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Public Comments

Divider Title: _____

# Public Comment Session

1. **James Sensenig**, American Academy of Naturopathic Physicians
2. **Candace Campbell,** American Preventive Medical Association
3. **Diane Davis**, University of Virginia Cancer Center
4. ~~**Katherine Gorton**~~, American Dietetic Association Susan Pitman
5. **Audrey Di Maria**, Secretary of Art Therapy Credential Board
6. **Judy Simpson,** American Music Therapy Association
7. **Richard Goldberg**, Private Practice
8. **Nancy Kristine Haller**, Feldenkrais Guild of North America Julie Merrill, ~~Amer. Assoc.~~ of
9. ~~**Christine Herlihy**, National Certification Commission for Acupuncture and~~ Oriental Medicine
10. ~~**Alice McCormick, National Certification Commission for Acupuncture and Oriental Medicine**~~
11. **Su Liang Ku**, Florida Institute of Traditional Chinese Medicine
12. ~~**Sharon Stevenson**~~, National Center for Homeopathy Sandra Chase
13. ~~**Barbara Moquin, National Naval Medical Center**~~ Edward Owens
14. **Matt Ward Russell**, National Integrative Medicine Council
15. **Carolyn Jones Sabatini**, Pharmavite Corp.
16. **Christina Walker**, The Shenk Human Energetic Institute
17. **Alan Dumoff**, Private Practice

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Divider Title: Sensenig

Sensenig # 47

# AMERICAN ASSOCIATION OF NATUROPATHIC MEDICAL COLLEGES

# AND

# AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

## TESTIMONY TO WHITE HOUSE COMMISSION ON CAM POLICY

WASHINGTON, D.C.

MAY 16, 2001

Dear Commissioners and Staff:

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

THE HEALTH OF THE AMERICAN PEOPLE IS AT RISK

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

PLURALISM IN AMERICAN MEDICINE

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

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

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

- assimilation impacts public safety

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

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

  - naturopathic physicians represent a separate and distinct medical system

    - distinct standards, licensing, credentials, accreditation

    - distinct body of knowledge, scope of practice

    - recognized as physician providers in eleven states

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

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

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

REIMBURSEMENT FOR CAM PRACTICES AND PRODUCTS

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

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

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

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

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

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

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

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

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

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

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

COORDINATION OF CAM RESEARCH

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

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

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

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

SPECIFIC POLICY RECOMMENDATIONS

1. **Commit to medical pluralism**

• embrace the fullness of diverse health care systems

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

• encourage licensing all CAM providers consistent with educational standards

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

> • establish CAM offices at and appoint naturopathic physicians and other licensed CAM professionals to the staffs of federal health care agencies, including NCCAM, NIH, DHHS, CDCP, Agency for Health Care Policy and Research, Bureau of Indian Affairs, Public Health Service, National Health Service Corps, VA, and HRSA
>
> •appropriate funds to layer a premium on any grant at NCCAM for including a CAM research institution instead of only a conventional one, and, for naturopathic institutions, it be a Council on Naturopathic Medical Education-approved naturopathic medical school that conducts research

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

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

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

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

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

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

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

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

• remove exclusionary language from existing federal laws and regulations

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

Indian Health Service policy-restrictive

National Health Service Corps - exclusionary

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

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

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

Graduate Medical Education - exclusionary

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

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

• fund a HRSA or DHHS National Credentialing Roundtable

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

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

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

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

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

• harvest existing information

• evaluate beyond clinical outcomes to global measures

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

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

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

Sincerely,

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Divider Title: Campbell

Testimony Before the
White House Commission on Complementary and Alternative Medicine Policy
Washington, D.C.
May 16, 2001
By Candace Campbell
Executive Director, American Preventive Medical Association

The American Preventive Medical Association was founded by physicians to be an advocate for health care freedom. We now have as members consumers, companies and practitioners from many disciplines. The tie that binds us as an association is the belief that American consumers should have the right to access the entire tool kit of therapies, not just those that have been sanctioned by one particular branch of health care.

We work primarily at the federal level to increase consumers' access to complementary and alternative (CAM) therapies. We do not promote one type of practitioner over another, or one therapy over another. Our goal, instead, is to increase patients' awareness and access to the full range of health care options, and to protect the practitioners who want to offer CAM therapies without fear of censure or recrimination.

I am here today to ask the Commission to recommend passage of the Access to Medical Treatment Act which will be introduced in the House this week and the Senate soon thereafter. I understand that you will be sending specific policy recommendations to Congress later this year, and I ask that you make the Access Bill one of those. A copy of the bill and background materials is included with my testimony.

Why, you may ask, am I requesting passage of legislation like this when the topics this week are research and reimbursement? Because we believe that Americans should have the right

to access therapies as soon as possible, and not have to wait decades for all the research to be in, or for the FDA to approve a drug. We believe that many lives could be improved and saved in those interim years. Simply speeding up the FDA approval process would not solve this problem.

As you may know, APMA led the effort to pass the legislation that created the National Center for Complementary and Alternative Medicine at NIH. We did this for two reasons: first, because the Office of Alternative Medicine was severely hampered by its status as an Office, and second, because we believe there is a crying need for more and better research into CAM.

Part of that legislation also created this White House Commission. We felt the need for a White House Commission level of review because there is presently no easy way to identify or coordinate federal efforts to support an integrated health care system. The left hand doesn't know what the right hand is doing. Resources cannot be managed effectively, and goals cannot be shared. Nor has there been a nationwide analysis of the needs or barriers to integration. How can we fix the system if we don't know where it's broken and where it's working? Our assumption is that the Federal Government is not doing everything it can to ensure that consumers have access to a full range of treatment options, and that it is also getting in the way of access and education regarding CAM. We felt that a White House Commission could survey the health care landscape, identify areas of need as well as barriers to integration, make specific policy recommendations, and help ensure a coordinated approach that would maximize federal resources and optimize health care.

You are also devoting time in these hearings to the subject of insurance reimbursement. Our members are split on this issue. For some, insurance reimbursement for CAM represents the great equalizer. It would ensure that more Americans have greater access to valuable therapies.

It would end the unfortunate dilemma faced by many patients who would prefer to receive CAM therapies but must settle for conventional treatments because that is what their insurance covers. Paying out of pocket is not an option. Why continue a system in which only the "haves" can truly choose their treatment, while the "have-nots" settle for what their insurance company allows.

On the other hand, we have many members who view insurance as silk shackles. They prefer not to accept insurance at all because it limits their income, creates a tremendous paperwork burden and now, thanks to the Health Insurance Portability and Accountability Act, exposes them to charges of insurance fraud for miscoding. HIPAA not only made insurance fraud a federal crime, with huge financial penalties and serious jail time, it also extended the Federal Government's reach beyond federal insurance program fraud to private insurance fraud. Given the fact that many CAM therapies do not yet have insurance codes, CAM practitioners are often forced to make due, choosing codes that seem to fit, or using locally accepted codes that will no longer be valid when the electronic filing requirements go into effect. This is a dangerous practice when such patchwork solutions can be deemed insurance fraud.

Many of our members also oppose the violations of senior citizens' rights caused by the Health Care Financing Administration's prohibition against private contracting. Surprisingly, Americans who are old enough to participate in Medicare may not private contract with a physician. This means that if Medicare deems a service unnecessary, but the patient wants it anyway, and his doctor thinks it would be beneficial, the patient may not pay for that service (private contract) if his doctor participates in Medicare. This is a gross violation of seniors' health care rights and an unwarranted interference in the doctor-patient relationship. A significant number of our members have opted out of Medicare so that they do not need

participate in what they believe is an unfair, unconstitutional system. To opt out, they must agree not to accept Medicare for a period of two years for any patient, and they must renew that "opt out" by filing an affidavit with the Department of Health and Human Services biannually.

For these practitioners, and many of our other members who are either unwilling or unable to opt out of Medicare, insurance coverage for CAM therapies would be no bargain, only more of the same – increased paperwork, government interference, reduced fees, restrictions on the number of visits and type of therapies available, increased hassle and an expansion of the violation against seniors' rights.

While APMA has encouraged the creation of ABC codes for CAM therapies by the private company Alternative Link, we do so with one caveat: that the codes not be used to create a CAM ghetto. As I'm sure you have heard these past few days, more than one practitioner organization has voiced concerns that a separate system of codes may result in marginalizing and eventually destroying CAM practices by establishing unreasonably low fees to CAM providers. So, while many will argue today for increased insurance coverage of CAM, I trust that the Commission will remain cognizant of the potential pitfalls when making policy recommendations.

All this debate over insurance reimbursement, however, begs the questions. If it's illegal to access many therapies, isn't it premature to talk about reimbursement? While we wait for sufficient research to be done to completely convince the medical community, and while we wait for the insurance issues to be settled, patients still want and need access to CAM therapies. It is both cruel and pointless to deny Americans access to therapies that could be improving and saving their lives.

Many of these therapies are used in other countries but not available in the United States. Many are considered experimental because they have not been approved by the Food and Drug Administration (FDA). Others are in the drug-approval pipeline but not widely available, even though they would be helpful and even life saving to people outside the clinical trial. The range and number of such unapproved therapies is both heartening and depressing. Why can't Americans have access to them? Why do they need to wait until the FDA has approved them? What of the therapies that will never get FDA approval, either because the foreign companies choose not to seek it, or because the therapies are non patentable?

Today, Americans' health care choices are considerably restricted to those approved by the FDA, and sanctioned by the American Medical Association, the Federation of State Medical Boards, and other enforcement bodies deeply entrenched in the allopathic medical model. As my teenage daughter would say, "Who died and appointed them God?" Why should we be asked to believe that one system has all the answers? The individuals and organizations making this most personal of all decisions on behalf of patients, know little or nothing about CAM therapies used effectively in other countries, or by the wide array of practitioners outside the allopathic community.

Why the lack of knowledge? For some, it is due to time constraints; they simply don't have the time to study new approaches or disciplines. For others, it's more a refusal to accept different ideas than a lack of knowledge. New ideas can be frightening and besides, we are told, if it was any good, they would have learned it in medical school. Another category of practitioners opposes the use of CAM because it represents a direct threat to their bottom line. If a person dedicates his life to becoming the best cardiac surgeon in the state, isn't it asking too much to expect him to embrace non-invasive CAM therapies that help patients avoid surgery?

Fortunately, health care isn't plumbing. It is an art as much as a science, and it should be allowed to constantly evolve. When the lid is slammed down on advancement (which often means experimentation and observation), patients lose. Instead of a health care system that encourages practitioners to incorporate new ideas and the best practices from around the world, we have a system that in all its glorious arrogance assumes that it is best and must not be challenged. To challenge the system is to risk personal and financial ruin. Just ask the APMA members who have gone bankrupt defending their right to offer their patients alternatives.

Patients are discovering this sad lack of freedom for themselves. Typically, they don't realize their lack of freedom until they are sick and up against the system. More and more, they are not settling for the options laid out for them by conventional medicine. They are investigating and researching, talking about their experiences and pushing the envelope. It's not only the terminally ill who are trying new things; it's also the ones who are sensitive to drugs, who prefer a more holistic approach, or who prefer to try the simplest, safest, least invasive approach first before resorting to the big guns of Western medicine. You all know the numbers; millions of Americans are now using alternative therapies. American consumers are voting with their feet, and finally, the medical community is taking notice.

Increasing numbers of medical doctors are educating themselves about CAM and incorporating it into their practices. They are tired of pushing antibiotics and surgery; tired of failure; tired of the side effects. For their trouble, they are being called quacks and charged with practicing sub-standard medicine when, in reality, they are just not blindly restricting themselves to the so-called standard of care. It takes tremendous nerve to step outside the box in this environment. It often takes deep pockets as well.

In response, APMA is supporting the Access to Medical Treatment Act. It probably should have been called the Health Care Bill of Rights. Scheduled to be reintroduced this week in the House and very soon thereafter in the Senate, the Access Bill enjoys strong bipartisan support. It would create a federal statutory right for consumers to use any therapy they desire, so long as they and their authorized practitioner follow the many consumer safeguards in the bill. This means that Americans would no longer have to sneak across the border into Mexico or fly to the Bahamas to get medical care. It means that products used safely and effectively for decades in Europe would be available easily and safely to Americans. It means that patients would no longer be forced to seek out an underground market in alternative therapies, or break the law to save their lives. It means that doctors who offer these products to their patients would no longer be treated as criminals or forced to defend themselves before medical boards that value tradition more than patient care.

To discourage fraud, practitioners and manufacturers would be forbidden to advertise such "unapproved" products, and prevented from making a profit on their sale. Patients would have to be fully informed of the risks and benefits, and of the fact that the FDA has not approved the product. Practitioners would not be allowed to exceed their scope of practice or violate state laws. Unfortunately, this means that in California, it would still be illegal for a physician to treat cancer with anything except chemotherapy, radiation and surgery, but since states have the constitutional right to regulate the practice of medicine, we must leave it up to state legislators to remove their own restrictions on patient freedom. I should point out that all of the many and thorough consumer safeguards (malpractice, scope of practice, anti-fraud, etc.) remain in place and would serve, as now, to protect patients.

I have attached a copy of the bill that will be introduced in the 107th Congress. It reflects the concerns and issues we have heard over the past six years that this legislation has been floating around. Consumer protections have been strengthened; reporting requirements for both positive and negative results have been added; data collection has been mandated; and informed consent procedures have been expanded to mirror those used in clinical trials. It has been on the back burner for six years because issues such as FDA Reform and Medicare Reform and the Patients Bill of Rights have bumped it from the short list. We were asked by the leadership to take a back seat until those bills could be addressed. But the time has come for the Access Bill. We, APMA, practitioners and the American public, have waited long enough for rights we should have had all along.

We think the bill provides a balance between increased consumer freedom and consumer protection. It reasserts Americans' right to make their own health care decisions, free from the tyranny of the established (and government funded) medical monopoly and the well-intentioned paternalism of the federal government. If it passes, Americans will move closer to an ideal health care system than any other nation in the world.

