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001. paper	Synopsis about NAET [Nambutripad's Allergy Elimination Technique] (partial) (3 pages)	nd	b(6)

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

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FOLDER TITLE:
WHCCAM Testimony, October 5-6, 2000 [3]

2011-0568-S
kc882

RESTRICTION CODES

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

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P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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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]

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Clinton Presidential Records
Digital Records Marker

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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.

Gonzalez

Divider Title: _____

Biographical Sketch: Nicholas Gonzalez, M.D.

Dr. Gonzalez graduated from Brown University, Phi Beta Kappa, magna cum laude, and subsequently received his medical degree from Cornell Medical College in 1983. During a postgraduate immunology fellowship under Dr. Robert A. Good, he completed a research study evaluating nutritional therapy in the treatment of advanced cancer. Since 1987, Dr. Gonzalez has administered intensive nutritional therapy to patients with advanced cancer. In July of 1993 he was invited to present selected case histories from his practice at the National Cancer Institute. Dr. Gonzalez then completed a pilot study with patients suffering inoperable pancreatic cancer. Nestec (Nestle) funded this study, which was published in the June 1999 (Volume 33, No. 2) edition of the journal *Nutrition and Cancer.* The positive pilot study results led to NIH funding of a controlled clinical trial comparing the Gonzalez therapy to chemotherapy in patients with inoperable pancreatic carcinoma. This NCI supervised clinical trial is being conducted at Columbia Presbyterian Medical Center in New York City.

Background Information: Nicholas Gonzalez, M.D.

The Scottish embryologist, Dr. John Beard, proposed in 1906 that the pancreatic proteolytic enzymes represent the body's main defense against cancer, and would be useful as a cancer treatment. Particularly during the first two decades of this century, Dr. Beard's thesis attracted some attention in academic circles, and several case reports in the medical literature documented tumor regression and even remission in terminal cancer patients treated with pancreatic enzymes. In 1911, Dr. Beard published a monograph entitled *The Enzyme Therapy of Cancer*, which summarized his therapy and the supporting evidence. After Dr. Beard's death in 1923, the enzyme therapy was largely forgotten. Periodically, alternative therapists have rediscovered Dr. Beard's work, and used pancreatic proteolytic enzymes as a treatment for cancer.

I began researching the use of oral pancreatic proteolytic enzyme therapy as a treatment for cancer after completion of my second year at Cornell University Medical College in 1981. At that time, I had the opportunity to meet Dr. William Donald Kelley, the Texas dentist who for twenty years had been treating cancer patients with a complicated nutritional therapy based on Beard's enzyme treatment. Although Kelley had been attacked in the press because of the unorthodox nature of his work, the Dr. Kelley I met was an unassuming man whose primary wish was to have his controversial work fairly evaluated by the academic medical world.

My research advisor at Cornell, Dr. Robert A. Good, the then President of Sloan-Kettering, agreed to support a case review of Kelley's patients, which I began as a medical student and completed during my immunology fellowship under Dr. Good. During my study, I reviewed nearly 10,000 of Dr. Kelley's patient records, which he kept divided between his Dallas and Washington State offices. I interviewed and evaluated intensively over 500 patients with appropriately diagnosed advanced cancer, and summarized my findings in an extended monograph completed in 1986 as partial fulfillment for my fellowship training.

The written report consisted of several sections. In addition to outlining Kelley's theoretical approach, I discussed at length 50 of his patients initially diagnosed with poor prognosis cancer, all of whom had enjoyed long term survival and/or apparent regression of disease while following their nutritional regimen. As a separate chapter, I also evaluated all cases of unresectable pancreatic cancer, both compliant and non-compliant, who had come to see Kelley between 1974 and 1982. I eventually identified 22 patients in this group. For all of these patients, I obtained complete medical records, including death certificates for those who were deceased. I interviewed all surviving patients repeatedly and at length, and in the case of those who had died, I interviewed family members as well as the original attending physicians.

Ten of these patients had visited Kelley only once and had never followed the protocol: these individuals had been discouraged from proceeding largely because

of the negative influence of family and physicians who thought Kelley to be an outright fraud. This population, with a median survival of only 60 days, served as a convenient control. Among the compliant patient group, several lived beyond five years. One patient in this group, with pancreatic cancer to the liver confirmed at the Mayo Clinic, has now been alive over eighteen years from her original diagnosis, survival unheard of in orthodox oncology.

Despite the careful documentation and the five-year investment of time, my attempts at publication were met with scorn and ridicule. It seemed no one in academic medicine could, at the time, accept that a nutritional therapy might produce positive results with advanced cancer patients.

In 1986, probably as a result of endless pressures, Dr. Kelley gave up research and patient care, and I myself have not spoken to him since 1987. In that year, I decided to move to New York to try and salvage the enzyme approach, and observe for myself the results with poor prognosis cancer patients. My goal throughout has been to generate research support, so that this method, if it indeed proved to have value, could be integrated into general medical treatment.

In July of 1993, the then Associate Director for the Cancer Therapy Evaluation Program at the National Cancer Institute invited me to present selected cases from my own practice as part of an NCI effort to evaluate non-traditional cancer therapies. I prepared for presentation 25 cases with poor prognosis or terminal illness who had either enjoyed long term survival or tumor regression while following my program. After the session, the Associate Director suggested we pursue a pilot study of our methods in ten patients suffering inoperable adenocarcinoma of the pancreas, with survival as the endpoint. Because the standard survival for the disease is so poor, an effect could be seen in a small number of patients in a short period of time.

Nestec (the Nestle Corporation) agreed to fund the trial, which began in January 1994. The study has been completed and was published in the June 1999 issue (Volume 33, Number 2) of *Nutrition and Cancer.* Of 11 patients followed in the trial, 8 of 11 suffered stage IV, (the most advanced) disease. Nine of 11 (81%) lived one year, 5 of 11 lived two years (45%), and 4 of 11 lived three years (36%), and two passed four years. In comparison, in a recent trial of the newly approved drug gemcitabine, of 126 patients with pancreatic cancer not a single patient lived longer than 19 months.

As a result of the pilot study, the National Cancer Institute, through the National Center for Complementary and Alternative Medicine, approved funding for a large-scale clinical trial comparing my nutritional therapy against chemotherapy in the treatment of inoperable pancreatic cancer. This study is being conducted under the Department of Oncology and the Department of Surgical Oncology at Columbia Presbyterian Medical Center in New York.

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Ann McCombs is an osteopathic family physician practicing in Kirkland, Washington. She has had successful careers in both teaching and marriage/family counseling before pursuing her first love: holistic medicine.

Dr. McCombs is a member of the Board of Trustees of the American Holistic Medical Association and is on the Board of Directors for Dr. Devi Nambudripad's Allergy Research Foundation and the Carbon Based Corporation (specializing in *individualized* biochemical diagnostic analysis). She is also a co-founder of the American Board of Holistic Medicine and is one of the founding members of its Board of Directors. In addition, she is a founder and the current Medical Director of the Center for Optimal Health in Kirkland, WA.

Board-certified in Pain Management, Neural Therapy and certified in N.A.E.T. (Nambudripad's Allergy Elimination Technique), Reiki, as well as the Hendricks' Body-Centered Psychotherapy and Brief Relationship Therapy, Dr. McCombs was also the first certified Neural Therapy Practitioner (including Neural Kinesiology) in the U.S. and is now Board – certified in that specialty and is on the faculty of the American Academy of Neural Therapy.

As an educationally based, holistic medical practitioner, Dr. McCombs is actively engaged in clinical practice, teaching and mentoring. Her unique approach, utilizing Non-Protocol Diagnosis and Treatment, puts her on the cutting edge of those physicians who assist clients on a daily basis to achieve optimal health and healing.

Dr. McCombs' professional goals are to create a health care reimbursement system for holistic medicine that works for everyone (clients, physicians, insurance companies); to provide a healing opportunity and environment for health care providers to heal themselves; to create an effective model of holistic clinical practice which includes the physician-dentist team that can be duplicated across the nation; to create and teach a Non-Protocol Medicine curriculum and, ultimately, to assist in founding a holistic medical school which will value this approach. Sooner or later, she plans to write a book or two about these principles and her professional and personal experiences in her own unique journey of achieving optimal health and assisting her clients to do likewise.

ANN BROWN McCOMBS
Curriculum Vitae Summary

HISTORY & TRAINING

Born Norfolk, VA (1947)
Currently
Private Practice - Seattle, WA (1989-1994); Bellevue, WA (1994-1998); Kirkland, WA (1998 to present)
Licensed to practice in Washington, California and Montana
Board of Trustees and Faculty Member, American Holistic Medical Association (1992-present)
Medical Director/ Co-founder, The Center for Optimal Health (1994-present)
Co-Founder, American Board of Holistic Medicine (1995)
Board of Trustees Member, Nambudripad Allergy Relief Foundation (1995-present)
Faculty, American Academy of Neural Therapy (1996-present)
Faculty, American Academy of Neural Therapy/Neural Kinesiology Division (1997-present)
Faculty Depts. of Integrative Medicine, Physiatric Medicine, Integrative Medical Dentistry, Integrative Manual Medicine and Dean of Clinical Integrative Medical Education, Capital University of Integrative Medicine (1997)

Educational Degrees and Certifications
Norview High School (1961-1965)
Mary Washington College (1965-1967)
Old Dominion University (Summer, 1967)
Brigham Young University (1967-1969) and (1969-1970)
B.S., Child Development/Family Relationships/Sociology awarded May, 1969
Graduate Study, Family Relationships/Family Counseling
James Madison University (1972-1973)
M.A., Education and Social Science awarded August, 1973
University of Utah (1974-1982)
Pre-med coursework and PhD coursework in Health Services Administration with allied fields in Gerontology, Epidemiology and Medical Social Work Graduate Certificate in Gerontology awarded May, 1987
Weber State College (Summer, 1976)
College of Osteopathic Medicine of the Pacific (1983-1988)
D.O. degree awarded June, 1988
Reiki Technique (First and Second Degrees) completed, 1985)
Directed Breath Course ("dry re-birthing") - Certified Coach since 1985
Doctors Hospital Medical Center (Rotating Internship), 1988-1989
Diplomate, National Board of Osteopathic Medical Examiners (1989)
Diplomate, American Academy of Pain Management (1992)
Diplomate, American Board of Neural Therapy (1997)
Hendricks Institute (1992)
Professional Certificates in Body-Centered Psychotherapy and Brief Relationship Therapy, awarded August, 1992.
American Academy of Neural Therapy (1993 - 1995)
Neural Therapy Practitioner Certificate awarded October, 1995 (first practitioner in the U.S. to receive this certification)
Nambudripad Allergy Relief Foundation (1994); MRT Instructor Certification
(Basic Course) since 1997
N.A.E.T. Practitioner Certificates (Basic and Advanced Techniques) awarded October/November, 1994.

Landmark Education Corporation (multiple courses, 1977-1992)
Lifespring, Inc. (all course offerings completed and assisted in, 1985)
Sutherland Cranial Teaching Foundation (2 Basic courses/1 Advanced course - 1985, 1986, 1988)
Fulford Percussion Courses (Basic-1988; Advanced-1992)
American Holistic Medical Association Annual Conference attendee and Lecturer/Workshop Presenter (1989-present)
Body Fueling Program, 1991

Transactional Analysis Courses (Basic and Advanced Self-Reparenting Skills, 1991-1992)
American Academy of Neural Therapy (1993-present)
All professional course offerings completed, then assisted in many as adjunct faculty to Dietrich Klinghardt, MD, PhD: Physician, Heal Thyself; Neural Therapy A, B, C; Neural Therapy Without Needles; Autonomic Response Testing: A.R.T.; Applied Psycho-Neuro-Biology: Psycho-Kinesiology (P.K.); Arm-Length Reflex Testing with Raphael Van Asche, D.O. (Austria); Pain Control Without Drug: with Prof. F.L. Jenkner, M.D. (Austria); Annual Conference attendee
American Academy of Biological Dentistry (Annual Conference attendee, 1993-present)
Applying New Essentials in Nutritional Medicine (courses in 1994,1995-Jeffrey Bland, PhD)
Second Annual Symposium in Functional Medicine attendee, 1994
Bio-Eclectic Research Group/Enderlein Enterprises (1995-present)
All course offerings in the use of the Sanum remedies, taught by U.S. and European faculty
American Academy of Neural Therapy/Neural Kinesiology Division (1995 - present)
All professional course offerings completed: Essentials of Cavitation Surgery/Holistic Dentistry; NK I, II, III; Biochemistry Component; Structural Component; Tofness Resonator Plate Diagnosis/SE-5 Course; Annual Conference attendee, 1997-present
Nambudripad Allergy Elimination Technique Annual Symposium attendee, 1995-present
NeuroLink (Basic Course) taught by Allan Phillips, D.O. (September, 1995)
Transformational Lessons (Pattern Perception Series): Robert Raleigh's work, taught by Cheryl Malakoff, Ph. D., completed October, 1997

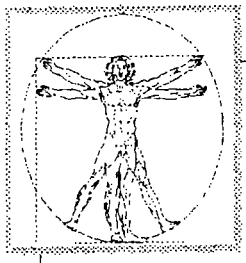
PUBLICATIONS

Article	AHMA Journal *Holistic Medicine**	HDA Journal *HDA Communicator**
Non-Protocol Diagnosis and Treatment: The Future of Medicine is Arriving?	Summer '96	Vol. 96, Issue 4 p. 6, 7
Neural Kinesiology/NAET: A Potent Combo	Fall '96	
Neural Kinesiology	Winter '97	Vol. 97, Issue 1, p. 14
The Physician/Dentist Team: Medicine for the 21st Century (with LaVar Riniker, DDS)	Spring '97	Vol. 97, Issue 2
Allergy Elimination IS Possible!	Summer '97	Vol. 97, Issue 3

* These articles can also be obtained from the AHMA Web Page @ HTTP://AHMAHOLISTIC.com

ORGANIZATIONS AND SOCIETIES (MEMBERSHIPS)
American Academy of Neural Therapy (1993-present)
American Academy of Osteopathy (1988-present; Undergraduate AAO: 1983-1988)
American Academy of Pain Management (1992-present)
American Association of Physicians and Surgeons (1993-present)
American Association of Physicians for Human Rights (1986-present)
American College of Osteopathic General Practitioners (1988-present; Student member: 1983-1988)
American Holistic Medical Association (1989-present)
American Medical Women's Association (1989-present)
American Osteopathic Association (1988-present; student member: 1983-1988)
American Preventive Medical Association (1996-present)
Cranial Academy (1988-present; student member; 1984-1988)
Nambudripad Allergy Relief Foundation (1994-present)
Occidental Institute Research Foundation Associate (1995-present)
Washington Osteopathic Medical Association (1989-present)

TEACHING EXPERIENCE: see Curriculum Vitae for details.
Project Headstart, Brigham Young University, Old Dominion University, James Madison University, University of Utah, AHMA, WOMA, Seattle University Pre-Health Professions Club, Seattle Central Community College, AAPM, AAOM, NARF, AANT, Capital University of Integrative Medicine, University of Vermont College of Medicine



Ann McCombs, D.O.
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PRACTICING HOLISTIC MEDICINE (PANEL)

I. NON-PROTOCOL MEDICINE – see handout

A. An IDEA whose time has come (is long overdue!)

B. PHYSICIAN AS EGALITARIAN client partner vs. the conventional one-up/one-down doctor-patient relationship

C. The *only* practical, effective and cost-effective GATE-KEEPER approach for managed care settings

D. *Individualized* diagnosis and treatment protocols aimed to expose the core and eliminate the roots of the illness vs. symptom treatment

E. Front-loaded vs. back-loaded SYSTEM: cost effectiveness over a lifetime vs. just in youth

II. 4-COMPONENT THEORY OF CHRONIC ILLNESS/PAIN
Dietrich Klinghardt, MD/PhD

A. Structural component

B. Electromagnetic component

C. Biochemical component

D. Psycho-Spiritual component

Non-Protocol Medicine:
A Practical Alternative to Managed Care

By Ann McCombs, D.O.

Medicine has come a long way in both the diagnostic and treatment arenas in the last 200 years, in particular, since World War II. However, the philosophical premise upon which diagnosis and treatment is based has remained fundamentally unchanged. **The protocol or "cookbook"** approach (which I define as the methods which work the majority of the time for the majority of the people) is still the mainstay of conventional medicine. In a crisis, this is not a bad approach to utilize in either the diagnostic or treatment arenas. But, what about those folks who do not neatly fit into the "majority" category, especially those with on-going chronic illnesses? Usually these clients are relegated to the diagnostic category "supratentorial" otherwise known as "it's all in your head". Their options for treatment are usually limited to: see a psychiatrist, have exploratory surgery or be treated symptomatically (usually with some drug) for the rest of their lives. Statistically speaking, such clients are out on the ends of the bell curve, which usually feels (to them) like they are being relegated to the outskirts of the health care system... because they are! No wonder these "non-majority" clients get upset, become disillusioned with protocol practitioners and turn to complementary and alternative medicine. From their point of view, who wouldn't be looking to explore their alternatives, given that kind of proposed diagnosis and limiting treatment plan?

It is my opinion that most physicians (MD, DO, DC, ND) are trained to diagnose and treat clients using the conventional (protocol or "cookbook") approach, even if they are trained to do so using "natural" medicines (e.g. vitamins, minerals, herbs, homeopathic remedies etc.) instead of synthetic medicines. Because managed care tends to only reimburse for protocol or "cookbook" procedures, the individuals who fall on the outskirts of the bell curve are left without adequate insurance coverage and can end up sacrificing their experience of health and well-being for chronic illness and a lifetime of pain and suffering. The reality is that specific healing processes are needed to achieve effective healing at the level of cause versus symptom reduction. These interventions must also be initiated at the right time and in the correct sequence, an approach to treatment which differs for each and every person (**non-protocol medicine**). This cannot be accomplished in the average 6 or 7-minute office visit espoused by managed care. Is this sacrifice really worth the extraction of an individual's "ounce of flesh for a pound of cure?" Perhaps it would be ***if*** the cost really was only an OUNCE of flesh and the outcome was a POUND of cure. Unfortunately, when the managed care system settles for symptom reduction as an acceptable outcome, it is more like a POUND of flesh for an OUNCE of cure (at best) or no cure (at worst). No wonder over 50% of the American population is seeking complementary and alternative medical approaches and are willing to pay out of pocket for them!

Non-protocol medicine is, quite simply, individualized medicine at its highest and most cost-effective best. There are several vehicles that can be utilized to accomplish this task. The best of them involves both the science

and the art of medicine, i.e. the use of both the left and right brains of physicians/healers. Examples of such approaches range from physician-medical intuitive teams like Norm Shealy and Carolyn Myss (see their book, The Creation of Health) to the brilliance of such outstanding and gifted individual practitioners as Milton Erickson, upon whom the fundamentals of Neuro-Linguistic Programming (NLP) are based. The rest of us whose talents lie somewhere in between these two extremes must rely on other techniques to assist us in accessing the information needed to most efficiently prioritize which problem to address in what order and to properly sequence an individual's treatment plan aôcordingly. No two (or ten) individuals' treatment plans will EVER be the same, even if they all have the same diagnosis in the conventional paradigm.

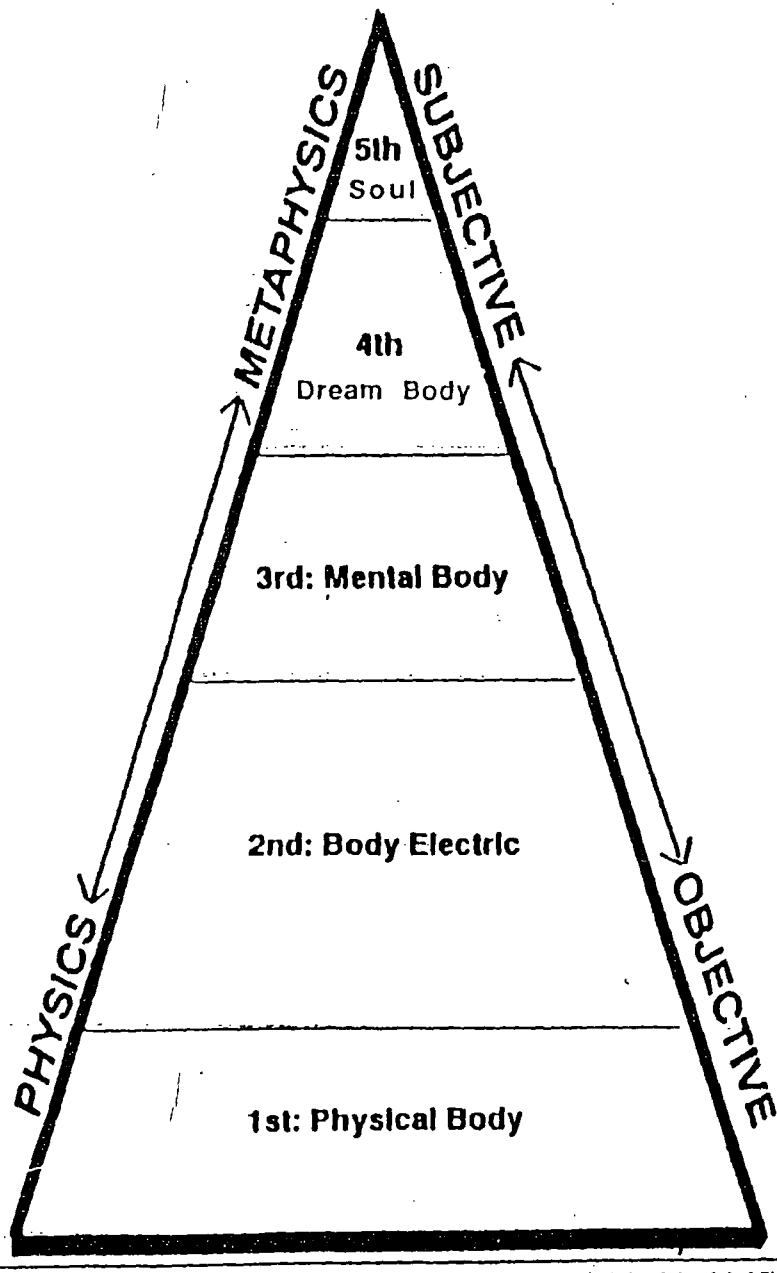
There are several different modalities which practitioners utilize in the nonprotocol medicine approach. Most commonly, the use of one that establishes a valid and reliable connection with an individual's autonomic nervous system (ANS) is preferred, as the ANS is the body's major feedback mechanism or early-warning signaling system from which to extract the critical information contained within a given individual re: how to heal that particular condition in that specific body or body area. I personally utilize Neural Kinesiology (NK) in my practice which is a state-of-the-art form of autonomic response testing that combines the best of applied, clinical and educational kinesiology with autonomic nervous system research. Other practitioners prefer EAV (Electro-Acupuncture according to Voll) or VEGA equipment to access the ANS, while still others utilize Computerized Regulation Thermography (CRT) or the like. However, none of these other approaches allows for the level of prioritizing diagnostic possibilities or sequencing treatment options better than NK, in my opinion. It has been my experience that this approach has allowed more "non-majority" clients to have successful treatment outcomes than any other approach I have yet encountered.

In summary, holistic medicine in many physicians' practices today is simply another form of **protocol or "cookbook" medicine**, utilizing natural medicines instead of synthetic ones, while still primarily treating symptoms rather than the underlying cause(s) of illnesses. In my opinion, this approach to holistic medicine is insufficient and misses the inherent meaning of the term altogether. The truth is: to treat the ***whole*** person, we need to include ALL the diagnostic and treatment modalities of both holistic and conventional medical models, if physicians are to perform their roles as Hippocratic oath-takers fully, effectively and with integrity. Non-protocol medicine, in my mind, is the only approach that makes sense for dealing effectively with chronic pain and chronic illness. It can also be utilized for acute illnesses and, sometimes, even in certain instances involving medical emergencies. Whole-person, optimal health ***is*** possible — with non-protocol medicine!

