research institution instead of only a conventional one, and, for naturopathic institutions, it be a Council on Naturopathic Medical Education-approved naturopathic medical school that conducts research

• use the term "every category of provider" in federal law

•has withstood challenges through both Democratic and Republican legislature majorities, has generated the most controversy, and is the most popular, as well as having been upheld by the US Supreme Court

• specific criteria must be met: the CAM profession must be regulated by the state Department of Health with licensure or certification; the scope of practice must allow the provider to treat the condition that the patient presents; the provider must be contracted to be eligible for reimbursement; the patient must have benefits covering a condition that is within the scope of practice of the chosen provider

• this is not the same as "any willing provider", nor is it a mandated benefit; it allows consumers access to a choice of the provider who will treat the condition in which they are seeking care

• insurers have the right to credential providers as long as the standards are consistent with those established by the Department of Health

• fund residency programs for naturopathic physicians so that they may provide care and conduct research along side MD/DO residents at federally-funded health clinics and hospitals

• authorize HCFA and provide appropriations to reimburse for licensed CAM services to Medicare recipients, the poor, uninsured and underserved

2. **Mandate a non-discrimination policy for reimbursement for licensed CAM providers in all federal health care programs and agencies**

• remove exclusionary language from existing federal laws and regulations

• examples of agencies with exclusionary language or no mandates (for naturopathic physicians and other licensed CAM providers):

Indian Health Service policy-restrictive

National Health Service Corps - exclusionary

Field and Public Health Research - Centers for Disease Control - no mandate or appropriation for funding

Outcomes Assessment and Cost Effectiveness - Health Care Financing Authority/Medicare-exclusionary

NIH Institutes for Cancer, Heart, Lung, Blood research need mandates for CAM "offices" for research.

Graduate Medical Education - exclusionary

• as a first step, fund residency programs for naturopathic physicians in rural health settings, and include student loan forgiveness programs and Medicare reimbursement

• improve reimbursement for both conventional and licensed CAM providers under federal programs for behavioral change (affects greater than 50% of major diseases and their costs)

• fund a HRSA or DHHS National Credentialing Roundtable

• investigate and integrate licensed CAM systems and modalities and training standards as credentialing requirements for provision of CAM services by all health care providers

• endorse inclusion of naturopathic physicians and other licensed CAM providers at HCFA's CPT "table"

• prohibit any "separate but equal" costly, segregational, and disintegrational CPT scheme for any physician level provider, especially naturopathic physicians, as it does not result from any profession-wide consensus

• use the model of the Washington State Insurance Commissioner's Work Group on a federal level

3. Fund research on utilization of naturopathic medicine and CAM providers

• harvest existing information

• evaluate beyond clinical outcomes to global measures

• include patient satisfaction, lost time/productivity, functionality, quality of life, use of conventional services and medications, emergency department visits, hospitalization

• mandate a GAO report on the cost savings possible through the incorporation of licensed CAM services and CAM products

We once again appreciate the opportunity to bring our concerns before you. Please contact us if you would like any further information or clarification.

Sincerely,

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Written Comments Only

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Evan Pugh Professor of the Solid State Emeritus • Professor of Geochemistry, Emeritus • Professor of Science, Technology and Society, Emeritus
Visiting Professor of Medicine, University of Arizona • Distinguished Professor of Materials, Arizona State University

May 1, 2001

Dr. Gerry Pollen
White House Commission on CAM
6701 Rockledge Drive
Room 1010, MSC-7707
Bethesda, MD 20817-7707

Dear Dr. Pollen,

I enclose my comments to be included in the packet for the Commission for the May 15-16th meeting. I hope you can get me on the public comment list on the 15th.

Sincerely,

Rustum Roy

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Comments for "Research" Session
May 16, 2001

by

Prof. Rustum Roy

Evan Pugh Professor of the Solid State Emeritus
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Visiting Professor of Medicine
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Distinguished Visiting Professor of Materials
Arizona State University

Research to Support CAM

A New Strategy for Funding Research: Modeled on DOD and Corporate Research

The questions of what, how, and when in research on what is called CAM are critical in designing what will no doubt be a very large research program – possibly a billion dollars per year – in the next several years.