Freedom to choose the therapies to treat, cure, prevent or mitigate one's disease should be the bedrock upon which all health care is based. The Access Bill would establish that freedom. I hope the Commission has the fortitude to make such a powerful recommendation.

# # #

# 48 Candace Campbe

**Why Is Passage Of The Access To Medical Treatment Act Necessary For All Americans?**

Medical doctors using only conventional therapies probably won't change their way of practicing medicine if the Access to Medical Treatment Act (AMTA) becomes law. The small percentage of doctors using alternatives in medicine, naturopaths, dentists, nutritionists and others however, will finally be free to use the therapies they believe are best for their patients, and no longer have to worry about harassment, censure, or recrimination.

As things stand now, those who hold one view of health care expect to be allowed to decide what constitutes legal methods of healing. It is just this kind of despotism that our Founding Fathers intended to prevent. Benjamin Rush, MD, a signer of the Declaration of Independence and personal physician to George Washington said: "Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship to restrict the art of healing to one class of men and deny equal privileges to others; the Constitution of the Republic should make a special privilege for medical freedoms as well as religious freedom."

Actually, access to the full range of therapies, products and medical devices is quite restricted in the United States today. Americans are prevented from using life enhancing and even life saving therapies that have been used in other countries for decades. In surveys done by the Competitive Enterprise Institute, emergency room physicians, oncologists, neurologists, neurosurgeons and cardiologists overwhelmingly favored access to unapproved drugs and devices, as long as the products carried a warning about their unapproved status. They also overwhelming agreed that the FDA's approval process has hurt their ability to treat their patients with the best possible care.

The FDA's present monopoly over approving new medical therapies is creating a two-tiered health care system. Those with more resources are able to access the best that the world has to offer. The rest of the population must make due with what the FDA has approved.

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**Examples of therapies that would be available under the Access to Medical Treatment Act**

Through conversations with various doctors, I have compiled the following examples. It is my understanding that none of these items are available legally in the United States at this time because they have not been approved by the FDA. They would be available if the Access to Medical Treatment Act.

1. Intravenous vitamins - delivering vitamins intravenously makes them a drug. They can be much more effective in treating diseases when delivered this way. They have been used to treat AIDs, cancer, and chronic fatigue, among other things. A witness at the House Government Reform and Oversight Committee testified that her breast cancer went into remission after beginning intravenous vitamin therapy, but the FDA won't allow her to import them anymore.

2. Full-body hypothermia - is an effective treatment for cancer. It should be done in a hospital setting, but hospitals will not provide it for cancer patients because it is considered experimental. In laymen's terms, the therapy heats the patients blood to levels that kill cancer cells, without damaging healthy cells.

3. Coley's toxin - this therapy has been used since 1890. It is still offered in Europe and Mexico, but not in the United States. Patients receive an injection of the toxin which results in the blood temperature increasing, which kills cancer cells. While it is effective, it is less so than full-body hypothermia.

4. Ukrain - this treatment for cancer has been called "elegant" by leading physicians. It is a nontoxic therapy that migrates only to cancer cells while supporting the immune system. It can also be used as a diagnostic tool, because it fluoresces cancer cells, making it easier to identify them throughout the body. For instance, a physician who suspects that a patient has bladder cancer could use Ukrain to find a malignant tumor.

Evidently NCI rejected proposals to study Ukrain because it didn't meet the parameters of their protocol. I was told that while it was effective and nontoxic, it did not reach the level of cell death required by the protocol. At present, the product is available in other countries, but the quality is inconsistent and it is very expensive because it is made in small quantities. It is patented, but the owner of the patent cannot afford to pursue FDA approval.

5. Calcium AEP - is "the treatment of choice" for autoimmune diseases in other countries of the world. Eighty percent of multiple sclerosis patients show major improvement on the therapy. It can also be used to treat juvenile diabetes and lupus, which are also autoimmune diseases. Based on Hans Nieper's concept, the product is not sold in the United States and the FDA confiscates shipments at the border. It was discovered 31 years ago and is now made by several small companies in other countries.

6. Mistletoe - has shown promise as a cancer treatment. At least six companies are selling a

product based on it; Eurixor is the most well known and supposedly the most effective. It works by building up immune parameters. Mistletoe is widely used in other countries.

7. Bloodroot - is also an effective cancer treatment, eight times stronger than Ukrain, according to several physicians. As a natural product, it is not patentable.

8. Tryptophan - is now available only by prescription through compounding pharmacies. It now costs $75.00 for one hundred 500mg. capsules; about five times more than when it was sold as a dietary supplement. It is also still available in hospital settings, and in baby food produced and sold in the United States. It is also available through veterinary supply houses.

9. Radio-labeled immunoglobulin therapy - for Hodgkins Disease is no longer available in the United States because the clinical trials were shut down. According to a witness before the House Government Reform and Oversight Committee, the trial was ended because the FDA did not get the proper paperwork at some point in the study.

10. Ozone therapy - is widely used in Europe for a number of diseases, including cancer and AIDs. It is my understanding that it works by heavily oxygenating the blood. The equipment has not been approved by the FDA, and the manufacturers have no interest in spending the money and time it would take to achieve such approval.

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**Access to Medical Treatment Act**
**Questions & Answers**

**Q. Will this bill cost the federal government any money?**

A. No. In fact, it could save the federal government and individual consumers billions of dollars because it encourages true preventive medicine and the use of natural remedies, which are often many times cheaper than conventional treatments. It also gives Americans access to therapies that are being used safely and effectively in other countries, but which are not available here because they have not been approved by the FDA. This bill will encourage the use of less-expensive, less-dangerous approaches first. It will also foster true disease prevention, not simply early detection, which is what passes for prevention today. In this sense, the bill could save the federal government billions of dollars in Medicare costs alone. The true savings, however, will be in preventing human suffering and death because the bill will give Americans access to therapies that will improve their quality of life, and even save their lives. It's difficult to put a cost on that.

**Q. How will this bill change the practice of medicine?**

A. Very little, but at the same time, very much. Doctors using only conventional therapies probably won't change their way of practicing medicine. The small percentage of doctors using alternatives in medicine, nutritionists, naturopaths and others, however, will finally be free to use the therapies they believe are best for their patients, and no longer be harassed, censured or subject to recrimination.

As things stand now, those who hold one view of health care expect to be allowed to decide what constitutes legal methods of healing. It is just this kind of despotism that our Founding Fathers intended to prevent. Benjamin Rush, MD, a signer of the Declaration of Independence and personal physician to George Washington said: "Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship to restrict the art of healing to one class of men and deny equal privileges to others; the Constitution of the Republic should make a special privilege for medical freedoms as well as religious freedom."

**Q. Don't people already have access? Why is this bill necessary?**

A. Actually, access to the full range of therapies, products and medical devices is quite restricted in the United States today. Americans are prevented from using life enhancing and even life saving therapies that have been used in other countries for decades. This bill is necessary because many states have chosen to be quite restrictive, and many medical boards,

hospital and HMO boards, and insurance companies make it difficult, if not impossible, for physicians to use unconventional therapies. For instance, in California, it is illegal for a doctor to treat cancer with anything except chemotherapy, radiation and surgery. Even if all of those measures have been tried without success, patients in California are not free to try something else. A doctor recommending another treatment could lose his license. In other states, doctors using safe and effective but unconventional therapies are threatened with censure or loss of license. The FDA has made it virtually impossible for practitioners to access therapies that are used safely and effectively in other countries, and has steadily increased its efforts to regulate the practice of medicine, even though that is not its responsibility. The agency is also slow to approve new devices, and clearly biased against natural remedies. Efforts to ease the FDA's death grip on access to drugs is met with strong resistance.

As a consequence, the federal government is creating a stratified health care system in which only the best educated and wealthiest Americans have access to the full range of care. If patients cannot depend on their practitioners to provide the best quality care available, the doctor-patient relationship will be completely undermined. The wealthiest patients will travel abroad to receive life saving treatment; the best educated will find, through dogged research, that they have other options and seek it out; and the rest of the population will have to make due with what the FDA has seen fit to approve.

Increasing numbers of US physicians see promise in alternative therapies but are afraid to use them for fear of being harassed, censured or worse. The AMTA would help eliminate much of that fear, and encourage the advancement of medical science by encouraging practitioners to use therapies that show promise. Perhaps the most important result of the bill will be the advancement of medicine, because it will free practitioners to use the full range of therapies and determine the most effective approaches to disease treatment and prevention.

**Q. Does this bill circumvent the FDA?**

**A.** The AMTA would not dismantle FDA or allow pharmaceutical companies to circumvent the agency, nor would the agency lose its responsibility for certifying treatments as safe and effective. The legislation merely attempts to open up a closed system to the utilization of alternative treatments. The strict claims restriction in the bill is designed to ensure that little incentive exists for marketing non-FDA approved treatments.

**Q. Won't people forego conventional therapies and perhaps suffer or die as a result?**

**A.** No. This red herring is always raised but both common sense and experience tell us that people don't avoid safe and effective therapies or gamble with their health, especially when their lives are at stake. In cases of non life-threatening, chronic disease, there is no harm in trying safe

alternatives. In cases of terminal illness, there is no harm in allowing patients to pursue other options when conventional therapies have nothing to offer them.

In many instances, people who use alternative therapies have already tried conventional methods to no avail. Others seek alternative therapies as an adjunct to their allopathic care. In some cases, patients prefer not to suffer the side effects of conventional therapies and look to alternatives because they are less toxic or allow them to maintain their quality of life. This bill lets the patient make this choice for himself.

Note, too, that the bill requires practitioners to fully inform their patients about all of their options, including conventional treatments. This will ensure, for instance, that patients of physicians using unconventional therapies will have the benefit of knowing about the full range of therapies available to them, plus the pros and cons of each. Patients of conventional physicians, on the other hand, may be unaware of their options because their practitioners are required only to inform them about treatments considered "standard of care." There is a lawsuit underway now in California against a hospital and tumor review board for their failure to inform a patient about an alternative therapy that has shown success in treating a form of brain cancer for which there is no conventional therapy, and of which the physicians were well aware.

**Q. Doesn't this bill open the door to quackery?**

**A.** No, the legislation provides that treatments will be administered by practitioners who are licensed or otherwise authorized to provide health care services. It does not permit them to provide services that are outside their normal scope of service; for instance, it won't permit acupuncturists to perform surgery. It does, however, help ensure that a practitioner would not be subject to disciplinary action solely because his treatment methods are considered unorthodox by the medical establishment.

We believe that individuals, not the federal government, the FDA or the American Medical Association, should be the final arbiters of individuals' health care regimens.

Most importantly, this bill covers only those therapies provided by an authorized practitioner who has personally seen and diagnosed the patient. It does not cover mail order or internet sales of unapproved products, or permit unauthorized practitioners to treat patients.

**Q. Does this shield doctors from malpractice claims?**

**A.** No. Doctors are still accountable for the welfare of their patients, and still held to the prevailing standards in providing care. Nothing in this legislation dilutes patients' abilities to sue a doctor for malpractice. In fact, the AMTA actually increases patients' rights by requiring full disclosure and informed consent before a practitioner can treat patients with an unconventional or non-FDA approved therapy.

**Q. Does this bill guarantee insurance coverage for alternative therapies?**

A. No. Such decisions will still be determined by the states and by individual insurance companies. The bill could make it more likely that insurance companies will be willing to cover alternatives, however, because they could do so knowing that the practitioners have the right to provide such therapies. By removing the fear of censure and FDA raids, the bill could free insurance companies to reimburse patients for a broader range of therapies. Several insurance companies have already begun providing coverage for acupuncture, massage, chiropractic and other therapies that were once considered unconventional. Consumers, of course, have already voted with their pocket books. According to an article in the *New England Journal of Medicine*, Americans spend over $10 billion dollars on alternative medicine, including nutritional supplements, even though only a fraction of that is covered by insurance.

**Q. Why is there such resistance from the allopathic medical community to the use of alternatives if they are safe and effective?**

A. Whenever the status quo is challenged, you can expect three stages of reaction. First, there is ridicule; second there is anger and recrimination; and third, there is acceptance. In 1848, Semmelweis proposed that child bed fever was caused by morbid matter carried from cadavers to the delivery room by his fellow physicians who refused to wash their hands. Of course, he was ridiculed at the time, but now the importance of hand washing would never be questioned. To achieve advancements in science and medicine, orthodoxy must be challenged. If we don't allow such challenges, the caliber of health care in this country will quickly fall behind.

It may be threatening to the U.S. pharmaceutical industry, but the decision to allow Americans access to drugs used safely and effectively in other countries should not be based on turf considerations or its effect on a company's bottom line. The determining factor should be whether or not that access will save or improve the quality of life of the patient in question.

**Q. Don't we need the FDA to approve these substances and therapies to ensure that they are safe and effective?**

A. "There is no greater frustration on the part of a treating physician than to know that the best and most up-to-date treatment cannot be made available or, more frequently, may lead to potential medicolegal action because of the inaction and delay on the part of the FDA," wrote the Center for Patient Advocacy. "This intrusion into the doctor-patient relationship must not be tolerated by a government agency whose primary job is the evaluation of safety, not clinical practice."

The FDA is not in the business of regulating the practice of medicine, yet it has tried to insert itself into the process through its hammerlock on the dissemination of scientific information, its attempts to classify natural substances as drugs, its delay in approving therapies that have been used successfully in other countries for decades, and its insistence that all drugs, whether approved elsewhere or not, go through the long and expensive FDA approval process. If Americans are to continue benefiting from the best health care in the world, the present system of regulation must be altered.

**Q. Why don't companies simply get their therapies approved by the FDA?**

A. The present system doesn't work for many unconventional therapies for several reasons.

♦ First, many of them involve natural substances which are not patentable. It costs over $300 million and takes a decade or more to achieve FDA approval of pharmaceuticals today. No company would undertake such an expenditure of time and resources to get FDA approval to make a health claim for injectable Vitamin C, for instance, because they could not recoup any of those costs.

