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An Open Letter to the White House Commission on Complementary and Alternative Medicine Policy

Part 1: Suggestions for Federal Policy

Alan Dumoff, J.D., M.S.W.

On March 8, 2000, President Clinton signed an executive order establishing a White House Commission on Complementary and Alternative Medicine Policy. The charge of the Commission is to make

> . . .legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine to Americans. The recommendations shall address the following:
> (a) the education and training of health care practitioners in complementary and alternative medicine;
> (b) coordinated research to increase knowledge about complementary and alternative medicine practices and products;
> (c) the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and
> (d) guidance for appropriate access to and delivery of complementary and alternative medicine.

The Commission is in the capable hands of James S. Gordon, M.D., former chair of the Advisory Council to the Office of Alternative Medicine (OAM) at the National Institutes of Health. He is joined by another alumnus of the OAM, its former director, Wayne B. Jonas, M.D. (See box entitled The Commission's Members.) While the impact the Commission can have on national policy is yet to be seen, particularly given an impending change of administration, this is certainly an opportunity to raise the level of national discussion about key improvements in practitioners' ability to offer, and patients access to, high quality alternative and complementary medicine (ACM) care. The opportunity should be significant regardless of whatever the voters decide in November; ACM has always been a relatively bipartisan issue, with many Democrats supporting progressive approaches to care and many Republicans believing that the government should not interfere with people's health care choices.

The Commission is holding a number of public forums throughout the United States to hear people's concerns and suggestions. A town hall meeting will, by the time of this printing, have been held in San Francisco, with meetings in additional cities yet to be held. (See The Commission's Schedule of Meetings.)

AUTHOR'S NOTE: In an effort to spark a dialogue with the Commission, I wrote a letter to the Commission with suggestions about matters that it could address that would improve the climate for ACM care in the United States. This letter has been adapted slightly for publication in a two-part article in the Journal. Notes in brackets were not included in the letter but rather serve to direct readers to additional information. Part 1 covers suggestions for federal policy and Part 2 will cover suggestions for state policy and regulatory policy in the face of scientific differences.

If you wish to contact the Commission to put forward your suggestions, please see the box entitled How to Contact the Commission.

To the White House Commission on Complementary and Alternative Medicine Policy:

The appointment of the White House Commission is a reflection of the continuing maturation of ACM as a legitimate part of U.S. health care delivery. In addition to the important roles practitioner training, increased research, and knowledge sharing play in moving ACM forward, the charge of the Commission to make "legislative and administrative recommendations" that provide "guidance for appropriate access to, and delivery of, complementary and alternative medicine" is critical, given the opportunity this presents to address very real obstacles to ACM care delivery. There are numerous federal regulatory barriers that make the difficult task of integrating ACM care within the health care system even more difficult. The Commission has the opportunity to address these barriers by inviting review or making specific policy recommendations as appropriate. In addition, there is considerable activity at

Health care is arguably the most regulated of any industry.

the state level that adversely impacts on the responsible integration of alternative medicine. While the Commission has no direct influence over the policies of the fifty states, it is certainly within this body's purview to raise issues of national policy that can guide the states on more appropriate ways to regulate access to and delivery of integrative care.

As an attorney engaged for more than a decade in matters of ACM integration with physicians, ACM practitioners, hospitals, clinics, and patients, I have had extensive opportunities to see in practice how federal and state policies affect practitioners who seek to offer patients the whole care that comes through integrative team efforts. I appreciate this opportunity to share with the Commission a few suggestions that arise from this experience.

As we are all aware, health care is the most regulated of all of the learned professions and is arguably the most regulated of any industry. Innovative practices can readily run afoul of regulatory requirements because, by their nature, they explore new methods of practice. A considerable number of the regulatory difficulties faced by ACM do not arise because regulators intend that result, but because the agencies involved simply did not have ACM "on their radar screens" when addressing concerns in conventional medical practice. The Commission can play a critical role in these arenas by raising awareness and encouraging agencies to alleviate the unintended consequences of specific policies that affect the delivery of ACM care adversely. Of particular concern are those regulations that create obstacles to the responsible integration of conventional and ACM services, such as those regulations addressing the propriety of billing arrangements that make structuring shared practice difficult.

On the other hand, not all such barriers are unintended. Some Food and Drug Administration (FDA) actions with respect to ACM drugs, medical devices, and supplements; the Federal Trade Commission's concerns about chelation therapy; the joint committee of the Health Care Financing Administration (HCFA) and the American Medical Association (AMA) rejection of more complete billing codes for ACM; and rulings barring certain ACM laboratory tests are clearly based on a rejection of the value of these ACM services. Similarly, many state medical boards are concerned about various physician ACM practices and have taken a variety of adverse actions. The Commission has an opportunity to increase tolerance for divergent views of health care by speaking with a national voice that educates and offers guidance about those specific issues of concern.

While much health care regulation is at the state level, such as the licensing of health care professionals, the federal gov-

Major medical insurers generally follow Medicare policies.

ernment plays quite a number of key roles. Within the HCFA, the FDA, and laboratory regulation lie a number of areas that have considerable impacts on ACM delivery.

The Health Care Financing Administration

In addition to administering Medicare and Medicaid, the Health Care Financing Administration's policies are critical not only because of the significant portion of the national health care dollars that flow through these programs, but because Blue Cross Blue Shield (BC/BS) and other major medical insurers generally follow Medicare policies. Effective changes in HCFA policy can therefore have a very broad impact on national care delivery.

"Incident to" Billing

Where physicians and ACM practitioners work together in integrative settings, a common and important method of obtaining reimbursement for ACM services is an arrangement in which the ACM practitioners work and bill under the physician. The physician hires these ACM practitioners as types of "physician extenders," offering services that the physician would like to make available. [There are a number of rules that must be met in order to "incident to" bill correctly, which were discussed at more length previously in the Legal Matters column.][1]

This method of billing was originally intended for physician assistants, nurse practitioners, physical therapists, and similar medical staff people that truly extend the biomedical services of the physician. Incident to billing is widely used to bill for psychologists and other "ancillary" staff members as well. In integrative clinics, acupuncturists, massage therapists, and a host of other professionals work and have their services billed by the employing and supervising physician where these professionals deliver services that can be appropriately billed.

The HCFA is likely to discontinue incident to billing arrangements in July 2001. The HCFA is of the opinion that the use of this type of billing has expanded beyond its original intent. As an alternative, the HCFA is proposing to

A Modest Proposal

Creation of a New Office or Position within the DHHS

This proposal concerns the creation of an office and/or position within the office of the Secretary for the Department of Health and Human Services (DHHS), perhaps within the Office of Public Health and Science. Excerpts from the Proposal from the Alternative and Complementary Health Practices Special Primary Interest Group (ACHP-SPIG) of the American Public Health Association (APHA) include coverage of current problems that creation of this office or position would alleviate:

1. The public has many great expectations for the NIH [National Institutes of Health] Center for Complementary and Alternative Medicine or NCCAM, but many of these are well outside the boundaries of NIH functions or mission. The incumbent for this position would analyze public demands and expectations, using surveys and other scientific methods as needed, and make recommendations to the Secretary as to which of these expectations, needs and demands can and should be addressed by the department.

2. Other departments have rising needs for expert consultation from DHHS in the area of alternative and complementary health practices (ACHPs). For instance, many military hospitals are asking their Offices of the Surgeons General (OSGs) for guidance on physician privileges in acupuncture and other ACHPs and those OSGs often call on [NCCAM] for assistance in providing guidance. These are education and certification issues that do not really come under the NIH mission and such requests from DOD [Department of Defense] and other departments would best be handled (or at least referred) through the DHHS Secretary's Office, rather than the current situation in which the OSGs contact the NIH [NCCAM] directly.

3. Initiatives, task forces and programs dealing with ACHPs are sprouting up from one end of DHHS to the other. While some have looked to [NCCAM] for guidance and coordination, that office has (properly) declined to play any more active a role than to facilitate communication and keep other DHHS components abreast of new scientific developments. There are several potential problems here that could be prevented by a central ACHP coordinating function within the Office of the Secretary. These include preventing different parts of the DHHS from adopting inconsistent public positions or policies and mediating potential conflicts between different DHHS components which might arise from inconsistent internal positions.