For more information, please ask for the following articles:

1) Neural Kinesiology (Autonomic Response Testing): The Diagnostic and Therapeutic Key to Non-Protocol Medicine
2) Neural Kinesiology and NAET — A Potent combo
3) Allergy Elimination IS Possible
4) One Patient's Experience of Non-Protocol Medicine

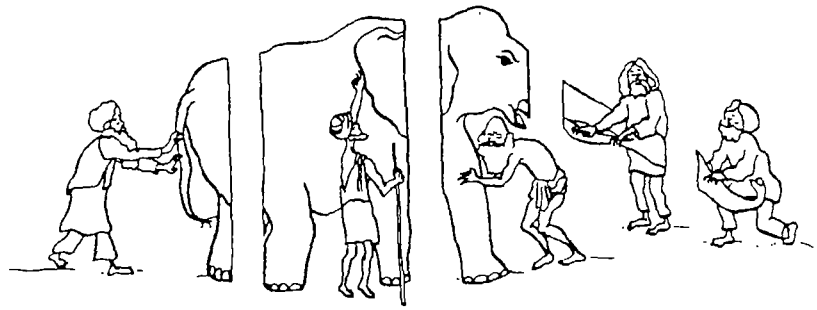
WHOLISTIC HE/ ND HEALING: A MAP



Our Experience at This Level	Anatomical and Conceptual Designation	Related Science	"Diagnostic" Method	Related Medical Treatment/Healing Techniques
• Bliss • Oneness with God	• Spirit • Soul • Higher Consciousness	• Religion • Spirituality	• Knowing • Awareness	• Self-healing • Prayer • True Meditation
• Symbols • Trance • Meditative State • Dreams	• "No-Mind" • Unconsciousness	• Mathematics • Quantum Physics	• Dowsing • Radiaesthesia • Dream-Interpretation	• Hypnotherapy • Radionics • Shamanism • Systemic Family Therapy
• Beliefs • Attitudes • Thoughts	• Mind (consciousness & sub-consciousness)	• Psychology	• Psychological Test (MMPI, etc.) • Homeopathic • Repertorizing	• Homeopathy • Psychotherapy • APN
• Feelings i.e. anger excitment etc.	• Nervous-System • Meridians • Chakras	• Physiology	• Thermogram • EEG, EKG • EMG etc. • Kinesiology • VAS; • Chin. Pulses • Kirlian Photography	• Bodywork/Touch • Acupuncture • Neural Therapy • Breath-Therapy • Emotional Release • Laughter
• Sensation (touch, smell etc.) and Action/ Movement	• Structure (organs, bones, etc.) • Biochemistry	• Mechanics & Chemistry	• Physical Exam, X-rays, MRI, Catscan, Lab-Tests	• Chiropractic, Surgery, Physical Therapy, Drugs & Herbs, Radiation Therapy

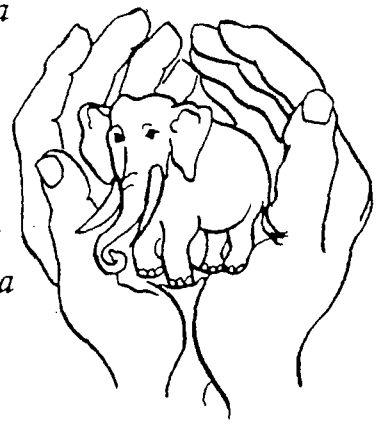
THE CENTER FOR OPTIMAL HEALTH

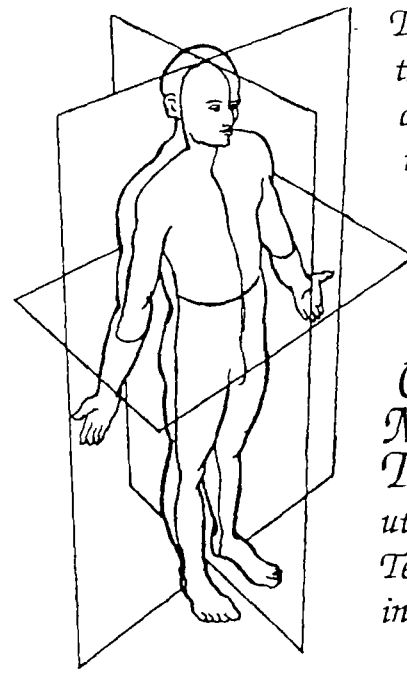
Ann McCombs, D.O.



Traditional Medicine (allopathic) examines the body in a "piecemeal" fashion. Thus, traditional medical therapy primarily focuses on treating a person's symptoms, often using drugs and/or surgery as the main therapeutic approach.

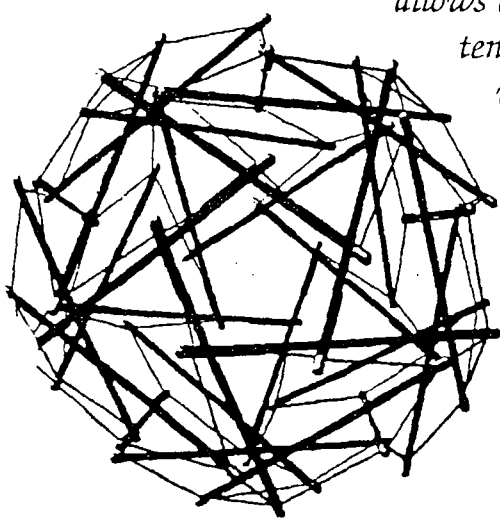
Because Osteopathic Medicine views a person as the sum of all his/her parts (physical, social, [illegible]nal, mental [illegible]iritual), D.O.'s examine the body as a complete structure-function unit.





Thus, osteopathic medical therapy focuses on treating the cause of a person's problem instead of the symptoms. In the physical realm, D.O.'s use their hands to diagnose and treat the body. This form of treatment is called Osteopathic Manipulative Therapy (OMT) and utilizes the principle of Tensegrity to balance the body in the 3 major planes of motion.

Tensegrity is a concept which originated with Buckminster Fuller. It is the engineering principle which allows a system to maintain integrity by always being in a state of balanced tension. To illustrate: if you touch this many-sided ball (made up of wooden sticks and elastic cord) at any point, you will see that every other point on the ball moves also, to some extent. This is how the fascia (connective tissue) of the human body also works. Because every muscle, nerve, organ, bone, etc. is surrounded by this shiny, thin, strong covering, we are connected by this fascia, head to toe. Were it not for this fascial envelope that surrounds all parts of us, we would not be able to be upright human beings, much less people who can move with grace and ease.



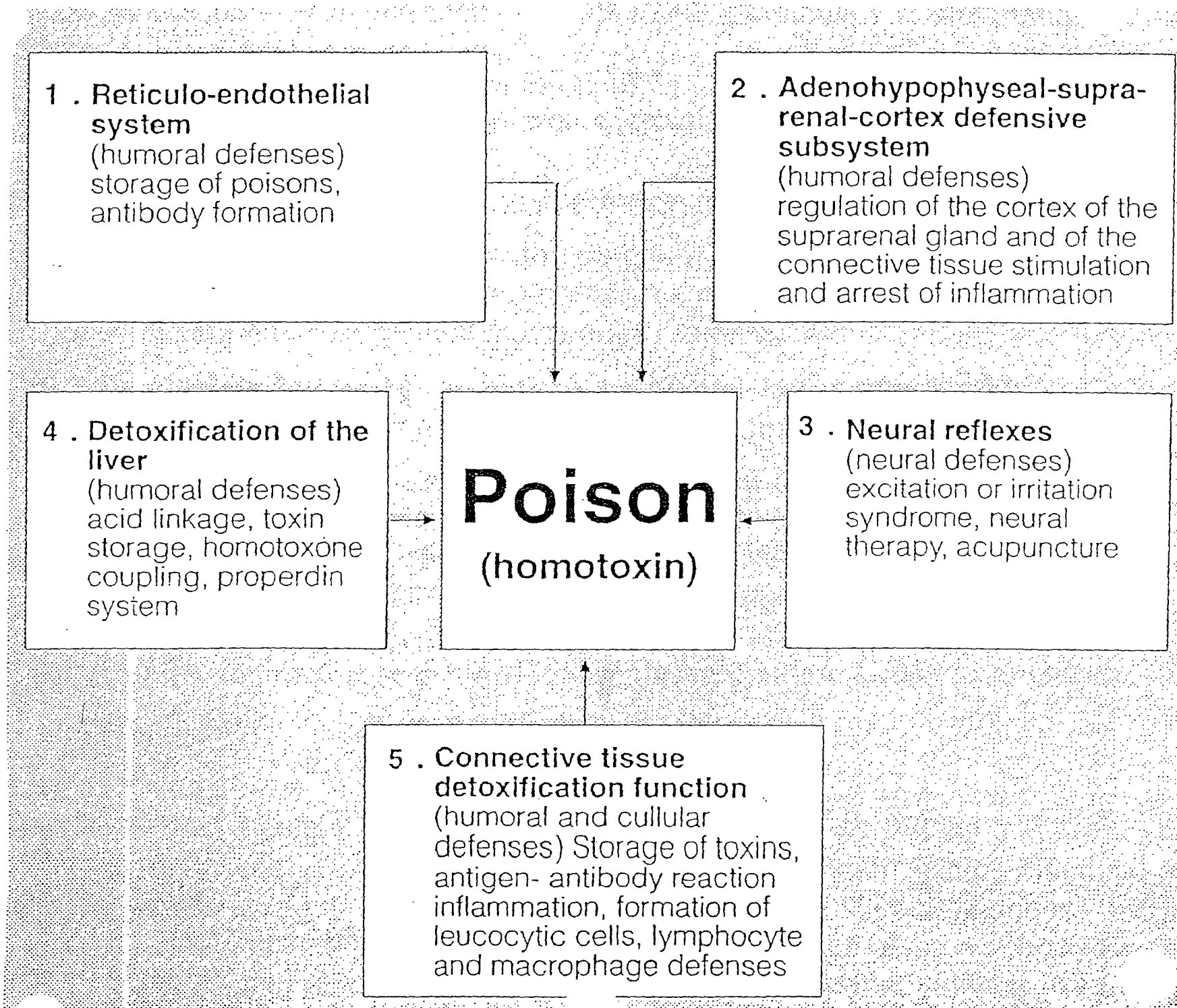
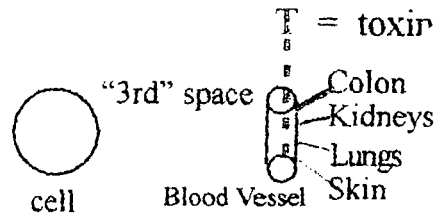
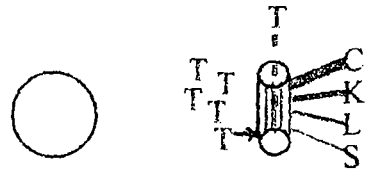
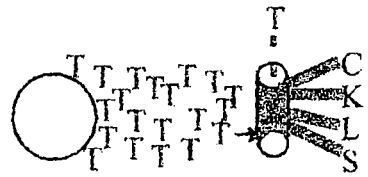

1 . Reticulo-endothelial system
(humoral defenses)
storage of poisons,
antibody formation
2 . Adenohypophyseal-supra-renal-cortex defensive subsystem
(humoral defenses)
regulation of the cortex of the suprarenal gland and of the connective tissue stimulation and arrest of inflammation
4 . Detoxification of the liver
(humoral defenses)
acid linkage, toxin storage, homotoxone coupling, properdin system
Poison
(homotoxin)
3 . Neural reflexes
(neural defenses)
excitation or irritation syndrome, neural therapy, acupuncture
5 . Connective tissue detoxification function
(humoral and cullular defenses) Storage of toxins, antigen- antibody reaction inflammation, formation of leucocytic cells, lymphocyte and macrophage defenses

Table of Homotoxicosis (abridged form)

	Recovery ←				Lingering Illness →		
	Humoral Phases/Diseases of Disposition				Cellular phases/Constiutional Diseases		
Tissue	Excretion phases	Reaction phases	Depostion phases		Impregnation phases	Degeneration phases	Neoplasm phases
1. Ectodermal a) Epidermal	Perspiration,sebum cerumen, etc.	Furnucles, eczema, dermatitis,eyrthema	Atheroma, warts,clavi keratosis,etc.		"Tattooing", Pigmentation, etc	Dermatitis, leprosy, lupus vulgaris, etc.	Ulcus rodens, basalioma, etc
b) Orodermal	Saliva, coryza, etc	Stomatitis, rhinitis, aphthous stomatitis	Nasal polypus, cysts		Leukoplakia, etc	Ozaena, atrophic rhinitis, etc	Cancer of the nasal and oral mucosa
c) Neurodermal	Neurohormonal, secretion of cells	Herpes zoster,Polio- myelitis(pyrexial stg)	Benign neuroma, neuralgia, etc		Migrane,tics, etc., virus infections(poliomyelitis)	Paresis,optic atrophy, multiple sclerosis, etc	Neuroma, gliosarcoma etc.
d) Sympaticodermal	Neurohormonal, secretion of cells	Neuralgia, herpes zoster, etc.	Benign neuroma, neuralgia, etc		Asthma, ulcus vent et duodeni, etc.	Neurofibromatosis, etc	gliosarcoma etc.
2. Entodermal a) Mucodermal	Gastrointestinal secretions, CO2, stercobilin,etc.	Pharyngitis, laryngitis enteritis, colitis, etc	Polypi of the mucous membranes, consti- pation, megacolon		Asthma, hoarsness, ulcus ventr, et duodeni carciniod, syndrome	Tuberculosis of the lung and of the intestine, etc	Cancer of the larynx stomach, rectum,etc
b) Organodermal	Bile, Pancreatic jce. thyroid hormones	Parotitis, pneumonia, hepatitis, cholangitis	Silicosis, goitre, cholelithiasis, etc		Toxic damage to the liver, pneumonopathy	Cirrhosis of the liver hyperthroidism,	Cancer of the liver gall bladder, lungs
3. Mesenchymal a) Interstitiodermal	Mesenchymal,inter- stitial substance	Carbuncles,abcesses phlegmons, etc	Adiposis, gouty tophi oedema, etc.		Forestages, of elephan tiasis, etc.influenzal	Scleroderma, cachexia velamen, vulvae, etc	Sarcoma of various locations, etc
b) Osteodermal	Haemopoiesis,etc.	Osteomylelitis,etc.	Osteophytosis etc.		Osteomalacia, etc	Spondylitis, etc	Osteosarcomas,etc
c) Haemodermal	Menses, blood and antibody formation	Endocarditis, typhus, sepsis, embolism etc	Thrombosis,sclerosis, Varicose veins, etc.		Angina pectoris, myocarditis, etc	Myocardial infarct, Pernicious anemia, etc	Myeloid leukaemia angiosarcoma,etc
d) Lymphodermal	Lymph,etc antibody formation	Angina tonsillaris, appendicitis,etc.	Swelling of the lymph glands, etc.		Lymphatism, etc	Lymphogranulomatosis	Lymphosarcomas Lymphatic leukemia
e) Cavodermal	Fluid, synovia	Polyarthritis, etc	Dropsy, etc		Hydrocephalus,etc	Coxarthritis, etc	Chondrosarcoma
4. Mesodermal a) Nephrodermal	Urine with catabolites, etc	Cystitis,pyelitis, nephritis, etc	Hypertrophy of prostate glands, nephrolithiasis		Albuminuria, hydroephorosis,etc	Neprosis, contracted kidney, etc	Renal carcinoma hypernephroma etc
b) Serodermal	Secretions of the serous membranes	Pleuritis, pericarditis peritonitis, etc.	Pleural effusions, ascites, etc.		Forestages of tumors, etc.	Tbc of the serous membranes, etc	Cancer of the serous membranes, etc.
c) Germinodermal	Menses,semen, prostatic fluid, ovul.	Adnexitis, metritis ovaritis,salpingitis etc	Myoma, hypertrophy of prostate,hydrocele, cysts		Forestages of tumors, (adnexa, uteurus, test.)	Impotentia virilis, sterility, etc	Cancer of the uterus ovaries, testes.
d) Muscolderma	Lactic acid, lactacidogens, etc	Muscular rheumatism myositis	Myogelosis, rheumatism, etc		Myositis ossificans etc	Dystrophia musculorum	Myosarcoma, etc
	Execretion principle, ezymes intact, tendency towards a spontaneous cure, favorable prognosis				**Condensation principle, enzymes damaged, tendency towards deterioration, dubious prognosis**		

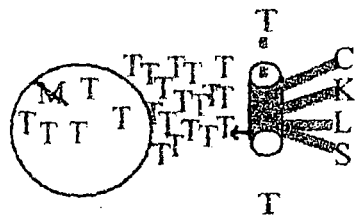
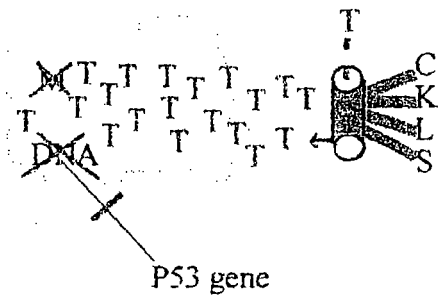
BIOLOGICAL DIVISION

Hans-Heinrich Reckeweg M.D., Biotherapeutic Index: Heel Biotherapeutics;
1(800) 621-7644 or www.heelbhi.com

SYMPTOMS	RECKEWEG PHASE	SYSTEMIC RESPONSE
None (healthy)	Phase 1 - Excretion	
Acute Symptoms	Phase 2 - Reaction	
Chronic Symptoms	Phase 3 - Deposition	

CELL WALL (diffusion reverses)

M = Mitochrondria

"tired"	Phase 4 - Impregnation	
"exhausted"	Phase 5 - Degeneration	
Cancer	Phase 6 - Neoplasm	

Daunderer: found some kind of toxin
at the core of 86% of all cancers biopsied.

THE CENTER FOR OPTIMAL HEALTH
Ann McCombs, D.O.

Accident, Acute Illness, Chronic Disease or Allergy?

Traditional medicine has taught us that allergic reactions are separate and distinct conditions, having no direct relationship to acute or chronic illnesses. Not so, according to Dr. Devi Nambudripad. She sees **allergies in a much broader scope,** challenging traditional approaches to both diagnosis and treatment of acute and chronic disease states.

Traditional approaches to allergy **diagnosis** include: through personal and environmental history, family history, blood tests and scratch tests. The Allergy Elimination approach to diagnosis can involve a comprehensive allergy screen using acupuncture meridian points, as well as a through environmental history and kinesology (muscle testing).

Say Goodbye To Illness

This Book Will Revolutionize The Practice of Medicine

Learn To Find The Cause Of Your Illness In The Privacy Of Your Home

Dr. Devi S. Nambudri[ad
D.C., L.A.c., R.N., PhD.
Best Selling Author of "Freedom From Allergy" and
"You Can Reprogram Your Brain To Perfect Health. "

Traditional approaches to allergy **treatment** include: allergy elimination diets, environmental avoidance, oral and inhaled medications and/or allergy injections. The Allergy Elimination approach to treatment involves a 20 minute exposure ton allergen while treating the specific acupuncture points with acupressure, an activator device, mild infra-red stimulation and/or acupuncture needles

Traditional allergy treatment **results** in desensitization to specific allergens, usually over long periods of time (months to years). Often re-exposure to an allergen causes recurrence of symptoms. The Allergy Elimination method, once complete (which can mean as little as one treatment or as many as several hundred treatments in severely allergic individuals) results in the **elimination** of that specific allergen as a problem FOR LIFE. Dr. Nambudripad claims and 80-90% **cure** rate for most allergens, thus greatly increasing a person's chances for immediate recovery from many chronic diseases. To whatever degree she is correct in her thinking and and successful with her treatment approach, Dr. Nambudripad's Allergy Elimination Technique (N.A.E.T.) could truly revolutionize the practice of medicine, as she boldly claims. My own clinical experiences using this treatment approach indicate that the N.A.E.T. method definitely has merit and shows much promise for treating **one of the major underlying causes of illness:** ALLERGIES.

THE CENTER FOR OPTIMAL HEALTH
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TOXIC CHEMICALS (xenobiotics) are the contaminants in our environment which keep people from reaching a state of optimal health. They cripple the mitochondria (power source) of the cells, thereby depressing a person's immune response in general, and intensify the body's allergic responses (per recent research by Russell Jaffe, MD, PhD, at the NIH). Xenobiotics are now being seriously examined as a potential root cause for many auto-immune diseases (e.g. fibromyalgia, multiple sclerosis, chronic fatigue syndrome, lupus, etc.).

EXAMPLES OF XENOBIOTICS INCLUDE:

alcohols, ammonia, internal toxins produced by the body itself, exhaust gases, fungicides, heavy metals or toxic elements from multiple sources, herbicides, medications, pesticides, solvents and petrochemicals, street drugs and volatile chemicals.

SOURCES OF XENOBIOTICS INCLUDE:

agricultural and lawn sprays; air fresheners, new appliances and electronics; art, craft and hobby materials; batteries; building products; new cars/trucks; cleaning solutions, solvents; commercial and industrial chemicals; contaminated foods and drinking water; dental materials; dry-cleaned clothes; engine fuels and exhausts; food and drink additives; furnaces; new furniture; rugs and carpets; household chemicals; industrial processes; lubricants; medicati paints, finishes, and paint thinner, photographic processes; rain, dew, fog; reproduction equipment; smoke; street drugs; welding and soldering.

DIAGNOSTIC TESTING helps the clinician to identify and quantify the type and degree of contamination present in a person's body. Once the nature of the toxicity is identified, the most appropriate therapy or combinations of therapies can be instituted for detoxification. One of the most effective methods to diagnosis toxicity is kinesiological (muscle) testing for **blocked regulation** within the autonomic nervous system. Blocked regulation is due to heavy metal toxicity 90% of the time, the primary source of which is the mercury contained in dental amalgam fillings. However, it is extremely important to remember that identifying the main source of toxicity may not be as significant as recognizing the **impact of the toxic load** on a person (as the above picture so aptly illustrates). In many chronic disease states, this factor alone is of **paramount importance** and may indeed truly be the "straw that broke the camel's back."

DETOXIFICATION THERAPIES are designed primarily to **reduce the toxic load** and **remove toxic chemicals** from the body. To detoxify successfully, physiological functions must be in optimal condition. Impaired physiology blocks or slows down detoxification. Nutritional deficits and metabolic imbalances result, thus impeding the detoxification process. To enhance this process and keep it moving without making people significantly ill, **in our clinic** we begin by addressing any autonomic nervous system (ANS) imbalance. Allergy treatments follow, if indicated, so that nutrients will begin to be absorbed. Referral to a **holistic dentist** is recommended, if indicated, for evaluation and treatment of dental foci (osteocavitations, infected root-canaled teeth), removal of amalgam fillings (with testing for bio-compatible replacement materials and electrogalvanism), and functional jaw orthopedic assessment. Oral and intravenous **chelation therapies** then follow, including periodic 24-hour urine collection to measure excretion levels of heavy metals from the body, trace mineral levels and therapeutic progress in general. **Intestinal hydrotherapy** is utilized as needed, and people are encouraged to reduce stress, eat well, increase water intake, exercise (followed by steam and/or sauna, if possible) and utilize whatever additional therapies that may be uniquely needed in their own healing process. Depending upon a person's toxic load, detoxification can take anywhere from 3 months to 3 years.

Devi S. Nambudripad,
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NARF
(Nambudripad Allergy Research Foundation)
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Professional Objective:

To bring NAET to every deserving individuals in the world

What is new?

NAET is a specialized holistic allergy elimination treatment procedure; it is developed by Dr. Nambudripad in 1983 and used ever since 1983. This is compiled from kinesiology, nutrition, chiropractic, and oriental medical procedures including acupuncture, and acupressure. To date, thousands of patients who could not find relief elsewhere have been successfully treated for both food and environmental allergies and allergy based diseases by NAET.

Back Ground:

Private practice in Nambudripad's Allergy Elimination Techniques (NAET) since 1984 in Buena Park, California.

Education:

Final Year Medical Student At UHSA, Antigua.
July 1995 - June 1988: Samra University of Oriental Medicine
Los Angeles (Acupuncture), Ph.D.
Jan. 1982 - June 1985: Samra University of Oriental Medicine
M.S. in Acupuncture
Sept.1981 - Sept. 1884: Los Angeles college of chiropractic
D.C.
June 1976 – 1981: Calif. State College of Los Angeles
B.S.
July 1976 : State Board of Nursing , California, R.N.

Professional Experience:

Dr. Nambudripad has her private practice in NAET (Chiropractic and Acupuncture) in Buena Park, California since 1984. She is a nationally and internationally known speaker, having traveled far

and wide and lectured on NAET many times. She has appeared on radios and television many times. She has been frequently featured in various magazines and newspapers.
Dr. Nambudripad conducts repeated clinical trials and double blind studies in NAET. She is presently engaged in training seminars in NAET, which are opened to currently licensed medical professionals in U.S., Europe, Australia and other countries. She has trained over 4,000 thousand medical practitioners in her special treatment procedure of allergy elimination that often renders permanent relief from allergies and various symptoms arising from those allergens

Publications:

She has written many articles and books on NAET. Her most recent books are:
"Say Good-bye to Illness"
"Say Good-bye to ADD and ADHD"
"Say Good-bye to Allergy-related Autism"
"Living Pain Free" with Acupressure
"The NAET Guidebook"
"Say Good-bye to Children's Allergies"
All these are available at: www. naet.com
www.amazon.com.
Barnes & Nobles
And many other book stores.