♦ Second, the definition of a drug is problematic; it hasn't kept pace with the science. Many doctors use injectable vitamins to treat, cure, prevent and mitigate disease, which technically turns those supplements into unapproved drugs. Intended use and labeling determine whether the very same substance is a supplement or a drug.

♦ Foreign companies are under no obligation to undergo the FDA approval process for drugs that are already approved in other countries. The cost of the process ($300+ million) and time involved are weighed against the potential value of accessing the U.S. market.

♦ Small U.S. companies and individual clinicians don't have the resources to complete a new drug application and run clinical trials. The Investigational New Drug process is lengthy, expensive, and requires a tremendous amount of paperwork. It must be administered under an Institutional Review Board (IRB) that is responsible for monitoring compliance with the protocol during clinical trials. The FDA must approve the protocol and determine the number and type of patients who will participate.

Patients who do not exactly meet the criteria would be denied access to the therapy during the clinical trial, which can take years to complete. The process is designed for testing drugs that may eventually be patented, so the applicant has every expectation that the considerable expense may eventually be recouped. This means that INDs are feasible only for large manufacturers who can afford to provide the product free to hundreds of physicians (an FDA requirement) who must then strictly adhere to the protocol, report their results to the IRB, and provide the drug for free to patients. It is simply not feasible for an individual doctor, in most cases, to fulfill the requirements of an IND, because of the incredible expense, manpower and time required; nor are the substances necessarily patentable.

The present system is designed to accommodate drugs developed by large pharmaceutical companies; drugs designed to treat one symptom of one disease, and drugs for which a tight

protocol can be designed, (ie: a drug to treat breast cancer in women over the age of 30 who have had surgery but not radiation.) The system does not have the flexibility to address the many and unique sources and designs of other types of drugs.

**Q. Does this bill pre-empt states' rights or state medical board authority?**

**A.** No. Each state still has the right to regulate the practice of medicine within its own borders. Eleven states -- Alaska, Colorado, Georgia, Minnesota, New York, North Carolina, Ohio, Oklahoma, Oregon, South Carolina and Washington -- have already passed access-type bills to ensure that alternative therapies are available to consumers. Efforts are also underway in California, Delaware, Florida, Kentucky, New Jersey, Massachusetts, Missouri, Virginia and Wyoming to pass similar legislation.

Some states are openly hostile to unconventional therapies, and several have even passed legislation outlawing specific treatments. In California, for instance, it is illegal for a doctor to treat cancer with anything except chemotherapy, radiation or surgery. Even if a patient has tried all of those and has been told conventional medicine has nothing else to offer, he still cannot receive an alternative treatment. Doctors providing such treatment could lose their license to practice. As a consequence, states are unwittingly driving people to other countries and creating a black market in health care. We are trying to rectify that scenario with the AMTA.

**Q. If this bill doesn't pre-empt states' rights to regulate the practice of medicine, how will it make a difference in states that are openly hostile to the use of alternative therapies?**

A. If you live in a hostile state, you may still have problems accessing therapies that would be allowed under this bill. Texas, for instance, has its own FDA, and may regulate products differently than the federal government. Nevertheless, AMTA does help in these situations because it creates a federal statutory right for consumers to use unapproved products, which means they will have a position from which to challenge any state restrictions to that right. Without AMTA, they have no such leverage. The bill also gives practitioners some leverage if they choose to go to their medical board or state legislature seeking changes in state laws or regulations. Most states look to the FDA for guidance. If this bill removes the federal prohibition from access to unapproved drugs and devices, a state may be more likely to consider allowing such access as well.

**Q. Isn't this really a state issue?**

**A.** Not solely, because federal policies, laws and the FDA directly impact how the states regulate the practice of medicine. State regulatory bodies do not operate in a vacuum. Most medical boards look to the FDA for guidance. If the FDA has not approved a drug, for instance, a state board is unlikely to allow its use. This is not to say the FDA has refused to approve the drug,

only that it has not approved it, perhaps because the manufacturer hasn't submitted an application for consideration. As outlined above, many of the therapies that would be accessible under this legislation are simply not patentable, and therefore the manufacturers would never seek FDA approval.

In addition, by not permitting the interstate shipment of unapproved items, the FDA effectively regulates the practice of medicine. The Access bill would permit the interstate shipment of substances used under the specified parameters outlined in the consumer protection language of the legislation. Passage of this legislation would send an important message to state boards: unapproved does not automatically mean ineffective or dangerous.

Too often, state boards demand strict adherence to the limits of "standard of care", when in fact, those standards should remain fluid to reflect advancements in medicine. Today's unapproved therapies may be tomorrow's standard of care.

**Q. What kinds of things, specifically, *will be* available if the bill passes, that are not available now?**

**A.** There are three main categories of products that would be available under the Access Bill.

1. Therapies that have been used in other countries, sometimes for decades, would be available in the United States. Many of them are quite effective, but have simply not been approved by the FDA, so Americans cannot access them unless they have the time and money to go abroad. For instance:

- an experimental cancer therapy using 714x is being used in Canada with impressive results;
- in Germany, ozone therapy is used to treat a number of conditions, with great success, but it is not available in the United States;
- former Iowa Congressman Berkley Bedell successfully recovered from Lyme Disease after conventional methods failed, by using an unapproved therapy. Although the therapy was safe, inexpensive and effective, it has not been approved by the FDA. Tthe individual who assisted him in producing the substance was charged with practicing medicine without a license and had to endure a lengthy and expensive trial before being acquitted. Hundreds of people have called Mr. Bedell, desperate for access to this therapy, but he must tell them that it is illegal for them to cure their debilitating disease using this effective therapy. The therapy is not available anywhere else in the world;
- full-body hypothermia is being used to treat cancer elsewhere in the world. It should be done in a hospital setting, but U.S. hospitals will not provide it for cancer patients because it is considered experimental. In laymen's terms, the therapy heats the patient's blood to levels that kill cancer cells, without damaging healthy cells.

- Coley's Toxin has been used to treat cancer since 1890, and is still used in Europe but not the United States. Patients receive a injection of the toxin which results in the blood temperature increasing, which kills cancer cells. While it is effective, it is less so than full-body hypothermia.
- in California, it is illegal to treat cancer with anything except surgery, radiation and chemotherapy. Intravenous nutrition therapy is prohibited.

2. Drugs undergoing clinical trials could be made available to individuals who do not fit the protocol. Under the present regime, the FDA is unlikely to allow such access, even if there is a strong likelihood that the drug would be advantageous, because the agency does not want to skew the data by including "outlyers" whose results would affect the statistical results of the strict protocol. Manufacturers also understandably want to limit the number of patients participating in clinical trials because they are not permitted to make a profit by selling the experimental drug to participating patients; it must be provided at no charge. The Access Bill would not completely remedy this situation but physicians would at least be allowed to make the drug available at cost, which is a dramatic improvement over the complete lack of access under the present system.

3. Natural products and therapies designed by individuals who have neither the means nor the resources to get FDA approval would still be available to patients. The Lyme Disease treatment which cured Berkley Bedell, for instance, would be accessible to thousands of patients who have not been cured by conventional antibiotic treatment.

**Q. Can't patients take advantage of the personal use importation system to access drugs used in other countries?**

A. Technically they can, but in reality this is quite difficult to do. Individuals are only allowed to purchase such unapproved drugs if there is no approved drug available in the United States for their condition. This eliminates access to drugs the patient may prefer to take for a myriad of reasons. It also leaves up to the FDA the choice of treatment, eliminating the patient's right to make that decision for himself. Assuming the patient is able to meet this burden of proof to the satisfaction of the FDA, he must then find a doctor to write a prescription for the foreign drug, and locate a foreign source willing to sell and ship it to him. He patient may only purchase a 30-day supply. When the product enters the United States, the FDA inspects it and sends a frightening letter to the recipient notifying him of the restrictions on his ability to continue importing the drugs. Patients are easily intimidated by the letter, and often misunderstand the intent, believing that they are no longer allowed to purchase the drug. Because the FDA does not keep statistics on the amount or duration of personally imported drugs, we have no way of monitoring the amount of access this system allows. We can say with certainty, however, that it is a cumbersome and unnecessarily intrusive process that can be navigated by only the most determined patients.

**Q. Would this bill legalize the use of marijuana for the treatment of medical conditions?**

**A.** No. The bill will not allow access to illegal drugs or interfere with state statutes outlawing any use of marijuana. It says, specifically, that the practitioner may not violate the Controlled Substances Act.

**Q. Would this bill legalize suicide?**

**A.** No. The purpose of the bill is to increase consumers' access to the full range of therapies, within the confines of a safe, regulated health care environment. The goal is to strengthen the doctor-patient relationship by returning decisions about therapy choice to the individual, and to promote advancements in medicine by allowing new and alternative approaches to emerge and be considered without fear of censure or harassment. The bill would not pre-empt state laws regarding suicide or physician-assisted suicide.

**The American Preventive Medical Association**
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(Original Signature of Member)

107TH CONGRESS
1ST SESSION

# H. R. _____

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IN THE HOUSE OF REPRESENTATIVES

Mr. DEFAZIO introduced the following bill; which was referred to the Committee on _____

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# A BILL

To allow patients access to drugs and medical devices recommended and provided by health care practitioners under strict guidelines, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Access to Medical Treatment Act of 2001".

**SEC. 2. DEFINITIONS.**

In this Act:

(1) ADULTERATED.—The term "adulterated" means any unapproved drug or medical device that in whole or part consists of any filthy, putrid, or decomposed substance that has been prepared, packed, or held under unsanitary conditions where such drug or device may have been contaminated with such filthy, putrid, or decomposed substance and be injurious to health.

(2) ADVERTISING CLAIM.—The term "advertising claim" means any representation made or suggested by statement, word, device, sound, or any combination thereof with respect to medical treatment.

(3) COSTS.—The term "costs" means a charge to patients equal to the amount necessary to recover expenses for making or obtaining the unapproved drug or medical device and providing for its transport to the health care practitioner. Such term does not include the fees charged by a health care practitioner for his or her professional services in admin-

istering, providing, or counseling the patient concerning the unapproved drug or medical device.

(4) DANGER.—The term "danger" means an adverse reaction, to an unapproved drug or medical device, that used as directed—

(A) causes serious harm to the patient in a case in which such harm would not have otherwise occurred; or

(B) causes harm that is more serious than side effects for drugs or medical devices approved by the Federal Food and Drug Administration for the same disease or condition.

(5) DRUG.—The term "drug" has the same meaning given that term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(6) HEALTH CARE PRACTITIONER.—The term "health care practitioner" means a physician or other individual who is a provider of health care, who is authorized under the law of a State to prescribe drugs or devices.

(7) INTERSTATE COMMERCE.—The term "interstate commerce" means commerce between any State or Territory and any place outside thereof, and commerce within the District of Columbia or

within any other Territory not organized with a legislative body.

(8) LEGAL REPRESENTATIVE.—The term "legal representative" means a parent or other person who qualifies as a legal guardian under State law.

(9) MEDICAL DEVICE.—The term "medical device" has the same meaning given the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(10) PATIENT.—The term "patient" means any person who seeks medical treatment from a health care practitioner for a disease or health condition.

(11) SECRETARY.—The term "Secretary" means the Secretary of the Department of Health and Human Services.

(12) UNAPPROVED DRUG OR MEDICAL DEVICE.—The term "unapproved", with respect to a drug or medical device, means a drug or medical device that is not approved or authorized for manufacture, sale, and distribution in interstate commerce under section 505, 513, or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360c, and 360e) or under section 351 of the Public Health Service Act (42 U.S.C. 201).

**SEC. 3. ACCESS TO MEDICAL TREATMENT.**

(a) IN GENERAL.—Notwithstanding sections 501(a)(2)(B), 501(e) through 501(h), 502(f)(1), 505, 513, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B), 351(e) through 351(h), 352(f)(1), 355, 360c, and 360e) and section 351 of the Public Health Service Act (42 U.S.C. 201) or any other provision of Federal law, a patient may receive, and a health care practitioner may provide or administer, any unapproved drug or medical device that the patient desires or the legal representative of the patient authorizes if—

(1) such practitioner has personally examined such patient and agrees to treat such patient;

(2) the unapproved drug or medical device is recommended by a health care practitioner within that practitioner's scope of practice under State law;

(3) the provision or administration of the unapproved drug or medical device is not a violation of the laws of the State or States in which the activity is carried out; and

(4) the health care practitioner abides by all of the requirements in subsection (b).