For more information, contact:

American Public Health Association
1800 I Street, N.W.
Washington, D.C. 20001
(202) 777-APHA
Fax: (202) 777-2534

For further discussion about this ACHP SPIG proposal, contact: Duchy Trachtenberg, L.C.S.W.-C., e-mail: duchy@erols.com

The ban on receiving anything that can remotely be construed as a kickback is quite troublesome for integrative practices.

expand the ability of physician extenders to submit claims to Medicare directly, thus obviating the need for incident to billing. The problem, of course, is that this is a classic case in which ACM services are "not on the radar screen," and because ACM practitioners are not listed as able to submit Medicare claims directly and generally poorly covered by other insurers, integrative clinics will have a difficult time finding other effective billing arrangements.

Recommendation: The Commission has an opportunity to ask the HCFA to review its anticipated policy with regard

The Thomas Navarro FDA Patient Rights Act (H.R. 3677)

To amend the Federal Food, Drug, and Cosmetic Act to restrict the authority of the Food and Drug Administration to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs.

IN THE HOUSE OF REPRESENTATIVES

February 16, 2000

Mr. BURTON [Dan Burton, Republican] of Indiana, with 38 cosponsors.

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to restrict the authority of the Food and Drug Administration to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs.

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 "Thomas Navarro FDA Patient Rights Act".

SECTION 2. INVESTIGATIONAL NEW DRUGS; RESTRICTIONS ON AGENCY AUTHORITY REGARDING CLINICAL HOLDS ON TRIALS AND EXPANDED ACCESS FOR PATIENTS.

(a) CLINICAL HOLDS—Section 505(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)) is amended by adding at the end the following subparagraph:

"(D) The Secretary may not under clause (i) or (ii) of subparagraph (B) place a clinical hold on an investigation of a drug on the basis that the Secretary has determined that—

"(i) there is another drug (including another investigational drug) that is or may be a safe and effective therapy for the disease or condition involved; or

"(ii) there is a comparable or satisfactory alternative therapy available for a patient who is receiving or will receive the drug as a clinical subject in the investigation, except that such restriction on the authority of the Secretary applies only if the patient declares in writing that the patient is aware of the comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the drug in the investigation, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy.

(b) EXPANDED ACCESS—

(1) INDIVIDUAL PATIENT ACCESS—Section 561(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)(1)) is amended by inserting before the semicolon the following: ", except that such conditions for the receipt by the person of the investigational drug do not apply if the person declares in writing that the person is aware that there is a comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the investigational drug, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy".

(2) TREATMENT APPLICATION—Section 561(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(c)(2)) is amended by inserting before the semicolon the following: ", except that such condition for the receipt by a patient of an investigational drug does not apply if the patient declares in writing that the patient is aware that there is a comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the investigational drug, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy".

*Note. The commas that appear within the quote marks are intended and show that the quoted material is to be appended onto an existing sentence in the legislation.

Responsible integrative medicine should be encouraged by removing or softening the barriers to physician involvement.

to changes in incident to billing, inviting public comment and working with leaders in the field of integrative medicine, to determine possible methods of acceptable billing that can be used by physicians who are working in ACM integrative clinics.

The HCFA's Regulation of Professional Relationships

[In addition, as covered in a previous column,[2] the physician ban on referral to entities the physician has any ownership in, and the ban on receiving anything that can remotely be construed as a kickback, are quite troublesome for integrative practices. Targeting excessive services or fraud, the purpose of these statutes is to restrict the kinds of relationships that health care practitioners can have with each other. So, it is not a surprise that these restrictions can make matters quite difficult in legally structuring shared practices.]

Physician Ban on Self-Referral: The Stark Prohibition. Originally crafted to bar physicians from referring to laboratories in which they had part ownership, resulting in an incentive for expensive and unnecessary tests, the so-called Stark rule has been expanded to cover a range of other services, including physical therapy. While limited to physicians, it makes structuring integrative services with physician involvement very difficult. Can a physician, for example, maintain a conventional practice, organize a separate, integrative facility to practice ACM for patients seeking that care, and refer between these two practices?

To do so legally, if it can be done, presents enormous legal difficulty and expense. Can a physician set up an integrative practice using independent practitioners under a management service organization, providing practice management services? If so, this still cannot be done without great legal difficulty. And, as yet another example, if a group so organized wants to share income from a laboratory within the practice, this group faces real legal challenges.

One unintended consequence of these difficulties is that they encourage ACM practitioners to organize without a physician because of the regulatory pressures that physician involvement brings. Responsible integrative medicine should be encouraged by removing or softening the barriers to physician involvement, a move that should make people who are concerned about ACM more comfortable with its rapid evolution.

Kickback Prohibitions. The other regulation of professional relationships that needs to be addressed has more widespread application, because no practitioner who can be covered under a government health plan can receive anything of value in exchange for a referral. This is, of course, intended to prevent the perversion of professional judgment regarding appropriate referrals. The problem is that this regulation makes structuring legitimate integrative efforts quite difficult. One concern is that integrative clinics often use independent contractors or partnerships because they are often not well

The Commission's Schedule of Meetings

Date	Site	Type	Topic
September 8, 2000	San Francisco, CA	Town Hall	West Coast/Region IX
October 5–6, 2000	Washington, DC	WHC	Research, Part I
October 30–31, 2000	Seattle, WA	Town Hall	West Coast/Region X
December 4–5, 2000	Washington, DC	WHC	Access and Delivery, Part I
January 26, 2001	New York, NY	Town Hall	North/Region II
February 19–20, 2001	Washington, DC	WHC	Information Dissemination
February 23, 2001	Atlanta, GA or in FL	Town Hall	South/Region IV
March 5–6, 2001	Washington, DC	WHC	Education/Training
March 12, 2001	Des Moines, IA	Town Hall	Mid-West/Region VII
March 16, 2001	Houston, TX or Albuquerque, NM	Town Hall	South-West/Region VI
April 9–10, 2001	Washington, DC	WHC	Research, Part II
May 14–15, 2001	Washington, DC	WHC	Access and Delivery, Part II
July 5–6, 2001	Washington, DC	WHC	Review Interim Report Draft
November 5–6, 2001	Washington, DC	WHC	Review Final Report
December 6–7, 2001	Washington, DC	WHC	Final Full Meeting
March 2002	Washington, DC	WHC	Closing Event

WHC = White House Commission [on Alternative and Complementary Medicine Policy]. Also, the number and location of Town Hall Meetings may change based on recommendations of the Commission.

There are a host of ACM services that are not covered in the CPT manual.

How to Contact the Commission

If you would like to support any of these recommendations or put forward your own concerns and suggestions to the Commission, contact:

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White House Commission on Complementary and Alternative Medicine Policy
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capitalized ventures that are able to risk retaining employees. The HCFA's relevant "safe harbors," exceptions allowing for safe practice, only extend to employees. This leaves many integrative efforts exposed to liability.

Can a group of practitioners hire a management team and pay it a percent of the physician's earnings to manage their practice management needs such as scheduling? Can a small integrative clinic pay a marketer a percentage of the money earned from the patients that are attracted? These and many other arrangements that are at least technically illegal create barriers to integrative practice.

Recommendation: The Commission has an opportunity to ask the HCFA and the Office of the Inspector General (OIG) at the Department of Health and Human Services (DHHS) to review its safe harbors and advisory opinions regarding Stark and anti-kickback rules in the light of these concerns. Public comment about the impact of such regulations on integrative medicine and the HCFA working with attorneys and leaders in the field would assist in the development of more appropriate policies.

Coding: HCFA/AMA Code Choices

Claims for services are submitted using codes set forth in the Physicians Current Procedural Terminology manual, known as CPT codes. These codes are established by a joint committee of the AMA and the HCFA. Because these codes are established from a biomedical orientation, inroads by ACM professions have been slow. There are limited codes for acupuncture and chiropractic, and there are also codes that can be used for massage and some mind-body techniques. ACM practitioners continue to face, however, a great number of difficulties when attempting to submit claims.[1] Such difficulties are quite serious because they not only make reimbursement more difficult but potentially expose practitioners to fraud charges.