By far the biggest danger the Commission faces is the temptation to equate all approaches to "research" with current NIH practices. Speaking as a research physical scientist with 50 years experience and very generous funding from public and private sources, I believe this would be an egregious error with very serious consequences. The research paradigm used by NIH is the so-called linear theory of R&D, namely that *science* leads to *applied science* which leads to *technology* which favorably impacts *society*. CAM research should turn much more to the reliable models used in the hard science and technology fields. While the linear paradigm has been under attack by historians and science policy experts for some 20 years (1,2), it has been completely demolished in the 1990s. The corporate culture (which does 60 percent of the R&D in the United States) of the *world* has universally switched philosophically to (what was done in practice anyway) *applications-driven basic research* as its basic R&D theory. There are no more corporate blue sky "basic research" labs anymore. In the U.S., by a seriously erroneous misreading of Vannevar Bush, NSF and NIH (1) created an enormously complex, hugely wasteful of human resources, system to perform the relatively simple task of disbursing money to competent scientists. The Department of Defense, and most of the major corporations, provide us with a model much more suited to CAM.

Hence, WHCCAM needs to be able to assert that it is on this very firm ground when it opts for the DOD and corporate model of *application (or outcomes)–driven research*, including very basic research (instead of the NSF-NIH model). In this model, all research keeps the "end" or purpose in view, even while working on esoteric detail. In this model, success is measured by real impacts on socio-technical realities. In this model, knowledgeable managers in touch with the field they supervise make the hard

decisions, and explain them to their superiors as needed. These are the real peers of the proposers: with direct accountability. In contrast, anonymous, undefined peers who may have virtually no knowledge of the person or the field make the decision in the linear system, with zero responsibility. In this model, nearly 30 percent of the investigators time is saved in the proposal process.

By far, the most potent argument for using this style of research management is the very existence of CAM. CAM is alive and well because of its success with the consumer and her/his direct judgment on success or failure. CAM is an applications-driven field, surely its research should not abandon its own *raison d'etre*. All CAM research should work backwards from the whole-person to the clinical cell and then to the molecular level. Derek Price of Yale, America's dean of science historians, asked us all to keep in mind that, "Thermodynamics owes more to the steam engine than vice versa," and, "The arrow of causality historically is largely from the technology to the science." Indeed, that science is applied technology. Exactly the opposite theory exists in most research funded by NIH. Observations of healing and clinical and epidemiological outcomes are the leads to basic science. The very best empirical outcomes-based science for thousands of years (traditional healing practices) has identified for the world many highly successful or suggestive healing modalities. These form the basis of a dozen major global healing systems. They are the golden nuggets to be followed upstream by the most modern methods.

Recommendation #1

Use applications-driven DOD (6.1 and 6.2) and corporate models for selecting research to be funded which emphasizes the track record or performance or the purpose, not the traditional so-called paper peer-reviewed NSF-NIH model, which relies on the promises of the proposer.

Certainly a major part of the CAM research should be to seek some level of understanding – not for itself alone – but in order to expand or improve its availability – of a successful CAM practice.

A Model from Modern Successful Physical Science/Engineering Research

The empirical fact is that in these fields, every scientist is on the lookout for observations of new properties, new phenomena, which are way "out of the box," far above all earlier reports, etc. It is those key observations of extraordinary properties (recall the High T_c superconductor) which trigger an avalanche of interest. In medicine, it has been the opposite so far: such observations have been ignored or scorned so far. The opportunity is enormous.

Recommendation #2

Especially in the early stages, identify the CAM procedures and practices from all over the world which are most extraordinary, which have the highest signal/noise ratio, and do research on them. Again from the DOD (and corporate) world, this is the only justification for its basic (6.1-6.2) money to be spent. This has a dual payback. We can identify the really new phenomena and causes, but it also presents the most weighty intellectual challenge to established physical science models of the 19th and 20th centuries.

Support research on the truly extraordinary observed in healing events.

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1. Deborah Shapley and Rustum Roy. "Lost at the Frontier." ISI Press, Philadelphia (1985).
2. Derek de Solla Price. Sarton Lecture, AAAS, Washington, DC (1983).

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Alternative-Treatment Field Raises Insurance Issues

LOS ANGELES TIMES MONDAY, MAY 14, 2001

Health Dollars & Sense

BOB ROSENBLATT

Americans by the millions are treating themselves with herbal potions, acupuncture, massage and other therapies outside the world of traditional medicine.