(b) REQUIREMENTS.—A health care practitioner may recommend, provide or administer any unapproved drug or medical device for a patient, pursuant to subsection (a), if that practitioner—

(1) does not violate State law by providing or administering the unapproved drug or medical device;

(2) does not violate the Controlled Substances Act (21 U.S.C. 801 et seq.) by providing or administering the unapproved drugs;

(3) has concluded based on generally accepted principles and current information that the unapproved drug or medical device, when used as directed, will not cause a danger to the patient;

(4) provides the recommendation under circumstances that give the patient sufficient opportunity to consider whether or not to use such a drug or medical device and that minimize the possibility of coercion or undue influence by the health care practitioner;

(5) discloses to the patient any financial interest that such a practitioner may have in the drug or medical device;

(6) has informed the patient in writing, prior to recommending, providing, or administering the unapproved drug or medical device—

(A) that the unapproved drug or medical device is not approved by the Secretary as safe

and effective for the condition of the patient and is considered experimental;

(B) of the foreseeable risks and benefits of the unapproved drug or medical device, including any risk to an embryo or fetus, and expected possible side effects or discomforts that the patient may experience and any medical treatment available if side affects occur;

(C) of any appropriate alternative procedures or courses of treatment (including procedures or courses of treatment that may involve the use of a drug or medical device that has been approved by the Food and Drug Administration), if any, that may be advantageous for the patient's condition;

(D) of any interactions the unapproved drug or medical device may have with other drugs, if any;

(E) of the active and inactive ingredients of the unapproved drug and the mechanism of action of the medical device, if known;

(F) of the health condition for which the unapproved drug or medical device is provided, the method of administration that will be used, and the unit dose;

(G) of the procedures that will be employed by the health care practitioner in using such a drug or medical device;

(H) of the extent, if any, to which confidentiality of records identifying the patient will be maintained;

(I) for use of such a drug or medical device involving more than minimal risk, of the treatments available if injury occurs, what such treatments involve, and where additional information regarding such treatments may be obtained;

(J) of any anticipated circumstances under which the patient's use of such a drug or medical device may be terminated by the health care practitioner without regard to the patient's consent;

(K) that the use of an such a drug or medical device is voluntary and that the patient may suspend or terminate treatment at any time;

(L) of the consequences of a patient's decision to withdraw from the use of such a drug or medical device;

(M) if any information described in subparagraphs (A) through (L) cannot be provided by the health care practitioner because such information is not known at the time the practitioner provides or administers such drug or medical device, that such information cannot be provided by the practitioner; and

(N) of any other information or disclosures required by applicable State law for the administration of experimental drugs or medical devices to human subjects;

(7) has not made, except as provided in subsection (d), any advertising claims for the unapproved drug or medical device;

(8) does not impose a charge for the unapproved drug or medical device in excess of costs;

(9) complies with requirements for reporting a danger in section 4; and

(10) has received a signed affidavit from the patient or the patient's legal representative confirming that the patient or the legal representative—

(A) has received the written information required by this subsection and understands it; and

(B) desires treatment with the unapproved drug or medical device as recommended by the health care practitioner.

The provisions of paragraph (8) shall not be construed to apply to dietary supplements.

(c) MANDATORY DISCLOSURE.—Any manufacturer of an unapproved drug or medical device shall disclose, to any health care practitioner that has received such drug or medical device from such manufacturer, all information available to such manufacturer regarding such drug or medical device to enable such practitioner to comply with the requirements of subsection (b)(3) and make a determination regarding the danger posed by such drug or medical device. Compliance with this subsection shall not constitute a violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) ADVERTISING CLAIMS EXCEPTION.—Subsection (b)(7) shall not apply to a health care practitioner's dissemination of information on the results of the practitioner's administration of the unapproved drug or medical device in a peer-reviewed journal, through academic or professional forums, or through statements by a practitioner to a patient. Subsection (b)(7) shall not apply to any accurate and truthful statement made in person by

a health care practitioner to an individual or a prospective patient.

**SEC. 4. CESSATION OF USE, AND REPORTING OF, DANGEROUS DRUGS AND MEDICAL DEVICES.**

(a) DUTY TO PROTECT PATIENT.—If a health care practitioner discovers that an unapproved drug or medical device causes a danger to a patient, the practitioner shall immediately cease use and recommendation of the unapproved drug or medical device and provide to the manufacturer of the unapproved drug or medical device and the Director of the Centers for Disease Control and Prevention—

(1) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(2) a written evaluation of the adverse reaction, including its physiological manifestations, duration, and the effect of cessation of treatment upon the patient's condition;

(3) any other information the health care practitioner deems pertinent to an evaluation of the adverse reaction;

(4) the name, occupation, business address, and business telephone number of the physician;

(5) the name of the unapproved drug or medical device and a description of the method of administration and operation, dosage, and duration of treatment;

(6) the lot number, if any, of the unapproved drug or medical device; and

(7) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information provided under subsection (a) shall immediately—

(1) cease sale and distribution of the unapproved drug or medical device pending completion of an investigation to determine the actual cause of the danger;

(2) notify all health care practitioners to whom the manufacturer has provided the unapproved drug or medical device of the information provided to the manufacturer under subsection (a); and

(3) report to the Secretary in writing that an unapproved drug or medical device (identified by name, known method of operation, unit dose, and intended use) that the manufacturer provided to a

health care practitioner for administration under this Act has been reported to be a danger to a patient and confirming that the manufacturer—

(A) has ceased sale and distribution of the unapproved drug or medical device pending completion of an investigation to determine the actual cause of the danger; and

(B) has notified health care practitioners to which the unapproved drug or medical device has been sent of the information it has received.

(c) INVESTIGATION.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, upon receipt of the information described in subsection (a), shall conduct an investigation of the unapproved drug or medical device that a health care practitioner has determined to cause a danger to a patient in order to make a determination of the actual cause of such danger.

(2) REPORT TO SECRETARY.—The Director of the Centers for Disease Control and Prevention shall prepare and submit a report to the Secretary regarding the determination made under paragraph (1), including a determination concerning whether the unapproved drug or medical device is or is not

the actual cause of danger or whether the actual cause of danger cannot be determined.

(3) DUTY OF SECRETARY.—Upon receipt of the report described in paragraph (2), the Secretary shall—

(A) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is the unapproved drug or medical device, direct the manufacturer of such drug or medical device to—

(i) cease manufacture, sale, and distribution of such drug or medical device; and

(ii) notify all health care practitioners to whom the manufacturer has provided such drug or medical device to cease using or recommending such drug or medical device, and to return such drug or medical device to the manufacturer as part of a complete recall;

(B) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is not such drug or medical device, direct the manufacturer of such drug or medical device to inform all health care

practitioners to whom the manufacturer has provided such drug or medical device of such a determination; and

(C) if the Director of the Centers of Disease Control and Prevention cannot determine the cause of the danger, direct the manufacturer of the drug or medical device to inform all health care practitioners to whom the manufacturer has provided such drug or medical device of such a determination.

(d) SECRETARY'S DUTY TO INFORM.—Upon receipt of the report described in subsection (b)(3), the Secretary shall promptly disseminate information concerning the danger to all health care practitioners in the United States, to the Director of the National Center for Complementary and Alternative Medicine, and to agencies of the States that have responsibility for regulating unsafe or adulterated drugs and medical devices.

**SEC. 5. REPORTING OF RESULTS OF UNAPPROVED DRUGS AND MEDICAL DEVICES.**

(a) REPORTING OF RESULTS.—If a health care practitioner provides or administers an unapproved drug or medical device, that in the opinion of the health care practitioner, produces results that are more beneficial than results produced from any drug or medical device approved

by the Food and Drug Administration, or produces other results regarding the effectiveness of the treatment relative to treatments approved by the Food and Drug Administration for the same condition, the practitioner shall provide to the manufacturer—

(1) the results of the administration of the drug or device;

(2) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(3) the name, occupation, business address, and business telephone number of the physician;

(4) the name of the unapproved drug or medical device and a description of the method of operation and administration, dosing, and duration of treatment; and

(5) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information under subsection (a) shall provide to the Director of the National Center for Complementary and Alternative Medicine—

(1) a complete copy of the information;

(2) the name, business address, and business telephone number of the manufacturer;

(3) the name, business address, and business telephone number of the health care practitioner who supplied information to the manufacturer;

(4) the name of the unapproved drug or medical device;

(5) the known method of operation and administration of the unapproved drug or medical device;

(6) the per unit dose; and

(7) the intended use of the unapproved drug or medical device.

(c) DIRECTOR'S DUTY TO MAKE PUBLIC.—The Director of the National Center for Complementary and Alternative Medicine shall review and analyze information received pursuant to subsection (b) about an unapproved drug or medical device and make available, on an Internet website and in writing upon request by any individual, an annual review and analysis of such information, and include a statement that such drug or medical device is not approved by the Food and Drug Administration.

**SEC. 6. OTHER LAWS NOT AFFECTED BY THIS ACT.**

This Act—

(1) shall not be construed—

(A) to have any effect on section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a); or

(B) to supersede any law of a State or political subdivision of a State, including laws governing rights and duties among health care practitioners and patients;

(2) shall not apply to statements or claims permitted or authorized under sections 403 and 403B of such Act (21 U.S.C. 343, 343–2); and

(3) shall not in any way adversely affect the distribution or sale of dietary supplements (as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

**SEC. 7. AUTHORIZED ACTIVITIES OF HEALTH CARE PRACTITIONERS.**

(a) INTRODUCTION IN INTERSTATE COMMERCE.—To the extent necessary to comply with this Act, a health care practitioner may—

(1) introduce an unapproved drug or medical device into interstate commerce;

(2) deliver an unapproved drug or medical device for introduction into such commerce;

(3) transport an unapproved drug or medical device in such commerce;

(4) receive an unapproved drug or medical device in such commerce and deliver the unapproved drug or medical device; and

(5) hold an unapproved drug or medical device for sale after shipment of the unapproved drug or medical device in such commerce.

(b) RULE OF CONSTRUCTION.—This Act shall not be construed to limit or interfere with the authority of a health care practitioner to prescribe, recommend, provide or administer to a patient for any condition or disease any unapproved drug or medical device lawful under the law of the State or States in which the health care practitioner practices.

**SEC. 8. PENALTY.**

A health care practitioner or manufacturer found to have knowingly violated this Act shall be denied coverage under this Act.

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Cole

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# TESTIMONY BEFORE THE WHITE HOUSE SUBCOMMITTEE ON THE DELIVERY OF RELIABLE AND USEFUL INFORMATION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

**Good afternoon. My name is Diane Cole, and I am an education coordinator at the University of Virginia Cancer Center. I address you on behalf of health care providers and educators who are mandated to educate patients and their families at cancer centers across the country.**

**What we know is that 50% or more of all cancer patients are using some form of complementary or alternative therapy; we are trying to address the quality of that information, for the protection of the patient. Our patients are very vulnerable to being taken advantage of by companies and products whose bottom line is profit instead of cure or quality of life. Many of them trust their health professionals to provide excellent medical care, but they want to do more for themselves that help them feel in control.**

**These patients are making decisions about and are spending thousands of dollars on some therapies and products that have very inconsistent data to support their benefit. When they search the web, there is no standard on which to judge the credibility of the websites. Many patients will not tell their physicians what CAM therapies they are using, and many physicians do not feel comfortable advising their patients about what CAM therapies to use, if any.**

**Members of our network hear patients express their frustration and confusion about what they should be doing in terms of CAM every day. In response to this, we have developed a Guide to CAM Resources which is not exhaustive, but it gives patients a start. This Guide is provided in your packet of information.**

**Our network offers the following observations for your consideration, based on our experience with this patient population:**

- **Students preparing to be health care professionals, as well as those already in the field, should be educated on complementary and alternative medicine practices and interventions. A better understanding of CAM services by all health care professionals is the best way to eliminate barriers and make CAM services more accessible.**

- **An oversight department in Health and Human Resources must be at the forefront of consumer safety issues, responsible for the labeling of herbal "natural" products and supplements. Consumers should be able to read a label and make good decisions about possible side effects and/or food/drug interactions.**

- **Medicare and third party reimbursement should be available to include modalities such as massage, acupuncture, and visits with other certified practitioners. Research in this area could prove that there is a real potential for tremendous cost savings to the burden of the present health care delivery system.**

- **Lastly, more research is needed in complementary and alternative medicine modalities. Research should encompass case studies and clinical trials that include the study of the placebo effect.**

**Thank you for the time dedicated to this important topic of Complementary and Alternative Medicine that now occupies a prominent position in the delivery of health care services to our cancer patients.**

# Summary
# White House Commission on Complementary and Alternative Therapy
# May 16, 2001, Public Testimony
# Presentation by Diane Cole, M.P.H.

**Who we are:**

A group of patient educators at NCI Designated Cancer Centers throughout the country. Included in our group are MD's, social workers, psychologists, chaplains, nurses, and health educators.

**Who we serve:**

Cancer patients and members of our communities

Within our network, we serve the needs of cancer patients (pediatrics and adults) throughout the spectrum of care – this includes diagnosis, treatment, rehabilitation, and end-of-life care. Many of us also serve our communities at large, providing education and awareness to people regarding health, lifestyle, and the early diagnosis of cancer.

**Description of the Need:**

- Fifty percent or more of all cancer patients are using some form of complementary or alternative therapy.
- Many patients trust their physicians to provide excellent medical care, but they want to do more for themselves that help them feel in control.
- Patients are making decisions about and are spending thousands of dollars on some therapies and products that have very inconsistent data to support their benefit.
- When patients search the web, there is no standard on which to judge the credibility of the websites.
- Many patients will not tell their physicians what CAM therapies they are using, and many physicians do not feel comfortable advising their patients about what CAM therapies to use, if any.
- The cancer patient population is very vulnerable to being taken advantage of by companies and products whose bottom line is profit instead of cure or quality of life.
- Education needs to be provided to let them know the importance of rigorous evaluation, and clinical trials are essential to knowing a therapy's risk and benefit. Patients are frustrated with the time clinical trials take to prove benefit to the cancer patient.

**What We Have Done:**

- Provided assistance in the past 2 years in developing parts of Dr. Jim Gordon's conference "Comprehensive Cancer Care: Integrating Complementary and Integrative Medicine."
- Developed a Guide to CAM Resources that we distribute throughout our network (attached).
- One member has contributed to a comprehensive guide to complementary and alternative therapies that can be found at http://www.canctr.mc.duke.edu/pated/CAM.asp
- Compiled a list of CAM fact sheets that have been written by and are provided at institutions across the country.
- We are currently in the process of developing FAQ sheets on CAM therapy.

**Our recommendations to the White House Commission on Complementary and Alternative Therapy:**

- Better education for all students preparing to be health professionals. This includes incentives for medical schools and nursing schools to include CAM information in their curriculum.
- More opportunities in continuing education for health professionals currently in the field. Continue the annual CAM conference and provide other affordable opportunities for education.
- Establish a department that regulates the labeling of herbal "natural" products and supplements. This department should also provide education to the public regarding reading labels, side effects, and food and/or drug interactions. Labeling should accommodate those of low literacy.
- Pass legislation that can expand third party reimbursement to cover more CAM therapies with certified practitioners (massage, acupuncture, meditation, etc.)
- Regulate the gathering of natural products from our world's rainforests.
- Increase funding for research that includes clinical trials on all aspects of CAM, including the placebo effect, pain management, and end-of-life care. Provide avenues where this research is then communicated to all health professionals and the public.
- Create a "seal" (like the Better Business Bureau has done) to indicate a standard of information provided on websites. This could be one indication for the consumer of reliable information.
- Provide better information to the consumer on how to evaluate studies, practitioners, and new products.
- Encourage collaboration among health organizations, such as what is being done within the patient education network, to work together not only on research but also on public education. Encourage collaboration especially between the mainstream/allopathic world and the CAM world.