A primary area of difficulty are the codes for office visits, known as evaluation and management (E/M) codes. These E/M codes describe the level of complexity a patient presents and the amount of time the practitioner spends with the patient. The level of visit makes an enormous difference in the amount of reimbursement. The circumstances under which the more complex codes may be used are subject to detailed requirements based upon a biomedical understanding about the healing interaction.[3] Holistic physicians, homeopaths, naturopaths, and other practitioners spend considerable time with patients because of an approach that requires careful and searching history taking to diagnose multisystemic problems as well as paying more careful attention to the healing interaction. Yet, for the vast majority of patients, it would be fraud to use the codes that reflect the time spent because the biomedical guidelines for complexity would not be met.

E/M codes are the most pervasive problem, but there are many others as well. Osteopathic physicians who still provide adjustments cannot bill for adjustments and office visits or other work on the same visit. Such artificial distinctions make providing whole care more economically difficult. Chiropractors, who provide a range of services such as joint mobilization and adjustment, are reduced to essentially a three-code profession under the CPT schema, an unnecessary devaluation of chiropractic offerings. While it remains up to insurers to choose whether or not they will pay for a code, lacking even the opportunity to submit, it makes it even more difficult to obtain a favorable response.

There are, of course, a host of ACM services that are not covered in the CPT manual. The panoply of energetic medicine techniques are not coded. Coding many of the mind-body techniques appropriately can be challenging. Codes for many naturopathic procedures are not

Another area of difficulty concerns medical devices used for unconventional purposes.

available, and those for midwifery are very limited, to name just a few.

Recommendation: The Commission has an opportunity to ask the HCFA/AMA committee to review its codes in light of the sophisticated development of many ACM fields and the growing reimbursement that is available as insurers recognize the value of ACM care or respond to state mandates to provide greater coverage.

The Food and Drug Administration

The FDA has a considerable impact on ACM delivery. The FDA's regulation of drugs, nutraceutical supplements, and medical devices all make an impact on the ability of ACM practitioners to serve their patients. While there have been many improvements, with the FDA recognizing that acupuncture needles—devices that have used for more than 4000 years—are no longer "experimental," and with Congressionally imposed restraints on the regulation of dietary supplements, the climate, in many ways, is tolerant of ACM care. There are notable exceptions, however.

The most tragic of these exceptions are the difficulties in obtaining fair consideration of the antineoplastin therapy. Stanizlov Burzynski, M.D., has faced criminal charges while his patients have faced undue restrictions in joining his clinical trials. One well-publicized case is that of Tom Navarro, a 4-year-old boy with a type of brain cancer that has responded well to antineoplastins, who has been barred by the FDA from receiving the treatment and whose caring parents have been accused of neglect because they chose this treatment over conventional treatments that hold little promise. In response to this case, Congressman Dan Burton (R-Indiana) has introduced a bill that would curtail the FDA's ability to bar patients from access to clinical trials. (See box entitled The Thomas Navarro FDA Patient Rights Act.)

Another area of difficulty concerns medical devices used for unconventional purposes. The FDA recently confiscated, and is pressing for criminal charges for the use of, a device used for ultraviolet blood irradiation, a technique approved for use in specific circumstances for leukemia, but also used for viral load syndromes by some holistic physicians. The FDA has also taken action against machines used for electroacupuncture known under variety of trade names. These actions are predicated upon differences in scientific world views.

With regard to the regulation of dietary supplements, national policy has been torn between Congressional efforts to maintain access to supplements and FDA concerns about standards of efficacy and safety. In the latest volley regarding health claims for dietary supplements such as vitamins, minerals, and botanical products, the FDA has interpreted Congressional language of the Dietary Supplement Health Education Act with a broad definition of disease that narrows the health claims that can be made for dietary supplements.[2] Anticipated claims, for example, that certain supplements lower cholesterol or ameliorate the side effects of chemotherapy were, at the last moment, rejected by the FDA as being unacceptable disease claims.[4] This ruling continues a long history of FDA policy aimed at limiting consumer information even though it may be truthful and not misleading. On the other hand, numerous commentators have expressed concern that the FDA's ability to act on legitimate issues of safety may indeed be too limited.

The common thread in these issues are overarching matters of public policy and decision making that balance differences in perception about science, clinical judgment, and the role of federal agencies in people's health care decision making. Such topics can be framed in a matter so overarching as to be not solvable, while weighing in on specific debates about federal policy could well be beyond the prudent reach of the Commission. It does seem, however, to be within the charge of the Commission to set forth guiding principles and methods that could assist federal food and drug policy more in accord with freedom to access care or information, such as truthful health claims, in light of the growing acceptance of the value of nutraceuticals.

Recommendations: Addressing these various FDA policies certainly presents a challenge to the Commission as it determines the scope of its efforts and its proper role. The Commission could to meet with officials of the FDA, set forth guiding principles about treating various ACM concerns, or make specific recommendations with regard to these and other FDA actions of concern.

When the rationale of a test is not accepted by an agency, it is difficult to conduct an assessment of the test's proficiency.

Clinical Laboratory Improvement Act

While too many ACM practitioners are unaware that laboratory testing is heavily regulated, there are some commonly used ACM laboratory services that, under federal law, must be certified. The Clinical Laboratory Improvement Act (CLIA)[5] is focused on ensuring that laboratory personnel are proficient and that equipment is able to provide accurate results. CLIA extends to laboratories within practitioners offices. Laboratories that simply draw blood, prepare it, and ship it to another laboratory; and perhaps do a few simple "waived" tests, such as some urine tests, face few requirements other than a certificate that they are exempt from the primary CLIA requirements. Performance of tests that have any complexity are not waived, and a laboratory can only perform them if that laboratory is accredited, requiring demonstrations of proficiency testing and training, a process that takes some investment. The primary legal difference is the complexity rating of the test; only tests that are designated as simple can be performed without some full regulatory involvement with CLIA.

The difficulty with ACM tests is largely caused by the difficulty biomedically oriented regulatory agencies have in evaluating the complexity of ACM tests. When the rationale of a test is not accepted by the agency, it is difficult for the agency to conduct an assessment of the proficiency required to gain an accurate result because, to that agency, no "accurate" result is possible. As a result, the Centers for Disease Control and Prevention (CDC), which evaluates test complexity for CLIA, has decided to default to a high level of complexity on some ACM tests.

While there is some variation among state CLIA offices, the CDC/CLIA has essentially defaulted two tests that are widely respected and used by ACM practitioners to a complex status. One of these tests is the Darkfield microscope, a remarkable test that allows practitioners to view blood serum in its live state. The other test is called biological terrain analysis (BTA), a test principally used by naturopaths and holistic physicians that uses blood, urine, and saliva to test pH, oxidative stress, and other factors to assess a patient's biochemical status. In addition, another test placed on the high complexity list is dental sensitivity testing, which is used by mercury-free dentists to determine allergic reactivity to alternative, composite materials. This little-known 1997 ruling* requires that practitioners who use Darkfield, BTA, and other alternative testing methods, must attempt to receive full CLIA accreditation, an approval that a state office may not give under any circumstances because that office rejects the scientific basis for these tests.

The decision to default to high complexity in these cases is symptomatic of the difficulty that agencies have in accepting alternative views of health and functioning. This same difficulty complicates and is interwoven with FDA issues as well as reimbursement and many other decisions. These CLIA decisions may comprise a discreet, manageable issue, that presents an excellent example of the regulatory difficulties ACM faces that could provide a model for addressing issues of scientific difference.

Recommendation: The Commission has an opportunity to assist the HCFA/CLIA/CDC in developing a national policy that allows for laboratory regulatory policies that are able to act as a model for making fair assessments of regulation in the face of differing theories of knowledge.

Department of Health and Human Services: Creation of an Office Within the Secretary's Office

Many of these foregoing concerns could be addressed by the creation of an office within the office of the Secretary for the DHHS. Such an office could take a broader view and assist in developing a consistent national policy that addresses issues of access to, and integration with, ACM services. This proposal has been put forward by the Alternative and Complementary Health Practices Special Primary Interest Group of the American Public Health Association (APHA). (See box entitled A Modest Proposal: Creation of a New Office or Position within the DHHS.)

One of the advantages of such an office would be a coordinated, high-level approach to issues that arise in various branches of the FDA and HCFA, with both agencies serving the office of the Secretary within the DHHS. National policy can also

*When I called the federal CLIA office in early 1999, the people in the office were not aware of this decision. When I checked with several CLIA state offices, I learned that each office has a different policy with respect to Darkfield microscopy.