Professional Affiliations:

President: Nambudripad's Allergy Research Foundation
American Chiropractic Association
California Acupuncture Association
AAAOM
Touch for Health
Board for Occipital Blindness
American Medical Students Association

SYNPOPSIS ABOUT NAET

ALONG WITH A FEW CASE STUDIES

Although the term "allergy" has been widely used in the medical profession and by the public for many decades, knowledge of the energetic nature of allergies is still in its infancy. Many people continue to think that allergies are limited to a group of symptoms such as runny eyes, sneezing and itchy skin. Fortunately there are growing number of health professionals and health oriented patients who are willing to see that there may be an allergic factor in most illnesses and disorders including cancer.

Tendency to react physically to various allergens is inherited, but may not manifest until later in life. It has been seen that age of onset of an allergic condition definitely depends on the degree of inheritance. Stronger the genetic factor, the earlier the probable onset. Sensitivity to any specific irritant can make the body imbalanced. Whenever the body becomes imbalanced, allergic symptoms can appear. Allergies can result from repeated exposure to a particularly strong or toxic allergen. So that the body's defenses become exhausted due to overwork. They may also be caused by serious trauma, major surgery, vaccinations, emotional stressors such as a drastic change in life style, huge financial loss, moving the residence or job into a toxic environment, change in family (death, divorce, separation, new marriage), losing a pet, etc. Any of these substances and circumstances can create energy imbalance in the body. Eventually it can lead to serious illnesses.

NAET offers an energetic solution to allergic conditions. NAET combines Chinese medical principles applied through kinesiology, chiropractic and acupressure/acupuncture. NAET was discovered in 1983 by Dr. Devi S. Nambudripad and she spent 17 years studying the effect of this technique on thousands of real patients. The patient is tested on a computerized instrument that is designed to painlessly measure the body's electrical conductivity at specific, electrically sensitive points on the skin, particularly on the hands. Muscle Response Testing (MRT) is the body's communication pathway with the brain. MRT is used to compare the strength of a predetermined test muscle in the presence and absence of a suspected allergen. If the particular test muscle weakens in the presence of an item, it signifies that the item is an allergen. The intensity of the allergic effect will depend on these factors: affected area in the body (meridians), duration of exposure, age of the patient, immune status of the patient, the amount of exposure of the item. If the muscle remains strong, the substance is not an allergen. The body will not have an adverse reaction in the presence of that item with repeated contacts in the future.

Allergies can be explained energetically according to Traditional Chinese Medicine (TCM) principles. The Chinese refer to the life force as "chi". According to Chinese medical theory, any obstruction (initial cause or an allergen) in the flow of chi circulation in the body will cause an imbalance leading to the beginning of an illness. When there is an obstruction or disturbance in the nerve energy flow, abnormal chemical messengers

are being produced. and neurological information cannot be circulated properly, with the result, physical, physiological or emotional balance cannot be maintained appropriately. This brings poor supply of nutrients to various parts of the body due to poor or abnormal nerve energy and blood circulation. Lack of nutrients will force to produce incomplete or abnormal cells, and abnormal cell functions. This will lead to abnormal growths, and functions of tissues and organs in the body. This may have started with one small area of the body initially. Since every cell in the body is interconnected, eventually this will involve the whole body, including meridians, blood circulation, organs, associated nerves and muscles filling up the body with abnormal cells and abnormal functions. These abnormal tissue and organs with new chemical messengers will not recognize the substances around the body giving rise to multiple allergic reactions to everything consumed or touched. The body might feel like living in a different planet or stay totally confused and lost not recognizing the neighborhood. This will again intensify the body's overall response to the surroundings; in our terminology, the person will have a poor immune system. The ability of the body to survive well in the outside world (outside of the body) is because of our immune system.

If we could some how make the body go back to the state like the one before the entry of the initial allergen we could go back to square one and start all over again. That's what we are trying to achieve when we treat with NAET. We reprogram the brain-responses to the original state one by one. With NAET we could deactivate or neutralize the effect of the allergens and create a friendly surrounding. This will help the brain perceive the world as an ally and will help to reinstate the body's normal cell productions and cell functions.

If we could identify the initial causative agent (an allergen) that triggered the chain of events of the allergic reactions that led to the secretion of the abnormal chemical messengers, NAET can be used to deactivate or neutralize or eliminate the initial allergen. Due to the severity of the affects of the allergen, sometimes it cannot be deactivated right away. It can be done after a series of deactivation of associated allergens but in some cases it can be done directly. When the initial allergen is deactivated or neutralized, the body functions can be restored to normalcy by supplying the right nutrients to each and every cell in the body thus producing the normal chemical messengers; cells allowing the normal cell functions to run smoothly thus helping to repair the tissue and organ damage (cancer), and perhaps allowing the body to return to previous state of health.

The purpose of MRT is to evaluate how the nervous system influences the muscle function in the presence of an irritant. MRT is used as a diagnostic component. Identification of the condition and isolation of the causative agent is achieved preliminary through MRT; with more advanced MRT testing techniques, the exact area of involvement (meridians, associated organs, nerve roots, physical, physiological or emotional involvements, etc.), the severity of the effect of allergen (distance of the allergen from the body), time of avoidance, distance, other related substances, etc. can be determined. After gathering all of the above information regarding an allergen, the actual treatment of reprogramming the brain is done through acupressure along the sides of the spine from thoracic one to lumbar five vertebrae and/or chiropractic manipulation of the spinal nerve roots in the presence of the isolated allergen introducing the allergen

properly into the body once again. This appropriate introduction of the allergen into the body and brain will reprogram the brain to the new memory as a pleasant one. After determining the restoration status of the body against the allergen as an ally, (MRT again at different areas as in meridian organ and nerves, physical physiological and emotional levels), acupuncture or acupressure is applied to a series of specific acupuncture points with the patient still holding the allergen. This is done to clear any more possible memory of the particular allergen left in the body under the umbrella of this allergen. Once the treatment is completed, patient is advised to avoid the treated allergen for next 25 hours, allowing the energy molecule to pass through the meridians with ease. From our hypothesis and experience, if the energy molecule is allowed to pass through (25 hours) without interference, then the brain accepts the allergen as a new friend. Future contacts do not bring any adverse reactions.

Our bodies are full of energy pathways. That becomes blocked if we come in contact with some adverse energy in our diet or living environment. If we allow these energy blockages to continue for long time affected tissue and organs will suffer the damages and unable to function properly. This malfunction create cancer or such diseases to replace otherwise healthy functions. If the energy pathways or acupuncture meridians are all open and free-flowing with vibrant energy you have no allergies --you have no disease.

I have had outstanding success in allergy and allergy-related cases. I have treated cases with history of anaphylaxis from peanut, shellfish, mushroom, egg, milk, hair dye, formaldehyde, perfumes, etc. and now they are able to use them in their daily lives without a trace of previous reactions. I have also treated many of cases of asthma, various types of arthritis, crippling types of fibromyalgia, migraines and other headaches, backaches, depression, schizophrenia related to allergies, attention-deficit hyperactive disorders, autism related to allergies and vaccinations, etc., with very good result. I have not treated cancer cases just with NAET because I am not permitted to treat cancer cases in California under my license as a chiropractor. So I don't know the efficacy of NAET just on cancer. I have treated various cancer cases in conjunction with medical treatments with excellent results. Some of the case studies I have quoted below. If NCI could give me the support legally and financially I need to conduct such a study that is "treating cancer using just NAET," I am most willing to conduct a study and find out the results. I have a few cancer patients approached me already and most of them are willing to go through just NAET if they could get it (ovarian cancer, stomach cancer, endometrial cancer, breast cancer, prostate cancer, pancreatic cancer).

This study could just prove how effective NAET is for the treatment of cancer. But when it comes to treatment, I prefer to treat patients in combination with chemotherapy, or vitamin therapy, or hormonal therapy. Because NAET can easily remove the adverse effect of chemo, radiation, vitamins, herbs, or hormones. So that patient's body can heal faster by killing the cancer cells at the same time supplying the appropriate nutrition for the body. After receiving NAET on chemo or other anticancer supplements, patients do not get side effects like nausea, indigestion, insomnia, hair loss, skin burns or damages, etc. After all, our goal is to get the patients well faster with whatever we can use.

Withdrawal/Redaction Marker
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. paper	Synopsis about NAET [Nambutripad's Allergy Elimination Technique] (partial) (3 pages)	nd	b(6)

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

OA/Box Number: 43238

FOLDER TITLE:
WHCCAM Testimony, October 5-6, 2000 [3]

2011-0568-S
kc882

RESTRICTION CODES

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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]
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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]

[001]

Case Study: 1

PATIENT: (b)(6)

DX: Atypical Epithelial Cells of Undeytermined Significance (ASCUS)

67 year old psychotherapist had her routine PAP smear test on 04-11-00 and which showed positive foe atypical Epithelial cells of undetermined significance class 11.

She chose to get treated by NAET only. She received NAET treatments for estrogen, progesterone, testosterone, uterus, vainal secretion, cancer signature, hypothalamus, fats, essential fatty acids, pituitary gland and combinations of these items. She took no other treatments. At the end of three months she was tested at the internis's office and the results showed that the cells were normal.

CASE 11

In June 1989, 58-year-old Marvin, a dentist came to me with the complaints of extreme fatigue, insomnia, nervousness, severe pains in all the joints, especially in the wrists and lower back. His history revealed that he was suffering from metastasis from his prostate cancer. He was operated for his prostate cancer in 1986. He was treated by chemotherapy and his disease seemed under control for a year. Then he began having low backaches and joint pains and found the cancer metastasizing to the spine.

He was back on chemotherapy for months without any significant improvement in his health. He was on disability for 7 months. He couldn't use his right hand and wrist due to pain and he was unable to function as a dentist.

After the necessary basic NAET treatments, he was treated for mercury, the toxin of his trade. He took eighteen treatments (18 office visits) to clear mercury and combinations.

Mercury
Mercury (2nd time). He began noticing more energy
Mercury + acid ———— Diminishing joint pains
Mercury + base -Diminishing lower backaches
Mercury + heat
Mercury + RNA
Mercury + DNA
Mercury + organ ——— Diminishing fatigue
Mercury + lung
Mercury + spleen ——— insomnia improved
Mercury + liver
Mercury + colon ———— improved digestion
Mercury + small intestine
Mercury + brain
Mercury + nerves
Mercury + parasympathetic nerves
Mercury + bone mix ——— no more wrist pains

Mercury + bone marrow ——— low backache with less intensity continued.

Mercury detox was done using NAET treatments. Selenium, vitamin C, and vitamin A were used for detox.

I made the samples of his weak dilutions (12 samples) and treated him for all of them together. When I retested on the next visit, he was weak again for 11 out of twelve. It took eleven more treatments to complete the dilutions. During the treatments for the dilutions, his symptoms of pain and discomfort steadily diminished.

His metastasis was completely resolved after a year of NAET treatment and he returned to his regular work as a dentist. He was also taking Lupron along with NAET. He was weaned off from Lupron. His cancer went into remission. He worked for six more years and retired in 1994 at age 65. He is 71 now and still leading a healthy life.

CASE III

PATIENT: (b)(6)

This Patient is also a board certified pediatrician and an oncologist, practicing in Fresno, California.

I was diagnosed with stage II breast cancer in 1987. I underwent lumpectomy of the right breast and axillary dissection, 6 cycles of chemotherapy with cytoxae, methotrexate, and 3-flurouracil and 6 weeks of radiation to the right breast. The cancer was ER/PR negative, nuclear grade III and 3 of 17 nodes had micrometastasis. It was well for ten years. I had my first child in 1992 and a second child in 1996.

In august 1996, I was diagnosed to have recurrent metastatic cancer in my right breast in the scar area, right axillary area, several bones in my spine and both sides of my pelvic bones. First, they treated me with radiation to the painful area, mainly the hip and back, then chemotherapy with Taxoterc. I also started monthly injections of Pamidtronate (a biphosphonate drug to strengthen bones). A simple mastectomy was performed in March 1998. The cancer did not totally go away after 9 cycles of chemotherapy. I was then referred to UC Davis Medical Center Cancer Center for further management.

May 1998, I underwent high dose chemotherapy with stem cell rescue (a.k.a. bone marrow transplant). Prior to this therapy, I started alternative therapy with nutrition, exercise, prayer, meditation, chi gong, and homeopathic medicine. After two months, I went back to work full time.

Seven months after the last treatment, new tumors were discovered in my chest wall, pleura, and liver. I also had pleural effusion in my right lung. In March 1999, I attended NAET for the basic training. In addition to the above mentioned complimentary medicine, I added allergy elimination in my armamentariun. I chose not to have other western medicine treatments since they did not seem to work on putting my cancer in remission. I opted to wait for a promising monoclonal antibody treatment but unfortunately, I had to wait until it was a year from the bone marrow transplant.

April 1998, I finished my NAET advanced I. Again, with the help of my husband, we tried to eliminate all the emotional allergies as best as we could. We also plowed through the basic NAET kit. Despite no treatments I seemed to be holding well

on my own. I had a setback three months later. I was in the Intensive Care Unit for hemorrhage in the right lung. A thoracostomy and thoracotomy procedure was performed. My sister-in-law helped with boosting my organs through the NAET technique. Every day in my hospital bed, I self-treated and continued the emotional treatments, some of which my family did for me.

The monoclonal antibody treatments were done at the UC Davis Medical Center in June and October 1999. This entailed being injected with a radioactive mouse antibody, which was then followed by a stem cell rescue. Multiple blood transfusions followed, both with red cells and platelets. I had severe allergic reactions to both.the mouse and the stem cell. Throughout this treatment, my husband treated me with NAET against the mouse antibody, stem cell and most of the medications used there. Because of NAET, we could reduce the side effects to minimal. It seemed that I was allergic to stem cell that may have been the reason it didn't work when I took that in 1998. I developed an antibody to the mouse, which at first was thought of as a negative sign. Now the researchers believe that this has gotten me a better response because my immune system is still fighting the cancer. Proof of this is that the liver lesions have continued to resolve 6 months after the last treatment and the pleural lesions, which were too numerous to count, have completely disappeared.

In April 2000, I attended the NAET advanced training, which centered on boosting and balancing. My energy via a personalized energy signature which I am now using to boost up my energy as I continue to take away my allergy to the cancer.

CASE IV
Name of the Patient: (b)(6)
Date Of First visit to the doctor: 10-08-97
DX: Non-Hodgkin's Lymphoma.
10-07-98 ; -09-30-99; 09-30-00: No evidence of: No evidence of new or recurrent diease.

19 year old Holly began getting short of breath and saw her family doctor. He found a bad heart murmur and sent her to a cardiologist the next day. He took an X-ray and told her immediately that the problem was not primarily in the heart, but that a tumor waspressing on top of the heart and causing the tumor. CT scan later the same day confirmed the presence of a tumor approximately fist-size pressing on the upper portion of the heart. That night a surgeon opened a small area of her chest to do a biopsy and said that the tumor was under so much pressure that it popped up toward him as soon as his knife cut into the chest cavity. He was very cooperative in saving a small piece of the biopsy material foe us to copy energetically to use in her treatment. Biopsy proved that she had a non-hodgkins lymphoma, which carries a worse prognosis than hodgkin's lymphoma.

Her oncologist gave permission to come to his office to make energetic copies of the chemotherapy agents he planned to give her. He told us that these substances were so toxic that OSHA would not allow any of these substances to be taken outside of the office. he told her and her family that she would receive 6 to 9 chemo treatments in the office at 3 week intervals, and that there was a likelihood that she may require radiation

treatments after that. but he said that they would do another CT scan after the 4th chemo session to restage the tumor.

we proceeded to treat her with vials containing the energetic signatures of the tumor and the chemotherapy agents, interweaving these and combinations thereof with treatments for basic allergens, usually giving two treatments per day, one on my way to work in the AM and one on my return in the evening.

When the second CT scan was done after the 4th chemo treatment, our daughter, (Holly's mother) overheard the oncologist outside the room dancing and singing, "It's gone. It's gone." He told them that the scan showed no sign of any remaining tumor, but he proceeded to give two more chemo treatments since six were considered the minimum for such tumors. Incidentally, his approach was approved by a specialist in lymphomas, I believe from St. Louis, who reviewed the Ct and a PET scan which he recommended.

We later wrote to Holly's oncologist to tell him in more detail what we had done in conjunction with his treatments. He never acknowledged whether NAET made any real difference in her outcome, he replied, "You made a remarkable recovery"

Holly had her follow-up check ups on a regular basis after 1 year, 18 months, two years, now three years later there is no sign of any tumor being present.

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: Templeton

John M. Templeton, Jr.

Dr. John M. Templeton, Jr. serves as president of the John Templeton Foundation, Directing all Foundation activities in pursuit of its mission to encourage progress in scientific and religious knowledge. He works closely with the Foundation's staff and international board of advisors of more than 35 leading scholars, scientists, researchers and theologians to develop substantive programs in this endeavor.

Dr. Templeton has been actively involved in the Foundation since its inception in 1987. In 1995, he retired from his medical practice to serve full time as president of the Foundation. His more than 25-year career as a physician and long-held spiritual beliefs provide both the formal science training and the commitment to advance the foundation's work.

After receiving a bachelor of arts degree from Yale University in New Haven, Conn., Dr. Templeton earned his medical degree from Harvard Medical School in Boston. He completed his internship and residency in surgery at the Medical College of Virginia in Richmond and subsequently trained in pediatric surgery under Dr. C. Everett Koop at The Children's Hospital of Philadelphia. After serving two years in the U.S. Navy, he returned to The Children's Hospital of Philadelphia in 1977, where he served on the staff as pediatric surgeon and trauma program director. He also served as professor of pediatric surgery at the University of Pennsylvania.

Dr. Templeton was board certified in pediatric surgery and surgical critical care and is a fellow of the American College of Surgeons. He has served as a board member of the American Trauma Society and as president of its Pennsylvania division. He is a member of the American Medical Association, the American Pediatric Surgical Association, the American Association for the Surgery of Trauma and the International Association for the Surgery of Trauma & Surgical Intensive Care. He has published numerous papers in medical and professional journals.

White House Commission on Complementary and Alternative Medicine Policy

Activities and Perspective of the John Templeton Foundation in the area of Spirituality and Healing in Medicine.

John M. Templeton, Jr., M.D.

One of the major missions of the John Templeton Foundation is in the broad and growing field of science and religion. As a part of this mission, the Foundation has been particularly interested in research and programs that address the role that science can play in our understanding of spirituality, faith, belief and religious practice and its beneficial impact on human beings. As a part of this commitment, the John Templeton Foundation has been supporting a number of initiatives in the area of spirituality and healing in medicine. Many of these initiatives are based on the large number of scientific studies that show the positive association of intrinsic religiosity, prayer, scriptural study and religious practice, both on health maintenance and recovery from illness. Most of these scientific studies are correlational. Namely, there is a correlation between religious practice and belief and outcome. There are only a few studies at this point that address the issue of mechanism of action whereby religious practice and belief can effect health outcomes. This is similar to the example of many advances in the history of medicine in which valid correlations were made prior to understanding the underlying mechanism. For example, the scientific studies that demonstrated the use of citric juices could prevent scurvy in sailors were a valid correlational study that proceeded the later understanding of the mechanism of action of ascorbic acid.

When there is a solid scientific basis for some component that has beneficial health impacts, we feel that these components pass into the realm of complementary medicine in which the approach in question can serve as a complement to traditional medical therapies. For example, working with a patient's intrinsic religiosity and beliefs would not replace the beneficial use of medications and/or surgery. Instead, spirituality and/or religion can be a positive complement to traditional medicine.

The following are some examples of initiatives funded and supported by the John Templeton Foundation.

1. The writing and publication of The Faith Factor: An Annotated Bibliography of Clinical Research on Spiritual Subjects by D. Matthews, D. Larson and C. Barry, July 1993. In this review study, 77% of the studies demonstrated a positive effect of religious variables, 17% were neutral or mixed, and 6% demonstrated negative effects from religious variables.

2. Beginning in 1995, we have supported the semi-annual Continuing Education Medical classes of Harvard Medical School on Spirituality and Healing in Medicine under the leadership of Dr. Herbert Benson.

3. We funded a consensus conference and report entitled Scientific Research on Spirituality and Health by D. Larson, J. Swyers and M. McCullough. This consensus conference addressed definitions of religion and spirituality, and the impact of religious practice and belief on physical health, mental health, addictions and neuro science.

4. In 1997, we funded a program to support exemplary courses in medical schools on Spirituality and Healing in Medicine. Presently up to 61 medical schools now include elective or required courses that address Spirituality and Healing in Medicine.

5. We funded a joint conference in 1999 involving the American Association of Medical Colleges and the National Institute for Healthcare Research which addressed a variety of subjects such as spirituality, culture and end-of-life care which might be considered part of the medical experience in both medical school and residency programs.

6. In 1998, we funded a major multi-institutional research initiative on assessing the efficacy of intercessory prayer. This project is under the direction of Dr. Herbert Benson of the Harvard Medical School. The results of this study will be available in the year 2001.

7. 1998, we funded a two-part research project on the efficacy of direct face-to-face prayer therapy in patients with moderate to severe rheumatoid arthritis. A second part of the study involved randomized, double-blinded studies on the efficacies of remote intercessory prayer on the follow-up health care status of patients with rheumatoid arthritis.

8. We have funded a number of medically related grants to study the efficacy of forgiveness on health care outcomes. The titles of these research initiatives include:

   a. Empirical study of forgiveness education with cardiac patients

   b. Forgiveness, health and well being in the lives of post-collegiate young adults.

   c. Embodied forgiveness: Empirical studies of cognitive, emotional and physical dimensions of forgiveness-related responses.

   d. Forgiveness at the end of life.

   e. Secular and spiritual forgiveness interventions for recovering alcoholics: a patient-treatment matching study.

9. We provided a major grant to the Center for the Study of Religion/Spirituality and Health at Duke University for the following purposes.

   a. Increase the volume of scientific research on Religion/Spirituality and Health both by researchers at Duke and by outside researchers located at other institutions.

   b. Assist in the development of programs on Religion/Spirituality and Health at other major institutions.

   c. Obtain grants from federal, foundation, private sector and industry sources for research on Religion/Spirituality and Health at Duke and assist other researchers outside of Duke to do the same.

   d. Influence public policy in order to increase federal funding in this area.

   This center is under the direction of Dr. Harold Koenig.

Some of the important issues to consider are the obstacles or barriers to more effective research. These barriers include:

1. Conceptual barriers in regard to the need to establish a consensus among researchers regarding what constitutes "religion" or "religiousness" or "religious commitment" or the more nebulous concept of "spirituality".

2. Methodological barriers such as the difficulty of establishing appropriate control groups.

3. Structural barriers such as the prior hesitation for the use of public funds for research on the social benefits of religious practice.

4. Professional barriers in that there are presently few centers or channels in which a professional can take the risk to advancement in their overall profession if they engage in spiritually or religiously based research. Solutions will include the prospect for supporting young and growing centers engaged in the conduct of research in the broad area of spirituality and healing in medicine. Both private and federal supported funding through the instrument of consultative bodies can supplement not-for-profit sector funding for research in these areas.

DYANNE M. HAYES

Ms. Hayes is vice president-programs for the Conrad N. Hilton Foundation and responsible for all of its grantmaking activities worldwide. An award winning grantmaker, she has been with the Foundation for ten years.

The Hilton Foundation is unique in that it does not consider unsolicited requests, adopting a major initiative approach: multi-million dollar awards long term. Its current portfolio of active grants totals more than $175 million and, on average, it awards an additional $32 million annually. Primary funding interests are: blindness (particularly the multi-handicapped blind child and the prevention of blinding trachoma); potable water development in West Africa and southern Mexico; early childhood development for infants and toddlers with disabilities; prevention and intervention efforts to end domestic violence; a school-based curriculum, *Project Alert*, for substance abuse prevention; the mentally ill homeless; the Hilton College of Hotel and Restaurant Management at the University of Houston; and the work of the Roman Catholic Sisters. Its Hilton Humanitarian Prize, at $1 million, is the largest of its kind to recognize an organization achieving exemplary results. Recent recipients include: African Medical Research Foundation (AMREF), Doctors Without Borders, and International Rescue Committee.

A few of her professional and civic activities include (*current):

Chair, Los Angeles Donors Roundtable
Board member, Southern California Association of Philanthropy
Founding Chair, Northern Nevada Grantmakers
Board member, State of Nevada Humanities Commission
Executive Committee, University of Nevada, Reno, Foundation

* Board of Councilors, USC School of Gerontology
* Board member, Conrad N. Hilton Fund for Sisters
* Board member, National Council Juvenile & Family Court Judges

WHITE HOUSE COMMISSION
On
COMPLEMENTARY & ALTERNATIVE MEDICINE POLICY
October 6, 2000

"Cocaine Alternative Treatment Study (CATS)"

Dyanne M. Hayes
Vice President - Programs
The Conrad N. Hilton Foundation
Reno, Nevada & Los Angeles, California

"COCAINE ALTERNATIVE TREATMENT STUDY (CATS)"

During 1993, Foundation program staff became increasingly concerned with the plight of pregnant addicts. Initially our thinking was to provide general operating support to one or more neighborhood clinics somewhere in the United States that specifically target this population. Preliminary exploration uncovered Michael Smith, M.D., founder of the Lincoln Clinic at the Bronx, New York. Dr. Smith is internationally known for developing the use of auricular acupuncture in the field of chemical dependency, including the treatment of pregnant addicts for more than a decade.