# Complementary and Alternative Medicine
# A Guide to Resources

## Articles/Books

**Alternative Medicine Handbook** by Barrie Cassileth. NY, NY: W.W. Norton, 1998. 340 pages. Available from W.W. Norton and Company, Inc. 500 Fifth Avenue, New York, NY 10110. 212-354-5500, FAX: 212-869-0856.

*This book describes 53 major alternative and complementary medicine practices. It does not recommend treatments, but instead provides information about their backgrounds, goals, benefits, and risks to help the reader make informed choices. It is divided into seven sections addressing different categories of alternative and complementary treatments. Each section contains several chapters, each of which include a brief introduction, a description of the alternative or complementary therapy, and information about the claims of practitioners, theories or beliefs upon which the therapy is based, available research, potential benefits, and where to find additional information. This book contains a list of complementary therapies for common ailments, a glossary, a list of professional degrees and titles, and an index.*

**An Introduction to Complementary and Alternative Therapies** by Georgia Decker, Ed. Pittsburgh , Oncology Nursing Press, Inc., 1999.

*This book is a good resource for nurses and other health care professionals. It is a concise overview of many complementary and alternative therapies including bioelectric, manual healing, biologic therapies, herbal medicine, diet and nutrition, and lifestyle changes. The reference list in each section leads the reader to more detailed resources. This book is well organized and user friendly.*

**Choices in Healing: Integrating the Best of Conventional and Complementary Approaches to Cancer** by Michael Lerner. Cambridge, MA: MIT Press, 1994. 667p.

*This book presents an overview of conventional and alternative medicine cancer treatments and a thorough discussion of the impact of a cancer diagnosis on the individual. Includes a glossary, a resource listing, and a list of professional training programs in spiritual and psychological approaches to cancer treatments.*

**Comprehensive Cancer Care: Integrating Alternative, Complementary, and Conventional Therapies** by James S. Gordon and Sharon Curtin. MA, Perseus Publishing, 2000.

*Based on the findings of the annual conference co-sponsored by the Center for Mind-Body Medicine and the National Cancer Institute, this book is a guide to the integration of conventional, complementary, and alternative medicines for cancer care.*

*The book includes:*

- *Reports on the most accepted and researched complementary and alternative practices, including assessments of their efficacy, side effects, cost effectiveness, and how they can best be integrated with conventional care*
- *Empowering advice for patients with clear action steps for speaking to doctors and evaluative guidelines for researching available treatment approaches*

- *Critical discussion of cutting-edge interventions such as nutrition, Chinese medicine, herbal therapies, mind-body approaches, and energy medicine that have undergone clinical trials and those which are now beginning to be employed.*

**The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines** edited by Mark Blumenthal. TX, American Botanical Council,1998.

*This reference provides information on 380 Commission E Monographs, which are based on clinical trials, field studies, case collections, scientific literature, unpublished proprietary data, and other carefully, reviewed information.*

*Both approved and unapproved herbs, component characteristics, and herbal combinations are addressed. Each monograph specifies composition, uses, contraindications, side effects, interactions, dosages, administration, pharmacological actions, warnings, precautions, and more.*

**Full Catastrophe Living** by Jon Kabat-Zin. NY, NY, Dell Publishing, 1990.

*This book is meant to serve as a practical guide for those readers, well or ill, who seek to transcend their limitations and move toward greater levels of health and well being. A practical guide to mindfulness, meditation and healing, the book is based on 10 years of clinical experience with more than 4000 people who participated in an eight week course, "The Stress Reduction and Relaxation Program", offered at the University of Massachusetts Medical Center in Worcester, MA.*

**Fundamentals of Complementary and Alternative Medicine** by M. Micozzi, NY, Churchill Livingstone, 1996. 303 p. Available from Churchill Livingstone, division of Harcourt Publishing. Subscriptions, Foots Cray Highstreet, Sidcup, Kent, 877-784-6463, 877-784-6464

*This book contains information about specific complementary and alternative medical therapy systems and approaches. The book presents medical, health, and science students, and interested readers with the foundations, tools, and historical context to understand the many fields of alternative medicine. It features chapters written by contributors on homeopathy, osteopathy, naturopathy, Ayurveda, Chinese medicine, Cuaranderismo, Western herbalism, and other systems. The book presents the contemporary complementary and alternative medical approaches that come from observations within, around and beyond the current Western, biomedical paradigm. The forward features an article by C. Everett Koop, the former U.S. Surgeon General. The list of contributors includes their professional affiliations. The book contains photographs and illustrations and is available on CD-ROM.*

**Herbal Medicine: Expanded Commission E Monograph** edited by Mark Blumenthal and Alicia Goldberg. TX, American Botanical Council, 2000.

*The original compendium, The Complete German Commission E Monographs-Therapeutic Guide to Herbal Medicines, developed by the American Botanical Council, set the benchmark as the leading government sanctioned authority on herbs. Now Herbal Medicine Expanded Commission E Monographs, selects the top 100 plus herbs and expands the depth of content, adding an extensive overview and supporting references to the literature. Full color photographs introduce each of over 100 herbs. Updated and expanded information enhances the value of the core Commission E material for quick referral and everyday use, including, extensive overviews and references, expanded sections on chemistry, pharmacology, contraindications, side effects, drug interactions, dosage and references, as well as name cross-*

*reference, safety, quality, and proper use during pregnancy and lactation. Herbal Medicine provides in-depth information from the best clinical evidence and research to describe each herb's botany, history, composition, safety, and therapeutic use. It presents the quality and efficacy of specific herbal formulations, provides supporting references to the literature and discusses drug interactions, toxicity, and dosage and administration issues.*

**Herbs Against Cancer** by Ralph Moss. Brooklyn, NY, Equinox Press Inc., 1998.

*This book traces the history and controversies surrounding the use of herbs to treat cancer. It focuses on only herbs from the western tradition, as well as some from the Native American tradition. Essiac Tea is covered in detail with other herbs such as Mistletoe, Grapes, Escharotics and Hemlock covered to a lesser extent. A discussion of paclitaxel (Taxol) from the Yew tree is also included.*

**Living Beyond Limits** by David Spiegel, M.D. A Fawcett Columbine Book published by Ballantine Books, 1993.

*Based on 15 years of research, Stanford University psychiatrist Dr David Spiegel outlines his proven program to help all people with chronic illnesses enhance the quality of their lives. The book delves into the essential healing connection between body and mind. It deals with important issues like strengthening family relationships, facing a shattering diagnosis head-on, facing the fear of dying, building and sustaining networks of support and improving communication with doctors.*

**Minding the Body, Mending the Mind** by Joan Borysenko. NY, Bantam Books 1988.

*In this highly readable layman's book, Dr Borysenko, co-founder and former director of the Mind/Body Clinic, New England Deaconess Hospital, uses personal stories to teach the reader how to use mental and physical exercises to transform one's life. The book teaches the reader how to use the "Relaxation Response" to boost the immune system, overcome chronic pain and alleviate symptoms of a host of stress related illnesses.*

**PDR Family Guide to Natural Medicines and Healing Therapies** edited by David W. Sifton. NY, Three Rivers Press, 1999.

*This consumer's guide addresses health care alternatives from age-old secrets of harmony, balance, and well being to the very latest nutritional discoveries.*
*Topics covered include:*

- *Which widely available herbs, vitamins, and minerals act like potent prescription medications*
- *How certain natural remedies interact with conventional drugs*
- *Self-help techniques*
- *How to locate and choose a qualified practitioner*

*This guide also addresses the latest findings on Acupuncture and Acupressure,, Aromatherapy, Ayurvedic Medicine, Biofeedback, Biological Therapies, Chiropractic Adjustment, Detoxification, Energy Medicine, Environmental Medicine, Homeopathy, Hypnosis, Light Therapy, Massage, Meditation, Mind/Body Medicine, Naturopathic Medicine, Orthomolecular Medicine, Tai Chi, Qigong, and Yoga.*

**PDR for Herbal Medicine.** NJ, Medical Economics Company, Five Paragon Drive, Montvale, 1999. Second Edition.

*This book is easy to use with a comprehensive section on medicine identification information. It consists of an alphabetical scientific and common name index, an indications index and therapeutic index. A drug/herb interactions guide, a color photograph herbal identification guide of more than 380 plants, an alphabetical compilation of approximately 600 herbal monographs and a glossary of common botanical terms is also included. It also contains a listing of poison control centers and drug information centers in the United States. The text is marketed primarily to health care professionals, but the general public will also find this reference easy to read. Information in the book is based primarily on European texts and sources, meaning that most of the references are from foreign sources. These would not be easily accessible if needed. Another drawback is that new information on herbal-drug interactions is constantly being discovered. The concern is that this book stays current, updating information regularly.*

**Spontaneous Healing** by Andrew Weil. N.Y., Borzoi Book published by Alfred A. Knopf, Inc., 1995.

*This book's theme is that the body can heal itself. The book is divided into three parts, including, part one which explains the existence of a healing system that interacts with the mind; part two which tells the reader how to optimize his or her healing system and part three which gives advise on managing illness, including an analysis of the strengths and weaknesses of conventional and alternative treatments.*

**Wherever You Go, There You Are** by Jon Kabat-Zin. Source: Hyperion, 114 Fifth Ave., NY, NY 10011, 1994.

*In this book, Jon Kabat-Zinn gives the reader a simple path for cultivating mindfulness in his or her life. It is a perfect book for those coming to meditation for the first time and to longtime practitioners. Just as a garden requires attending to cultivate flowers and eliminate weeds, mindfulness also requires regular cultivating. Cultivating the mind is to bring it to wakefulness meditation.*

## Videos

**Affirmations for Getting Well Again** (Carl Simonton, M.D.)
www.simontoncenter.com/Pages/fbooks.htm; 800-459-3424
Publisher: TouchStar Productions, Seattle (1996) Length 35:00

*The purpose of this video is to unite mind, body and spirit for a personal wellness journey. The video is half affirmations and half guided imagery. O. Carl Simonton presents the introduction. Beautiful scenes, pleasant, relaxing music. The first half includes nature scenes with new age music and printed affirmations on the screen. The last half of the video, the screen is blank (eyes closed) for guided imagery for chemotherapy.*

**Affirmations for Living Beyond Cancer** (Bernie Siegel, MD)
www.touchstarpro.com; 800-759-1294

**A New Vision of Living & Dying** (Sogyal Rinpoche)
www.store.yahoo.com/zamamerica; (800) 256-5262; (415) 392-2066

**Complementery Therapies: Empowering the Cancer Patient** (Xenejenex, 1999)
617-632-2931, available for $5.00 to any NCI affiliation or patient

**Choice in Cancer** (Michael Lerner, PhD)
Commonweal, 415.868.0970

**Conversations at the Edge: Healing and the Spirit** (Rachel Naomi Remen, M.D)
Commonweal, 415.868.0970

**Focus on Healing Through Movement and Dance** (Sherry Davis)

**Gentle Yoga for the Physically Challenged** (Margot Kitchen)
www.yogacalgary.org/pricelist.html

**Healing and the Mind Series** (Bill Moyers):
www.shopping.yahoo.com/video/

- Volume 1: The Mystery of Chi
- Volume 2: The Mind Body Connection
- Volume 3: Healing From Within
- Volume 4: The Art of Healing

**Kids Tell Kids What It's Like... When a Family Member Has Cancer** (Cancervive)
310-203-9232, 6500 Wilshire Blvd., Suite 500, Los Angeles CA 90048

**Living with Cancer** (S. F. Regional Cancer Foundation)
www.blockbuster.com

**Look Good... Feel Better: Caring for Yourself Inside and Out** (CTFA Foundation)
www.lookgoodfeelbetter.org; 800-395-LOOK

**Mind & Body** (David Spiegel)

**On With Life: Practical Information On Living With Advanced Breast Cancer** (NABCO)
www.nabcoinfo@aol.com; 888-80-NABCO

**Prepare for Surgery, Heal Faster: A Guide of Mind-Body Techniques** (Peggy Huddleston )
www.healfaster.com/private.html; orders@healfaster.com

**One Move At a Time: Exercise For Women Recovering From Breast Cancer Surgery**
(Christine Clifford); www.cancerclub.com

**Relax, Refresh and Be Your Best** (Naomi Judith Offner)
www.gentleyoga.com; naomi@gentleyoga.com; (760) 598-5224 or (800) 655-6668
1176 Belmont Terrace, Vista CA 92084

## Audiotapes

**Guided Imagery and Meditation**
**Healing Images**
**Meditations for Finding the Key to Good Health**
**Meditations for Everyday Living**
**Meditations for Peace of Mind**
(Bernie Siegel, MD)
www.touchstarpro.com; 800-759-1294

**Positive Imagery For People With Cancer**
**Healing Journey**
(Emmet Miller)
www.cygnus.uwa.edu.au/~gaianet/nam/Miller-audios.html

**Healing Imagery for People Facing Surgery** (Patricia Palmer, EdD)
www.ecap-online.org; 800.759.1294
*This tape includes imagery to help you feel calmer, decrease your need for pain medications and accelerate your recovery process. Use before, during and after surgery. 2 tapes*

**Healing Through Surgery - Subliminal - Prepare Your Body for Surgery**
www.ecap-online.org; 800.759.1294
*This tape is intended to be played before, during and after your operation.*