A central aspect of access to care is, of course, the ability to pay for it.

be served by creating an office with the ability to drive quests for innovative solutions that include integrative care and that are based on a view of significant health needs and gaps within existing programs. Such an office could, for example, serve as a springboard for demonstration projects that study the cost effectiveness of integration into services for specific DHHS populations, such as patients who are receiving disability social security payments.

Recommendation: The Commission would be well served to support the suggestion of the APHA to establish within the office of the secretary of DHHS an office dedicated to ACM policy. This office should have high-level input into the FDA, the OIG, and HCFA regarding matters of ACM policy.

Legislation

Access to Medical Treatment Act

The American Preventive Medical Association, under the direction of Candace Campbell, the Association's executive director, has been steadily moving the Access to Medical Treatment Act (AMTA)[6] through Congress. This bill would allow state licensed practitioners to use treatments within their scope of practice even though the FDA has not approved them for use, as long as patients are informed of the treatment's status and a national data bank of adverse reactions is created.

Recommendation: The AMTA represents a reasonable balancing of patients' rights of access, professionals' rights to practice their professions, and concerns about safety and information about adverse events. The Commission could assist in moving this legislation, which has sat too long on the Hill, forward by lending it its support.

Matters of Reimbursement

A central aspect of access to care is, of course, the ability to pay for it. The most immediate and far-reaching federal impact on reimbursement derives from Medicare reimbursement policy. Efforts have been made since the early 1990s to pass legislation that would add acupuncture to Medicare as a covered service. Chiropractic does receive some Medicare coverage, although it has had its struggles with Medicare policy. Until recently, for example, chiropractors were required to have X-rays in order to bill for a patient but the X-rays were not covered, creating a real bind for many Medicare patients. These decisions are both legislative and administrative in nature because the broad strokes of legislative will and the detailed decisions inside the HCFA both have significant impacts on payment. (See Managed Care Update, by Billie M. Spaight, this issue, for information on two lawsuits that the American Chiropractic Association has filed with regard to Medicare+ coverage and BC/BS policies for D.C.s)

Private insurers also face barriers in covering ACM services that need to be addressed. Indeed, a representative of the health insurance industry is on the Commission; and the company represented is one that has been involved in the expansion of ACM insurance coverage.

Recommendation: Reimbursement policy is a highly complex algorithm combining actuarial data, budgetary concerns, medical viewpoints, and social policy. As the Commission determines how the government can best reassess legislative and administrative policy, the best role for the Commission may be to determine what agencies and what resources need to be at the table together in order to create a reimbursement policy that matures along with the growth of the field. □

References

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6. 106th Congress, H.R.2635.

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Report of the White House Commission on Complementary and Alternative Medicine Policy

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FAX TO--- Dr. Stephen Groft FROM- Paul W. Scharff, MD
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(For the Town Hall Meeting in New York City on January 23rd, 2001)

I. Coordinated research can be helpful with CAM practices and products with the following provisions:

a.- that SCIENCE AND RESEARCH IS CHANGING – thus dictation by government, the insurance industry and conservative medical societies should not become the sole determinants of what constitutes good research. Government agencies, medical schools, pharmaceutical companies and insurance industries tend to use research to make inflexible decisions not warranted by the research and which are arbitrary at times.

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e. – that a realization come about of how INDIVIDUAL therapies have to be for a given person. Many patients come to a CAM practice which is known for the individualization in therapeutics. Needed are careful studies (some are on board) to show how, in fact, research impacts practice – indications so far are inconclusive and point to the lack of use of research by individual practitioners. There have been complaints of how little the recommendations of Consensus Panels are taken up by those who practice.

f. – that one lives by the fact "WHAT IS ONE MAN'S MEDICINE IS ANOTHER MAN'S POISON" – researchers, in general, do not take this to be the case sufficiently. Mortality studies with conventional therapies address this loudly.

g. – that in doing research, it is necessary that the researcher not be adversarial, nor indulgent.

h. – that research should not be used thinking that therapeutic robots can be created.

II – Access to CAM and reimbursement has become such a problem for many reasons, but four issues can stand out (not the usual).

a. Many patients (and a growing number of therapists) distrust the conventional and fear the potential dangers in conventional therapies while the conventionally trained physicians often do not consider the "side reactions" (adverse reactions) or try to minimize the problems. Those who fear, feel that they have a right to have their choice supported by insurance companies or whatever "the system". This DISTRUST will have to be dealt with and many do not think that such a *psychological factor* is so determinative.

b. Those sold on the dogma that the conventional is the only possible way, totally distrust the CAM therapies and make propaganda against these therapies using the support of the medical schools, the insurance companies, the federal agencies (which are often very poorly informed and could care less), yet there is a growing public awakening that there is more than one road to Rome. DOGMATISM will have to be dealt with – again a *psychological factor.*

c. Those who are into insurance and the production of medicines in health care, which is becoming a progressively large money making industry, LIVE WITH THE ILLUSION THAT THE CARE OF THE ILL AND THE FURTHERENCE OF WELLNESS IS NOT EXPENSIVE. This is a *psychological and economic* dimension of health delivery.

d. Without well-trained and able therapists, and some confidence in these therapists, it will be difficult to gain trust and a needed flexibility. One must come to realize that wellness and therapeutics is costly.

III – Education, Training, Certification and Licensure and Accountability.

a. Accountability at a serious level might be called a MORAL issue. Involved are fiduciary issues in terms of the patient, society and one's particular profession. Discussion of ethical issues is a beginning, bur remains as ideas for action, for deeds. Moral points to actions where skill, devotion to helping the maintenance of health, the ill and the dying are in the best interest of the individual and serving the social good. IT MAY BE ONE OF THE GREAT ILLUSIONS OF OUR PRESENT TIME THAT THE FINANCIAL INCENTIVES WILL REAP ACCOUNTABILITY.

b. Uniformity in CAM may be its death, as it is just the non-uniform that lives at the heart of the creative therapist who serves the individual health needs of the ill person. Uniformity to a degree within the varying schools, systems, discipline, and modalities is a need, and a relation with what can be viewed scientifically, as noted above, is a need. A well trained therapist may need to not only know his or her own discipline, but to know when another school, system, discipline or modality might serve a given individual. The diversity of mankind is vast, and a uniform system of the dogmatic medical paradigm of modern western medicine is what so many are revolting against while slowly appreciating the value of modern medicine.

c. In order for CAM to serve, gaining confidence of the dogmatists, the conservative scientists, and the biased in conventional circles (medical schools, insurance companies, businesses and pharmaceutical companies) – as well as the public at large, education, training, certification and licensure will be needed. However, EACH SCHOOL, SYSTEM, DISCIPLINE AND MODALITY WILL HAVE TO SAY WHAT IS NEEDED FOR EACH TO WORK IN ANY DEGREE OF FREEDOM, IN AN ACCOUNTABLE WAY

d. Federal legislation, followed by state legislation will be needed to support the above changes (impossible to imagine twenty years ago). Only then will the rights of human beings in regard to health, healing and wellness be observed as a right in a democratic society.

e. Safety and efficacy is a part of accountability, but again what is one man's poison may be the next man's therapy, and for this to be a guiding rule, a sense for the individual-ness of each person and progressively his or her wellness and healing has to be part of the equation.

IV. – Information for the wellness and the therapy as well as healing of individuals is needed, BUT –

a. This is an issue of accountability – as noted above this is in the long run a MORAL issue determined by a real concern for the wellness, the therapy and healing of individuals, and in the case of society at large, public health issues.

b. CAM practitioners have to be aware, as is the case with all therapists, that truth and not self interest become the foundation for all communication – a basis for honest information.

c. Personal motives for economic gain can be a detriment for proper handling of information. An aspect of accountability is a sense for service, a bit of altruism (at least a little bit) and a degree of humility in regard to a particular school, system, discipline or modality. THESE ARE THE SUBTILTIES OF accountability which many, if not most, do not wish to touch, and yet determine accountability.

d. There are increasing possibilities of offering information – and this information perhaps should be sifted by a known group within a school, system, discipline or modality, and not tampered with by government institutions, but known to a government institution. Issues of freedom of speech are important here. Only slowly has CAM begun to use the many modes of communication. Within each school, system, discipline, or modality there will be a need to

observe this freedom and here the potentials of LEGAL ISSUES should be foreseen, even be permitted. Legislative action should support freedom of action and speech and should not take it away. That is what should be the case on the Federal level as well as the state. The result has been to have "Medical Access Laws" enacted state by state. This newly surfacing freedom will need to be observed on a federal level and to this end the Federal Medical Access Law needs to be passed.