Encouraged by discovering this low cost, mobile treatment option, Foundation staff returned to Los Angeles to inquire of various neighborhood clinics and community-based hospitals why acupuncture was not included as a treatment option for the pregnant addict. To the one, each physician acknowledged there was a great deal of positive anecdotal information available on the potential of this approach, yet until a scientific clinical trial proved it safe and successful it would not be considered. Foundation staff then realized that this is the niche the Hilton Foundation might fill - funding the first-ever clinical trials to determine the efficacy of acupuncture as a treatment option for cocaine addiction, particularly for the pregnant cocaine addict.

To this end, Herbert D. Kleber, M.D., senior executive vice president and medical director at the Center on Addiction and Substance Abuse (CASA), was asked to submit a proposal to the Foundation on CASA's behalf. As the Principal Investigator he assembled the following:

Scientific Advisory Board
Steve Birch, Lic. Ac.
Thomas E. Feucht, Ph.D.
Mindy Fullilove, M.D.
Thomas R. Kosten, M.D.
Michael Smith, M.D.
Alan Trachtenberg, M.D., M.P.H.
George Woody, M.D.

Co-investigators
S. Kelly Avants, Ph.D.
Arthur Margolin, Ph.D.
Thomas McLellan, Ph.D.

The six trial sites and their principal project investigators were:

Yale University	Arthur Margolin, Ph.D.
University of Washington	Elizabeth A. Wells, Ph.D.
University of Miami	Janet Konefal, Ph.D., M.P.H.
UC Los Angeles	Elena Khalsa-Denison, M.D., Ph.D., Frank H. Gawin, M.D.
UC San Francisco	James L. Sorenson, Ph.D.
Hennepin County, MN	Milton L. Bullock, M.D., Patricia A. Culliton, M.A., Dipl.Ac.

Hilton Foundation Grant Overview
In May 1994 the Foundation awarded CASA $1,664,596 over four years, half the cost of a $3,329,191 study. This was a "challenge" grant whereby CASA was to raise within six months the remaining funds necessary to complete the study; this date was later extended to June 1995. In 1998 an additional $106,000 was awarded by the Foundation to offset costs of hiring additional follow-up interviewers at three trial sites.

Funding Challenges

The Hilton Foundation diligently sought funding partners from other Foundation colleagues, particularly those whose primary mission is wellness and/or health care. Although there was positive interest and great fascination at staff levels, our partnership offer was declined at board levels as "too risky" and "too far out".

Meanwhile, CASA was discovering its own challenges in seeking private and public monies. Ultimately, and we believe due to Dr. Kleber's preeminence, it identified the following:

$ 900,000	Office National Drug Control Policy
500,000*	National Institute on Drug Abuse
100,000	National Institute of Justice
664,595	CASA (from its core operating budget)
$2,164,595	

* Tapping into an existing grant at Yale, because the CATS study design was developed by Dr. Arthur Margolin, using an identical design.

Research Design & Methods

Subjects: The original strategy was to enroll 600 subjects (225 methadone, 225 primary cocaine, and 150 pregnant women). By 1997 it was determined that none of the sites were successful in retaining pregnant addicts once recruited; thus, the population which stimulated the Foundation's initial interest was eliminated. Final enrollment of 519 (189 methadone and 330 primary cocaine) was completed in November 1998. Subjects were randomly assigned to one of three conditions:

1. Auricular acupuncture: 4 needles inserted in regions of the ear used to treat cocaine addiction based on the treatment protocol developed by Lincoln Clinic's Dr. Smith;

2. Control or sham: 4 needles, same type and size as used for the active treatment, inserted subcutaneously so that they did not penetrate the cartilage in the helix of the ear; or

3. Relaxation control: subjects listening to a variety of recorded tapes on relaxation techniques.

For the first six weeks of the study, subjects in each of the three groups received treatment daily; for the last two weeks, treatment was given three times per week.

Patients were paid $10/week the first seven weeks and $30 for the eighth week. In addition $20 was paid at both the three and six month follow-up interviews and evaluations.

A Modified Double Blind: It was a complex task to design a sound and valid study for a controlled evaluation, considering that acupuncture is an Eastern medical tradition whose conceptual framework is far removed from the biochemical and scientific foundations of Western medicine. Thus, a double blind study, modified in that neither the patient nor the person "rating" the effectiveness knows whether treatment has actually been rendered at an active or presumed inactive site, while the needle insertion is carried out by an experienced acupuncturist assuring that the conditions are correctly administered.

Ethical Issue: An issue was raised regarding the use of pregnant women in the study. Five leading ethicists were engaged (Daniel Callahan-Hastings Center; Ed Pellegrino-former president Catholic University; Father Richard McCormack-Notre Dame University; Father William Smith-St. Joseph's Seminary; and Robert Levine-Yale University). At the end of their discussion, there was unanimous agreement there is no evidence that acupuncture is harmful to the fetus and because there is mixed evidence of acupuncture's efficacy in treating cocaine addiction, this is an ethical experiment.

Inability To Successfully Recruit/Retain Pregnant Women for the Study: In itself, this difficulty is the subject of a separate report to be produced by CASA. Despite a year-plus of a variety of endeavors and frequent, intense discussions among all of the sites and CASA staff it became discouragingly apparent that recruitment should be stopped. Preliminary findings identified four likely obstacles:

1. Characteristics of the population: lack of trust, confidentiality worries, child custody issues, shame and denial, multiple needs with scant resources.

2. Characteristics of the CATS design and recruitment procedures: lack of transportation (public and/or private), lack of daycare, food provision for the homeless subjects, and inability to establish a site where the woman already visits, like a shelter or doctor's office. Additionally, the inclusion/exclusion criteria used for clinical studies; i.e., maximum gestational age for enrollment was 28 weeks. This population typically comes for prenatal care very late in pregnancy for reasons enumerated above.

3. Characteristics of the health care system referral sources: competing priorities of clinics or their staff believing their clients needed more services than CATS could offer. Lack of outreach workers from the same community, of the same ethnicity and gender.

4. Characteristics at the specific sites: the physical, logistical layout (no elevator, multiple stops at several buildings), some women did not want to go to a site where heroin addicts would go, and, in Seattle, one street outreach worker noted the enormous competition among researchers for pregnant women.

Study Results

Results are expected before year end 2000.

7/99

Daniel Callahan

Director, International Programs, The Hastings Center

Daniel Callahan was the co-founder of The Hastings Center, Garrison, N.Y., and its Director and President from 1969 to 1996. He is presently Director of its International Programs and a Senior Fellow at the Harvard Medical School. He is also an Honorary Faculty Member, Charles University Medical School, Prague, the Czech Republic. The Hastings Center is a research and educational organization founded in 1969 to examine ethical issues of medicine, biology and the environment.

Dr. Callahan received his Ph.D. in philosophy from Harvard, an M.A. from Georgetown University, and his B.A. from Yale.

Dr. Callahan holds honorary degrees from Oregon State University, the University of Colorado, Williams College, and the University of Medicine and Dentistry of New Jersey. He is an elected member of the Institute of Medicine, National Academy of Science; a member of the Director's Advisory Committee, Centers for Disease Control; and a former member of the Advisory Council, Office of Scientific Integrity, U.S. Department of Health and Human Services. He won the 1996 Freedom and Scientific Responsibility Award of the American Association for the Advancement of Science.

Dr. Callahan is the author or editor of 35 books. They include *False Hopes* (Simon & Schuster, 1998); *The Troubled Dream of Life: In Search of a Peaceful Death* (Simon & Schuster, 1993); *What Kind of Life: The Limits of Medical Progress* (Simon & Schuster, 1990); *Setting Limits: Medical Goals in an Aging Society* (1987); *The Tyranny of Survival* (1973); *Abortion: Law, Choice and Morality* (1970); *Ethics in Hard Times* (1982); and, with his wife, Sidney, *Abortion: Understanding Differences* (1984). He has contributed articles to *Daedalus, Harpers, The Atlantic,* the *New England Journal of Medicine*, the *Journal of the American Medical Association, The New Republic,* and other journals.

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*A full curriculum vitae is available upon request.

Complementary and Alternative Medicine:
The Scientific and Pluralistic Challenge
A Project of
The Hastings Center

For over two years, The Hastings Center—a research institution devoted to ethical and policy questions of medicine and biology—has been carrying out a research project on complementary and alternative medicine (CAM). It principal purpose has been to explore the public interest in CAM as an important social phenomenon, to determine just how much pluralism of goals and methods medicine can responsibly accommodate, and to examine the question of appropriate scientific methodology to validate claims made in behalf of CAM.

The project brought together specialists from the fields of medicine, folklore, philosophy and the philosophy of science, sociology, statistics, and epidemiology. While we were looking for people interested in CAM, not ready to dismiss it out of hand, we also wanted the group to contain people who have no professional interest in CAM as medical practitioners and who are not active in assorted CAM interest groups. The Director of the project, Daniel Callahan, is a philosopher by training and has never made personal use of CAM, as is the case with a number of other project participants.

Three general conclusions were reached by the research group:

1.That CAM is an important medical and social phenomenon and is worthy of serious and sustained study. It is a mistake to dismiss it as mere quackery or to suggest (as some have done) that it should not even be studied because of the implied legitimation that research on it implies.

2. CAM should be the subject of a broad research agenda, looking at scientific questions of validation but also at what it says, directly or indirectly, about the public's assessment of mainline medical practice and care.

3. There is no single, all-purpose scientific methodology suitable for evaluating CAM. The need is to determine what kinds of methodologies are most appropriate for evaluating the different forms of CAM as well as evaluating why it is that people often respond positively to it even when there seems no scientific basis for them to do so.

The final results of the project are now being edited as a book to be published in 2001 by the Georgetown University Press.

The following papers will be published in the book:

Loretta Kopelman, a philosopher, on "The Role of Science in Conventional and Complementary Medicine."

Kenneth Schaffner, a physician and philosopher of science, on "Assessments of Efficacy in Biomedicine"

Bonnie O'Connor, a social scientist, on "The relationship between personal experience and the CAM research agenda."

David Hufford, a folklorist, on "Cultural Diversity and CAM"

David Larson, a physician, on "Spirituality in Clinical Care"

Paul Wolpe, a sociologist, on "A Sociological Perspective on CAM"

Howard Brody, a physician and philosopher, on "The Placebo Effect: Implications for Alternative Medicine"

Asbjorn Hrobjartsson, a Danish methodologist, on "Placebo Intervention: What Is Its Clinical Effect?"

Tom Whitmarsh, a Scottish physician, on "Assessing Trials of Homeopathy in Clinical Medicine"

Wayne Jonas, a physician and former director of the NIH Office of Alternative Medicine, on "the research agenda of CAM"

Alfred Tauber, a physician and philosopher, on "Concluding Reflections on the Project and Its Papers."

Daniel Callahan, Project Director

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Chang, Michele (OD)

From: Terri.Ades@cancer.org
Sent: Tuesday, October 03, 2000 4:55 PM
To: Chang, Michele (OD)
Subject: Bio

Terri B. Ades, MS RN, AOCN, holds the position of Director, Health Content for the American Cancer Society, responsible for the Society's strategic direction - to provide accurate and current cancer-related information to the public. This involves developing, reviewing, and maintaining cancer information distributed through a variety of channels, such as printed booklets, consumer books, health professional textbooks, web content, and a cancer information database for use by the American Cancer Society National Call Center. Ms. Ades also is the staff responsible for the Society's Advisory Group on Complementary and Alternative Methods for Cancer Management, a position she has held for 6 years. The Society recently published the American Cancer Society Guide to Complementary and Alternative Cancer Methods under her leadership.

Ms. Ades has been with the American Cancer Society National Home Office for the past eleven years and some of her accomplishments in addition to the above book include: successfully planning and convening five national conferences for health professionals; editing the 6th and 7th editions of A Cancer Source Book for Nurses; development of a ACS web-based Cancer Drug Database; and serving as a medical content reviewer for the consumer books, ACS Breast Cancer Journey and Caregiving, a Step-by-Step Resource for Caring for the Person for Cancer at Home.

When joining the American Cancer Society, Ms Ades brought 12 years clinical oncology experience with adults and children. Her oncology experiences included coordinating a NCI-sponsored Community Clinical Oncology Program (CCOP) at the Medical College of Georgia; an advanced practice oncology nurse position at Indiana University Medical Center in Indianapolis; and a pediatric oncology nurse clinician at the Medical University of South Carolina. She is certified in advanced practice oncology nursing and is certified as a family nurse practitioner.

Teresa

AMERICAN CANCER SOCIETY - 1999 FACT SHEET

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer through research, education, advocacy, and service.

It is one of the oldest and largest voluntary health agencies in the United States, with over two million Americans united to conquer cancer through balanced programs of research, education, patient service, advocacy, and rehabilitation.

ORGANIZATION

The American Cancer Society, Inc. consists of a National Society, with chartered Divisions throughout the country and over 3,400 local Units.

THE NATIONAL SOCIETY

The National Board of Directors provides basic representation from the divisions and additional representation on the basis of population.

The National Society is responsible for overall planning and coordination of public and professional education, providing technical help and materials to divisions and units, and administering programs of research, medical grants, and clinical fellowships.

THE DIVISIONS

These are governed by volunteer members of Division Boards of Directors, both medical and lay, throughout the United States and Puerto Rico.

THE UNITS

More than 3,400 local Units are organized to cover the counties and communities in the United States. There are thousands of community leaders who direct the Society's programs at this level.

VOLUNTEERS

The Society's mission of cancer control is carried out by over 2 million volunteers nationwide who donate their time and services.

STAFF

Professional staff include 4,418 working in Division and Unit offices, as well as a staff of 463 in the National Home Office.

HOW THE AMERICAN CANCER SOCIETY FIGHTS CANCER

Research: The aim of the Society's research program is to determine the causes of cancer and to support efforts to prevent and cure cancer. The American Cancer Society is the largest source of private, not-for-profit cancer research funds in the United States, second only to the United States government in total dollars spent.

To date, the Society has invested more than $2.2 billion in cancer research and has provided grant support to 30 Nobel Prize winners early in their careers.

The Society's overall annual expenditure in research has grown steadily from $1 million in 1946 to almost $108 million in fiscal year 1999.

The research program focuses primarily on peer-reviewed projects initiated by beginning investigators working in leading medical and scientific institutions across the country. The research program consists of three components: extramural grants, intramural epidemiology and surveillance research, and the intramural behavioral research center.

Prevention: Primary cancer prevention means taking the necessary precautions to prevent the occurrence of cancer in the first place. Prevention programs are designed to help adults and children make health-enhancing decisions and act on them.

The Society's programs focus primarily on:

Tobacco Control
Relationship between diet and physical activity and cancer
Promoting comprehensive school health education
Reducing the risk of skin cancer

Detection and Treatment Information and Education: The Society also seeks to provide the public and health care professionals with information, through the dissemination of its early detection guidelines and its detection education and advocacy programs, in order to ensure that all cancers are found at the earliest possible stage, when there is the greatest chance for successful treatment. This is accomplished through national conferences and workshops, audiovisual and print publications, the American Cancer Society web site and the National Call Center, as well as clinical awards, professorships, and scholarships.

Patient Services: To ease the impact of cancer on patients and their families, the American Cancer Society provides service and rehabilitation programs, as well as patient and family education and support programs.

ADVOCACY AND PUBLIC POLICY

Cancer is a political, as well as medical, social, psychological, and economic issue. Policy makers at all levels of government make decisions every day which impact the lives of more than 8 million cancer survivors, their families, and all potential cancer patients. The Society's advocacy initiative strives to influence public policies at all levels, with special emphasis on laws or regulations relating to:

The use, sale, distribution, marketing, and advertising of tobacco products, particularly to youth.

Improved access for all Americans, particularly poor and underserved Americans, to a range of health care services for the prevention, early detection, diagnosis, and treatment of cancer and care of cancer patients

Increased federal funding and incentives for private sponsorship of cancer research to prevent and cure cancer.

Advocacy for the rights of cancer survivors.

American Cancer Society advocacy efforts are successful because they rely on the combined voices of a community-based grassroots advocacy network of Society volunteers and other partners who have successfully influenced or supported laws and regulations enforcing the United States Food and Drug Administration's role in regulating tobacco products as "drug delivery devices, "enacting health insurance market reforms to ensure portability and continuity of health insurance coverage for individuals with a history of cancer or other serious illness, improving third-party coverage for cancer prevention and treatment clinical trials, including payment for patient care costs, and increasing federal funding for our National Cancer Program.

THE AMERICAN CANCER SOCIETY'S INCOME AND BUDGET

All American Cancer Society income results from donations made by the public, investment income, and government grants.

Of unrestricted contributions, 60% stays in the division where the funds are raised. These funds principally support local education and service programs, and to a lesser degree, administration and fundraising. Each division determines how funds will be allocated.

The funds coming to the National Society are earmarked for the nationwide research program; medical grants and fellowships; and national Society programs, administration, and fundraising.

Total support from the public during 1999 was just over $620 million.

Total expenditures for Division and National offices were represented as:

Research - 20%
Prevention - 20%
Detection/Treatment - 14%
Patient Services - 17%
Management & General - 7%
Fundraising - 22%

The American Cancer Society Research Program Activities Related to Complementary and Alternative Medicine

The American Cancer Society research program invests $100 million annually in which 85% is vested in grant funding for cancer research. The remaining 15% is distributed to Epidemiology and Surveillance, the Behavioral Research Center, and Operations.

The American Cancer Society Behavioral Research Center is one of only 2 centers in the world conducting research on human behavior as it affects the prevention, detection, and treatment of cancer. The center studies the needs and problems of 100,000 cancer survivors and their families; cigar smoking and perceptions of risk; and complementary therapies used by cancer patients and survivors. The Complementary and Alternative Medicine studies include:

- CAM use frequency of cancer survivors
- A survey of attitudes of oncology professionals towards patients' use of CAM
- The frequency and impact on quality of life of breast cancer survivors using CAM.

The ACS Epidemiology and Surveillance Department research includes:

- Cancer Prevention Studies (CPS) focusing on Causes and Risk Factors for Cancer
  - CPS I (1959) 1 million participants
  - CPS II (1992) 1.2 million participants

- Nutrition Study (1992, -97. –99) 184,000

- LifeLink (1998-2000) Collection of Blood Samples from 40,000 – 65,000 Nutrition Study Participants

The ACS Epidemiology and Surveillance CAM-related research includes:

- Current CPS and Nutrition
  - Multivitamin (folic acid) and Colorectal Cancer.
  - Vitamin C and E and Colorectal Cancer.

- Design phase of Cancer Prevention Study III
  - Interactions between environmental factors and human genetics.

With the Extramural grants program, grants are awarded mainly to research scholars meeting the following criteria: beginning investigators; and working in universities, medical schools, hospital and research institutions. The grant offers 4 years of funding up to $250,000. There are three types of training grants:

- Post Doctoral Research Fellows
- Clinical Research Training Grants
- Health Professional Training Grants.

Training grants are available offering unique programs of support for Oncology Nurses, Social Workers, and Primary Care Physicians focusing on cancer control.
Extramural grants funded CAM research includes:

- Use of pre-surgery hypnosis: effect on post-surgery recovery of breast cancer patients
- Use of hypericin from St. John's Wort to treat tumors of the pancreas
- Use of vitamins A and D for biologic modulation chemotherapy of advanced breast and prostate cancers
- Applications of acupuncture for pain management

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: Ruddon

RAYMOND W. RUDDON, M.D., Ph.D.
Biographical Sketch

Raymond W. Ruddon, M.D., Ph.D., is the Corporate Vice President of Science & Technology at Johnson & Johnson. Dr. Ruddon serves as the Chief Scientific Officer and heads the Company's Corporate Office of Science and Technology. He assumed this position on February 1, 2000.

Dr. Ruddon joined the Corporation in 1997 in the Corporate Office of Science & Technology as Corporate Director, Science & Technology. He also serves as Adjunct Professor of Pharmacology at the University of Medicine & Dentistry of New Jersey-Robert Wood Johnson Medical School.

Dr. Ruddon's career includes service on the faculty of the University of Michigan, where he was the Maurice H. Seevers Professor of Pharmacology and chaired the Department of Pharmacology from 1981-1990. He also served as the Associate Director for Basic Science Research of the University's Comprehensive Cancer Center. He received the Distinguished Faculty Achievement Award from the University of Michigan in 1988. In 1990, he became a member of the faculty of the University of Nebraska, where he was the Eppley Professor of Oncology and Director of the Eppley Cancer Center. From 1976 to 1981, he was Director of the Biological Markers Program at the National Cancer Institute.

Dr. Ruddon earned a bachelor of science in chemistry, Summa Cum Laude, from the University of Detroit. He has a Ph.D. in Pharmacology and an M.D. from the University of Michigan.

He has authored over a 100 scientific papers and five books. One of these, Cancer Biology, now in its third edition, is a widely used text in the field of oncology. He is also co-editor of the classic textbook in pharmacology, Goodman and Gillman's "The Pharmacological Basis of Therapeutics."

Dr. Ruddon currently serves on the External Advisory Committee of the Cancer Institute of New Jersey, and chairs the Oncology Interest Group and the Disease Prevention-Health Promotion Task Force at Johnson & Johnson. He is also an Associate Editor for Pharmacological Reviews.

PRESENTATION TO THE WHITE HOUSE COMMISSION
ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

We wish to thank the White House Commission on Complementary and Alternative Medicine for inviting Johnson & Johnson to address this very important area of public health concern. Meetings such as this will help focus public policy initiatives to assure that this important approach to the prevention and treatment of human disease reaches its full potential. We want to address the Commission concerning the issues involved in facilitating research in the area of complementary and alternative medicine. Johnson & Johnson has addressed this expanding need for research and product development in complementary and alternative medicine in a number of ways. We believe that complementary and alternative medical products provide a new approach to disease prevention that is different from traditional medicines that are aimed primarily at treatment rather than prevention.

At Johnson & Johnson, we have taken the following initiatives to address this focus:

1) In 1997, we established a Disease Prevention / Health Promotion Task Force consisting of members from a number of Johnson & Johnson operating companies. This Task Force had the following specific aims:

   a) To review the current literature regarding the role of disease prevention and health promotion strategies in the health focus areas of interest decided upon by the Task Force.

   b) To identify the key individuals, research groups, and organizations who are leaders in each field and arrange for opportunities to consult with them about the status of research and potential opportunities in their field.

   c) To identify and prioritize the best leads that provide an opportunity for Johnson & Johnson, based on market size, quality of supporting data, consumer self-selection, proprietary protection, and fit within Johnson & Johnson operating companies' existing business competencies and platforms.

   d) To assess the need for further research and the best way to accomplish it (e.g., Corporate Office of Science & Technology (COSAT) Seed Grants, Focused Giving Grants, etc.) in order to bring a potential product into development.

   e) To develop a way to monitor progress of research in the field of disease prevention/health promotion and to anticipate future product opportunities.

   The Task Force interviewed or visited on site leading investigators in the field of alternative medicine, including groups from Harvard Medical School, Johns Hopkins University, the University of Illinois-Chicago, Rutgers, the National Cancer Institute, and others. The Task Force also sponsored a symposium on antioxidants in October, 1998 that stimulated some collaborations between Johnson & Johnson and academic

investigators. Johnson & Johnson has used its Seed Grant Program to sponsor academic-industry research collaborations. One ongoing project is at the University of California-Berkeley for research on screening and mechanism of action studies for natural products with antioxidant activity.

2) Johnson & Johnson companies have also been active in the development of products for disease prevention such as BENECOL to reduce cholesterol levels and Splenda™, an artificial sweetener that diabetics can use.

We would like to offer the following suggestions on questions posed by the Commission.

1) What can be done to expand the current research environment and can the private sector stimulate complementary and alternative medicine research?

It is clear that solid basic research needs to be carried out to provide fundamental knowledge on the mechanism of action of complementary and alternative medicine agents and practices, on the ways to identify active components in complex mixtures of agents, and on preclinical pharmacology and toxicology. Robust clinical protocols must be employed to verify that complementary and alternative medicine agents and procedures truly produce the claimed clinical results. Private industry can help these efforts through research collaborations with academic and research institute groups. A number of such collaborations could be cited as precedent, including the Human Genome Project, the SNP consortium, and the recently funded Alliance for Cellular Signaling.

2) What types of incentives are needed to stimulate research on complementary and alternative medicine practices and interventions and, as a corollary, what are the obstacles/barriers and possible solutions?