**Healing Yourself: A Step by Step... Health Through Imagery** (Martin Rossman, M.D.)
800-726-2070

**Health Journey** (Belleruth Naparstek):
- for People Experiencing Stress
- for People Undergoing Chemotherapy

www.healthjourneys.com; 1-800-800-8661

**Mindfulness Meditation Practice Tapes** (Jon Kabat-Zinn)
www.mindfulnesstapes.com; Stress Reduction Tapes, P.O. Box 547, Lexington MA 02420

**Pain Control with EMDR** (Mark Grant)
www.netstoreusa.com/abbooks/157/1572240741.shtml

**Prepare for Surgery, Heal Faster** (Peggy Huddleston)
www.healfaster.com/private.html; orders@healfaster.com

**Preparing for Surgery** (Henry Bennett, PhD)
800.213.3223; Patient Comfort Inc, 204 Park Avenue, Madison NJ 07940

**Relax, Refresh and Be Your Best** (Naomi Judith Offner)
www.gentleyoga.com; naomi@gentleyoga.com; (760) 598-5224 or (800) 655-6668
1176 Belmont Terrace, Vista CA 92084

**Relaxation and Guided Imagery** (Martin Rossman, M.D.)
800-726-2070

## Video/Audio Ordering Companies

**Conference Recording Service**
1308 Gilman, Berkeley, CA 94706
510.527.3600 fax: 510.527.8404

**East West Books**
www.eastwest.com; 800.909.6161 fax: 650.988.9884

**Explorations**
800.720.2114; video tapes and many other yoga-related or cancer-related products are available.

**Gaia Bookstore**
www.darmer.com/gaia.htm; 510.548.4172 fax: 510.548.6134
1400 Shattuck Ave., Berkeley, CA 94709

**Sounds True**
www.soundstrue.com; 800.333.9185

**TouchStar Productions of Meadville,PA** (Barry Bittman, M.D.)
www.ecap-online.org; 800.759.1294

**Yahoo Online Video Shopping**
www.shopping.yahoo.com/video

## Websites

**Acupuncture.com**
http://www.acupuncture.com/

**AICR**
http://www.aicr.org/aicr.htm

**Alternative and Complementary Medicine Center-HealthWorld Online**
http://www.healthy.net/clinic/therapy

**The Alternative Medicine Homepage**
http://www.pitt.edu/~cbw/altm.html

**American Cancer Society**
http://www.cancer.org/alt_therapy/index.html
*This site provides general information on complementary medicine. This includes definitions, resources, articles, and other websites.*

**Ask NOAH about: CAM**
http://www.noah.curry.edu/alternative/alternative.html

**Center for Mind-Body Medicine**
http://www.healthy.net/cmbm

**Commonweal Home Page**
http://www.commonweal.org/canproj.html
*The Commonweal web page provides information on specific resources that include the credible Choices in Healing text by Michael Lerner, Herbal Therapies for Cancer, Recent Research Reports,etc.*

**Dr. Andrew Weil's Homepage**
http://www.pathfinder.com/drweil

**Health Journeys Website**
http://www.healthjourneys.com

**The National Cancer Institute CancerNet-Complementary and Alternative Medicine**
http://cancernet.nci.nih.gov
*Provides credible information on specific types of complementary and alternative therapies (for example: Shark Cartilage, Gerson Therapy, Laetrile, etc.)*

**National Center for Complementary and Alternative Medicine**
http://nccam.nih.gov/
*The NCCAM website provides information about this federal program and how it is organized. It includes news and events, research grant information, and educational resources.*

**NIH Office of Dietary Supplements Database**
http://odp.od.nih.gov/ods/

**Oncolink Specialty Site**
http://oncolink.upenn.edu/specialty/complementary

**Rosenthal Center for Alternative / Complementary Medicine – Columbia University**
http://cpmcnet.columbia.edu/dept/rosenthal/

**Steve Dunn's Cancer Guide**
http://cancerguide.org/alternative.html

**University of Texas Center for Alternative Medicine Research in Cancer**
http://www.sph.uth.tmc.edu:8052/utcam/
*This website includes information on the alternative medicine program at the University of Texas. It also includes links to other resources and a review of current therapies.*

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Comments of the American Dietetic Association #50
Before the White House Commission on Complementary and Alternative Medicine Policy
Washington, DC 20036
May 16, 2001

The American Dietetic Association represents 70,000 food and nutrition professionals who serve the public by promoting nutritional health and well being. Many ADA members are licensed, registered dietitians who provide medical nutrition therapy and preventive nutrition counseling to hundreds of thousands of Americans each year. To date, 43 states, the District of Columbia and Puerto Rico have laws that recognize the dietetic professional. ADA members base work on sound information drawn from peer-reviewed nutrition research and credible sources representing scientific consensus.

The members of ADA generally see nutrition-related CAM therapies as potential components of medical treatment and patient care in which qualified health care professionals work together to provide scientifically sound, safe or empirically proven therapies to better serve patient needs. ADA members welcome additional research that can support broader application of CAM practices. We believe patients who utilize nutrition-related CAM modalities should receive care from those who have appropriate knowledge, training and expertise. We also believe that dietetic professionals are valuable members of the extended team of CAM providers and play an important role in the integration of nutrition with other modalities of treatment.

Science supports the role of preventive nutrition and the role of medical nutrition therapy, or "MNT," in managing disease. However, continued research is needed to evaluate fully many CAM practices and to provide the substance for evidence-based medicine. ADA urges that any preventive or treatment strategy—conventional or CAM—be supported by sound science and evidence based practice before being integrated into a health care strategy.

ADA recognizes that nutrition interventions such as MNT or the use of dietary supplements, may reduce or eliminate the need for more costly medications or treatments. In the case of medical nutrition therapy, we have science to verify the role dietetics plays in medical care and outcomes research to demonstrate the effectiveness of MNT in treating diabetes, renal disease and cardiovascular conditions. A major research project is underway to evaluate health care utilization, costs and health outcomes of MNT on obese patients with Type-2 diabetes.

To help consumers make wise choices about food and dietary supplements, dietitians can provide nutrition counseling and education and can work with patients in developing a sound strategy to obtain nutritional health. Dietitians are the best resource for consumers who need or desire nutrition guidance and are most qualified to provide advice about whether to consume dietary supplements, which ones, and in what amounts.

For example, European studies support use of St. John's Wort for mild depression, which can be purchased for half the cost of a selective serotonin reuptake inhibitor. While this herb may be safe and efficacious for some, St. John's Wort has been shown to interfere with the efficacy of certain drugs such as Coumadin, cyclosporine, digoxin and protease inhibitors, and should not be consumed by patients who rely on those medications. There are many examples of food-drug or supplement-drug interactions, which makes evident the need for dietitians, especially as more Americans consider the use of dietary supplements.

ADA regularly monitors health care coverage for nutrition and nutrition-related services with the goal that all Americans have access to nutrition services supported by evidence-based medicine and provided by RDs.

Nutrition services are covered through reimbursement payments in some hospital, home health and post-acute care settings, but inconsistently among insurance plans and generally at levels inadequate to meet the needs of many Americans, particularly older Americans (IOM, 2000). The situation for the nation's elderly in likely to improve dramatically next year, as the Medicare Medical Nutrition Therapy Act goes into effect, providing MNT to Medicare patients with renal disease or diabetes. Congress also is considering legislation to expand the benefit to include cardiovascular disease.

Even with data showing that MNT coverage leads to fewer complications, fewer and shorter hospital stays and reduced costs for expensive treatments, overall reimbursement for nutrition services remains discouraging. Some managed care plans provide limited coverage and it appears the number of plans and the scope of coverage is increasing. The emergence of specialized insurance networks called "affinity networks" also is improving coverage. These networks offer CAM and many cover nutrition services provided by registered dietitians. However, in some cases CAM networks do not adequately screen providers and may offer nutrition services provided by less qualified individuals. We believe their emergence may help improve access to nutrition counseling for wellness or disease management provided these networks require nutrition providers to have the RD credential.

ADA is also encouraged that government and private-sector groups have begun to explore the prospect of public and private health care coverage for the treatment of obesity.

We hope work will progress rapidly to advance our understanding of the role of nutrition in preventing or delaying the onset of many chronic diseases, and to substantiate through evidence-based practice that coverage of nutrition services is a wise investment in public and private health care programs.

The American Dietetic Association urges the White House Commission to consider the following recommendations for its report to Congress and the President:

- Expand Medicare coverage of nutrition services to include all conditions where MNT is adequately supported by outcomes data (e.g., cardiovascular disease).
- Continue research to substantiate benefits and cost savings of nutrition interventions for cancer, osteoporosis and HIV/AIDS.
- Develop model obesity programs, compile outcomes data, and explore coverage of obesity treatment within Medicare and Medicaid programs.
- Encourage research that emphasizes and promotes wellness and "health" care beyond the current focus on disease management.
- Encourage research to identify effective strategies to assist consumers in appropriately selecting food, dietary supplements, fortified or functional foods, and nutrition-related complementary and alternative medicine therapies.
- Increase the number of randomized, controlled trials and reproduce results to determine whether individual dietary supplements can effectively treat or prevent diseases or other health conditions.
- Mandate quality and safety assurance measures for dietary supplements.

Direct comments or questions to:
Kate Gorton
Director, National Nutrition Policy
American Dietetic Association
1120 Connecticut Avenue, N.W., Suite 480
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Audrey Di Maria, ATR-BC
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*Secretary*

ATCB
Art Therapy Credentials Board

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A
T
C
B

## Art Therapy Credentials Board

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Greensboro, NC 27403-3660
877-213-ATCB (2822)
Fax: 336-547-0017
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www.atcb.org

## Credentialing Body

Registration of Art Therapists
Certification of Art Therapists
Recertification of Art Therapists
Oversees the Board Certification Examination

## Mission

The mission of the ATCB is to promote, develop, and encourage the art, science, and practice of art therapy through standardized procedures for registration and certification.

## Purpose and Goals

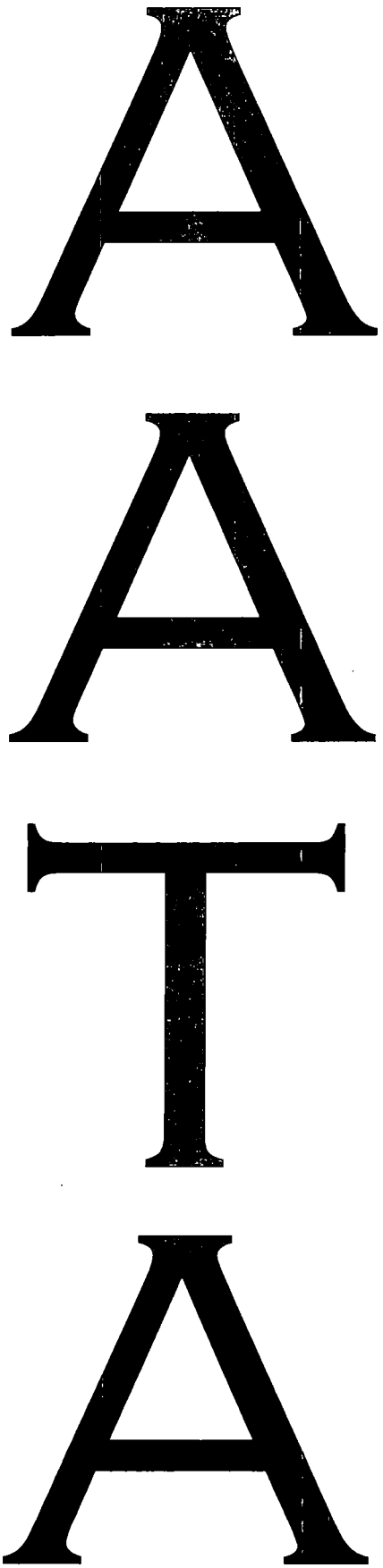
To protect and benefit the public through maintaining and developing standards of practice in the field of art therapy.

## Registration

The designation "ATR" (Art Therapist Registered) is granted by the Art Therapy Credentials Board (ATCB) to individuals who have successfully completed the required educational and professional experience.

## Board Certification

The designation "ATR-BC" (Board Certified Art Therapist) is granted by the ATCB to registered art therapists who have successfully passed the national certification examination. Recertification is provided every five years by documentation of continuing education, publication, presentation, exhibition, and other activities which demonstrate continuing professional competence.



# American Art Therapy Association

1202 Allanson Road
Mundelein, Illinois 60060-3808
888-290-0878 or 847-949-6064
FAX: 847-566-4580
E-mail: arttherapy@ntr.net
www.arttherapy.org

## Membership Organization

Develops standards of excellence for Educational Programs and for Professional and Ethical Practice

Sponsors opportunities for continuing education through Regional and National Conferences

## Mission

The American Art Therapy Association, Inc. is an organization of professionals dedicated to the belief that the creative process involved in the making of art is healing and life enhancing. Its mission is to serve its members and the general public by providing standards of professional competence, and developing and promoting knowledge in, and of, the field of art therapy.

## Purpose and Goals

- Encourage the highest quality art therapy service to clients
- Facilitate communication among members and colleagues
- Support legislative efforts at the state and federal level
- Disseminate information to the general public
- Recognize excellence in clinical, professional, educational, and research activities

## Publications

- Art Therapy: Journal of the American Art Therapy Association
- Quarterly Newsletter
- Annual Conference Proceedings
- A Guide to Conducting Art Therapy Research
- A History of Art Therapy in the United States

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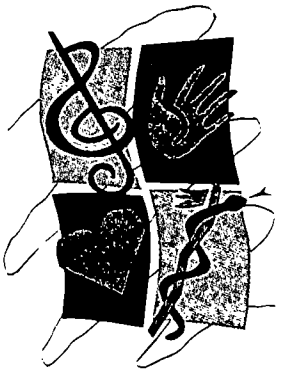
Divider Title: Simpson

52

May 16, 2001

To: White House Commission on
Complementary and Alternative Medicine Policy

From: Judy Simpson, MT-BC
Government and Public Relations Associate
American Music Therapy Association



AMERICAN
MUSIC
THERAPY
ASSOCIATION

Music therapy is an established health profession in which music is used to address physical, emotional, cognitive, and social needs of individuals of all ages. We have a 50-year history of contributing to the treatment of individuals with a variety of disabilities and illnesses with more recent expansion of services to include prevention and wellness programs. Board certified music therapists use both instrumental and vocal music strategies to facilitate changes that are non-musical in nature. After assessment of the strengths and needs of each client, qualified music therapists provide indicated treatment and participate as members of the interdisciplinary team to support a vast continuum of outcomes.