Paul W. Scharff, MD – 1/17/2001

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a. Many patients (and a growing number of therapists) distrust the conventional and fear the potential dangers in conventional therapies while the conventionally trained physicians often do not consider the "side reactions" (adverse reactions) or try to minimize the problems. Those who fear, feel that they have a right to have their choice supported by insurance companies or whatever "the system". This DISTRUST will have to be dealt with and many do not think that such a *psychological factor* is so determinative.

b. Those sold on the dogma that the conventional is the only possible way, totally distrust the CAM therapies and make propaganda against these therapies using the support of the medical schools, the insurance companies, the federal agencies (which are often very poorly informed and could care less), yet there is a growing public awakening that there is more than one road to Rome. DOGMATISM will have to be dealt with – again a *psychological factor*.

c. Those who are into insurance and the production of medicines in health care, which is becoming a progressively large money making industry, LIVE WITH THE ILLUSION THAT THE CARE OF THE ILL AND THE FURTHERENCE OF WELLNESS IS NOT EXPENSIVE. This is a *psychological and economic* dimension of health delivery.

d. Without well-trained and able therapists, and some confidence in these therapists, it will be difficult to gain trust and a needed flexibility. One must come to realize that wellness and therapeutics is costly.

III – Education, Training, Certification and Licensure and Accountability.

a. Accountability at a serious level might be called a MORAL issue. Involved are fiduciary issues in terms of the patient, society and one's particular profession. Discussion of ethical issues is a beginning, bur remains as ideas for action, for deeds. Moral points to actions where skill, devotion to helping the maintenance of health, the ill and the dying are in the best interest of the individual and serving the social good. IT MAY BE ONE OF THE GREAT ILLUSIONS OF OUR PRESENT TIME THAT THE FINANCIAL INCENTIVES WILL REAP ACCOUNTABILITY.

b. Uniformity in CAM may be its death, as it is just the non-uniform that lives at the heart of the creative therapist who serves the individual health needs of the ill person. Uniformity to a degree within the varying schools, systems, discipline, and modalities is a need, and a relation with what can be viewed scientifically, as noted above, is a need. A well trained therapist may need to not only know his or her own discipline, but to know when another school, system, discipline or modality might serve a given individual. The diversity of mankind is vast, and a uniform system of the dogmatic medical paradigm of modern western medicine is what so many are revolting against while slowly appreciating the value of modern medicine.

c. In order for CAM to serve, gaining confidence of the dogmatists, the conservative scientists, and the biased in conventional circles (medical schools, insurance companies, businesses and pharmaceutical companies) – as well as the public at large, education, training, certification and licensure will be needed. However, EACH SCHOOL, SYSTEM, DISCIPLINE AND MODALITY WILL HAVE TO SAY WHAT IS NEEDED FOR EACH TO WORK IN ANY DEGREE OF FREEDOM, IN AN ACCOUNTABLE WAY

d. Federal legislation, followed by state legislation will be needed to support the above changes (impossible to imagine twenty years ago). Only then will the rights of human beings in regard to health, healing and wellness be observed as a right in a democratic society.

e. Safety and efficacy is a part of accountability, but again what is one man's poison may be the next man's therapy, and for this to be a guiding rule, a sense for the individual-ness of each person and progressively his or her wellness and healing has to be part of the equation.

IV. – Information for the wellness and the therapy as well as healing of individuals is needed, BUT –

a. This is an issue of accountability – as noted above this is in the long run a MORAL issue determined by a real concern for the wellness, the therapy and healing of individuals, and in the case of society at large, public health issues.

b. CAM practitioners have to be aware, as is the case with all therapists, that truth and not self interest become the foundation for all communication – a basis for honest information.

c. Personal motives for economic gain can be a detriment for proper handling of information. An aspect of accountability is a sense for service, a bit of altruism (at least a little bit) and a degree of humility in regard to a particular school, system, discipline or modality. THESE ARE THE SUBTILTIES OF accountability which many, if not most, do not wish to touch, and yet determine accountability.

d. There are increasing possibilities of offering information – and this information perhaps should be sifted by a known group within a school, system, discipline or modality, and not tampered with by government institutions, but known to a government institution. Issues of freedom of speech are important here. Only slowly has CAM begun to use the many modes of communication. Within each school, system, discipline, or modality there will be a need to

observe this freedom and here the potentials of LEGAL ISSUES should be foreseen, even be permitted. Legislative action should support freedom of action and speech and should not take it away. That is what should be the case on the Federal level as well as the state. The result has been to have "Medical Access Laws" enacted state by state. This newly surfacing freedom will need to be observed on a federal level and to this end the Federal Medical Access Law needs to be passed.

Paul W. Scharff, MD – 1/17/2001

Groft, Stephen (NCCAM)

To: Joseph Fins; Chang, Michele (NCCAM)
Subject: RE: December summary

I think this issue

-----Original Message-----
From: Joseph Fins [mailto:jjfins@med.cornell.edu]
Sent: Friday, January 12, 2001 9:52 PM
To: Chang, Michele (NCCAM)
Cc: Groft, Stephen (NCCAM)
Subject: December summary

Dear Michelle and Steve,

Thanks for doing this summary. It will be a tremendous help to us as we go forward. Just one ommission which I think is significant. I said that I felt that it was ethically untenable to go forward with a CAM benefit before there was a universal health care benefit. I invoked the Plessy v Ferguson case echoing what Julia had said about access and the under-served, arguing that allopathic and CAM therapies are not equal and that an endorsement of a Federal CAM benefit in the absence of universal allopathic health care or a drug benefit would be untenable. CAM therapy should not be an alternative care for people simply because they can not afford allopathic medicine. This engendered some debate from fellow commissioners, especially Bill Fair ...In any case, I think that someone should go back to the transcripts and put this question over what constitutes access as a bookmark as I think it will be an important point to reach consensus on as we move forward together.

Again, thanks for all your good work. I am looking forward to NY and our February experiment with process. Both should be fun.
Best,
Joe

>Greetings, Commissioners!
>
>Attached please find the summary of the December 4-5 meeting on Access and
>Delivery of CAM Services.
>
>Please review this summary and provide us with any comments on format, style
>and content. You may provide you comments by e-mail directly to Michele.
>
>Thanks!
>
>
>Attachment converted: hard drive:Rsummary.rtf (RTF /MSWD) (00195D1A)

Note from The Desk of
Joseph M. Kaczmarczyk, DO, MPH

25 Jan 01

The attached article literally contains something for every member of the staff and is germane to the WHCCAMP.

Please note that the full-text references cited are available on-line at ***http://www.bmj.com***.

FYI,
Joe

BMJ Explores The Future of Integrative Medicine

In conjunction with a London-based conference co-sponsored by the Royal College of Physicians and the National Center for Complementary and Alternative Medicine (NCCAM) the January 20 issue of the *British Medical Journal* devotes numerous articles to the subject of integrative medicine. The articles, written by both British and American integrative medicine authorities, discuss such pertinent complementary and alternative medicine (CAM) topics as doctor-patient relationships, medical education, legal regulation, research methodology, and integrative medicine models from developing countries.

Homeopathic physician, Owen, and colleagues urge fellow physicians to consider the implications of patients' growing use of CAM treatments on clinical training and practice. Owen et al describe a model of CAM medical education currently used in the curriculum at the University of Southampton. In an accompanying editorial, the University of Maryland's Brian Berman notes that, "healthcare professionals, patients, and our healthcare system can only benefit if medical education bridges the gap with complementary and alternative therapy."

Mills, research coordinator of the Complementary Health Studies Programme at the University of Exeter, reviews the UK's regulatory structure for CAM governance and the impact of the recent House of Lords report on CAM therapies. Mills recommends that each CAM discipline establish its own regulatory body to oversee appropriate standards of care and competency.

Representing NCCAM, the National Institutes of Health's Nahin and Straus review the challenges of conducting rigorous clinical investigations of CAM efficacy and make recommendations for improving clinical trial designs. They note that high quality research "requires a commitment by the research community, as well as sustained financial support from governments and industry."