In order to provide incentives to private industry, intellectual property issues must be resolved. Cooperative scientific consortiums, whether industry and academic or industry and governmental, raise intellectual property rights issues for all concerned. Even assuming significant consumer demand for a product or device, a reasonable business plan cannot be constructed to enter that market unless some marketing protection is available in return for substantiating the public health benefits of the product. Since some health-enhancing complementary and alternative medicine products or devices have small market potential, additional approaches such as legislative exclusivity remedies (e.g., orphan drugs) may be necessary in order to provide incentives to establish that these products or methods are safe, effective, and have desirable public health benefits. Finally, without established, transparent regulatory pathways, well-established and well-meaning corporations like Johnson & Johnson cannot fulfill the public health need for complementary and alternative medicine products.

3) How can complementary and alternative medicine and conventional research communities be more effectively integrated to stimulate and coordinate research?

In order to accomplish this, we would suggest the following:

a) Expanded communication between traditional and conventional medicine experts.

b) Acceptance of high quality complementary and alternative research for publication in conventional scientific journals.

c) Cooperative effort between private and Federal funding for research in this area.

d) A rigorous review process, involving both academic and industry scientists, to evaluate the scientific merit of research proposals.

e) Protected marketing rights for substantial, meaningful and costly research programs.

In conclusion, acknowledging that intellectual property rights must be respected, we wholeheartedly endorse the concept of coordinated research programs (between private and Federally funded and between traditional and conventional medical experts), in order to transform medical science into the healthcare that American consumers want and need.

Raymond W. Ruddon, M.D., Ph.D.
Corporate Vice President
Science & Technology
Johnson & Johnson

Frank C. Sciavolino, Director, Naturaceuticals

Joined Pfizer, Medicinal Discovery in December 1967
Ph.D. Organic Chemistry

Zithromax

- Proposed and led the Macrolide Antibiotic Discovery and Exploratory Development program that produced Pfizer Zithromax

Nagoya

- Worked as second-in-command with Dr. Hess to implement Discovery Operations in Japan

Celebrex/Valdecoxib

- Led the Central Research Team responsible for identifying and orchestrating the Pfizer/Searle Alliance on Cox-2 inhibitors

Naturaceuticals (since 1998)

- Worked closely with Dr. Bindra to implement the Naturaceuticals initiative at Pfizer
  Senior author of the Naturaceutical Business Plan
  Orchestrated the Phytopharm deal on anti-obesity candidate, P-57

ISSUES IN THE DEVELOPMENT OF HERBAL DRUGS

Frank C. Sciavolino, Pfizer Inc.

Chairman Gordon, Commissioners, Dr. Groft - Thank you for the invitation to present comments from the private sector to the White House Commission on Complementary and Alternative Medicine (CAM) Policy. The focus of my remarks today will be on one aspect of CAM, drugs from botanical or herbal sources. I will also comment on what we think is needed to stimulate CAM research.

Several years ago, we established a research and development initiative at Pfizer to assess whether botanical remedies represent a viable source of new prescription medications. We instituted this program because nature has traditionally been a fruitful harbinger of new medicines. By some accounts, nearly 60% of all pharmaceuticals have their origins in natural products. Morphine, cortisone, penicillin, paclitaxel and lovastatin are but a few examples of prototypical molecules occurring in nature that have led to medicines which are safe, effective and quality assured. The largely empirical screening methods that produced so many of the useful natural product-derived drugs discovered during the middle of the last century have now fallen into disfavor because they are highly labor intensive and increasingly unproductive.

More recently, R & D in the pharmaceutical industry has trended toward molecular design and the use of automated chemical technology to synthesize huge libraries of compounds that can be screened in ultra-high speed ways against novel biological targets. The revolutionary advances in molecular biology, genetics, robotics and information technology have propelled drug research in this new direction. However, the link between pharmacological activity against newly discovered molecular targets and clinical effectiveness in specific disease indications is not always clearly understood nor fully charted, despite the best efforts of our brightest minds. Consequently, clinically validated mechanisms and clinically effective new chemical entities remain highly prized milestones in drug research and development.

The road from an idea to a new medicine is long, treacherous and expensive. This journey from a newly observed biological concept in the laboratory to a medically available registered drug typically takes 10-15 years, at a cost which has been estimated by the Tufts University Center for the Study of Drug Development to be in the range of $400-500 MM. A key factor contributing to the time and expense metrics associated with drug development is attrition. Most drug candidates nominated by sponsors for clinical development fail to become registered pharmaceuticals. For every 5-6 drug candidates that reach Investigational New Drug (IND) status, industry experience indicates that only one becomes a product. The majority fail for a variety of technical reasons, most of which involve safety, efficacy and the benefit-to-risk judgment, but other less prominent parameters such

as bioavailability and stability may contribute to the decision to halt development. This is the reality of pharmaceutical R & D.

With passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994, a resurgence of interest in herbal medicines is beginning to take hold and natural products are again attracting attention as a potential source of new medicines. The seminal change that is kindling fresh interest in nature as a reservoir of useful medicines is the increasing recognition of herbal medicine by regulatory agencies. Enabling policy changes dealing with botanical drug regulation are beginning to be addressed. The draft Guidance for Industry on Botanical Drug Products, which the FDA published for comment in August of this year, appears to be a meaningful first step toward opening the door for sponsors to conduct randomized, controlled clinical trials to confirm the efficacy of botanical mixtures in patients. This impending change could shift the focus of natural products research, from what was largely a laboratory effort seeking lead structures for chemical modification, to a clinically driven initiative with product orientation. Final guidance from the FDA on the registration of botanical drugs would be a landmark event that could stimulate investment in this area by interested sponsors.

In our natural medicines initiative at Pfizer, we have coined the term *naturaceutical* to designate prescription drugs of plant or natural origin that have been rigorously characterized for safety, efficacy and quality. The development paradigm for a *naturaceutical* differs from the established pharmaceutical strategy in that it seeks to rapidly address clinical efficacy upfront with candidates having anectodal or folklore histories of use in humans. Opportunities with proven clinical efficacy then become the subjects of more costly investments for full-scale registration of a safe and effective product.

If botanical medicines are to be developed as true pharmaceuticals, *naturaceuticals*, their development must be conducted to the highest standards of safety, efficacy and quality; there can be no compromise on the science or medicine of *naturaceuticals*. We see the level of investment that would be required for the NDA registration of a *naturaceutical* to be comparable to a pharmaceutical. Therefore, a key issue in developing botanical medicines is the need for an incentive mechanism to provide for a return on investment. One possibility is a Waxman-Hatch-type data or marketing exclusivity period that would allow the sponsoring investor to fully develop the medical and commercial potential of natural medicines.

Nature has been an unparalleled source of unique chemical structures with extraordinarily potent pharmacological activity. We urge the Commission to recommend enabling policy that will provide incentive for the private sector to invest more substantially in the research and development of natural medicines.

Mark Blumenthal
Biography

Mark Blumenthal is the Founder and Executive Director of the American Botanical Council (ABC), an independent, non-profit group dedicated to disseminating accurate, reliable, and responsible information on herbs and medicinal plants. He is the Editor/Publisher of *HerbalGram*, an international peer-reviewed quarterly journal whose contents reflect the educational goals of ABC. He is also Adjunct Associate Professor of Medicinal Chemistry at the University of Texas at Austin, College of Pharmacy, teaching a graduate level course on herbal products in today's pharmacy.

Mr. Blumenthal is senior editor of a book of English translations of *The Complete German Commission E Monographs—Therapeutic Guide to Herbal Medicines.* This publication has been ranked second in the top medical books published in 1998. It is a rational system for evaluating the safety and efficacy of herbal medicines.

He has a comprehensive background in the area of herbs and medicinal plants with more than 25 years of diverse experience as an herbal advocate, consultant, educator, researcher, writer and advisor. Since 1988, he has been an educator and researcher in his role as executive director of ABC.

Mr. Blumenthal also has extensive experience in the field of non-profit work. In 1975 he was a founding board member of the Herb Trade Association (HTA) and was elected President of the HTA in 1977. In 1983 he was a founding board member of the American Herbal Products Association (AHPA). That same year he helped co-found the Herb Research Foundation (HRF) and was elected Vice President of HRF. In 1988 he founded the American Botanical Council, of which he is Executive Director and President of the Board of Trustees. Through his organizational affiliations Mr. Blumenthal has been a leader in the herb movement in such areas as quality control of herbal products, ethics in labeling and marketing, legal and regulatory issues, and research and education.

In 1977 Mr. Blumenthal began publication of *Herb News,* a quarterly herb publication designed for the herb trade, allied industries, and health professionals, as a publication of HTA. In 1983 he founded *HerbalGram*, a quarterly newsletter for AHPA and HRF. With the formation of ABC in 1988, *HerbalGram* became the journal of ABC and the HRF.

His articles on herbs and medicinal plants have appeared in numerous magazines, including (in addition to *HerbalGram) Let's Live, East-West Journal (*now called *Natural Health), Herbs, Longevity, Vegetarian Times, Healthy Living,* and several medical and scientific journals including *Medical Nutrition, Allergy Research, Pharmacy in History* and the new *American Journal of Natural Medicine*. For eleven years he wrote a bimonthly column for *Health Foods Business*, and for the last nine years he has written a monthly article for *Whole Foods*, a leading trade magazine for the natural foods and dietary supplement industries. He has contributed chapters on herbs to Reader's Digests *Family Guide to Natural Medicine* (1993), *Alternative Medicine: The Definitive Guide (*Future Medicine Publishing, 1994), and the *Poisoning and Toxicology Compendium (Lexi-comp,*1998) for which he wrote the chapter on Herb Safety. He edited and wrote the foreword to the best-selling *The Complete Medicinal Herbal* by Penelope Ody (Dorling-Kindersley, 1993), and has edited *Miracle Cures* by Jean

Caper, *Herbs for Your Health* by Steven Foster, and *The Guide to American Folk Medicine* (Reader's Digest, 1999). He recently served as a consultant to National Geographic's new book *The Healing Herbs.*

He also serves or has served on the editorial boards of the following publications: *Vegetarian Times, Natural Health, Let's Live, Protocol Journal of Botanical Medicine, Interweave Press,* and *Nutrition Science News.* He is an advisor to the Center for Alternative Medicine at the University of Texas at Houston, School of Public Health, and a member of the steering committee of the American Herbal Pharmacopeia. Also, he is on the Board of Advisors for the Center for Integrative Therapies in Pharmaceutical Care for the Massachusetts College of Pharmacy. He is currently a reviewer of herbal monographs for both the American Herbal Pharmacopeia and the United States Pharmacopeia.

His consultancies include participation in the preparation of the final draft of the World Health Organization's "Guidelines for the Assessment of Herbal Medicines" (1991). Mr. Blumenthal has also participated as a reviewer of research grant proposals made to the Office of Alternative Medicine at the National Institute of Health. He testified before the Presidential Commission on Dietary Supplement Labels, presenting an overview of the Regulation of Botanicals and Phytomedicines in Europe, to assist the Commission in its goal of providing truthful, non-misleading information to consumers making informed health care choices.

Mr. Blumenthal is instrumental in creating one of the first series of homestudy courses in Phytomedicines for pharmacists. These homestudy courses are produced in conjunction with the Texas Pharmacy Foundation, an approved provider of continuing pharmaceutical education.

He has also initiated the Ginseng Evaluation Program, a survey testing for identity and quality of over 500 commercial ginseng products sold in North America.

Mr. Blumenthal is a popular speaker on herbal issues and has made hundreds of presentations to universities, professional and trade associations, and numerous consumer, pharmacy, nursing, medical, regulatory, agricultural, non-profit industry groups. He is a popular guest on radio and television talk shows and has appeared on more than 400 programs in the past ten years. He is also a major source of information for journalists, editors, and freelance writers, and is quoted extensively in articles for the trade and popular press.

To schedule an interview or presentation for Mr. Blumenthal contact Beverley Ferguson at 512-926-4900 ext.121. For further information on the American Botanical Council and *HerbalGram*, call 512-926-4900, write to the American Botanical Council, PO Box 144345, Austin, TX 78714-4345, or visit our webpage: www.herbalgram.org

Revision Date: 09/28/00

MISSION: The American Botanical Council is the leading nonprofit educational and research organization disseminating science-based information that promotes the safe and effective use of medicinal plants and phytomedicines.

American Botanical Council is a nonprofit 501c3 tax-exempt research and education organization founded in Austin, Texas in 1988.

ABC's goals are:

- To create a superior quality herbal education research center
- To provide excellence in herbal education
- To continue as an internationally recognized authority on herbal medicine
- To create and meet demand for herbal information
- To develop strategic relationships with academic centers, government agencies, consumer and trade organizations.

ABC remains committed to previous goals through current and ongoing initiatives.

These initiatives include:

PUBLICATIONS

HerbalGram

HerbalGram is a quarterly journal/magazine that is science-based and peer reviewed. Each issue deals with recent research, regulatory issues, market updates, plus feature articles and monographs dealing with herbs and phytomedicines. *HerbalGram* has been nominated twice as best magazine of the year in the Alternative Magazine awards by the *Utne Reader* – in two categories: Science and Environment (1999) and Health and Lifestyle (1997). ABC publishes *HerbalGram* for the members of the Herb Research Foundation.

HerbClip™ Educational Mailing Service

HerbClip™ is sent twice a month to a network of research scientists, academicians, government officials, and industry leaders in the areas of medicinal plants and the botanical and pharmaceutical sciences. Through this service, ABC provides valuable information about compelling issues affecting the research, marketing and responsible use of medicinal plants. HerbClip™ summarizes articles drawn from a wide variety of newsletters, scientific journals, government documents, mainstream media, and special reports. Each clipping contains an executive summary of an article with insights, perspectives, and linkages to other articles and issues, plus a copy of the original article. ABC also makes these summaries available on a searchable CD-ROM database.

German Commission E Monographs

The German Commission E is the expert committee of the German counterpart to the U.S. FDA that evaluated safety and efficacy of about 300 herbs, based on critical reviews of the available medical and scientific literature. The results were monographs published by the German government to be used as package inserts for guiding consumers and health professionals on the appropriate therapeutic parameters for the herbs, sold as drugs in German pharmacies. ABC translated and edited these monographs, publishing them as *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines.* This 685-page book was published in 1998 and was warmly received by both consumers and healthcare professionals. It is the first "alternative medicine" title to be ranked as one of the top three books published in the medical and allied healthcare professions (*Doody's Medical Book Review Journal*,1998), receiving a ranking of #2 out of a total of 3500 books published that year in the area of medicine and allied health sciences.

A sequel publication, *Herbal Medicine: The Expanded Commission E Monographs,* was published in 2000 to provide more scientific information that documents the efficacy of the herbs most commonly used in the U.S. today. The 107 monographs feature an expanded overview of the herb, description, chemistry and pharmacology, uses, contraindications, side effects, use during pregnancy and lactation, interactions with other drugs, dosage and administration, references, additional resources, footnotes specifying which sections are from the Commission E, and color photographs of each herb.

Health Professional Continuing Education

ABC and the Texas Medical Association are working together to produce the *Healthcare Professional's Guide to Commonly Used Herbs*, an introduction to the clinical evidence that supports the safe and efficacious use of 30 of the most common herbs on U.S. the market today. This book will be both a useful reference tool plus an accredited continuing education module for four major disciplines: medical, nursing, pharmacy, and dietetics. The project will be completed in the spring of 2001.

Herb-Med-Web™

Herb-Med-Web™ is an extensive program providing databases and herbal medicine educational and research content to health-based and e-commerce Internet web sites. As web sites proliferate, a primary distinguishing feature of the top sites is the quality and scientific nature of the education content available to the user. The information provided by ABC through Herb-Med-Web™ has been peer reviewed and examined for accuracy and validity, and includes information and articles from: *HerbalGram*, ABC's Third Party Literature and Continuing Education materials, HerbClip summaries, and an herbal image library of four-color photos of medicinal plants. Additional materials include *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines* (in interactive format) and *Herbal Medicine: The Expanded Commission E Monographs.*

Special Educational Projects

In keeping with ABC's vision to provide excellence in herbal education, ABC is developing the *Saw Palmetto Education Project* and other projects that focus on specific herbs and/or herbal categories (hops and medicinal mushrooms are in the planning stages). The *Saw Palmetto Education Project* will result in the 16th booklet in the Botanical Booklet Series

and a literature review. This will provide a solid scientific basis that describes the medicinal benefits of saw palmetto.

Ongoing Activities

As a nonprofit organization, ABC maintains various ongoing educational and research projects of importance to the herb community and the general public:

Assistance to media – ABC is one of the primary sources of science-based herbal information to the national and international media. On a daily basis ABC receives calls from members of the press, including freelance writers, asking for information and interviews on various subjects related to herbs.

Ginseng Evaluation Program – Concerned about the quality of various commercial ginseng products, ABC and two university laboratories have tested close to 500 ginseng products and developed revised analytical methodologies to detect marker compounds in various types of ginseng. The testing method is being adopted by the AOAC (Association of Official Analytical Chemists) as the official method for testing ginseng products. The report on the project and its results will be published early 2001.

Third Party Literature – ABC continues to develop and distribute third party literature as provided for in the Dietary Supplement Health and Education Act of 1994 (DSHEA). The most recent addition is the 8-page booklet, *Aloe*, in the Botanical Booklet Series. This series covers leading herbs and contains well-referenced, peer-reviewed profiles for the benefit of consumers, healthcare professionals, journalists, researchers, etc. ABC offers additional science-based, peer-reviewed educational materials for public use.

Rainforest trips – ABC continues to sponsor, in conjunction with the Texas Pharmacy Foundation and International Expeditions, ethnobotanical tours that offer continuing education credit for pharmacists and physicians courses set in the rainforests of Africa, Belize, Costa Rica, and Peru.

Demonstration herb gardens – Over the course of 1999 ABC designed and built 15 herb gardens at its new 2.5 acre headquarters, the historic Case Mill Homestead. These gardens are open to the public for educational tours.

Council for Responsible Nutrition
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Annette Dickinson, Ph.D.

Annette Dickinson is Vice President for Scientific and Regulatory Affairs for the Council for Responsible Nutrition (CRN), a trade association representing more than 100 manufacturers of dietary supplement products. A recognized expert and author, Dr. Dickinson has 27 years experience on behalf of the dietary supplement industry. She was appointed by President Clinton to the Commission on Dietary Supplement Labels and is a frequent witness before the U.S. Congress and at public meetings convened by the U.S. Food and Drug Administration. Her expertise includes the legal and technical aspects of marketing dietary supplements, including provisions relating to labeling, advertising, and good manufacturing practices. She is responsible for analyzing and responding to new regulatory or legislative proposals as well as evaluating new scientific research relating to the safety and benefits of dietary supplements. Dr. Dickinson is a recognized leader in the development of industry and government policies based upon current science.

A frequent contributor to national and international meetings and technical symposia, Dr. Dickinson is often called upon by the print and electronic media to represent the industry view on issues affecting dietary supplements. She earned her Ph.D. in nutritional sciences and her M.S. in food sciences from the University of Maryland.

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PRIVATE SECTOR ROLE IN STIMULATING RESEARCH ON COMPLEMENTARY AND ALTERNATIVE MEDICINE: PERSPECTIVES FROM THE DIETARY SUPPLEMENT INDUSTRY

Statement of Annette Dickinson, Ph.D.
Vice President, Scientific and Regulatory Affairs
Council for Responsible Nutrition
before the
White House Commission
on Complementary and Alternative Medicine Policy
October 5-6, 2000

The Council for Responsible Nutrition (CRN) is a trade association representing more than 110 companies in the dietary supplement industry. Our membership includes companies that supply the bulk ingredients used in dietary supplements as well as the national brands and store brands of finished products available to consumers through all types of retail outlets including supermarkets, drug stores, discount chains, health food stores, direct sales, mail order, and the internet. Our member companies provide all types of dietary supplements defined in the Dietary Supplement Health and Education Act, including vitamins, minerals, amino acids, botanical products, and specialty supplements.

CRN was established in 1973 and prides itself on developing policies and programs for dietary supplements based on sound science. CRN's science staff currently includes four individuals with expertise in nutrition, toxicology, natural products chemistry, and genetics. We are in the process of creating a new executive position charged with the specific responsibility to identify opportunities for research partnerships with government and academia, and to help industry members take advantage of such opportunities to maximize their own contributions to the body of current scientific evidence. As part of this effort, we will also seek to be actively involved in the development of agency research agendas and the establishment of priorities based on optimizing impacts on public health. Dr. Cathy Fornous of our staff will be taking on these responsibilities.

We are pleased to be able to offer some suggestions on the role of the private sector in stimulating research into complementary and alternative medicine, from the perspective of the dietary supplement industry. Our responses will be tied to the specific questions posed in the letter of invitation to participate in this forum.

How can the private sector stimulate CAM research?

- Industry should be encouraged to submit its studies to peer-reviewed journals for publication.
- Industry should provide data from its unpublished studies to assist in selection of therapies for further study and contribute to the study design. For example, these data may help to narrow dosage range for phase I studies and alert investigators to potential side effects.
- Industry could provide vitamins, minerals, botanicals or other dietary supplement ingredients for clinical studies and assist in the formulation of appropriate placebos.
- Industry could co-sponsor symposia or conferences to provide networking opportunities between researchers and clinicians. CRN is currently planning one such conference for November 2001, in cooperation with the American Society for Pharmacognosy.

What are the obstacles/barriers and possible solutions to accomplish this goal, e.g., incentives?

- Convene meetings with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by industry.
- Generate a clinical trials guidance document outlining the standard components and proper design of study protocols. CRN's Dr. John Cardellina is currently working on this type of document, and will be seeking partners to contribute to its content and enhance its value. Resources that will be used in preparing the guidance document include existing NIH guidelines and information being compiled by the International Conference on Harmonization (ICH).
- A mechanism is needed for industry to share study results that may involve proprietary information. The (soon to be launched) ODS CARDS database might serve as a repository for a listing of unpublished studies, identifying the lead investigator or contact person.
- Standardized products that are commercially available should be used in clinical trials, when possible. If special formulations are used that the consumer cannot buy off the shelf, then the study results don't translate directly to the general population.
- Industry needs to form partnerships with clinicians or academia (depending on the type of study). Various mechanisms are needed to bring together these disparate communities. CRN is in the process of establishing a Dietary Supplement Information Center, in cooperation with a major academic institution, and this Center could play a role. Also, a special website could be established to facilitate communications regarding ongoing research needs and opportunities.

How can private sector CAM research be better coordinated with federally supported CAM research?

- Industry representatives need to participate on advisory councils, particularly at NIH. A visible representative can address the concerns of clinicians and government officials and serve as a bridge between the public and private sectors.
- A primer on funding mechanisms (for research and conferences) within government agencies that apply to industry should be compiled, to explain Cooperative Research and Development Agreements (CRADAs), small business grants, investigator-initiated (R01) grants, and contracts.
- Ongoing research and potential funding opportunities need to be more visible and private studies need to be added to government databases. For example, CRISP is an excellent tool to seek out information on federally funded studies. However, it needs to be updated more expeditiously and expanded to include clinical trials that are not federally funded. The ODS CARDS database will target dietary supplement research. The project should receive sufficient funding to include nongovernment funded research and be updated weekly. NCCAM serves as good model for its open visible process in determining future research projects. Concept ideas are discussed at its advisory council meetings, approved concepts are posted on the website and within a few months a request for applications (RFA) is issued and also posted on the website. A document explaining how each research agency determines its research agenda would be helpful.
- Consensus conferences should be held to highlight CAM therapies and remaining research gaps. For example, a conference on the safety and value of ephedra for weight loss could make a valuable contribution in this area of controversy. A conference on St. John's wort should be held after completion of the NCCAM-NIMH funded study centered at Duke University.