To advance the awareness of music therapy, I have provided materials for the commission's review, including a CD-ROM containing 35 years of published, peer-reviewed research. This existing research not only addresses direct benefits dealing with specific illnesses but also demonstrates how music therapy can contribute to the amelioration of pain and distress that sometimes occurs with conventional treatments and invasive procedures. For example, the clinical application of music during chemotherapy treatments has been shown to reduce anxiety and nausea in oncology patients.

Intervention benefits have received attention outside of our association publications as well. In a recent Journal of the American Medical Association, music therapy research in a neonatal intensive care unit was featured. Data on the physiological benefits of music therapy included improved oxygen saturation levels, increased weight gain, and shortened length of stay. These positive outcomes, however, have not translated into more research opportunities or more access to services. If we know it can make a difference, what steps are necessary to provide and reimburse music therapy in every neonatal ICU? How do we progress from any positive research finding to increased access and coverage for effective music therapy interventions?

The truth of the matter is that music therapy is not just a nice thing to provide to patients, it's a serious intervention supported by scientific evidence. Even with our long history, we don't have the necessary volume of research projects to make primary reimbursement easy. We have nowhere near what other related disciplines have when it comes to research funding. The lack of understanding and acceptance by the federal government, along with limited funding for research, direct services, and reimbursement, seriously restricts access to music

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therapy services. Without federal recognition and support, it's difficult to conduct the multi-site, large sample, longitudinal studies that we need to demonstrate the outcomes and cost effectiveness third party payers require. The current method leaves music therapists as freelance advocates with each provider and insurance case manager to prove music therapy is a valid treatment worthy of reimbursement.

We know music therapy can make a difference in healthcare, but we need help in getting that message to decision-makers. The American Music Therapy Association would appreciate the Commission's assistance in securing research funding and third party reimbursement for music therapy.

Thank you.

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Divider Title: Goldberg

Presenter #53
Richard I. Goldberg, LCSW-C, BCD
Suite 306 ~ 4330 East-West Highway ~Bethesda, Maryland 20814
Telephone: (301) 652-7792 ~ Email: goldberg@erols.com
on behalf of Steven Vazquez, Ph.D.
May 16, 2001

# White House Commission On Complementary and Alternative Medicine Policy

In the process of studying seasonal affective disorder, science has determined that serotonin is the intermediary through which light stimulation alters unwanted emotional states. A method called Emotional Transformation Therapy has profoundly extended this principal by combining specific colors with psychotherapy and a new type of eye movement. However, there are seven primary blockages in the healthcare research system that currently impede the systematic scientific study of this modality. These include scientific bias against novel ideas, human emotion, color, and the use of psychotherapy in the treatment of S.A.D. Other factors include private practice discovery versus university research, synergistic versus reductionistic process, and equal access to funding regardless of vested financial interest.

## Scientific Bias Against Novel Ideas

Scientific research funding is awarded to projects that have already been supported by numerous other studies. When science has not had interest in a certain subject, the novel idea cannot be supported by previous studies enough to warrant real consideration for funding.

**Recommendation:** Provide an arena for novel ideas to be demonstrated. If the demonstrations prove efficacious, then open avenues for funding.

## Scientific Bias Against Human Emotions

The scientific value system advocates logical thinking, intellectual reasoning and objectivity and, in the process, devalues human emotions. This narrow perspective leads to studies about moods as mechanical conceptions of human functioning that seek to block or remove "bad emotions". Emotional Transformation Therapy focuses on embracing, exploring, and working through emotions as the subject learns new autonomous functioning during the transformation.

**Recommendation:** Advocate a broader perspective when studying human emotions that is inclusive of the arts, psychotherapy, and spirituality.

## Scientific Bias Against Color

Color has been seen as an element of the arts. Science has overlooked color stimulation as a possible means for serious healing in either medicine or psychology. Emotional Transformation Therapy is a breakthrough process that uses color as a major component for facilitating deep and rapid transformation of serious conditions.

**Recommendation**: Public awareness campaigns may help to reduce ignorance of the effects of light and color in healing.

## Scientific Bias Against Psychotherapy For S.A.D. Treatment

The scientific study of seasonal affective disorder has demonstrated bias against psychotherapy. In over 600 research studies on S.A.D. since 1984 not one of the 600-plus S.A.D. studies has investigated the efficacy of psychotherapy as part of treatment. Before 1984, psychotherapy was accepted treatment for depression of all types.

**Recommendation:** Reward broader perspectives with opportunities to publish successful case interventions in a journal created for that purpose. Research grants could then be awarded to the most promising modalities

## Private Practice Discovery Versus University Research

In private practice psychotherapists must innovate continuously because of the uniqueness of each client. University based scientists develop their research ideas and then apply them to actual people. Psychotherapists may often be in a better position to create new solutions, but do not often possess the resources or training to produce research.

**Recommendation:** Government support through technical scientific assistance may produce many exciting new solutions that would otherwise go uninvestigated.

## Reductionistic Versus Synergistic Processes

The value placed on reductionistic research by scientists tends to omit synergistic or multilevel/multidimensional interventions that may often provide better treatment outcomes. The single cause "magic bullet" search effectively overlooks some potentially higher quality treatments such as Emotional Transformation Therapy.

**Recommendation:** Encourage outcome studies of synergistic processes like Emotional Transformation Therapy through more funding for this type of research.

## Equal Funding Resources

Most research funding is related to financially vested interests. Emotional Transformation Therapy and other multidimensional modalities currently offer no financial incentives to investors. Therefore funding resources are limited.

In conclusion, wisdom dictates that equal opportunity for funding should not be denied for reasons of financial interest or philosophical bias. Policy should encourage research endeavors by virtue of their potential merit in the pursuit of human healing.

Presenter #53
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**A Research Imperative: Emotional Transformation Therapy**

**White House Commission on Complementary and Alternative Medicine Policy**

**By: Steven Vazquez, Ph.D.**

I am speaking on behalf of a new and powerful method that combines light stimulation with psychotherapy, often combining with the use of a light-emitting machine.

Seasonal Affective Disorder (SAD) was identified in the professional research literature in 1984. There have now been hundreds of studies documenting that certain forms of light stimulation into the eyes have the ability to improve unwanted mood states. It was initially thought that the mechanism by which this takes place was via the alteration the brain's biological clock which affects our night/day cycles called circadian rhythms. As research progressed, it became accepted that light stimulation facilitated mood changes largely through the serotonin neurotransmitter system. In addition, research demonstrated that other moods, such as anger, anxiety, and depression in forms other than SAD, could be beneficially affected. Unfortunately, this research led exclusively to symptom-remedy methods through the use of various light devices without a facilitator which almost always provided only temporary relief. This meant that improvements needed repeated fixes, thus resulting in a dependency and no real learning, understanding, or new coping skills on the part of the person being treated. Essentially, light stimulation became another pill.

## Scientific Bias Against Novel Ideas

Scientific research funding is awarded to studies that generally have already been supported by numerous other studies. It seems that an hypothesis must already have been "proven" in order to acquire research funding to demonstrate it further. In other words, there is little or no opportunity for an innovative idea to be adequately studied.

**Recommendation:** Alternative medicine practitioners should be allowed to demonstrate the efficacy of their approach in person. If a certain modality can be shown to produce positive results based on some set of agreed-upon criteria, government grants should become available for further research.

## Private Practice Discovery Versus University Research

University researchers and therapists in private practice tend toward two different processes of discovering new ideas for eliminating human suffering. Therapists in private practice encounter psychological challenges on a daily basis. Regardless of the therapeutic orientation therapists must innovate continuously because each person is unique. The factors that necessitate creative adaptation on the part of the therapist in private practice are not present in the university setting. On the contrary, the university professor typically conceives of a new idea in the relative vacuum of theory, and then determines a research design that tests the validity of the hypothesis. This approach to research, while more standardized, fails to address the cumulative observations of therapists in private practice. The preponderance of research, however unfortunately constricted, takes place in the university setting, and is not inclusive of valid discoveries made by professionals in the field. This is comparable to eliminating from medical texts all of the hard won discoveries made during battlefield surgery. Finding a way to investigate and validate the observations of mental health professionals and alternative medicine practitioners is essential to maximizing our cultural progress towards a more complete understanding of healing. Private practitioners are not salaried, and thus unable to allot the amount of time necessary for a major research project. Therefore, the creative psychotherapist is rarely in a position to test what he or she already knows to be efficacious. By virtue of these limitations, the system inadvertently blocks research outlets for the psychotherapist who has an important perspective and creative solutions to contribute.

**Recommendation:** Provide technical scientific assistance to professionals outside the university research environment to capitalize on the discoveries in the private sector.

## Synergistic Versus Reductionistic Processes

The hierarchical value system of scientific research holds reductionistic approaches as the most highly respected. In treatment, this usually means that scientists look for the "magic bullet" that is the single cause for a cure of a disease or a mental disorder. Consider the possibility that the better cures may be synergistic; so that two, three or four factors when combined in a certain manner result in a better outcome. This type of approach has a limited chance of being funded even if efficacious. It will be seen as soft research that is not cause-and effect-specific enough to be accepted in the larger scientific community.

In the field of SAD treatment, there are over 600 research studies. and in only one study was there an inquiry about what the subject was thinking and feeling during light stimulation. When scientists studied color, the reductionistic approach seldom accounted for the person's emotional state during the exposure. I discovered the ***radiant biosynthesis effect*** in which certain wavelengths of color are matched with specific emotional states that result in a profound transformation of the subject's thoughts, feelings, physiology, etc. However, the color exposure alone or the state of mind alone does not tend to transform the patient's state significantly.

**Recommendation:** Encourage outcome studies as much as basic research. Encourage outcome studies of synergistic procedures that show promise. More funding may assist in overcoming some scientists' reluctance to involve themselves in studies viewed as "soft" among their peers.

## Scientific Bias Against Human Emotions

Logical thinking, intellectual reasoning and objectivity characterize the philosophy underlying the scientific approach. All of these types of thinking involve the avoidance of human emotion. This narrow perspective itself devalues emotions whereas the arts embrace and explore the range of human emotions. In acting, one must physically express emotions; in painting, one visually displays emotions, and in writing one transforms emotions into language.

These divergent philosophies strongly impact the way in which emotional issues are pursued in research. Scientific studies are replete with attempts to stop, block or eliminate emotions, which are seen as obfuscating the clarity with which an experiment is performed. In contrast to the standard scientific approach, the arts are informed by emotion. The arts explore emotions and utilize metaphor in service of deeper understanding. The scientific view leads to the use of surgery, drugs, electroshock and other methods that stop the "bad" feeling. On the other hand, the arts tend to demonstrate how working through emotions while negotiating various challenges cause a character to learn on the way to resolution of the "bad" feeling. Both approaches may end up with the initial emotional problem changed, but the artist's way is richer and the person has been empowered by drawing on his own potential for recovery. Emotional Transformation Therapy uses the artist's concept in psychotherapy.

**Recommendation:** Our perspective upon which these studies are based should be broadened to include the arts, social sciences and other views. This should be done for the purpose of seeking a more humane type of treatment that affirms the unique repertoire of emotions that sets humans apart from all other life.

## Scientific Bias Against Psychotherapy For SAD Treatment

SAD scientific research is biased against psychotherapy. Since 1984, when SAD was first identified in the professional literature, there have been over 600 published studies. In all of these studies in the 1999 Canadian Guidelines For SAD Treatment, there are zero studies that assessed the effectiveness of psychotherapy for treatment.

Before the identification of seasonal affective disorder as a separate type of depression, psychotherapy was the most commonly utilized treatment modality. Success in treatment was commonplace then. However, once it was discovered that light could be used to treat SAD, scientific studies tended to focus on the use of light and ultimately, anti-depressants. While light is helpful, the new SAD approach changed the method to one of temporary relief that required daily use and created a dependency on new light devices. Essentially, no new learning took place in the individual during these processes and the length of time for treatment at least tripled to 3 or more years before the condition subsided. It is likely that this SAD approach represents a decline in the effectiveness of treatment from psychotherapy, but we do not know because it either never occurred to scientists to study the effectiveness of psychotherapy or no one was willing to fund such a study.

**Recommendation:** There have been massive funding grants provided by both private and governmental sources for this "trend" in treatment (over 600 research studies since 1984). Those responsible for allocating funds may not have understood the consequences of this shift in focus. A change in policy could readmit a synergistic psychotherapy approach to current research.

## Scientific Bias Against Color

Color has been cherished by the arts for a long time. Architects use it for both beauty and profit. Theatre has used colored stage lighting to create moods and of course, the great painters have used it for their masterpieces. The Fortune 500 companies invest millions to employ artists because the choice of color in marketing is well known to affect consumer buying. However, scientists generally see color as primarily aesthetic and as having no real power in serious medicine or psychology. Our society has institutionalized scientific "truth" to be superior to artistic "truth".

Although there have been scientific studies on color, most of these studies address the ways in which color can be used to manipulate the consuming public. Few if any studies have been concerned with color's potential to heal the physical body or transform emotional states. Emotional Transformation Therapy is a breakthrough process that uses color to rapidly transform some of the troublesome human conditions.

**Recommendation:** This exists an issue of bias and preference. Policies could be altered to encourage awareness regarding these types of biases through public relations campaigns. Additionally, studies involving color and light in psychotherapy could be funded to produce data familiarizing the scientific community and the public at large with the power of light and color.