While CAM use in industrial nations is a relatively recent phenomenon, many developing countries have been grappling for decades with the policy issues of integrating complementary medicine into national healthcare infrastructures. Gerard Bodeker, Chair of the Commonwealth Working Group on Traditional and Complementary Health Systems at the University of Oxford, outlines the lessons learned by China, India, South Korea, Malaysia, and Africa and how these regions have approached regulation, insurance reimbursement, herbal medicine manufacturing standards and practitioner training.

The entire BMJ issue is available on line at: http://www.bmj.com.

References

Berman BM. Complementary medicine and medical education. *BMJ.* 2000;322(7279):121-122.

Bodeker G. Lessons on integration from the developing world's experience. *BMJ.* 2000;322(7279):164-167.

Mills SY. Regulation in complementary and alternative medicine. *BMJ.* 2000;322(7279):158-160.

Nahin RL , Straus SE. Research into complementary and alternative medicine: problems and potential. *BMJ.* 2000;322(7279):161-164.

Owen DK, Lewith G, Stephens CR. Can doctors respond to patients' increasing interest in complementary and alternative medicine? *BMJ.* 2000;322(7279):154-158.

House of Lords

Session 1999-2000
Publications on the internet
Science and Technology Committee Publications

Science and Technology - Sixth Report

Here you can browse the report together with the Proceedings of the Committee. The published report was ordered by the House of Lords to be printed 21 November 2000.

CONTENTS

Visit to the Marylebone Health Centre, 12 April 2000

APPENDIX 5

Visit to the University of Southampton Medical School and the Centre for the Study of Complementary Medicine, Southampton, on 9 June 2000

APPENDIX 6

Special visit to the Glasgow Homeopathic Hospital by two members of the Sub-Committee on 24 August 2000

APPENDIX 7

Sub-Committee 1

APPENDIX 8

List of Witnesses

APPENDIX 9

Acronyms

Note
Written and oral evidence received by the Committee is published in two separate volumes (HL Paper 48 and HL Paper 118).

In the text of the Report:

Q refers to a question in oral evidence;
p refers to a page of written evidence printed in HL Paper 118; and
P refers to a page of written evidence printed in HL Paper 48.

1/31/01

Questions and Comments on Commission Report

1. Approach?

Options: 1) Focus on interim report and then expand for full report; or

2) Focus on developing full report and then in late May or early June begin condensing for interim report

Note: Have already started developing sections I, II, and III of report (see revised outline below), but before I go any further want to make sure this is agreeable.

2. Structure?

House of Lords, Science and Technology-Sixth Report, provides a good template for structure, particularly in terms of appendices, etc. (See Handout)

-One appendix we have already agreed is necessary is a description of site visits (Continuum Center for Health and Healing; will reconstruct others; what are they?)

-Other appendices:

-List of Witnesses?

- Descriptions of subcommittees and activities?
- Minnesota visit?
- Acronyms and Glossary,
- Etc.

3. Style and Substance Issues?

What about tables, graphs, or photography?

Will there by any cover design? Desktop publishing?

How do we handle editing and authorship? Will whole commission act as editorial board? (e.g., for citations etc.)

Note: There were problems with Chantilly after it was published.

Schedule? When is deadline for submission of final report to GPO? When should we begin meeting with them? How will interim report be handled?

3. Suggestions for Recommendations:

1. Why not ask the working groups to come up with short-term, medium-term, and long-term recommendations?

   The short-term (and possibly some of the more "doable" medium-term) recommendations would be the ones released in the interim report.

   The rest of the medium- (2- to 5-year) and long-term (5- to 10-year) recommendations would be in the final report.

4. Meeting Summaries:

Length?

Structure?

Content?

Purpose?

Revised Outline for Parts I, II, and III.

Part I: Introduction

(A) Short introductory piece explaining what led to the formation of the Commission, including utilization information) (**We need this piece so that we can make a compelling case that the Commission has an important and urgent mission. This will also help in marketing the report**)

(B) The Commission: It's Mandate and Activities

(1) The Purpose of the Commission
(2) Town Hall Meetings
(3) Regular Meetings that include public hearings

(C) The Commission Report
(1) It's purpose and scope
(2) How to utilize the report

Part II: Guiding Principles and Perspectives of CAM Interventions and Practices

(A) What is CAM?
(B) World view of major CAM traditions
(C) Focus on Health, Wellness, and Disease prevention
(D) Concerns with the delivery of CAM interventions and products (refer to part V for more details)
(E) Concern with integration of CAM approaches and treatment into conventional medicine.

Part III: Historical Perspective on CAM Regulation and Integration

(A) Legislative and Executive Actions
(B) Other Federal and state activities
(C) Integration efforts to date (e.g., behavioral medicine consensus conference and OBSSR Report etc.)

Identify Plan for involving these groups in discussion of th

TOM HARKIN
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COMMITTEES:
AGRICULTURE
APPROPRIATIONS
SMALL BUSINESS
LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510-1502

FAX COVER SHEET

TO: Steve Groft

FR: Sabrina

Number of Pages to Follow: 2

COMMENTS:

If there is a problem with this transmission,
please call:
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FAX: (202) 228-0404

THANK YOU

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Center for Science and the Public Interest (Mike Jacobson)
Gail Shearer, Health Care Government Relations Manager (Jerry)
202 332 9110

Consumers Union
Adrienne Hahn, Legislative Counsel
202 462-6262

Public Citizen
Frank Clemente, Congress Watch Director
(202) 588-1000

American Public Health Association
Sarah Lister, Director of Government Relations
202 682 0100

White House Commission on Complementary and Alternative Medicine Policy
Outreach to Health Care Groups

Association of American Medical Colleges
Dave Moore
202 828 0400

Association of Schools of Allied Health Professionals
202 293 4848

American Cancer Society
Dan Smith
202 661 5700

National Breast Cancer Coalition
Jennifer Katz, Government Relations Manager
202 296 7477

American Academy of Pediatrics
Graham Newson, Director Department of Federal Affairs
202 347 8600

Health Insurance Association of America
Marianne Miller, Director Federal Regulatory Affairs and Policy Development
202 824 1600

Association of American Health Plans
Julie Goon, Director
202 778-3200

Washington Business Group on Health
Sally Coberly, Director Public Policy
202 408 9320

PhRMA
Barry H. Caldwell, Vice president for Federal Affairs
202 835 3400

American Medical Association
Richard Deem, Government Affairs
202 789 7400

American Nurses Association
Marjorie Vanderbilt, Director of Government Affairs
202 651 7000

produce even more dramatic results.

The symptoms of hypothyroidism include depression, a sense of being too cold or too hot, fatigue, memory difficulties, heart rate disturbances and hair loss. AACE (American Association of Clinical Endocrinologists) experts recommend that people experiencing some of these symptoms get a blood test that measures thyroid stimulating hormone (TSH). Nearly 13 million Americans have thyroid disease, says the AACE, but more than half of these cases remain undiagnosed.

==========
COMPLEMENTARY AND ALTERNATIVE MEDICINE ON THE RISE IN U.S.
==========

More Americans than ever are embracing complementary and alternative therapies, with greatly increased attention and interest expressed by the medical and scientific communities as well.

In December, 1995, the AMA passed a resolution encouraging the scientific evaluation of practices and procedures of unconventional medicine, and encouraging its members to become better informed regarding alternative or unconventional techniques.

Eighty percent of U.S. medical students want training in CAM (Complementary and Alternative Medicine) therapies, and 60 percent of physicians have referred patients to CAM practitioners, according to the National Institute of Health's Office of Alternative Medicine (Jonas, 1997). Sixty-nine percent of Americans use unconventional medical therapies. (Stanford University National Survey, September 1998) and 67 percent of HMO's offer at least one form of complementary alternative care.

Sixty-four percent of US medical school offer courses in CAM. Of the 123 courses reported, 84 (68%) were stand-alone electives, 38 (31%) were part of required courses, and one (1%) was part of an elective, Thirty-eight courses (31%) were offered by departments of family practice and 14 (11%) by departments of medicine or internal medicine. (JAMA, September 2, 1998)

The CAM marketplace is currently valued at $24 billion or more, with an annual growth rate close to 15% (Rauber; Modern Healthcare September 7, 1998.)