Are they being smart and safe consumers?

Sometimes, but not always. The reality is that there is a lot that is not known about the effectiveness of various alternative therapies. Despite growing demand for these services by the public, and the eager response of the insurance industry to meet that demand, the verdict is still out.

Your spouse or neighbor may be singing the praise of alternative treatments, but you should approach them with caution. Remember that the scientific gold standard is the clinical trial: Researchers test the effectiveness of a treatment on two groups of people, one that actually receives the treatment or compound and one that does not. They then determine if there is a difference in the health results between the two groups. This is the test before any new prescription medication goes on the market in the United States.

Not so for the shelves of herbs, pills and dietary supplements at your local pharmacy or natural food store. They are marketed without any of the scientific proof of effectiveness that the Food and Drug Administration requires before prescription drugs are allowed on the market.

We should know a lot more about what works and doesn't in three or four years, when a flood of data will come from trials being conducted at medical centers across the country under the direction of the National Center for Complementary and Alternative Medicine. The federal agency, a division of the National Institutes of Health, has a research budget of $90 million.

Until then, consumers must ponder many decisions and questions: Do I believe the treatment is safe without formal evidence? Is it worth looking for health insurance that provides some coverage for alternative therapies, or am I better off paying out of pocket? Even when all these decisions are made, and the consumer decides to pursue an alternative therapy, it is vital that the consumer's regular medical doctor stay informed. Some herbs and dietary supplements can interact with prescription drugs, posing a health risk. Most of the time "patients don't tell and we don't ask," said Dr. Harley Goldberg, director for complementary and alternative medicine for the Kaiser-affiliated Permanente Medical Group in Northern California. "The main message is talk to your doctor,' " he said.

You should never be embarrassed or hesitant to tell your physician that you are seeing other health practitioners or taking nontraditional medications. And doctors should do a careful and diplomatic job of learning about what patients are doing.

"It is vital to elicit a comprehensive history and find out every other therapy the person is undergoing," said Dr. Dexanne Clohan, who oversees medical networks for health insurance giant Aetna in Orange, Riverside and San Bernardino counties.

"You've got to encourage patients to be candid, to talk about whether they are taking herbs they received from outside the country," she said.

The popularity of alternative medicine poses a big dilemma for health insurers involving how to reconcile two potentially conflicting goals: the necessity to pay only for therapies with a scientifically proven benefit, and the economic incentive to give patients what they want, what sells.

"One of the dilemmas is knowing what is safe and effective," said Dr. Charles M. Cutler, chief medical officer for the American Assn. of Health Plans, an HMO trade group. "That's what leads to limited coverage."

Chiropractic seems to have moved in the mainstream of coverage, with most health insurers offering at least one plan that covers chiropractic visits. Typically, they are capped, perhaps at 12 or 20 treatments in a year. "The public is saying, I want to move in this direction, and insurers and employers are responding to that," said Pat Jackson, vice president for professional development and research at the American Chiropractic Assn.

However, the scientific researchers have yet to give their blessing to chiropractic as a valid treatment proved by clinical trials. With consumers insisting that it does work, employers have been moving to make it available to employees.

The insurance industry also has responded to the popularity of alternative medicine. Blue Cross of California, a large health insurer, is waiting for state regulators to approve an "ultra premier" policy, offering all the regular doctor and hospital coverage, plus lots of extras: 24 visits a year to an acupuncturist, $300 worth of massage treatment, $300 toward a health club membership and $500 for any herbal medicines. The policy would cost $300 a month for an individual, about double the cost of a typical policy in the Los Angeles market.

Blue Shield of California has arranged for a list of alternative practitioners—from massage therapists to somatic education programs—that offer a 25% discount on their customary fees. The company doesn't cover their services as part of regular health insurance.

Aetna has a 2-year-old "natural alternatives" program, with a list of more than 7,000 providers in 37 states, offering a plethora of services, including massage and nutritional counseling. Aetna members get discounts on acupuncture, massage and nutrition counseling. Customers also can order products for exotic treatment methods such as aromatherapy, biomagnetics and flower essences. Aetna says the alternative provider information on its Web site gets more "hits" than any other part of the site, including medical doctor and hospital lists.