**Equal Funding Sources**

In most cases research is driven by the prospect of financial gain. For example, the pharmaceutical industry provides the vast majority of research funding for depression, which in turn creates more revenue for the drug companies. Financial success, while a valid motivational force, can distract grantors from their unbiased altruistic mission, which is the pursuit of the relief of human suffering. It appears that the system of research and healthcare is so huge that nobody is really guiding the ethical focus of "Does this research actually represent the best possible step toward optimal healing of human suffering?"

More efficient and consistent treatment modalities may allow a patient to attain desired results faster, however, the psychotherapist will experience a declin3e in income as a result. Paradoxically, in today's healthcare market, a patient's limited number of authorized visits may result in deeper and more permanent healing by the use of alternative treatment modalities. Interestingly enough, the research's pursuit of "quick fixes" in mental health, such as Emotional Transformation Therapy are in the best financial interest of all concerned especially the patients and the HMO's themselves.

**Recommendation:** Equal access to research funding should not be denied for reasons of financial interest, philosophical bias or precedent. Rather, all research endeavors should be evaluated based on their merit in the realm of human healing.

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Haller

Divider Title: _____

Nancy Haller
Feldenkrais Guild of North America

There is an enormous need in our country to have a statement defining "What is Health?" We are working to add to the burdened systems without an overall statement that gives some structure to light the end of the tunnel. When a public statement of health is made, the programs, people and products necessary to meet the statement to fulfill the outcomes are made available. Language will be vital to this process and needs to be inclusive and powerful. Looking into the future and understanding that it will take a century of generations to change the overall health of this nation, there is no better time than now to begin.

Once there is a statement for people to hear, see, think about, then gradually there will be action to meet the concepts and bring the reality to life. We all hear the statements contrary to health in our daily lives and we have followed them. Advertising has made catch phrases that we can recite and when we come to the place of making choices, they ring in our heads and influence our decisions. It is possible to use these same concepts to the advantage of people in relationship to their health.

Achieving health across the nation is a broad subject that requires allopathic, alternative, folk medicine, spirituality, environment, research, education and cooperation. There are models where all of these have a place, are deemed appropriate and necessary. Education and trust are paramount to begin this ongoing change in the whole structure. We need a campaign that begins in multiple directions coming from the stated mission for health in this country. The ultimate goal is survival.

This is the long-term project that needs to be addressed. Within the structure is a place for everything that is involved in creating a healthy society. It is understandable that there would be opposition to this concept. Many huge corporations have made billions supporting our unhealthy lifestyles.

Short term needs for health include creating the programs to fill the needs of people in prevention and care, education and accessibility to the programs by the people, trained professionals to work on many levels of care as the needs arise and options for payments that are affordable and will allow profits to the insurance companies. We are headed in a direction that is appropriate, yet it seems to be scatter shooting into the dark.

There is need for the empowerment of people to trust that they are the ultimate physician and we as practitioners are here to listen and aid in their health decisions, offer directions for appropriate services and recovery. As practitioners, we have the obligation to be educated, informed, cooperative, and able to hear the request to aid the client with their choices, suggest appropriate treatments or services and products. We have the need to have insurance coding that will accurately define the work or product that is provided. The insurance companies require that accurate billing is done and then they are responsible to insure that the practitioners have timely payments for services rendered. Acceptance by the public that they hold a portion of the payment responsibility, also

allows them to participate more fully in the ownership of their health and well being. Finding appropriate avenues for ease in acceptance of death will also be a portion of the work that is necessary for the future. The circle is possible.

Recommendations to the Commission are:

Make recommendations to the President that are large enough to encompass the growing needs of the public for generations to come. Create a Statement of Health for the country to develop and embody over the next century. Become leaders for the people with health and wellness programs that are tangible, affordable and responsible.

Build a nationwide education campaign to bring awareness to all people that health is possible and we are working together to achieve the goal. Educate the people about health from the prenatal to death. Include commitments to self-care, exercise and nutrition in the education process to begin to empower the public that the responsibility for their health begins with themselves.

Create and offer financial incentives to practitioners in training to work with people in areas that have the highest immediate needs. Develop respect for the diversity, education, and knowledge of the different practices and how to network and refer to the appropriate method of work for the best interest of the client and their needs at that time.

Offer incentives to corporations to fund and support the health of the nation. Build programs for mutual funding for research, insurance, tax incentives, and other programs to meet the ongoing needs of the growing population.

Require insurance companies to pay for services rendered within a specific time period to support the practitioner's decision to accept the added burden of billing and waiting for payments. Have appropriate codes for the services and products so that there is opportunity for accuracy in billing. Utilize a specific system of coding designed for reporting what type of service, products prescribed, length and number of visits to collect data for research.

Health, education and implementation are lifetime goals that will span many future generations. This is the opportunity for an evolutionary change in the attitude and intention of all people in relationship to their health and wellness.

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Merrill

Divider Title: _____

## #55 Julie Merrill, L.Ac., American Association of Oriental Medicine

Good Afternoon Commissioners. My name is Julie Merrill. I am an Oriental Medicine practitioner, a board member of the American Association of Oriental Medicine and the Vice-President of the Maryland Oriental Medicine Association. The AAOM is the oldest and largest national organization for acupuncture and Oriental Medicine professionals.

Let us return to the topic covered on Monday and Tuesday, CAM Coverage and Reimbursement. Do you see this (New York City Subway) token (hold up). Can you see the hole in the middle? Oriental Medicine practitioners' current reimbursement is just like this: a token with a hole in the middle of it. The hole in the middle of the token represents inadequate coverage. Proper coverage for services provided by properly trained practitioners can fill that hole by providing broader access to health care that actually has the potential to provide savings to the federal government. Federal programs and private insurance companies must reimburse for Oriental Medicine's full scope of practice: acupuncture, moxibustion, herbal therapy, manual therapy, nutritional counseling, etc. in conjunction with our diagnosis, evaluation, and treatment planning at each office visit. These treatments replace and reduce other more costly health care expenditures. This coverage should be mandated as a means to reduce the need for costlier interventions.

As for the analogy of the token, Oriental Medical professionals are concerned about the "tokenism" of various "discount" programs being fraudulently marketed by health plans to appear as a premium "benefit." Such token attempts can be replaced by broader-based healthcare industry mechanisms like the ABC insurance coding system developed by Alternative Link, discussed in yesterday morning's panel. While there are currently 2 CPT codes for acupuncture, a more complete coding system such as that developed by Alternative Link would not only aid in the equitable reimbursement of Oriental Medicine and CAM services, it would also improve tracking ability and further outcome research.

Other initiatives are also already underway. AAOM supports the Hinchey bill that would provide coverage of acupuncture to Medicare patients and federal employees. AAOM also supports continuation of the personal Medical Savings Account insurance option as a way to cover preventative healthcare services.

The hole in the center of the token also represents a gap in the logic that better trained practitioners are paid less than those who are less trained. A practitioner with a Masters or Doctorate in Oriental Medicine has the ability to make an individualized differential diagnosis to more specifically and effectively treat a patient than someone who has training in a completely different form of medicine who subsequently studied Oriental Medicine for 200 hours. To fill that hole, it is imperative that any licensed acupuncturist be able to bill for their full scope of practice, and that there be no multi-tiered billing for any service. There must be equal pay for equal services for licensed providers.

The federal government obviously wants to get on the moving train of quickly broadening healthcare options in this country, as evidenced by the formation of this Commission. To move forward, federal and private health care coverage systems should reimburse licensed Oriental Medical practitioners to carry out their full scope of practice, paralleling current billing procedures, so that the provision of healthcare services in the United States can branch onto a new track, with ancient wisdom propelling it.

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Ku

Divider Title: _____

# Testimony ( #56)

## for the May 16, 2001 public hearing of

# The White House Commission on Complementary and Alternative Medicine Policy.

Submitted by:
Su Liang Ku, President of
Florida Institute of Traditional Chinese Medicine,
St. Petersburg, Florida 33709
Phone: (727) 546-6565, Fax: (727) 547-0703
E Mail: fitcm @ gte. net

Dear Honorable Members of the White House Commission on Complementary and Alternative Medicine Policy:

Thank you for the opportunity to testify in front of your Commission and to share my suggestions and input regarding the future Policy on Complementary and Alternative Medicine.

I would like to focus my testimony on Traditional Chinese Medicine / Oriental Medicine, hereinafter referred to as TCM.

*Definition: For the purpose of this testimony, the term TCM refer to the form of health care practice (examination, diagnosis and treatment of patients), that is based on the general philosophy of Yin-Yang and Five element concept, all the basic and clinical theories of Traditional Chinese Medicine, with emphasis on the holistic and differentiation of syndromes of individual patients, and the treatment modalities including Acupuncture, Herbal medicine, Tuina massage and manipulation, diet and life style counselling, and the recommendation of therapeutic meditation and exercises.*

**1. Do you have ready access to CAM practices and interventions?**

Currently there are many patients who do not have the access to TCM services and products because TCM practices and products are not covered by their health insurance. This has greatly diminished the patients' privilege of accessing TCM care and interventions to benefit their health. Especially for those poor and/ or senior citizens who have many chronic medical problems which can be effectively relieved by TCM but Medicare does not cover the TCM services.

In order to protect the health and well-being of our citizens, and to make this form of medicine more accessible, and at the same time to reduce overall health care expenses, additional Federal and State laws and policies need to be established to better recognize TCM in the following format:

**A. TCM be recognized by Federal and State laws and policies as a form of standard medical practice.**

**B. TCM services and products be appropriately and adequately covered and reimbursed by all Federal and State programs and private health care coverage systems. This shall include:**

Medicare.
Government employee health insurance policies.
Workman's compensation programs.
Any form of medical supplement programs.
Any form of rehabilitative programs.
All insurance companies licensed to do business in a State's jurisdiction.
Medicaid.
Others

**C. All Federal and State funded health care programs and facilities be urged to provide quality TCM services and products to all patients who seek them.**

Reasoning:

A. TCM is utilized by approximately 40% of Americans.

*TCM is a well established, well documented, and complete medical system that has been practiced for thousands of years on billions of patients. Within its 30 short years (since 1972) of availability to the American citizen, TCM has been well received and is now utilized by approximately 40% of Americans as a primary health care service on a more frequent basis.*

B. TCM is effective, safe and economical.

*Americans are interested in having aTCM services for their health care because TCM is very effective, safe and yet very economical. The effectiveness can be revealed by the fact that 40% of Americans have turned themselves from knowing nothing about TCM in 1972 to becoming faithful patients of TCM with a majority of them paying out of their own pocket. The safety and economy of this practice can be easily revealed by the low malpractice insurance premium paid by TCM physicians: Average under $1,000.00 per year for a coverage of $ 500,000 per incident and $1,000,000 aggregate.*

*While it is to the best interest of the citizens / patients to be able to benefit from TCM services and products, it is also to the interest of the governmental and public programs, as well as private sectors, to cover TCM services because of the lower reimbursement expenses.*

C. TCM is a well regulated professional practice.

*TCM practice has been well regulated by the related State Departments or Board of Acupuncture, Currently over 40 States have established laws and/or rules / policies regulating the practice of TCM. Adequate examination and licensing procedures are in place and all TCM practitioners are duly licensed and / or registered. This should provide feasibility for adopting the above rules and policies, as well as assurances for the safe and effective practice.*

**2. How can access to safe and effective CAM practices and interventions be improved?**

The access to safe and effective TCM practices and interventions may be improved by adopting clear policies defining the qualified provider by requiring one or more of the following:

**A.** National board certificate.

*Certified as a Diplomat by the National Commission for the certification of Acupuncturist and Oriental Medicine ( Dipl. NCCAOM) )*

B Licensed by State Board of Acupuncture.

C. Educational and training background.

*Currently the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM) is accrediting TCM programs at a Masters degree level with a minimum 60 semester credit hour towards a Baccalaureate degree from an accredited college as prerequisite, plus a 4 academic year / 150 semester credit hour program of course work on TCM as the entry level to the practice. ACAOM has also adopted standards to accredit programs on a Doctoral level with a minimum requirement of 4000 clock hour or 222 semester credit hour course work in addition to the 60 semester credit hours as prerequisite . Foreign TCM graduates range from 4 to 6 years ( 4,000 to 6,000 clock hours) of medical schooling as entry level to TCM practice and an additional 3 to 6 years of schooling as an advanced training.*

It is important to regocnize that TCM is a complete yet unique medical discipline with over 30,000 medical texts ( not including journals) exist. This body of knowledge cannot be learned in a couple of hundred hours or by a non-residential training.

*In the past 30 years of TCM practice in U.S., of the very few malpractice incidents of acupuncture or herbal medicine, most were caused by practitioners other than those who have received adequate training, or who were licensed by the State Board of Acupuncture or certified by the national board ( NCCAOM). Therefore in order to ensure that patients have access to safe and effective TCM practice and intervention, the requirement of the above mentioned standards is essential.*

*In regards to the safety of certain herb; It is the interest of both the government and public that a professional service should be regulated while making that service available to the patients who seek or need it instead of being eliminated. This is similar to the utilization of certain drugs or surgical procedures, it should not be eliminated because it had problems caused by the utilization by unqualified practitioners. The use of those herbs shall be limited only by qualified practitioners such as licensed TCM physicians.*

**3. What type of CAM practice and interventions should be reimbursable through federal programs or other health care coverage system?**

TCM practice and interventions performed by qualified practitioners as defined in # 2 above, should be reimbursable through federal programs or other health care coverage systems.

*The following service items within the scope of TCM practice should be reimbursable:*

1. *All the TCM examination, evaluation and diagnosis procedures.*
2. *All the standard TCM treatment modalities such as:*
   - A. *Acupuncture*
   - B. *Herbal medicine.*
   - C. *Tuina massage and manipulation.*
   - D. *Diet and life style counselling.*
   - E. *Recommendation of therapeutic meditation and exercise.*

*The specific sub-categories and the adjunctive diagnostic and treatment methods of TCM practices and products that may be considered for reimbursement may be defined based on the scope of practice permitted by the State Licensing laws and rules, and / or by the training received by the provider.*