Clinical Trial Database

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Cramer

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ELAINE H. CRAMER, MD, MPH

Division of Emergency and Environmental Health Services
Centers for Disease Control and Prevention
4770 Buford Hwy, Mailstop F-16, Atlanta, GA 30341
Phone: 770-488-7325; E-mail: ecramer@cdc.gov,

EDUCATION

1998 to 1999	**Master's in Public Health (MPH),** Quantitative Methods Harvard School of Public Health Boston, Massachusetts
1986 to 1990	**Doctor of Medicine, (MD)** Faculty of Medicine University of Manitoba, Canada
1983 to 1986	**Chemistry, Faculty of Science** University of Winnipeg Winnipeg, Canada

POSTDOCTORAL TRAINING

1996 to 1998	**Epidemic Intelligence Service Officer** Division of Prevention Research Epidemiology Program Office Centers for Disease Control and Prevention
1990 to 1992	**Family Practice Medicine Postgraduate Training Program (CCFP)** Faculty of Medicine University of British Columbia, Canada

LICENSURE and CERTIFICATION

1998	**Diplomat, American Board of Family Practice**
1997	**Licentiate, Composite State Board of Medical Examiners** Georgia, US
1993	**Advanced Cardiac Life Support Update** Canadian Medical Board of Examiners
1992	**Specialty Certification in Family Medicine (CCFP)** Registered Member of the College of Family Physicians of Canada
1991 to present	**Registered Member of College of Physicians & Surgeons** British Columbia, Canada
1991	**Licentiate, Medical Council of Canada**
1990	**United States Federation Licensing Examination (FLEX)**
1990	**Advanced Cardiac Life Support, Advanced Trauma Life Support**

PROFESSIONAL EXPERIENCE

1999-present	**Medical Epidemiologist** Division of Emergency and Environmental Health Services National Center for Environmental Health Centers for Disease Control and Prevention Atlanta, Georgia
1996 to 1999	**Medical Epidemiologist** Division of Prevention Research and Analytic Methods Epidemiology Program Office Centers for Disease Control and Prevention Atlanta, Georgia
1997 to present	**Clinical Instructor** Department of Family and Preventive Medicine Faculty of Medicine Emory University Atlanta, Georgia
1991 to1996	**Staff Family Physician** Vancouver General Hospital Burnaby General Hospital Vancouver, British Columbia, Canada
1991 to 1996	**Locum Family Physician/Rural and Emergency Family Medicine** Vancouver, British Columbia Queen Charlotte Islands, British Columbia,
1991 to 1996	**Sexual Assault Consultant Physician** Greater Vancouver Sexual Assault Service British Columbia, Canada
1993 to 1995	**Ship Emergency Physician** Holland America Line, Westours Inc. 300 Elliot Avenue, Seattle,Washington,
1993 to Present	**Court Qualified Medical Expert** Supreme Court of Canada Expert in Sexual Assault, Injury to Human Body British Columbia, Canada
1988	**Basic Training Canadian Military** 735 Communications Regiment Mobile Command, Department of National Defense Manitoba, Canada 1992 Emergency Medicine

AWARDS AND HONORS

2000 **James H. Nakano Citation**
National Center for Infectious Diseases, CDC
For outstanding scientific paper published in 1999
A Multistate, Foodborne Outbreak of Hepatitis A
New England Journal of Medicine 1999; 340:595-602

1999 **Charles C. Shepard Science Award Candidate**
For excellence in science
A Multistate, Foodborne Outbreak of Hepatitis A
New England Journal of Medicine 1999; 340:595-602

1998 **Secretary's Award for Distinguished Service**
For outstanding public health intervention during multi-state outbreak of hepatitis A involving frozen strawberries distributed through USDA school lunch programs
Donna E Shalala, US Department of Health and Human Services

1998 **Harvard Tuition Entrance Scholarship**
Harvard School of Public Health
Boston, MA

1997 **US Public Health Service Honor Award**
CDC Olympic Public Health Practice Team
For exceptional public health service at the 1996 Centennial Olympic Games
Public Health Practice Program Office
Centers for Disease Control and Prevention, US Dept. Human Services

COMPLEMENATRY AND ALTERNATIVE MEDICINE RESEARCH ACTIVITIES

1999 **National Alternative Medicine Ambulatory Care Survey: A survey of complementary and alternative care providers in Four States.**

- Principal investigator of naturopathic clinical encounters and preventive services provided by alternative providers.
- Collaborative project with Group Health Cooperative of Puget Sound, Harvard Center for Alternative Medicine Research funded by Agency for Health Care Policy and Research

1999

An Evaluation of Naturopathic Treatment of Menopausal Symptoms

- Principal Investigator
- Community Health Centers of King County
- Sponsored by National Center for Alternative Medicine Research, NIH.

ANALYTIC FIELD INVESTIGATIONS

1999- present	**Epidemiologic Field Investigations of Cruise Ship Outbreaks** Vessel Sanitation Program Division of Emergency and Environmental Health Services National Center for Environmental Health
1997-1999	**Epidemiologic Field Investigations of Complementary and Alternative Medicine** Pilot Studies and Protocol Development Consultancy to the Office of Alternative Medicine National Institutes of Health
1997	**Project Development for the Enhancement of Tuberculosis Control Activities, Infectious Disease Surveillance Activities, and Water Sanitation** United States Agency for International Development and Division of International Health, CDC Almaty, Kazakhstan/Ashgabat, Turkmenistan
1997	**An Outbreak of School-Associated Hepatitis A in Maine** Maine State Bureau of Health Augusta, Maine
1996	**The Impact of Los Angeles County Department of Health Services Restructuring on Acute Communicable Disease Reporting** Los Angeles, California
1996	**CDC/Atlanta Committee for the Olympic Games Medical Surveillance** 1996 Summer Olympic Games Atlanta, Georgia

PROFESSIONAL PRESENTATIONS

March 1999	**Key Note Speaker: An Overview of Alternative Medicine** Women's Health Women's Lives Sponsored by Senator Byron Dorgen and US Dept. Health and Human Services Bismarck, North Dakota
June 1998	**An Overview of Alternative Medicine** Clinical Grand Rounds Rome, Georgia
December 1997	**Alternative Medicine: Relevance to Public Health** Dr. David Satcher and Senior Executive Staff Director and Senior Executives Centers for Disease Control and Prevention
November 1997	**An Overview of Alternative Medicine** Clinical Grand Rounds Northside Hospital Atlanta, GA
August 1997	**Epidemiology Applied to Alternative Medicine**

	International Assembly for the Establishment of a Research Agenda for Traditional Medicine Office of Alternative Medicine, National Institutes of Health Rockville, Maryland
May 1997	**A School-Associated Outbreak of Hepatitis A in Maine** Hepatitis Epidemiology Section Rounds Division of Viral and Rickettsial Diseases National Center for Infectious Diseases Centers for Disease Control, Atlanta, Georgia
February 1997	**The Impact of Restructuring of the Los Angeles County Dept. Of Health Services on Acute Communicable Disease Surveillance** Division of Prevention Research and Analytic Methods Epidemiology Program Office, Centers for Disease Control, Atlanta, Georgia
November 1996	**Heat-related Illness at the 1996 Summer Olympic Games** American Public Health Association Conference New York City, NY
October 1996	**An Evaluation of the 1996 Summer Olympic Games Health Information Surveillance System** Epidemiology Grand Rounds Centers for Disease Control and Prevention, Atlanta, Georgia

SCIENTIFIC CONFERENCES & CONTINUING MEDICAL EDUCATION

April 1997	**Research Methods in Epidemiology** Koger Center, CDC
March 1997	**Alternative Medicine: Implications for Clinical Practice and State of the Science Symposium** Harvard Medical School & Beth Israel Deaconess Med. Center Boston, MA
February 1997	**SAS Fundamentals: A Programming Approach** Centers for Disease Control and Prevention Atlanta, GA January 1997
January 1997	**Symposium on Statistical Methods** **Statistical Bases for Public Health Decision Making** CDC and ATSDR Symposium Atlanta, GA
October 1996	**Epidemic Intelligence Service Fall Surveillance Course** Centers for Disease Control and Prevention Atlanta, GA
July 1996	**Epidemic Intelligence Service Summer Course** Centers for Disease Control and Prevention Atlanta, GA

BIBLIOGRAPHY:

Original Articles:

Cramer, EH, Jones P, Keenan NL, Thompson BL. Is Naturopathy as Effective as Conventional Therapy for Treatment of Menopause Symptoms? 1999 Submitted to *Menopause*

Cherkin D, Eisenberg D, Deyo R., Cramer EH, Hart G, et al. Demographic, Training and Practice Characteristics of Licenced Acupuncturists, Chiropractors, Massage Therapists and Naturopaths in Four States. 2000 For Submission.

Hutin YJ, Pool V, Cramer EH, et al. A multistate, foodborne outbreak of hepatitis A. National Hepatitis A Investigation Team. N Engl J Med. 1999 Feb 25;340(8):595-602.

Wetterhall SF; Coulombier DM; Herndon JM; Zaza S; Cantwell JD Medical care delivery at the 1996 Olympic Games. Centers for Disease Control and Prevention Olympics Surveillance Unit. JAMA. 1998 May 13;279(18):1463-8.

Prevention and management of heat-related illness among spectators and staff during the Olympic Games--Atlanta, July 6-23, 1996. MMWR Morb Mortal Wkly Rep. 1996 Jul 26;45(29):631-3.

Conference Papers:

Cramer EH, Coloumbier D, Herndon J, Lyerla R, Pappaiouannou M, Schluter W, Wetterhall S, Zaza S. Heat-related Illness at the 1996 Summer Olympic Games. Annual American Public Health Association Conference. November 1996, New York City, NY

Scientific Reports

Cramer EH. Trip Report: An Outbreak of Gastroenteritis aboard the Disney Magic Cruise Ship, Associated with Frozen Shrimp. June 2000

Cramer EH. Trip Report : An Evaluation of Integrative Therapy for Breast Cancer. Pilot Studies and Protocol Development of Epidemiologic Field Investigations of Complementary and Alternative Medicine. Sponsored by The Office of Alternative Medicine, National Institutes of Health

Cramer EH. Trip Report : An Evaluation of Alternative Medicine for the Treatment of Menopausal Symptoms. Pilot Study and Protocol Development of Epidemiologic Field Investigations of Complementary and Alternative Medicine. Sponsored by The Office of Alternative Medicine, National Institutes of Health

Cramer EH, Lloyd EE, Chao SM, Run G, Tormey M, Mascola L, Zaza S. Trip Report: The Impact of Restructuring of the Los Angeles County Dept. Of Health Services on Acute Communicable Disease Surveillance. Sponsored by the Los Angeles County Dept of Health Services.

Cramer EH. Project Development for the Enhancement of Tuberculosis Control Activities, Infectious Disease Surveillance Activities, and Water Sanitation in Almaty, Kazakhstan and Ashgabat, Turkmenistan.. Final Report to United States Agency for International Development and Division of International Health, CDC

CDC Field Investigations of Complementary and Alternative Medicine: A Pilot Study

Authors: Elaine H. Cramer, M.D., M.P.H.[1]
Paul Jones, M.S.[2]
Nora L. Keenan, PhD.[3]
Betsy L. Thompson, M.D., M.S.P.H.[2]

From 1997 through 1999 the National Institutes of Health collaborated with the Centers for Disease Control and Prevention (CDC) to evaluate the feasibility of and to develop protocols for conducting preliminary epidemiologic investigations of popular complementary and alternative (CAM) therapies in the clinical setting. The objectives of the investigations were to evaluate the strengths and limitations associated with a field-based research approach and to identify CAM modalities and systems of care that show potential therapeutic benefit to patients, suitable for more extensive scientific evaluation.

One of the investigations conducted by CDC was a retrospective cohort study to compare naturopathic therapy at the naturopathy clinic of Community Health Centers of King County (CHCKC), Washington with a stratified random sample of patients treated with conventional medical therapy for selected menopausal symptoms at the six conventional clinics of CHCKC. We compared baseline characteristics and medication use by patients and were able to ascertain the type and quantity of medications prescribed for each study patient. As well, in an effort to compare menopausal symptom changes, we attempted to address the substantial differences between the users of naturopathic and conventional treatments by regression analysis.

Patients receiving naturopathic treatment differed at baseline from those receiving conventional treatment. They had higher incomes, were less frequently smokers, were more likely to participate in a regular exercise program, and reported higher frequencies of decreased energy, insomnia, and hot flashes. The majority of patients receiving naturopathy were treated with black cohosh and were dispensed a single or multiple vitamin supplement. The majority of patients receiving conventional treatment received conjugated or esterified estrogens. Of patients who were treated with naturopathy, one third received concurrent HRT. Patients who attended conventional clinics were more likely to receive antidepressant and antihypertensive therapy.

By these methods, we were relatively easily able to characterize the differences in baseline characteristics and medication use by patients treated with two distinct systems of care for

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[2]Epidemiology Program Office, Centers for Disease Control and Prevention, Atlanta, GA

[3]National Center for Chronic Disease Prevention and Health Promotions, Centers for Disease Control and Prevention, Atlanta, GA

menopausal symptoms in the clinical setting. When adjusted for age, weight, smoking status, regular exercise program, monthly income, and antihypertensive therapy, by repeated measures analysis, preliminary data showed patients treated with naturopathy were about seven times more likely than conventionally treated patients to report improvement for insomnia and decreased energy and about as frequently as patients who were treated conventionally to report improvement for anxiety, hot flashes, menstrual changes, and vaginal dryness.

Biographical sketch for Leanna J. Standish, ND, PhD
September 29, 2000

Leanna J. Standish, ND, PhD, LAc, Director of the Bastyr University Research Institute and AIDS Research Center Principal Investigator. She is a licensed naturopathic physician with a 25-year career as a research scientist in experimental neuroscience with numerous publications. Her clinical practice specializes in cancer, AIDS, Hepatitis C and neurological diseases. Trained at the Downstate Medical Center in New York and the University of Massachusetts, Dr. Standish received her doctoral degree in 1978. She completed a postdoctoral fellowship in psychopharmacology at the Yerkes Primate Center Research Center at Emory University in 1979-1980. Prior to her work in natural medicine research and naturopathic medical practice, she served for two years as Visiting Scientist and Senior Fellow at the University of Washington's Department of Physiology and Biophysics. Dr. Standish also directs the Breast Cancer Research Program at Bastyr University and was recently appointed as a member of the Advisory Council for NIH's National Center for Complementary and Alternative Medicine, as well as on the NCI Cancer Advisory Panel for Complementary and Alternative Medicine. Currently she is principal investigator on several NIH/NCCAM funded research projects in the areas of HIV/AIDS and basic neurophysiological research on mind/body interaction.

White House Commission on CAM Policy

October 5, 2000

Leanna J. Standish, N.D., Ph.D., L.Ac
Director of Research
Bastyr University
14500 Juanita Drive Northeast
Kenmore, WA 98028-4966

What are the obstacles
to scientific research on CAM?

1

Until 1998 there were three major obstacles:

- Lack of federal funding
- Lack of fair peer review at the NIH
- Lack of CAM experts trained in research

2

With the establishment of NCCAM came both funding and a review committee with CAM expertise.

NCCAM Strategic Plan and its implementation under Dr. Straus are excellent.

3

Remaining obstacles:

1. Need for FDA procedures and policies
2. Need for research infrastructure and training at CAM institutions that have CAM expertise
3. IRBs at non CAM institutions that lack understanding of CAM research issues

4

1. Lack of FDA policies and procedures for the efficient oversight of CAM substances

- Example: homeopathic IGF-1 in HIV-related wasting
- Example: Ultrahigh dilutional IL-2 in HIV disease

5

Solution:

Request FDA to establish CAM Task Force comprised of both CAM experts and experts in conventional biomedicine to develop policies and procedures for dealing with CAM substances that have a long history of safe use or are UHD CAM substances.

6

White House Commission on CAM Policy

Leanna J. Standish, N.D., Ph.D., L.Ac

2. Need for research infrastructural support at CAM academic centers

Only seven CAM institutions (9%) received funding from OAM/NCCAM in 1992-99 compared to 76 conventional institutions (91%).

Potential risk of lack of CAM research by CAM experts is potential loss of the best ideas, most significant concepts, and more important therapies.

7

Possible Solutions:

NCCAM support for planning grants to CAM academic centers to develop research agendas and strategic plans for implementation.

RFA specifically for CAM institutions to develop research infrastructure (equipment, laboratory construction, training and small research grants).

8

3. Lack of CAM training among members of IRBs at conventional medical schools

E.g. Hepatitis C research on combination naturopathic medical protocol

9

Potential Solutions:

Allocate funds to NCCAM and OHRP to provide training to IRBs at institutions adjacent to and/or collaborating with CAM institutions active in research.

Require a CAM expert to be on IRBs that review CAM clinical proposals.

10

Summary recommendations:

1. Request FDA to establish CAM Task Force comprised of both CAM experts and experts in conventional biomedicine to develop policies and procedures for dealing with CAM substances with a long history of safe use as well as UHD CAM substances.
2. NCCAM support for planning grants to CAM academic centers to develop research agendas, clinical trial consortiums, and strategic plans for implementation.
3. RFA specifically for CAM institutions to develop research infrastructure (equipment, laboratory construction, training and small research grants)
4. Allocate funds to NCCAM to provide training to IRBs at institutions adjacent to and/or collaborating with CAM institutions that are active in research, or those that are research-ready.

11

LYDIA S. SEGAL, M.D.

CURRICULUM VITAE

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Springfield VA 22150
703-536-1487
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fax 703-9221341

LICENSURE:

Virginia: Available and current
Maryland: Available and curent
DEA#: Available and current

EDUCATION:

UCLA Helms Institute of Acupuncture 2000
Johns Hopkins School of Public Health, MPH – May 2000
University of Arizona, M.D. - May 1985
University of Arizona, B.S. - Aug 1979 (General Biology)
University of Arizona, B.A. - May 1974 (Journalism)

POST-GRADUATE TRAINING:

Family Practice Resident Program - University of Oklahoma
Health Services Center - July 1985 - June 1988

POST-GRADUATE AWARDS:

Intern of the Month by the Emergency Room Faculty, Oklahoma Memorial Hospital, May 1986

BOARD CERTIFICATION:

American Board of Family Practice 1995-2002

SOCIETY MEMBERSHIPS:

American Academy of Family Practice
Virginia Family Practice Medical Society

POST-GRADUATE EMPLOYMENT:

94 - 00 Kaiser Permanente – Mid-Atlantic Permanente Medical Group-Atlantic States
89 - 94 Kaiser Permanente North Carolina

PROFESSIONAL INTERESTS:
Complementary and alternative medicine, psychoneuroimmunology, health care reform and policy, family counseling, preventive health and outpatient procedures

PROFESSIONAL VOLUNTEER ACTIVITIES:
92 - 93 Physician preceptor at local family practice residency
91 - 92 Volunteer physician at Shelter Medical Clinic for the homeless

EMPLOYMENT HISTORY:
80-83 Graduate Teaching Assistant Dept of Biology, U. of Arizona, Tucson, AZ
75-76 Free-lance sports photographer in South Lake Tahoe, CA.
75-76 General assignment reporter and photographer, Mesa Tribune, Mesa, AZ
Received award for the best news story from Arizona Press Women's Association for article on medical malpractice.

PUBLICATIONS:
The Disorientation Manual: A guide for freshman medical students;
Co-editor and publisher, 1982, Tucson, AZ
Kaiser Permanent Journal Winter 1998 – CAM issues

PERSONAL DATA:
Birth date: May 12, 1952
Birthplace: New York City, NY
Personal interests: whitewater solo canoeing, hiking, and meditating
Community interests: Leadership Charlotte, Graduate Class XIV, 1993

REFERENCES: available upon request

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35 Segal

KAISER PERMANENTE
Medical Center
Falls Church

Overview: Kaiser Permanente is the largest non-profit HMO in the United States. Currently, we insure 8.5 million people, of which one half a million are local. We operate facilities in the following regions: Mid-Atlantic and Ohio, Southeast, Colorado and Kansas, California, Northwest, and Hawaii. We maintain a partnership with Group Health Puget Sound in the Pacific Northwest.

Each region creates its cam offering independently, based on the standards of mandated by the community and the philosophy of the medical group. Delivery of services may be in a Kaiser Permanente medical facility or in a provider's office in the community. Most community-based providers are associated within a network.

Service description: Cam services are offered in three insurance types: base coverage, optional rider, and affinity-discounted fee for service. Generally speaking, when offered as part of the base or optional rider, cam services require medical review. The process starts with a review of the evidence based medical literature to validate which modalities best treat which disorders. It is the perspective of the Permanente medical groups that the integration of cam services with traditional medicine improves the quality of care for patients.

Depending upon the region, services include acupuncture, biofeedback and manual therapy (e.g. chiropractic). Naturopathy and massage therapy are also covered in the Pacific Northwest.

Discounted fee for service, i.e. affinity, networks are also offered to members but come without medical review. In addition to those listed above, services may include homeopathy, health clubs and healers skilled in a variety of ethnic traditions.

Research: Due in part to our large population base and integration of cam services, several regions have clinical research projects in complementary and alternative medicine. Some studies are funded internally and some via government grants. CAM utilization issues are starting to be examined in some regions using our extensive electronic medical record keeping.

Classes and products: Regions offer, through their health education departments, an array of complementary and alternative medicine related classes including meditations, yoga and herbs. Most regions offer a number of cam related products that are sold either in medical centers or through catalogues. Products include herbs and supplements, books, and tapes.

Douglas S. Lloyd MD MPH FACPM
HRSA Visiting Scholar - ASPH
1101 15TH Street, Suite 910
Washington, DC 20005

Douglas S. Lloyd MD MPH is the HRSA Senior Scholar at the Association of Schools of Public Health in Washington, DC. He has been the Director of Public Health Practice for HRSA, Connecticut Commissioner of Health, President of ASTHO and Chairman of the Public Health Foundation. He received his MD from Duke and is board certified by the American Board of Preventive Medicine.

****

The White House Commission on Complementary and Alternative Medicine Policy
October 5 and 6, 2000 – Humphrey Building, Washington, DC

Douglas S. Lloyd MD MPH FACPM
HRSA Senior Scholar at the Association of Schools of Public Health

SYNOPSIS

The Association of Schools of Public Health represents twenty-eight accredited schools of public health. New training centers, funded by the Health Resources and Services Administration and by the Centers for Disease Control and Prevention have recently been designated to devise new approaches to training today's public health practitioner who may have a career that spans many different fields and responsibilities.

Public Health is multidisciplinary and the scope of community issues requires a variety of talents so schools of public health maintain experts in many fields. Departments of biostatistics, epidemiology and behavioral sciences are found in all schools. These key areas are central to most research done in the community and it is likely that faculty are currently involved in complementary and alternative medicine (CAM) projects. Certainly these disciplines and the faculty from them can be very helpful to future research and education in CAM.

A project was begun this summer that will develop a model for teaching chiropractic students public health. The Yale School of Public Health and the Bridgeport (CT) College of Chiropractic will be developing a working group composed of chiropractic and public health experts. The panel will assess the baseline attitudes, knowledge, and behavior of students, faculty and practitioners in chiropractic toward public health. Based on these findings, a workshop will convene to analyze them and begin the task of developing a curriculum and workbook for future students.

Complementary and alternative medicine is in a growing phase. Public interest has been well established and conferences such as this one underscore the awareness and involvement of the NIH and FDA, other federal agencies, universities, foundations, and the private sector. As the research agenda grows, and it will, we wish to ask our colleagues to remember that the nation's schools of public health are an ideal environment for complementary and alternative medicine research.

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CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

William H. Dietz, M.D., Ph.D.

Dr. Dietz is the Director of the Division of Nutrition and Physical Activity in the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention (CDC). Prior to his appointment to the CDC, he was a Professor of Pediatrics at the Tufts University School of Medicine, and Director of Clinical Nutrition at the Floating Hospital of New England Medical Center Hospitals. He received his BA from Wesleyan University in 1966 and his MD from the University of Pennsylvania in 1970. Following an internship at Children's Hospital of Philadelphia, he spent 3 years in the Middle America Research Unit of the National Institute of Allergy and Infectious Disease in Panama studying insect-borne viruses. After the completion of his residency at Upstate Medical Center, he received a PhD in Nutritional Biochemistry from Massachusetts Institute of Technology.

In addition to his academic responsibilities in Boston, Dr. Dietz was a principal research scientist at the MIT/Harvard Division of Health Science and Technology, Associate Director of the Clinical Research Center at the Massachusetts Institute of Technology, and Director of the Boston Obesity/Nutrition Research Center funded by NIDDK. He has been a councilor of the American Society for Clinical Nutrition, and past president of the North American Association for the Study of Obesity. In 1995 he received the John Stalker Award from the American School Food Service Association for his efforts to improve the school lunch. Dr. Dietz served on the 1995 Dietary Guidelines Advisory Committee. He was a member of the NIDDK Task Force on Obesity. In 1998, Dr. Dietz was elected to the Institute of Medicine of the National Academy of Sciences. In 2000, he received the William G. Anderson Award from the American Alliance for Health, Physical Education, Recreation and Dance. He is the author of over 100 publications in the scientific literature, and the editor of two books, including A Guide to Your Child's Nutrition.