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White House Commission on Complementary and Alternative Medicine Policy

Proposed Meeting Schedule*

DATE	SITE	TYPE	TOPIC
February 22-23, 2001	Washington, D.C.	WHC (4)	EDUCATION/TRAINING
March 16, 2001	Minneapolis, MN	Townhall (4)	
March 26-27, 2001	Washington, D.C.	WHC (5)	INFO DISSEMINATION and WELLNESS
May 14-15-16, 2001	Washington, D.C.	WHC (7)	RESEARCH II and REIMBURSEMENT
July 2-3, 2001	Washington, D.C.	WHC (8)	REVIEW INTERIM REPORT DRAFT
October 4-5, 2001	Washington, D.C.	WHC (9)	PROGRESS ON FINAL REPORT
December 6-7, 2001	Washington, D.C.	WHC (10)	REVIEW FINAL REPORT
March 2002	Washington, D.C.	WHC (11)	CLOSING EVENT

*This information, including dates and locations, may change based on recommendations from the Commission. Updates are posted on our website: http://whccamp.hhs.gov as soon as they become available.

White House Commission on Complementary and Alternative Medicine Policy

COMMISSION ROSTER

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Dr. **James S. Gordon**, of Washington, DC, who will serve as Chair of the Commission, is currently the Director of the Center for Mind-Body Medicine. Previously, he chaired the Program Advisory Council at the Office of Alternative Medicine of the National Institutes of Health. In addition to maintaining a private practice in Psychiatry and Medicine, Dr. Gordon has been a Clinical Professor at the Georgetown University School of Medicine in the Departments of Psychiatry and Family Medicine since 1980. He is a member of the National Institute of Health's Cancer Advisory Panel and was the Director of a Special Study of Alternative Services for the President's Commission on Mental Health. He has written extensively on the subjects of psychiatry and alternative and holistic care, and serves on the Editorial Boards of Alternative andComplementary Therapies and Alternative Therapies in Health and Medicine. He received his A.B. from Harvard College and his M.D. from Harvard Medical School.

Dr. **George M. Bernier, Jr.**, of Galveston, TX, is a hematologist/oncologist and is currently the Vice President for Education at the University of Texas Medical Branch. Previously, he was Vice President for Academic Affairs, Dean of Medicine, and a Professor of Medicine at the University of Texas. Dr. Bernier has held academic appointments at the University of Pittsburgh, Dartmouth-Hitchcock Medical Center in Hanover, New Hampshire, and at Case Western Reserve University in Cleveland, Ohio. He has published numerous articles and abstracts, and several books. He received a B.A. degree from Boston College and a M.D. degree from Harvard University.

Dr. **David E. Bresler**, of Los Angeles, California, is one of the first contemporary American scientists to study and research acupuncture, guided imagery, and other mind/body approaches. As a professor in the UCLA Departments of Anesthesiology, Gnathology/Occlusion and Psychology, he applied his findings to treating clinical problems that did not respond well to conventional care, beginning with chronic pain. As the Founder and Executive Director of the UCLA Pain Control Unit, he and his team created the first multi-disciplinary, university-based chronic pain program in America. Dr. Bresler has authored or co-authored numerous publications, as well as twenty books and workbooks. Currently, Dr. Bresler serves as Associate Clinical Professor of Anesthesiology at the UCLA School of Medicine, Executive Director of the Bresler Center, Clinical Consultant to the UCLA Pain Medicine Center, Dean of Mind/Body/Spirit of the University of Integrated Studies, and Co-Director of the Academy for Guided Imagery. Dr. Bresler received his B.A. from Brandeis University, his M.A. from Bryn Mawr College, and his Ph.D. from UCLA. He received his Certificate in Acupuncture from the Institute for Taoist Studies.

Mr. Thomas Chappell, of Kennebunk, ME, is the co-founder and CEO of Tom's of Maine, which he co-founded with his wife Kate in 1970. It is a company that produces innovative, natural personal products and natural wellness products in a caring and creative work environment. Mr. Chappell is founder and CEO of the Saltwater Institute, a learning institute of leaders seeking to integrate their valu into their personal and professional lives. He is active in many philanthropic organizations, among them an Advisory Council member for the Center for Study of Values in Public Life at Harvard Divinity School, Harvard Divinity School Dean's Council, and a Board Member of the Nature Conservancy of Maine. He has written two books, The Soul of a Business and Managing Upside Down. Mr. Chappell received his B.A. from Trinity College and his Master's in Theology from the Harvard Divinity School.