==========
U.S. PATIENTS DISSATISFIED WITH ANTIDEPRESSANT RESULTS
==========

Most Americans being treated for major depression feel that their condition is not fully under control, and many have stopped using prescribed drugs because of side effects, according to a survey released in January (Chicago, Reuters Health).

The survey of 1,001 patients, conducted by the Chicago-based National Depressive and Manic-Depressive Association, showed that while 85% of patients felt antidepressant therapy had had a positive effect on their lives, fewer than one quarter said their depression was under complete control in the 2 months prior to the survey, even though they had been taking medication for 3 to 5 years.

Forty-seven percent of those surveyed reported side effects from medication. Of those, 55% had stopped taking the antidepressants altogether and another 17% skipped doses.

"Patients should not be left to believe that they have to tolerate problems with side effects needlessly," the National Depressive and Manic-Depressive Association said in a report released with the survey.

Groft, Stephen (NCCAM)

From: Stux.Gabriel@t-online.de
Sent: Thursday, February 15, 2001 8:30 AM
To: Hannah Bradford
Subject: Hannah, USA

Dear Hannah,

there is no new report on CAM in Germany.
They made a new regulation for the payment of acupuncture by insurances. Patients which are state insured – 80 % of the population – are getting reimbursement for acupuncture only for chronic headache, low back pain and osteoarthritis. This new regulation includes a major scientific evaluation of the acupuncture even with RCT and cost effectiveness survey.
The state insurance companies have to pay for the survey, which is done by 3 major university departments including Münchner Modell of Dieter Melchard. In one of the started studies they have already more then 2000 patients in the RCT part of the study.
I hope this information is useful for you.
Can you send this information to Brian and Richard?
I hope you are well.
Thank you again for showing me NIH.
I will be in California also in May when the San Francisco-Conference takes place, but I will be at a Medicine Buddha teaching of the Dalai Lama in San Jose. Probably I can make it for an evening to San Francisco.
It would be nice if you could come to one of the Santa Barbara Chakra weekends.

Best wishes

Gabriel

Groft, Stephen (NCCAM)

To: Fisher, Ken (NCCAM)

Subject: RE: Swyer's Schedule

I understand. I think Jim Swyers schedule needed some work not reflected in schedule. i indicated to Jim S. that I did not want a Jim to Jim direct correspondence or communications. Everything through me and out to Jim G and back to me to Jim S

-----Original Message-----
From: Fisher, Ken (NCCAM)
Sent: Thursday, March 01, 2001 1:34 PM
To: Groft, Stephen (NCCAM)
Subject: Swyer's Schedule

Steve: I have read Jim's schedule and have a couple of points we may need to discuss.

1. It is not apparent what and where you want me to do in the process. Either I don't understand what we discussed or it was not evident to Jim.

2. More importantly, I think you should reconsider the first step, March 7th. Parts I-III set the tone of the report. Therefore all the staff need to read it and agree that the first parts are off on the right step. If the draft is read by only you and Jim, it will be a bully-pulpit for Jim's views. While I respect his knowledge, expertise, and experience, the WHCCAMP report will only have impact if it is objective and balanced. These are two matters which are essential but where Jim is perhaps not fully cognizant of the importance.

3. Lastly, while probably unintentional, the work of drafting and reviewing the report seems to be a Jim and Jim exercise. I am seriously concerned that if this comes to pass, there may be either a staff revolt (after all, they are doing the work) or a Commissioner revolt(their names and reputations are involved) precipitating a minority section to the report.

You're paying me to play the devil's advocate; here's the first deliverable! kdf
Kenneth D. Fisher, Ph.D.
Senior Scientific Advisor
White House Commission on Complementary
and Alternative Medicine Policy
301-435-7592
301-480-1691 (fax)

Groft, Stephen (NCCAM)

From: Kaczmarczyk, Joseph (NCCAM)
Sent: Monday, March 12, 2001 5:17 PM
To: Chang, Michele (NCCAM)
Cc: Groft, Stephen (NCCAM)
Subject: Strategic Planning Input

12 Mar 01

Michele,

My approach to this may be rather different in that I was very attentive during the President's 27 Feb 01 speech to Congress, as I listened for potential opportunities.

Using that approach, I identified the following potential opportunities which also may be termed "areas" or "building block" [as per earlier discussion]:

- Women's Health
- Patients Bill of Rights
- Doubling the NIH Budget
- Doubling the Number of Patients Seen at Community Health Centers
- Increasing the Role/Visibility of the Department of Education

Although the groups I'd consider contacting in terms of Women's Health can be stratified in a number of ways, the primary groups should include, in my opinion:

- ACOG
- North American Menopause Society (NAMS)
- ACCME
- Consumer Groups... for example...
  Breast Cancer Coalition
  Menopause (I can't identify the "right" organization at this time)

Secondary groups, in my opinion, conventional medical organizations such as ACGME, NBME, and AAMC.

While I have thoughts about the Patients Bill of Rights and doubling the number of patients seen at community health centers that I can elaborate on tomorrow, I'd like to say for now that I see the patients Bill of Rights as being a very critical and powerful vehicle. For example, I see the entire debate about the differential in the number of hours between LAc's and physicians engaged in medical acupuncture resolved by requiring full disclosure of training in a Patients Bill of Rights. I also see a Patients Bill of Rights as being an integral component of the Interim Report.

That's all for now,
Joe

3/13

Steve,

As discussed

Gerry

I added an early communication from Wagner de Jonckheere, etc —

U.S. Senator
TOM HARKIN OF IOWA

http://www.senate.gov/~harkin/ (202) 224-3254

FOR IMMEDIATE RELEASE
July 13, 2000

Contact: Jennifer Frost/ Shannon Tesdahl

Statement of U.S. Senator Tom Harkin (D-IA) at the CAM Commissioner Swearing-in

The White House Commission on Complementary and Alternative Medicine Policy will provide legislative and administrative recommendations to the President and Congress to assure that public policy maximizes the benefits to Americans of appropriate use of complementary and alternative medicine (CAM).

Harkin, long-time champion of improved research and freedom to choose alternative therapies, worked through the LHHS Appropriations subcommittee to establish the then Office of Alternative Medicine at the National Institutes of Health (NIH) in 1991 to investigate and validate alternative therapies. In 1998, Harkin sponsored successful legislation to elevate the Office to the new National Center for Complementary and Alternative Medicine at NIH to improve research and consumer information in this growing area.

"Thanks, Bruce, for that kind introduction. I'd also like to recognize Secretary Shalala and our President and First Lady for their great work on behalf of Complementary and Alternative Medicine. No other administration has taken such a comprehensive look at the potential of CAM or worked so hard to improve the quality of health care available to all Americans.

"And thanks to the commissioners and to each of you for your commitment to quality health care. It's been said that in times of great change, there are two kinds of leaders: Those who usher out the old and are called pallbearers, and those who usher in the new and are called torchbearers. This is truly a room full of torch-bearers, and I'm proud to be with you today.

"We are here today because of consumers. Over 40 million Americans regularly use some form of alternative treatment or therapy. In 1997, Americans made 629 million visits to CAM providers: that's more than the number of visits they made to primary care physicians. And studies show that Americans spend approximately $27 billion for alternative therapies, mostly out of pocket.

"Now, ten years ago, when I first started working on this issue, things were very different. Studies showed that a lot of people were using CAM remedies, but no one was talking about it. It was often publicly dismissed as quackery, and the medical community frowned upon it.

-MORE-

"I knew that I wanted to bring CAM out into the open. I wanted to provide for research and examination. That's why I used my position as Chair of the Subcommittee that funds health research to allot $2 million dollars to start the first ever Office of Alternative Medicine at NIH.

"We've come a long way since then. Today, 60% of physicians have referred patients to CAM practitioners. Today, 64% of U.S. medical schools offer courses in CAM. And today 80% of medical students and 70% of family physicians want training in CAM therapies.

"The $2 million Office of Alternative medicine is now the $100 million National Center for Complementary and Alternative Medicine. Of course, that's still less than one half of 1% of the total NIH budget. But it's a good start.

"More and more medical pioneers like Dr. Jim Gordon are integrating alternative medicine with mainstream practices. More and more medical schools like the University of Iowa are teaching alternative medicine right along with conventional medicine.