3/2000

CDC

Project Title: Development and Application of a Practice Based Approach to Assess Successful Complementary and Alternative Medicine Practices

Project Description: The use of complementary and alternative medicine (CAM) for the treatment of acute and chronic diseases in the United States is widespread. Nonetheless, limited attention has been given to the identification of potentially effective CAM therapies. This project will develop and apply the standards necessary for a practice based assessment of potentially successful CAM therapies. In the first year of the project, the recipient will convene an expert panel to develop the process necessary for a practice based assessment of the success of CAM therapies. The panel should include representatives from the CDC, the National Center for Complementary and Alternative Medicine at National Institutes of Health (NIH), the Agency for Healthcare Research and Quality, experts in CAM research, and other representatives as appropriate. Partnerships with existing NIH-funded CAM Centers are encouraged. The panel will prioritize approaches, specify the conditions of greatest interest, determine whether the outcome of interest should be symptom relief and/or cure, and develop case definitions and outcomes for the conditions of interest. The panel will also determine additional information required including but not limited to characteristics of CAM therapies to make a valid assessment of their therapeutic potential. The panel's conclusions will be incorporated into a chart abstraction form, with definitions and guidelines for the chart abstraction process. In addition, the panel and/or PRC must develop a detailed study protocol. The forms and process should be piloted in at least two CAM practice settings, that may be drawn from practices previously identified by an NIH survey three years ago. The pilot study should be designed in a manner that tests the reliability of the survey instrument, and assesses the barriers to the implementation of the protocol in CAM practices, including the financial incentives necessary to enlist the participation of CAM practices. Based on the results of the pilot studies and discussions with the expert advisory panel at a second expert advisory panel meeting, the forms, process, and study protocol should be revised. In year two, additional practices will be assessed, the final number to be determined based on estimates of the time, resources, and costs required.

6M 1991
9M 1992
60 M - last 10 years
Survey - Practitioners & determine feasibility of CAM
- Pattern of use

CDC

Project Title: Methods to Identify Promising Complementary or Alternative Therapies for Lethal Illnesses

Project Description

Complementary and Alternative Medicine is in widespread use in the United States. Nonetheless, only limited information is available regarding the utility of some CAM approaches for potentially lethal diseases, because many CAM practitioners practice outside conventional medical settings, do not assess or report their treatment results in the conventional medical literature, or have only anecdotal successes. This project includes funds to explore methods to identify successful CAM approaches for diseases such as cancer, progressive neurologic diseases, or other lethal diseases.

Project Activities

Project activities will include the exploration of viable mechanisms to identify patients with lethal illnesses cured by CAM. Mechanisms to identify patients, illnesses, and successful therapies might include telephone surveys of CAM practitioners, review of newsletters or websites, review of CAM literature and meeting abstracts, contact with patient support groups, or follow-back on CAM treated survivors who offer testimonials. Applicants are encouraged to consider and pursue other strategies to identify CAM treated successes, including interviews with experts in the field, and discussions with or focus groups of CAM practitioners. When reportedly successful cures are identified, additional case-finding will be pursued through either the identified case, practitioner, or other approaches. Applicants should include their strategies to explore treatment successes among ethnic groups, including Hispanics, African Americans, Asians, and Native Americans. Based on the cases identified, the applicant should outline how therapeutic success can be objectively confirmed, explore the willingness of CAM practitioners to document the therapy that was administered, and identify pertinent issues related to informed consent. These approaches should be piloted with one or two subjects to assure that they are successful. The results of these studies will be summarized in a report to the CDC, and should include the disease entities and therapies that appear most promising. The report will include suggested designs for case detection and confirmation.

W. CRAIG VANDERWAGEN, M.D.

Director, Division of Clinical and Preventive Services

Office of Public Health

Indian Health Service

W. Craig Vanderwagen, M.D., began his career with the Indian Health Service (IHS) an agency of the Public Health Service (PHS) within the Department of Health and Human Services (HHS), in 1981. His initial assignment was in the IHS Albuquerque Area Office as a General Medical Officer of the PHS Commissioned Corps at the Zuni Indian Hospital.

As the Director for the Division of Clinical and Preventive Services, Dr. Vanderwagen is responsible for the full scope of clinical health care programs, including quality assurance and preventive programs. Technical and policy guidance is issued for IHS direct and tribal health programs for a wide variety of health care programs, including alcohol and substance abuse, dental services, diabetes and other chronic disease prevention, mental health, emergency medical services, nutrition & dietetics, nursing services, pharmacy services, and maternal and child health.

Dr. Vanderwagen has received many awards and commendations since he began work for the IHS. In 1991, he received a PHS Exceptional Capability Promotion. In 1989, he was awarded a Commendation by the Secretary of the HHS for his leadership on the Inter-Agency Task Force on Indian Alcohol.

Dr. Vanderwagen is a board-certified family physician and maintains an active clinical practice in addition to his responsibilities in program development and administration. He is published in several medical journals covering family practice, including *Medical Education, Children Today*, and *Hospital and Community Psychiatry*. Dr. Vanderwagen is a frequent speaker to medical students and the general public on the techniques employed by the IHS to elevate the health status of American Indians and Alaska Natives.

Dr. Vanderwagen was raised on the Zuni Indian Reservation in New Mexico and considers that his home. He and his wife, Suzanne, currently reside in the Washington, D.C., metropolitan area with their three children.

- Tribal Govt
- Very little for urban   Research / Dollars
$400/capita
Role of traditional Healer is variable
Role of Tradition
558 Tribes   Traditional-Research
Do not fund Currently - Traditional Healers
Need to work with Tribal authorities
NIH / Native American Center for Health Research - Plan for
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Indian Health Service

Year 2000 Profile

Based on 1998-2000 data & 2001 budget request
Numbers are approximates

- **The Indian health care system** provides services to members of federally recognized tribes. It consists of:

  - **Indian Health Service (IHS) direct health care services**
    IHS services are administered through a decentralized system of 12 Area offices and 84 service units.
  - **Tribally operated health care services**
    Tribal facilities are operated under the authority of the Indian Self-Determination and Education Assistance Act (Public Law 93-638, as amended), Titles I and III. There are 44 Title III compacts, funded through 63 Annual Funding Agreements, with a total funding amount of approximately $588 million. These compacts represent 262 tribes (more than 47% of all tribes and over 32% of the total IHS user population). There are also approximately 285 tribes and tribal organizations that contract under Title I, with a total funding amount in excess of $468 million.
  - **Urban health care services and resource centers**
    There are 34 urban projects, ranging from community health to comprehensive primary health care services

- **Population Served:**
  - 557 federally recognized tribes in 35 States
  - 1.47million American Indians and Alaska Natives residing on or near reservations
  - 330,000 American Indians in urban areas.

- **Patient Services** *(tribal and IHS facilities)*:
  - Inpatient Admissions: 67,000
  - Outpatient visits: 6.7 million
  - Dental visits: 2.1 million

- **Appropriations:**
  - FY 2000 IHS budget appropriation: $2.4 billion
  - FY 2001 President's IHS budget request: $2.6 billion
  - Per capita personal health care expenditures: IHS - $1,351 U.S. general population - $3,766

- **Third-party collections:**
  - FY 1999: 394 million
  - FY 2000: 405 million (estimated)

- **Human Resources:** Total IHS employees: 14,720

	Total	Physicians	Nurses	Dentists	Pharmacists	Engineers	Sanitarians	*Indian*	*Non-Indian*
Comm. Corps	2110	334	411	288	346	251	128	360	1750
Civil Service	12610	587	2318	15	65	96	27	9645	2965
Indian	10005	71	1142	14	69	72	41	N/A	N/A
Non-Indian	4715	850	1587	289	342	275	114	N/A	N/A
Vacancy rates	**13%**	**10%**	**11%**	**25%**	**13%**	**6%**	**5%**	N/A	N/A

- **Facilities**

	Hospitals	Health Centers	Alaska Village Clinics	Health Stations	Residential Treatment Center
IHS	36	63	N/A	44	5
Tribal	13	158	160	76	28

Indian Health Service

DIRECTOR'S INITIATIVES

August 2000 UPDATE

Since Dr. Michael H. Trujillo's appointment as the Director for the Indian Health Service in 1994, he has identified ten Director's Initiatives to receive special attention and emphasis and reflect the vision for Indian health. The Public Affairs Staff, Office of the Director, Indian Health Service, provides this *Update of the Director's Initiatives*. For questions about the initiatives, please contact the individuals listed for each initiative.

Traditional Medicine Initiative

Indian Elder Care Initiative

Indian Women's Health Initiative

Indian Children and Adolescent Initiative

Injury Prevention Initiative

Domestic Violence and Child Abuse Prevention Initiative

Health Care Financing Initiative

State Health Initiative

Sanitation Facilities Initiative

Oral Health Initiative

THE WASHINGTON POST

OLYMPICS

Notebook

For U.S.'s Favor Hamilton, A Tough Pill to Swallow

Associated Press

Suzy Favor Hamilton blames anti-inflammatory pills for contributing to her fall in the final of the 1,500 meters at the Sydney Olympics.

"That makes me angry, that I should have known better," Favor Hamilton told the Capital Times of Madison, Wis., in Wednesday's editions.

She said she began taking Relafen and the over-the-counter medicine Aleve three weeks prior to the Summer Games to combat lingering hamstring soreness that flared up late in the summer. In Australia, Favor Hamilton said she took as many as six pills per day while preparing to compete in the 1,500. She was a medal favorite in the event, having run the best time in the world this year.

Unaware that the pills promote water loss, Favor Hamilton said she did not compensate by boosting her fluid intake. She also said she ignored signs of dehydration, dizziness and increased heart rate and breathing.

BY MIKE BLAKE—REUTERS

Dehydration caused by anti-inflammatory pills led to Suzy Favor Hamilton's fall at Olympics.

Indian Health Service

Traditional Medicine Initiative

August 2000 UPDATE

For more information on the Traditional Medicine Initiative, contact: Kermit Smith, D.O., M.P.H., Chief Medical Officer, Office of the Director, Indian Health Service (IHS), (301) 443-1083.

The Director's Traditional Medicine Initiative emphasizes the alliance of traditional and modern medicine practices between community traditional healers and IHS health care providers. Through this initiative, the agency seeks to foster formal relationships between local service units and traditional healers so that cultural values, beliefs, and traditional healing practices are respected and affirmed by the IHS as an integral component of the healing process.

During 1995 and 1996, 12 discussion circles were held in Indian Country to seek advice from traditional healers and tribal leaders on how to address traditional medicine. In response to concerns identified in the discussion circles, decisions regarding traditional healers are to be based upon what the local community considers appropriate. The IHS will honor the preferences of local communities in identifying traditional healers and determining how and if they should be incorporated and compensated into the medical model. It is the local community's responsibility to approach and orient local health care providers about tribal and/or community culture and traditions.

A concern also expressed in the discussion circles is how the IHS will raise sensitivity about traditional healing among its health care professionals and how the IHS Area Offices and local service units will consistently interpret and apply the IHS policy on traditional healing practices. The IHS Traditional Cultural Advocacy Program (TCAP) is an important means of ensuring that traditional healing practices are respected by IHS employees in all the agency's services and programs. The TCAP policy statement was updated in 1994 affirming the director's commitment to protect and preserve the inherent right of all American Indians and Alaska Natives to believe, express, and exercise their traditional religions.

ACCOMPLISHMENTS

The topic of traditional medicine is routinely included in the topics discussed at national meetings and conferences. Workshop discussions on traditional healing at the National Indian Health Board Consumers Conferences consistently confirm that traditional healing practices must be respected and supported by local IHS delivery sites. Including traditional healing as an agenda topic for IHS, tribal, and tribal organizations meetings emphasizes the importance of incorporating western medicine and traditional healing practices and to develop respect for family choice in using only one or balancing the use of both of them.

Indian Health Service

Indian Elder Care Initiative

August 2000 UPDATE

For more information on the Elder Care Initiative, contact Dr. Bruce Finke, Zuni/Ramah Service Unit, Indian Health Service (IHS), (505) 782-4431 or Dave Baldridge, Executive Director, National Indian Council on Aging, (505) 292-2001.

The goal of the Indian Elder Health Care Initiative is to support the development of high-quality services for American Indian and Alaska Native elders by acting as a consultation and liaison resource for IHS, tribal, and urban Indian health programs. The Director is concerned about the quality of life of Indian elders because they hold a central role in Indian families and communities. The number of elders is increasing rapidly, especially the oldest old. The need to develop a range of services to assist elders as they age in their home communities has been identified as a high priority. The core activities of the initiative are in information and referral, technical assistance and education, and advocacy. These activities are accomplished in partnership with a variety of tribal, state, federal, and academic programs.

ACCOMPLISHMENTS

We have a growing list of over 400 providers in a variety of disciplines throughout the Indian Health System with an interest in and commitment to elder care. This Elder Care Resource Group now forms the backbone of the Elder Care Initiative. Efforts to support these providers in their work include a partnership with the national consortium of university-based Geriatric Education Centers for educational outreach.

The Initiative continues to promote and support the development of interdisciplinary elder care teams at IHS, tribal, and urban Indian program sites. Teams operating at a variety of sites examined program issues and elder care policy, identified local resources, added innovative services, and developed educational conferences.

The RPMS-compatible Comprehensive Elder PCC is now available. This state-of-the-art tool guides health care providers through a comprehensive, functionally oriented geriatric evaluation, and aids in collecting data on the functional status of American Indian and Alaska Native elders. Guidelines for preventive care for the elderly are now in development.

Efforts continue to support the development of improved palliative care. A model hospice program is in development with a tribal home health agency.

Home and community-based long-term care continues to be an area of intense focus. The Initiative has aided in the development of a training curriculum for home caregivers. A Public Health Framework for Elder Care has been used both in advocacy and in planning at the community level. This framework envisions the Indian communities and tribal governments as the points of focus for elder care planning and is available for local use.

A page established on the IHS web site provides information about the Initiative and educational opportunities, as well as links to resources on aging for the professionals and for elders and their families. The web site is available at *www.ihs.gov/medicalprograms/eldercare*. The monthly "Focus on Elders" section of the "IHS Primary Care Provider," a journal for health care professionals working with American Indians and Alaska Natives, contains articles on elder program descriptions and educational opportunities. In honor of National Elders Month in May 2000, the Provider published an annual edition featuring clinical and descriptive articles on elder health and health care.

Educational outreach efforts have included presentations at a variety of professional and tribal meetings. Advocacy efforts continue within the Indian Health Service.

Indian Health Service

Indian Women's Health Initiative

August 2000 UPDATE

For information on the Indian Women's Health Initiative, contact: Sandra Dodge, CNP, Women's Health and Public Health Nurse Consultant, Office of Public Health, Indian Health Service (IHS), (301) 443-1840.

The director identified Indian women's health as a program emphasis area in 1994. The Indian Women's Health Initiative focuses on access to preventive services; increased surveillance and screening for diseases; increased community education; increased number of female providers; and establishing support groups and mentoring programs for young women in their communities. The focus has been on increasing access to direct services and networking with the Public Health Service (PHS) Office on Women's Health, other PHS agencies, and private organizations on Indian women's health.

The National Indian Women's Steering Committee is an advisory board to the Director of Indian Health Service comprised of IHS employees and American Indian and Alaska Native women. The National Indian Women's Resource Center (NIWRC) is a non-profit organization that supports the activities of the National Indian Women's Health Steering Committee and interacts with other public and private organizations for the benefit of Indian women's health. The Steering Committee and the Resource Center are part of a national network to advocate for education, policy development, increased access to health promotion and disease prevention activities, healthy lifestyle behavioral changes, and to collaborate with and educate and advise policymakers, consumers, and others on issues of American Indian and Alaska Native women's health.

ACCOMPLISHMENTS

The NIWRC received funding from the Office on Women's Health in 1997 and 1998 and conducted eight "Indian Women in Action" community mobilization workshops in tribal and urban communities. In 1999, three workshops were added for a total of 11workshops. The workshop training increased the capacity of local women to address their health issues, learn skills to provide their issues to community and political leaders, and initiate local support groups.

In partnership with the IHS, the Centers for Disease Control and Prevention funded 15 Indian health sites to provide breast and cervical cancer screening services. These early detection programs increased the number of Indian women receiving Pap tests and mammograms. In addition, the IHS funded nine 5-year competitive grants for Indian Women's Health Demonstration Programs to increase services, improve data collection, and encourage research for American Indian and Alaska Native women.

The software used by the IHS to track PAP smears and colposcopies was broadened to include a full range of breast and cervical cancer screening and tracking functions in addition to being modified to be more user friendly.

In 1999 a nurse consultant was hired to coordinate the women's health care programs and activities. National coordination will focus on encouraging IHS, tribal, and urban Indian health programs to emphasize women's health care throughout the life cycle. Other focus areas include increasing community education and access to preventive services for women's health and creating partnerships with state and regional programs so that Indian women's health needs benefit from the newest health research and resources.

PLANS

The NIWRC and the IHS will conduct eleven focus groups in four communities to obtain women's perceptions of the impact of recent health changes. The NIWSC members will be expanded to include representation from the young adult age group.

The IHS continues to update the annual data report, "Indian Health Focus: Women." The publication is available upon request.

Indian Health Service

Indian Children and Adolescent Initiative

August 2000 UPDATE

For more information on the American Indian and Alaska Native Children and Adolescents Initiative, contact: Leo Nolan, Office of the Director, Indian Health Service (IHS (301) 443-7261, or Dr. Craig Vanderwagen, Office of Public Health, IHS, (301) 443-3024.

The American Indian and Alaska Native Children and Adolescent Initiative, referred to as the "youth initiative," demonstrates the director's commitment to address the challenges facing the health status and quality of life of Indian children and adolescents. Many objective indicators show an alarming disparity in the health status and the general well-being of Indian youth as compared to that of other American youth. The indicators focus interest on the broader quality of life issues for Indian children and adolescents encompassing their physical, mental, social, educational, environmental, economic, cultural, and spiritual well-being. The agency is promoting a multi-agency approach to address the disparity issues.

ACCOMPLISHMENTS

The White House Domestic Policy Council Working Group on American Indians and Alaska Natives approved a Policy Initiative for Indian Children and Adolescents as proposed by the IHS in 1997. The policy initiative's intent was to improve the quality of life for American Indian and Alaska Native children and adolescents and help them become healthy adults by focusing existing resources and programs directed toward youth. In 1997, the IHS conducted the first multi-agency meeting. After the initial meeting, a Domestic Policy Council Subgroup on Indian Youth was formed. The subgroup held three work sessions with regular participation from 10 federal departments, the Environmental Protection Agency, and the United National Indian Tribal Youth (UNITY), Inc. This subgroup drafted an "Executive Order: Initiative for American Indian and Alaska Native Children and Youth" which was presented during a White House briefing in October 1997.

The IHS and UNITY sponsored a conference for federal and non-federal agencies and organizations in February 1998 to share information about the policy initiative and to enlist support for Indian communities. Input from the conference was used to ensure personal development of Indian children and youth within the context of developing safe and healthy homes and communities. An information sharing session was held later in 1998 specifically for non-federal organizations to learn about the mission, goals, and programs of the IHS, the UNITY, the Bureau of Indian Affairs, the Administration on Native Americans, the National Congress of American Indians, and the National Indian Education Association.

In FY 1999 the agency worked with the White House, SAMHSA, and the DOJ to develop a collaborative grant process for mental health services for children youth and families. This was the first time that these agencies have worked to issue collaborative grant announcements and ease the application process. The grants are to be awarded in FY 2000. In FY 1999, the agency also supported a UNITY meeting in Denver to highlight the needs and the leadership among Indian youth. This conference provided recommendations for tribal governments to guide youth program direction

PLANS

In FY 2000, the IHS is cosponsoring a "Summit on Youth Violence and Alcoholism" with the DOJ and other Federal agencies. This conference will feature top policy makers in dialogue with tribal leadership on the needs and "best practices" for prevention and treatment of youth violence associated with alcohol use.

Indian Health Service

Injury Prevention Initiative

September 2000

For more information on the Injury Prevention Initiative, contact: Kelly M. Taylor, Principal Injury Prevention Consultant, Office of Public Health, Indian Health Service (IHS), (301) 443-1054.

Deaths to children and young adults throughout Indian country are most often the result of traumatic injury. This initiative strives to call attention to this emerging public health crisis and to effect a positive change in this troubling statistic. Motor vehicle crashes are the leading cause of traumatic injuries to American Indians and Alaska Natives. In addition to preventing motor vehicle crashes, other injury prevention focus areas are injuries to the elderly as a result of falling, burn and fire injuries that occur in the home, traumatic brain injury as a result of not using bicycle helmets, and drowning.

The IHS Injury Prevention Program's mission is to decrease the incidence of severe injuries and death to the lowest level possible and increase the ability of tribes to address their injury problems. Injuries to American Indian and Alaska Native people have decreased by more than 50 percent since 1972, but continue to be the leading cause of death for American Indian and Alaska Native people up to 44 years of age. More than $150 million is expended annually for the treatment of these injuries. Implementation of effective injury prevention programs can improve the quality of life for Indian people and redirect the use of limited contract health care funds for treatment of other health conditions. Through this initiative, the IHS also promotes capacity building by increasing the understanding about the problem, sharing effective solutions, and assisting communities to devise ways to implement solutions.

ACCOMPLISHMENTS

To assist tribes in building infrastructures for injury prevention capacities, as part of an ongoing aggressive public health campaign to prevent traumatic injury, the IHS awarded 5-year grants totaling more than $1 million to 25 tribes beginning in fiscal year 2000.

An interagency agreement between the IHS and the U.S. Fire Administration funded six tribal communities to build their capacity to reduce fire injuries. The initiative facilitated the expansion of the Native American Injury Prevention Coalition beyond its North Dakota origin to include South Dakota and Montana.

The Navajo Nation Safety Belt Campaign resulted in an 80% seat belt usage on the reservation. A cost analysis of the campaign indicated annual savings of more than $9 million in treatment costs for injuries and a 30%reduction in hospital stays attributable to injuries.

Three video conferences on violence prevention approaches for communities were cosponsored by the IHS, Harvard University, the Department of Education, the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration.

The Safe Tribal Communities Campaign for American Indian and Alaska Native Youth was reactivated in fiscal year 1998. Working in partnership with the United Tribes Technical College (UTTC), the U.S. Department of Transportation, and the CDC, the IHS assisted in the development of an associate of applied science degree in injury prevention. In 1998, the UTTC began offering injury courses toward the A.A. degree. The first five graduates completed their degree requirements in May 2000. Three will begin working for their tribes, and two additional students are now pursuing additional college degrees.

PLANS

- Expand the tribal infrastructure grant program to as many as 25 new tribes, if congressional appropriations for injury prevention are increased.
- As they are completed, share the results of multiple evaluation projects designed to determine the effectiveness of direct interventions as well as building tribal capacity in injury prevention courses.

Indian Health Service

Domestic Violence and Child Abuse Prevention Initiative

August 2000 UPDATE

For more information on the Domestic Violence and Child Abuse Initiative, contact: Ramona Williams, Family Violence Prevention Program, Office of Public Health, Indian Health Service (IHS), (505) 248-4245.

In response to growing concerns about violence against women and child abuse and neglect in American Indian and Alaska Native communities, the director added the Domestic Violence and Child Abuse Prevention Initiative in October 1996. The initiative's purpose is to improve the IHS, tribal, and urban Indian health care response to domestic violence by providing education, training, and support to health care providers. The goal is to improve health care providers' capability to provide early identification and appropriate, culturally competent responses to victims of violence against women and related issues of child abuse in American Indian and Alaska Native communities.

The IHS established a Family Violence Prevention Program and gave it the leadership role in 1996 to work with tribes to implement this initiative. The program provides technical assistance, policy and program development, and training to American Indian and Alaska Native communities regarding issues of domestic violence and related issues of child abuse and other forms of family violence and suicide. The program collaborates with local, regional, and national programs to accomplish the initiative's goals and advocates for culturally competent service delivery for American Indian and Alaska Native victims of violence.

ACCOMPLISHMENTS

Training in 10 states was provided to improve the health care response to domestic violence. The program and the Family Violence Prevention Fund, the leading national program focusing on issues of violence against women, collaborated to sponsor the two-day training. Teams from eight IHS facilities in the 10 states completed the training, and teams from three other medical facilities that mainly serve American Indians and Alaska Natives also completed the training. After their training, these teams provided training for other health care providers in their facilities. As a result of this training effort, approximately 150 health care providers in IHS, tribal, and urban Indian facilities were trained in early identification and appropriate intervention and prevention of domestic violence.

PLANS

The IHS Mental Health and Social Service Program will work with the IHS Area Offices to assure that staff is appropriately trained and local policies and procedures are established for these health concerns.

The program will pursue IHS funding for use in a full partnership effort with the Family Violence Prevention Fund to provide training to IHS, tribal, and urban Indian health program staff nationwide.

Indian Health Service

Health Care Financing Initiative

August 2000 UPDATE

For more information about the Health Care Financing Initiative, contact Elmer Brewster, Division of Managed Care, Office of Public Health, Indian Health Service (IHS), (301) 443-1016, or Kitty Marx, Division of Regulatory and Legal Affair, (301) 443-1116.

The Health Care Financing Initiative originated from the Director's concern about the lack of understanding by federal and state government agencies about the U.S. Government's moral and legal obligations to provide health services to 550 federally recognized tribes. The IHS initiated discussions with the Health Care Financing Administration (HCFA) to increase understanding about this unique relationship and the need for consultation with tribal governments by federal and state agencies on actions that affect them. Discussions have focused on Medicaid program (1115 and 1915b) waivers, Medicare and Medicaid reimbursement, legislation, the Children's Health Insurance Program (CHIP), and important HCFA policy and operational issues related to the Indian health care system.