Dr. Effie Poy Yew Chow, of San Francisco, CA, is the founder of the East West Academy of Healing Arts in 1973 and, more recently, The EWAHA Qigong Institute, the American Qigong Association, and the World Qigong Federation. She is the recipient of over twenty awards including "The Humanitarian of the Year 1999" and the "Visionary of the Decade 2000" awards. She has been the only Qigong Grandmaster and acupuncturist involved in the development of national health policies within DHHS. She was also involved in the first Ad Hoc Advisory Panel of the Office of Alternative Medicine at NIH. She has made over two hundred and fifty media appearances and interviews in the area of complementary and alternative medicine. Dr. Chow received her training in Traditional Chinese Medicine and Qigong in China, Hong Kong, Taiwan, Canada, and the United States. She is a registered public health and psychiatric nurse and has received a Master's degree and a Ph.D.

Mr. George Thomas DeVries, III, of Rancho Santa Fe, CA, is Chairman, President, CEO and co-founder of American Specialty Health, Inc. and its subsidiaries, American Specialty Health Plans, American Specialty Health Networks, American Specialty Health Systems, and Healthyroads.com. In his position, he manages complementary and alternative health care benefits, networks and services for over 100 health plans covering over 40 million Americans. American Specialty Health Plans is a licens specialty health plan covering over 4 million Californians for chiropractic and acupuncture. America. Specialty Health Systems is a health services intermediary in over 20 states serving over 1.7 million members. American Specialty Health Networks is a national health services organization serving over 35 million Americans and offering a national provider network of over 19,000 chiropractors, acupuncturists, massage therapists, dieticians, naturopaths, and fitness clubs. Healthyroads.com is a complementary healthcare consumer products company offering e-commerce and mail order. Mr. DeVries was the National Entrepreneur of the Year for Health Sciences in 2000. Mr. DeVries has published a number of articles and has lectured on alternative health care in managed care and third-party reimbursement. He received a B.A. from the University of California at San Diego.

Dr. William R. Fair, M.D., of Longboat Key, FL, was, until recently, the Florence and Theodore Baumritter/Enid Ancell Chair of Urology, and was Chief of the Urology Service at Memorial Sloan-Kettering Cancer Center in New York City. Currently, he is Emeritus Professor of Urology at the Joan and Sanford I. Weill Medical College of Cornell University and Member Emeritus at Memorial Sloan-Kettering. Dr. Fair serves on the Cancer Advisory Panel for the National Center for Complementary and Alternative Medicine. He is the Editor-in-Chief of Molecular Urology and the Associate Editor of Alternative Therapies in Health and Medicine, and on the editorial boards of other highly respected journals. He has published extensively in the areas of urology and oncology. He chairs the Committee on Complementary and Alternative Medicine of the American Urological Association, and is Chairman of the Clinical Advisory Board of Haelth, LLC. Dr. Fair received his B.S. from the Philadelphia College of Pharmacy and Science and his M.D. from Jefferson Medical College.

Dr. Joseph J. Fins, of New York, NY, is an internist and Director of Medical Ethics at New York Weill Cornell Medical Center of New York - Presbyterian Hospital, Associate Professor of Medicine and Medicine in Psychiatry at the Joan and Sanford I. Weill Medical College of Cornell University, Associate Professor in the Program in Clinical Epidemiology and Health Services Research at Weill Cornell Graduate School of Medical Sciences, and Associate for Medicine at The Hastings Center. He lectures extensively and has written widely in the field of Medical Ethics. Dr. Fins received his B.A. from Wesleyan University and his M.D. from Cornell University Medical College.

Dr. Veronica Gutierrez, of Lake Stevens, Washington, practices with Gutierrez Family Chiropractic. She is a professional member of the World Chiropractic Alliance, serving on the Board of Directors. She serves as Chair of the Council on Women's Health and Director of Programs in Public Policy. Dr. Gutierrez has been very active in the chiropractic community, serving on many boards and commissions. She has received numerous awards in her profession, including awards from the Chiropractic Society of Washington, the Straight Chiropractic Academic Standards Association, and the International Chiropractic Association. Dr. Gutierrez received her Doctor of Chiropractic from Palmer College of Chiropractic and did post-graduate work at Cleveland College of Chiropractic.

Dr. Wayne B. Jonas, of Alexandria, VA, is currently a member of the Department of Family Medicine of the Uniformed Services University of the Health Sciences F. Edward Hebert School of Medicine. Previously, Dr. Jonas served as the Director of the Office of Alternative Medicine for the National Center for Complementary and Alternative Medicine at the National Institutes of Health. Prior to that, he served as the Director of the World Health Organization Collaborating Center for Traditional Medicine. He has authored and co-authored numerous publications on alternative and homeopathic treatment and care. Some of his current research includes projects in environmental toxicology, neurotoxicology, stroke, and biofield healing. Dr. Jonas received a B.A. from Davidson College and a M.D. from Bowman Gray School of Medicine.

Sister Charlotte Rose Kerr, R.S.M., of Baltimore, MD, is a Registered Nurse, a Practitioner of Traditional Acupuncture and, since 1977 a Senior Faculty Member at the Traditional Acupuncture Institute. Previously, she was an Assistant Professor of Nursing at the University of Maryland School of Nursing. Sister Kerr has been a member of the Advisory Council of the National Institutes of Health (NIH) Alternative Medicine Program. She has spent several summers in Europe, studying such subjects as Theology and Healing. In her work, Sister Kerr emphasizes the integration of Western traditional medicine and complementary healing methods. Sister Kerr received her B.S.N. from the University of Maryland School of Nursing. She received her Master's Degree in Public Health from the University of North Carolina and another Master's Degree in acupuncture from the College of Traditional Chinese Medicine, U.K.

Ms. Linnea Larson, of Oak Park, Illinois, is Associate Director of West Suburban Health Care (WSHC), Center for Integrative Medicine in Oak Park. Previously, she was the Behavioral Science Coordinator at WSHC Family Practice Residency Program. She was a clinical social worker at St. John's Hospital in Springfield, Illinois, where she provided inpatient and home hospice services and was also associated with the St. John's Center for Mind-Body Medicine. She also has worked as a family therapist and as a lecturer at the University of Illinois at Springfield. Ms. Larson received a B.A. from Knox College and a M.S.W. from the University of Illinois at Urbana-Champaign.

Dr. Tieraona Low Dog, of Corrales, New Mexico, currently serves as the Medical Director for the Tree House Center of Integrative Medicine in Albuquerque. With more than twenty years in the field of botanical medicine, she was recently elected to serve as Chairperson for the Dietary Supplements and Botanicals Expert Panel for the United States Pharmacopoeia. Dr. Low Dog received her medical degree from the University of New Mexico School of Medicine. She is part of the core faculty for Columbia University's Botanical Medicine Course for Physicians. Dr. Low Dog is currently working with Beth Israel on the development of a continuing medical education program on herbal medicine for physicians. She frequently lectures on the subject of herbal medicine. In 1998, she received the International Martina de la Cruz award for her work with indigenous remedies.

Dr. Dean Ornish, of Sausalito, CA, is one of the founders, and the president and director of the non-profit Preventive Medicine Research Institute. He is Clinical Professor of Medicine at the University of California, San Francisco, and a founder of the Osher Center for Integrative Medicine there. He was the first to prove that heart disease is reversible by changing diet and lifestyle. He has published many books and academic papers and has received numerous awards in recognition of his work. Dr. Ornish received a B.A. from the University of Texas and completed his medical training at the Baylor College of Medicine in Houston, Harvard Medical School, and the Massachusetts General hospital. He was a clinical fellow in medicine at the Harvard Medical School. Dr. Ornish was recognized by Life magazine as "one of the 50 most influential members of his generation."

Dr. Conchita M. Paz, of Las Cruces, NM, has maintained a private practice, in which she specializes in family medicine, for ten years. Currently, she serves as a part-time faculty member at the University of New Mexico School of Medicine and at the Southern New Mexico Family Practice Residency Program. She was Chairperson of the Family Practice Department and serves on a number of committees at Memorial Medical Center. Dr. Paz received her B.S. and M.D. degrees from the University of New Mexico