ACCOMPLISHMENTS

In recognition of the need for a more collaborative working relationship, the IHS and HCFA have established a joint Indian Health Steering Committee co-chaired by the Deputy Director of IHS and the Deputy Director of HCFA. This committee provides oversight and direction to three primary subcommittees: Legislation, Operations, and Cost Reports. In response to issues generated at national consultation meetings held in 1999 with Tribes across the country, a recent HCFA meeting was held in July 2000 to report to Tribes on the status of many of those issues. Based on these meetings and further staff subcommittee work, policy will be developed and recommended to leadership for implementation. The HCFA staff continues to provide training and education to Tribes and the IHS at major national meetings with consumers, medical records officers, business officers, and IHS leadership.

PLANS

The IHS continues to work with HCFA staff on various policy issues stemming from the regional tribal consultation meetings. Policy information will be referred to subcommittees of the Joint Steering Committee when necessary. Several IHS/HCFA meetings are planned to discuss the development of joint action work plans on policy issues affecting IHS and Tribes. The IHS will continue to work with HCFA on legislative initiatives; e.g., reauthorization of the Indian Health Care Improvement Act, reimbursement policy and program operations issues, and negotiating the HCFA Medicare and Medicaid rates.

Indian Health Service

State Health Initiative

August 2000 UPDATE

For more information on the State Health Initiative, contact: Elmer Brewster, Division of Managed Care, Office of Public Health, Indian Health Service (IHS), (301) 443-3024 or Kitty Marx, Division of Regulatory and Legal Affairs, Office Management Support, IHS, (301) 443-1116.

The State Health Initiative is the focal point for information and legal perspectives on state health care reforms and Indian health issues. Indian health partners should be knowledgeable about federal and state proposals for funding health care programs so that Indian health interests are represented in the decision making process. The initiative provides technical assistance for interfacing with state health care reform initiatives, federal waiver demonstrations, and Indian health programs.

States are assuming a larger role in the development and financial aspects of their health care programs. Federal oversight and funding is being delegated to states as part of health and welfare reform. The Health Care Financing Administration (HCFA) and the IHS provided written advice to state Medicaid directors that they are to consult with tribes in their states when drafting Medicaid waiver proposals. The HCFA is consulting with Tribes through its Regional offices and at the Headquarters levels on Medicare and Medicaid issues, such as the Medicaid program waivers, state plan amendments, the State Children's Health Insurance Program (SCHIP), and program and reimbursement issues.

ACCOMPLISHMENTS

On October 6, 1999, the IHS, HCFA, and Health Resources Services Administration published new policy guidance and proposed regulations exempting American Indians and Alaska Natives from any cost sharing provisions under CHIP for their eligible children. This guidance provides that state plans or amendments that impose cost sharing on American Indians and Alaska Natives will no longer be approved. A national meeting was held in Washington, D.C., in July 2000 with tribal leaders reporting back information on specific policy issues raised during 1999 regional tribal consultation sessions.

PLANS

The IHS continues to review and comment on the state waivers as standard procedure. The IHS continues to work with HCFA staff and through the IHS/HCFA Joint Steering Committee to assess policy development on major program and reimbursement issues relating to Medicare, Medicaid, CHIP, IHS, tribal, and urban Indian programs. Ongoing consultation activities among the HCFA, IHS, tribes, urban Indian programs, and states will continue on policy development and implementation.

Indian Health Service

Sanitation Facilities Initiative

August 2000 UPDATE

For more information on the Sanitation Facilities Initiative, contact: E. Crispin Kinney, P.E., Environmental Engineering Branch, Division of Facilities and Environmental Engineering, Office of Public Health, Indian Health Service (IHS), (301) 443-1046.

The Director's Sanitation Facilities Initiative focuses on expanding services to existing Indian homes, to communities, and to new and renovated homes. A safe and adequate water supply and waste disposal system contributes to the health of communities. Safe water and sanitation is lacking in 7.5 percent of Indian homes compared to 1 percent of homes in the U.S. general population. In some sections of the IHS service area, these percentages are as high as 25 and 35 percent. When homes have adequate sanitation systems, the prevention of disease and preservation of public health are significantly improved. Families with satisfactory environmental conditions in their home, which includes safe water and sewerage systems, require approximately 75 percent fewer medical services and place fewer demands on the IHS, tribal and the Indian health primary health care delivery system.

Tribal governments have worked in partnership with the IHS to construct essential sanitation facilities for American Indian and Alaska Native homes and communities since the Indian Sanitation Facilities Act (Public Law 86-121) was passed in 1959. The Indian Health Care Amendments of 1988 (P.L. 100-173, section 302) required the IHS to develop a 10-year funding plan, to be submitted in 1990, to meet a goal of providing safe and adequate sanitation facilities for all American Indian and Alaska Native homes and communities. The funding to reduce the sanitation deficiency backlog has been approximately 60 percent of the needed annual appropriation level to achieve the goal set in 1990 by the year 2000. After 10 years of funding, progress has been made, but approximately 25,800 Indian homes still lack either or both a safe water supply and adequate sewage disposal system . The IHS has identified a total backlog of 2,902 needed sanitation facilities construction projects costing $1.75 billion to provide all American Indians and Alaska Natives with safe drinking water and adequate sewage disposal in their homes.

ACCOMPLISHMENTS

Since 1990, the IHS and tribes provided an annual estimate of the sanitation facilities required and the total funding needed for essential sanitation facilities. In 1999, the IHS provided essential new sanitation facilities to over 10,000 homes. This was accomplished with contributions of over $35 million from tribes and federal agencies, in addition to the $89.3 million funds appropriated to IHS for this purpose. The IHS is improving working relationships with federal agencies, including the Environmental Protection Agency the Department of Agriculture, and the Bureau of Reclamation, for the joint funding of projects. Several new projects were initiated in 1999, which could not have been served solely with IHS-appropriated funds.

PLANS

The IHS will seek to increase seek supplemental funds from non-IHS sources to meet the backlog of identified needs, and will continue to foster relationships with these entities to improve working relationships with them.

Indian Health Service

Oral Health Initiative

August 2000 UPDATE

For more information on the Oral Health Initiative, contact: Dr. Chris Halliday, Acting Principal Dental Consultant, Office of Public Health, Indian Health Service (IHS), (301) 443-1106.

The Director's Oral Health Initiative focuses on improving the oral health status of the American Indian and Alaska Native population through existing services and by responding to recruitment and funding challenges. Oral diseases seldom result in death or severe disability and therefore are often overshadowed by other health priorities, particularly in times of serious resource constraints. However, the connection between oral health and quality of life is highlighted by the findings from Indian communities participating in a recent World Health Organization oral health study (available by contacting Dr. Halliday). The study showed that:

- 33% of school children report missing school because of dental pain.
- 25% of school children and almost 50% of adults avoid laughing or smiling. 20% of school children avoid meeting other people and 50% of adults avoid conversations because of the way their teeth look.
- As a consequence of dental pain, almost 25% of adults are unable to chew hard foods, almost 20% report difficulty sleeping, and 15% limit their activities (i.e., work and leisure).
- 75% of the elderly experience dental symptoms, and 50% perceive their dental health as poor or very poor and are unable to chew hard food.

These "quality of life measures" were 200% to 400% more severe for the Indian study respondents than those from any other study site responding to the survey. This represents significant threats to American Indian and Alaska Native people's self-esteem, ability to learn, secure employment, and ability to reach their full potential. The IHS has addressed the ravages of oral disease in Indian communities, which range from two to ten times the national rate depending on the condition, with a dentist-to-population workforce roughly half the national average. Dental health has consistently been identified as a high priority in surveys of American Indians and Alaska Natives. Furthermore, during the budget request process for fiscal years 2000, 2001, and 2002, the IHS Area stakeholders identified dental health as one of the top funding priorities for the agency

ACCOMPLISHMENTS

During FY 2000 much progress has been made in furthering the Oral Health Initiative. This includes:

- A data analysis of the Oral Health Status and Treatment Needs Survey was completed.
- Grants were awarded to the Northwest Portland Area Indian Health Board, Alaska Tribal Health Consortium, Intertribal Council of Arizona, and All Indian Pueblo Council to operate dental centers.
- A full time dental recruiter was hired
- The charter of the National Oral Health Council was completed
- Loan repayment awards were made to 29 IHS/tribal dentists; over twice the awards made in FY 1999.

PLANS

The goal of this initiative is to improve the oral health status of the American Indian and Alaska Native people by increasing access to essential treatment and preventive oral health services. The plan to accomplish this includes:

- Increasing resource commitment to recruiting dentists for IHS and tribal programs, including loan repayments
- Developing an agenda and an action plan for the National Council of Oral Health
- Implementing an IHS/CDC initiative to increase access to fluoridated community water supplies.
- Publishing the results of the Oral Health Status and Treatment Needs Survey.

Indian Health Service
A Quick Look

"Healthy American Indian and Alaska Native people and communities are at the center of my vision for Indian health."

Michael H. Trujillo, M.D., M.P.H., M.S.
Assistant Surgeon General
Director, Indian Health Service

Members of more than 550 federally recognized American Indian and Alaska Native tribes and their descendants are eligible for services provided by the Indian Health Service (IHS). The IHS is a U.S. Public Health Service (PHS) agency within the Department of Health and Human Services (HHS). The IHS provides a comprehensive health service delivery system for approximately 1.8 million of the nation's estimated 2.4 million American Indians and Alaska Natives. Its FY 2000 appropriation was approximately $2.4 billion. The IHS strives for maximum tribal involvement in meeting the needs of its service population, most of whom live on or near reservations and in rural communities in 35 states, mostly in the western United States and Alaska.

FEDERAL-TRIBAL RELATIONSHIP

Federally recognized Indian tribes and Alaska Native corporations have a government-to-government relationship with the United States. This unique relationship has been given substance through numerous treaties, Supreme Court decisions, legislation, and Executive Orders.

The IHS is the principle federal health care provider and health advocate for Indian people. The principal legislation authorizing federal funds for health services to recognized Indian tribes is the Snyder Act of 1921. It authorized funds " . . . for the relief of distress and conservation of health . . . [and] for the employment of . . . physicians . . . for Indian tribes throughout the United States."

Congress passed the Indian Self-Determination and Education Assistance Act (Public Law 93-638, as amended) to provide tribes the option of assuming from the IHS the administration and operation of health services and programs in their communities, or to remain within the IHS administered direct health system. Congress consequently passed the Indian Health Care Improvement Act (P.L. 94-437) that is a health specific law that supports the options of P.L. 93-638. The goal of P.L. 94-437 is to provide the quantity and quality of health services necessary to elevate the health status of American Indians and Alaska Natives to the highest possible level and to encourage the maximum participation of tribes in the planning and management of those services.

MISSION, GOAL, AND FOUNDATION

The mission of the IHS, in partnership with American Indian and Alaska Native people, is to raise their physical, mental, social, and spiritual health to the highest level.

The goal of the IHS is to ensure that comprehensive, culturally acceptable personal and public health services are available and accessible to all American Indian and Alaska Native people.

The foundation of the IHS is to uphold the Federal Government obligation to promote healthy American Indian and Alaska Native people, communities, and cultures and to honor and protect the inherent sovereign rights of tribes.

HEALTH CARE DELIVERY

Preventive measures involving environmental, educational, and outreach activities are combined with therapeutic measures into a single national health system. Most IHS funds are appropriated for American Indians and Alaska Natives who live on or near reservations or Alaskan villages. Congress also has authorized programs that provide some access to care for American Indians and Alaska Natives who live in urban areas.

Health services are provided directly by the IHS, through tribally contracted and operated health programs, and through services purchased from private providers. The federal system consists of 36 hospitals, 63 health centers, 44 health stations, and 5 residential treatment centers. In addition, 34 urban Indian health projects provide a variety of health and referral services.

The IHS clinical staff consists of approximately 921physicians, 303 dentists, 411 pharmacists, 90 physician assistants, and 2,729 nurses. The IHS also employs allied health professionals, such as nutritionists, health administrators, engineers, and medical records administrators. There is approximately a 13% vacancy rate for health professional positions in the IHS, ranging from a vacancy rate of 5% for sanitarians to 25% for dentists.

Through P.L. 93-638 self-determination contracts and self-governance compacts, tribes and Alaska Native corporations administer 13 hospitals, 158 health centers, 28 residential treatment centers, 76 health stations, and 160 Alaska village clinics.

All 36 IHS-operated hospitals and all 13 of the tribally operated hospitals are accredited by the Joint Commission on Accreditation of Health Care Organizations.

FACILITIES CONSTRUCTION AND MAINTENANCE

Since 1960, more than 230,000 or approximately 92% percent of Indian homes, have benefited by IHS funding of water and sewerage facilities, solid waste disposal systems, and technical assistance for operation and maintenance of these facilities and services. The age-adjusted death rate from gastrointestinal disease for American Indians and Alaska

Natives has decreased by 91 percent since 1955, the year the IHS was established.

The funding to reduce the sanitation deficiency backlog is approximately 60 percent of the needed annual appropriation to meet its funding goal by Year 2000. The IHS also funds construction of new and replacement hospitals and ambulatory care facilities and staff quarters. The average age of IHS facilities is 32 years, with some older than 60 years. According to the National Academy of Sciences, organizations should put approximately 2 to 4 percent of the value of facilities into the maintenance and improvement of those facilities. The IHS is able to allocate only 1.4 percent of a building's value to their upkeep and maintenance.

DIRECTOR'S INITIATIVES

Since Dr. Michael H. Trujillo's appointment as the Director of the IHS in 1994, he has identified ten initiatives to receive special attention and emphasis and reflect the vision for Indian health. The ***Traditional Medicine Initiative*** emphasizes the alliance of traditional and modern medicine practices between community traditional healers and IHS health care providers. The ***Indian Elder Care Initiative*** supports the development of high-quality services for Indian elders. The ***Indian Women's Health Initiative*** focuses on access to preventive, surveillance, and screening services, community education, and support groups and mentoring programs. The ***Indian Children and Adolescent Initiative*** focuses on addressing broad quality of life issues of Indian youth. The ***Injury Prevention Initiative*** focuses on decreasing the incidence of severe injuries and death as a result of injuries. The ***Sanitation Facilities Initiative*** focuses on expanding services to existing, new, and renovated Indian homes and increasing safe and adequate water supply and waste disposal systems to communities. The ***Domestic Violence and Child Abuse Prevention Initiative*** focuses on improving response to domestic violence by providing training and support to health care providers. The ***Health Care Financing Initiative*** focuses on increasing understanding by federal and state government agencies about the unique legal relationship between the U.S. Government and tribal nations. The ***State Health Initiative*** provides technical assistance for Indian health programs to interface with federal and state health care reform initiatives and federal waiver demonstrations so that Indian health interests are represented in the decision making process. The ***Oral Health Initiative*** focuses on improving the oral health by increasing access to essential treatment and preventive services and responding to recruitment and funding challenges.

SUCCESSES

The Indian health care system presents a successful model for indigenous people around the world because of its respect for cultural beliefs, its blending of traditional practices with the modern medical model, and its emphasis on public health and community outreach activities.

The agency's consultation with tribal governments and its facilitation of Indian people's involvement in policy development and agency decision making has lead to their participation in setting program and budget priorities and advocating for their health needs. The agency's consultation practices can be model for the entire Federal Government. The HHS is the first to issue a department-wide tribal consultation policy, the first to hold regional Listening Councils with tribal leaders, and the first to hold a department-level consultation meeting so that tribal leaders and representatives could present their needs and priorities for the HHS FY 2001 budget request.

The Indian health model and the participation of Indian people in decisions affecting their health has produced significant health improvements for Indian people: ambulatory medical care visits increased by 1200% since 1955; Indian life expectancy increased by 12.2 years since 1973; mortality rates have decreased for maternal deaths, tuberculosis, gastrointestinal disease, infants deaths, unintentional injuries and accidents, pneumonia and influenza, homicide, alcoholism, and suicide; and Indian homes with safe water and sanitary waste disposal increased from 15% in 1955 to over 90% by the end of 1998.

CHALLENGES

Indian people continue to experience health disparities. Indian life expectancy (71 years) is about 5 years less than that for the U.S. general population. Death rates are significantly higher for Indians compared to the U.S. general population for alcoholism (627%), tuberculosis (533%), diabetes (249%), accidents (204%), suicide (72%), and homicide (63%) (rates adjusted for miscoding of race on state death certificates). Indian families are 7.5 times more likely than the average American family to live in homes that have sanitation facilities that do not meet current environmental laws and regulations.

The authority for the Indian Health Care Improvement Act (P.L. 94-437), regarded as the legal cornerstone for IHS to provide health care services to American Indians and Alaska Natives, expires at the end of fiscal year 2000. The agency has pursued a collaborative strategy to ensure that IHS, tribal, and urban providers are fully consulted throughout the process to reauthorize the legislation. As a result of collaboration, a tribally developed draft of proposed legislation was submitted to Congress and the Administration in October 1999. The House and the Senate have introduced identical language bills and have begun to hold hearings with American Indian and Alaska Native governments and representatives. The Administration is reviewing the draft legislation in preparation for future hearings.

Policymakers and Indian people are concerned about the health care funding deficiencies for Indian people. The agency has asked a stakeholder workgroup to research what it would cost to provide similar services of a mainstream health insurance plan to Indian people and to present a credible method of determining how IHS appropriations meet the need of providing comparable services.

Tribal governments that have exercised their right to self-determination by assuming the administration and operation of programs from the IHS require adequate funding to cover the additional costs the Federal Government is not subject to. Adequate contract support costs are necessary to ensure the tribal delivery of health care services to their communities.

The Federal treaty obligation to provide health services to American Indians and Alaska Natives is borne primarily by the IHS. The Administration and the Congress support the elevation of the Director of the IHS to the Assistant Secretary level, which would result in greater advocacy and involvement in the Department of Health and Human Services budget, operational, and program priority decision-making process, as well as policy matters that effect Indian health care. The final step in establishing the Assistant Secretary for Indian Health is contingent on Congress passing the elevation legislation.

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Burkholder

Divider Title: _____

Mr. Randy Burkholder currently serves as Associate Vice President of Public Affairs at AdvaMed, the Advanced Medical Technology Association and is a noted expert on health policy and medical technology. Prior to joining AdvaMed, Mr. Burkholder founded *Device and Diagnostics Reimbursement News*, a bi-weekly news journal on medical technology payment policy, and published *The Reimbursement Directory*. He also has edited *Medical Devices, Diagnostics and Instrumentation – The Gray Sheet*, a leading weekly news journal on medical technology regulatory and business issues. Mr. Burkholder is a graduate of Tufts University in Medford, Massachusetts.

AdvaMed
Advanced Medical Technology Association

An Overview of Medical Technology

The Advanced Medical Technology Association (AdvaMed) is the largest medical technology trade association in the world, supported by more than 800 medical device, diagnostic products and health information systems manufacturers of all sizes. AdvaMed is the only medical device association that operates globally to promote a legal, regulatory and economic climate that advances health care by assuring worldwide patient access to the benefits of medical technology.

AdvaMed member firms provide nearly 90 percent of the $68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the $159 billion purchased annually around the world. Together, AdvaMed companies form a strong and effective partnership to support policies and practices that provide timely delivery of new medical technologies throughout the global health care market.

AdvaMed represents and industry that is diverse and highly innovative.

There are approximately 6,000 medical device and diagnostics companies in the U.S. These companies produce everything from miniature cardiac pacemakers and minimally invasive surgical instruments to "gene-on-a-chip" lab tests and bioengineered skin substitutes.

The vast majority of medical device and diagnostics are small, with fewer than 50 employees. As a group, these smallest firms represent nearly 80% of medical technology companies but are responsible for only 10% of sales. In contrast, the largest 2% of companies are responsible for about 45% of sales.

Research and development spending by medical technology companies has grown steadily over the past five years, rising from 8.4% in 1995 to 12.9% in 1998. In some segments R&D spending is much higher. *In vitro* diagnostic test companies, for example, put 23% of sales revenue back into research and development in 1998. Makers of surgical and medical instruments spent 14% of sales on R&D.

Product life-cycles are very short for medical technology, averaging about two years. In some fields, such as cardiology, life-cycles are even shorter. One of the main reasons for this is that medical technology innovation often consists of incremental improvements in existing technology.

Medical technology innovation draws on contributions from many fields of science, reflecting an innovation process that is complex, non-linear and resource-intensive.

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Demakis

Divider Title: _____

JOHN G. DEMAKIS, M.D.

Director, Health Services Research and Development Service

Dr. Demakis is a graduate of the University of Illinois School of Medicine in 1962. He did his residency in internal medicine and fellowship in cardiology at the Cook County Hospital in Chicago.

Dr. Demakis served as Assistant Chief of Medical Service at the Hines VA Hospital from 1972- 1976. In 1976 he became one of the first Associate Chiefs of Staff for Ambulatory Care in the VA also at Hines

In 1982 Dr. Demakis became the first Director of the Midwest Center for Health Services and Policy Research. He served in this capacity until 1998 when he accepted the position of National Director of the Health Services Research and Development Service in Washington, DC.

Dr. Demakis is Professor of Medicine at the Loyola University Stritch School of Medicine in Chicago.

His research interests have included primary care and ambulatory care and data base systems. Most recently he was the Principal Investigator of a large cooperative trial evaluating the effectiveness of computerized guidelines in VA general medical clinics.

Medical and Prosthetic Research

Program Description

In meeting its mission, the Department of Veterans Affairs Medical and Prosthetic Research program (VA R&D) capitalizes on the unique opportunities provided by the veterans health care system. In response to recommendations from the Research Realignment Advisory Committee, VA R&D has realigned its priority areas to more appropriately target research projects that address the special needs of veteran patients and to balance research resources among basic and applied research to ensure a complementary role between the discovery of new knowledge and the application of these discoveries to medical practice. VA R&D is an intramural program: it allocates appropriated funds to VA facilities to conduct research on the high priority health care needs of veterans under the supervision of VA employees. Unlike NIH and some other Federal agencies, VA R&D does not make grants to colleges and universities, cities and states, or any other non-VA entity.

Stakeholders: The immediate stakeholders of the VA R&D program include current and future veteran patients, their family members, VA health care providers, and, in fact, all health scientists. In addition, VA R&D benefits such groups as the veterans service organizations, other components of the Federal research establishment, academic health centers and Congress. Ultimately, all consumers and practitioners of health care benefit from VA's research.

Function/Activity: The VA R&D program administers the medical and prosthetic research appropriation. Funds from this appropriation support VA medical center employees conducting research projects, initiated on the basis of their own scientific interests, or in response to invitations from the R&D Office in Headquarters. These projects could be classified in several ways, but it is convenient to do so with reference to the organizational units (within the R&D office) involved in the selection, after peer review, of applications for funding and administering the awards resulting from successful applications. The four units are:

Cooperative Studies Program – Cooperative Studies Research has recently been separated from the Medical Research and Health Services Research programs and is directed toward large multi-site clinical trials. Cooperative Studies supports the

clinical trials with its own statistical support centers and its own FDA approved pharmacy. The research determines the efficacy and cost effectiveness of new medications and new treatment strategies of direct benefit to the veteran population in the areas of aging, chronic disease, mental illness, special populations and military occupations and environmental exposures.

Health Services Research and Development Service – Health Services Research is directed toward improving the outcome effectiveness and cost efficiency of health care delivery for the veteran population. The program supports investigator initiated research projects, the training of clinicians in applied clinical research, centers of excellence devoted to specific aspects of health care delivery and service directed projects addressing clinical management needs. The research focuses on the translation of research findings to clinical best practices for all veteran patients. Particular contributions are made in the areas of aging, substance abuse, health systems and special populations.

Medical Research Service – Medical Research strives to understand the disease process so that efficient, rational interventions can be made to cure or alleviate the effects of disease. The program supports investigator initiated research projects, the training of clinicians in basic and clinical research, and centers of excellence devoted to specific diseases. The research done in areas particularly relevant to the veteran population include aging, chronic disease, mental illness, substance abuse, military occupations and environmental exposures.

Rehabilitation Research and Development Service – Rehabilitation Research is dedicated to the development and applications of science and engineering to improve the care and quality of life for the physically disabled. The program supports investigator initiated research projects, the training of clinicians and engineers in rehabilitation research, centers of excellence devoted to specific disabilities and technology transfer. The research is done in areas particularly relevant to the disabled veteran population – aging, sensory loss and trauma related illness.

To receive funding, applicants must submit proposals for scientific merit review and, if approved and funded, conduct and report the research under the general administrative guidance of the local VA facility research office. The conduct of research requires compliance with all applicable policies, including those pertaining to the protection of human and animal subjects and to the protection of employee health.