Joseph E. Pizzorno, Jr., N.D., of Seattle is one of the world's leading authorities on science-based natural medicine. A physician, educator, researcher, and expert spokesperson, Dr. Pizzorno is co-founder and founding president of Bastyr University, the first fully accreditated, multidisciplinary university of natural medicine in the United States. Dr. Pizzorno is the author of Total Wellness and co-author of the Textbook of Natural Medicine and the Encyclopedia of Natural Medicine. In 1996, he was appointed to the Seattle/King County Board of Health, the first natural medicine practitioner in the country to receive such appointment. In 1999, Dr. Pizzorno was elected Chair of the American Public Health Association Special Primary Interest Group on Complementary and Alternative Medicine. He has been licensed as a naturopathic physician in Washington State since 1975. Dr. Pizzorno is now President Emeritus and Senior Advisor to the President of Bastyr University. In September 2000, the Cancer Treatment Centers of America recognized Dr. Pizzorno as Humanitarian of the Year. He currently travels worldwide, lecturing and promoting science-based natural medicine and integrative healthcare. He also co-founded a company to bring natural medicine concepts to corporate health promotion programs.

Mr. Buford L. Rolin, of Atmore, AL, has been the Health Administrator for the Poarch Band of Creek Indians since 1984. He is a member of the State of Alabama Public Health Advisory Board and a member of the Board of Directors of the Creek Indian Heritage Memorial Association. Mr. Rolin is currently the Chairman of the Creek Indian Arts Council. He is the former Chairman of the National Indian Health Board, and he still serves as a member of the Executive Committee and as a Member-At-Large. He has received several awards from the National Indian Health Board, and he has also received a Lifetime Achievement Award from the Poarch Band of Creek Indians. Mr. Rolin attended the Health Services Administrators Development Program at the School of Community and Allied Health of the University of Alabama and Pensacola Junior College.

Ms. Julia Scott, of Washington, DC, is Past President of the National Black Women's Health Project (NBWHP), a national membership organization that focuses on wellness, self-help, and health advocacy. Previously, she was Director of the Public Policy and Education Office of NBWHP. Ms. Scott was Special Assistant to the President and Coordinator of the Adolescent Pregnancy Child Watch at the Children's Defense Fund. She has directed and administered to several foundations and community health agencies and has written numerous articles on African American Women's health. Ms. Scott was educated in nursing at the Waterbury Hospital School of Nursing.

Dr. Xiao Ming Tian, of Bethesda, Maryland, is Director of the Academy of Acupuncture and Chinese Medicine and Wildwood Acupuncture Center. Dr. Tian is currently conducting a National Institute of Health (NIH) supported clinical trial with Georgetown University Medical School to treat fibromyalgia patients using acupuncture. He has completed many research projects on the use of Chinese herbal medicine and dietary supplements to treat and prevent arthritis, sports injuries, and fibromyalgia, in collaboration with NIH and the U.S. Department of Agriculture Nutrition Center. In 1991, Dr. Tian was the first person to be appointed a Clinical Consultant of Acupuncture to the NIH medical staff. He is an Adjunct Assistant Professor of Preventive Medicine at the United States Uniformed Health Service. Dr. Tian is the President of the American Association of Chinese Medicine. He is also the Honorary Director of the China Association of Traditional Chinese Medicine and Vice President of The International Academy of Medical Qigong, both in Beijing, China. He currently serves as an advisor to World Health Organization and Pan-American Health Organization on traditional medicine. Dr. Tian received his Medical Degree from Beijing Medical University and was a Ph.D. Research Fellow at NIH.

Dr. Donald W. Warren, of Clinton, Arkansas, currently practices general dentistry, which includes dental cranial osteopathy, an alternative and complementary approach to health; temporomandibular joint dysfunction treatment, an alternative treatment for head, neck and facial pain and orthodontics/orthopedics. Since 1989, Dr. Warren has presented seminars on dental cranial osteopathy, temporomandibular joint dysfunction treatment, contact reflex analysis and designed clinical nutrition, and correct dental occlusion. Since 1999, these seminars have been accredited by the Academy of General Dentistry. He also instructed a hands-on clinic at the Texas College of Osteopathic Medicine, hosted by the Sutherland Cranial Teaching Foundation. Dr. Warren has taught in the United States, the United Kingdom, and Australia. Dr. Warren received a B.A. from Hendrix College and a D.D.S. from the University of Tennessee College of Dentistry. Since then, he has continued to study in his fields of expertise and is a diplomat of the American Board of Head, Neck and Facial Pain.

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