"This is just what Americans are looking for. They want less invasive, less expensive, less impersonal medical treatment. They want remedies that are safe, holistic, and affordable. They want to be involved in their own health care. They want medical practitioners to listen to them and to think of them as a whole person, not just an entity with an illness. Most of all, they want medicine that works, whether it's old or new, run-of-the-mill or out-in-left-field, traditional or alternative.

"And we've got an obligation to help. We're making a good progress on one side of the equation. Over the past decade, NCCAM has funded ground-breaking studies on therapies ranging from acupuncture to Ginkgo biloba to Melatonin to St. John's Wort to treat illnesses ranging from Osteoarthritis to Alzheimer's to sleep disorders to depression.

"But research is only half the battle. Scientific breakthroughs can't get far when they have to fight their way through a jungle of outdated public policy. It's time the government caught up with the people.

"That is why I provided funding to create this Commission. We need your expertise and recommendations on how to change administrative procedures and legislation. We need your advice on how to best integrate CAM practices into mainstream medicine and training. On whether students being trained in CAM practices should be eligible for the same loans and grants we give to conventional medical students. On whether current licensing and accreditation standards for CAM fields are appropriate. On what incentives we can create to increase private sector support for research on natural products, many of which aren't patentable. And on whether CAM therapies should be covered or subsidized by the government and private plans.

"And let me be clear, this Commission does not answer to NIH or anyone else. This is a White House Commission formed to answer to the American people.

"And my intent is to make this process as open as possible. You've got to talk to Americans. Solicit their ideas, listen to their complaints and take their advice so that we can best meet their needs. Again, I thank this administration for its work to advance CAM research and public policy, and I look forward to working with the Commission in the coming months."

-30-

BARBARA A. MIKULSKI
MARYLAND

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United States Senate

WASHINGTON, DC 20510-2003

July 13, 2000

White House Commission on Complementary and
Alternative Medicine Policy
Old Executive Office Building
The White House
Washington, DC 20501

Dear Members:

Congratulations on being appointed to the White House Commission on Complementary and Alternative Medicine Policy. As members of this commission, you will play a vital role in advising the President and Congress on how we can best make public policy meet the day-to-day needs of Americans who use complementary and alternative medicine. You are being charged with an enormous responsibility. The recommendations you make will affect the well-being and health of countless Americans.

We know that millions of Americans already make use of complementary and alternative medicine. That's why Congress established the Office of Alternative Medicine within the National Institutes of Health in 1992 and elevated the Office to the National Center for Complementary and Alternative Medicine in 1998. Now, as millions more continue to explore alternative health care, we must live up to our responsibility to make sure that we put sound public policy in place which addresses all issues related to the practice of complementary and alternative medicine.

Advances in complementary and alternative medicine bring new challenges and opportunities for policy makers. It opens new doors and creates new options for patients. Your dedication and commitment will help ensure that Americans can walk through those doors armed with sound information and can make the most of these new opportunities as they seek a higher quality of life.

I send best wishes to the members of the Commission as you take up this new charge and I look forward to working with you.

Sincerely,

Barbara A. Mikulski
United States Senator

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TAB C

Secretary Shalala's Agenda - July 13, 2000

Swearing-In Ceremony - The Vice President's Ceremonial Room, Old Executive Office Building, Room 238
The White House Commission on Complementary and Alternative Medicine Policy

Part I

11:00 a.m. - 11:15 a.m. Reception and Meeting with Commission Members

Before the meeting, you will informally meet the Commission members. Stephen Groft, Executive Director of the Commission, will introduce them to you. Dr. James Gordon will chair the Commission. Five other Commission members will not be sworn in today. Chris Jennings from the White House Office of -------- and Sue Greenberg Deputy Associate Director of Presidential Personnel

Part II

11:15 a.m. - 11: 25 a.m. Opening Remarks

- Commission Members, Congratulations. It's a great honor for me to be here today. I thank you for meeting the need to improve the health and well-being for all and the work you do every day, making life better for all Americans.

- Before I talk about the journey in front of us, I want to take a moment to look back at the series of events that led to today's activities. The Complementary and Alternative Medicine initiative was established at NIH in 1991 to investigate, evaluate, and validate CAM interventions and provide health care providers and the consumers reliable

information to make informed decisions about appropriate use. We all know that many of these interventions have been available to native populations for hundreds of years.

- Utilization of CAM interventions continues to increase here in the United States. In 1998 an estimated 42 per cent of the population of the United States utilized these services. Nearly $27 billion were expended with approximately $12 billion in non-reimbursable expenses in the search to improve health and wellness. This expanded use and the need for more research and training opportunities and better evaluations led to the establishment of the National Center for Complementary and Alternative Medicine at the NIH. We are extremely pleased with the development of this Center and their activities, under the direction provided by Dr. Stephen Straus.

- As the utilization of CAM interventions continues to increase, the need becomes more essential for administrative policies and legislative initiatives to address the integration of CAM services into the medical care system, provide for adequate reimbursement for CAM services, appropriate licensing, training and education of all providers of CAM interventions, and methods to provide readily accessible and easy to read information describing the benefits and shortcomings of these interventions to health care providers and the general public.

- The task of the Commission is to provide recommendations to me that can be transmitted to the President for appropriate administrative and legislative initiatives to improve the health care and wellness of all segments of the United States population.

- By signing the Executive Order this year, the President lifted the issues related to Complementary and Alternative Medicine to the highest levels of government. As the head of the Department responsible for these activities, I intend to keep them there. The needs of all citizens must be a core mission of every Federal department and agency. I don't consider this simply an administrative obligation. This is a moral obligation to the public - and good government being responsive to the

needs of its citizenry.

- Today is a great moment in history. We have an opportunity through the partnership provide by the Commission structure to fulfill the purpose and spirt of the Executive Order.

- I want to recognize and give an opportunity for two other individuals who were instrumental in facilitating the Executive Order and the appointment of the Commission members to speak to you.

11:25 a.m. - 11:30 a.m.	Remarks	Chris Jennings
11:30 a.m. - 11:35 a.m.	Remarks	Senator Tom Harkin

Part III

11:35 a.m. -11:45 a.m. Swearing-In of Commissioners

Steven Ottenstein will assist the Secretary with the swearing-in.

At the conclusion of the ceremony, the Commissioners will want to have individual pictures taken with you. At noon, the Commissioners will travel to the Humphrey Building for lunch and preparation for the afternoon session of their first meeting scheduled to begin at 2:00 p.m.

Thoughts on the Commission for Complementary and Alternative Medicine Policy

Wayne B. Jonas

Since I am unable to be at most of the first meeting of the Commission I have provided the following thoughts for the group to consider.

To achieve its goal of formulating effective policy recommendations for the integration of complementary and alternative medicine (CAM) into the health care systems the Commission will need address several issues.

1. Public training and input: CAM is a public phenomenon and so input and understanding of public motivations for CAM use are essential. In addition, methods of training public members and incorporating public concerns into ongoing decisions about information dissemination, education and training, coordination of research, and access to CAM are needed.

2. Definitions: A definition and description of CAM should be formulated. The current definition of CAM as those practices that are excluded from conventional medicine is inadequate. The definition should clarify the contributions CAM offers our health care system and the criteria that are important for prioritizing development of particular practices and approaches to integration. An emphasis on health promotion and health support (that create wellness) as a primary orientation to treatment of chronic disease are key. In addition providing a holistic approach to medical care that values subjective and low-impact approaches should be a focus.

3. Information: Providing reliable and useful information about CAM requires identifying the primary uses for which different types of information are produced. Different audiences value different types of information and use it in different ways. Clarification of the primary types of information needed and how to development and provide the public with these types of information should be addressed.

4. Research strategies: Once the types of information desired are clarified a coordinated research strategy can be developed to obtain that information. Thus Commission task (b), coordinated research, follows Commission task (c), identification of information needs. Not only is a clear process for prioritizing the many possibilities in CAM research needed, also mechanisms to assure public input (as recommended by a recent IOM report) into this process must be established. Ways to support basic science research (into areas of public interest in CAM) and to stimulate private investment into knowledge and technology transfer of CAM discoveries are

especially important.

5. Education and training includes: 1) the minimum knowledge, skills and attitudes needed by conventional health care professionals for the proper management of CAM areas, 2) standards for assuring quality expertise and professionalism of CAM specialists. In addition, issues such as 3) training in evidence and ethics-based skills, 4) culturally-sensitive health care delivery, 5) patient education and 6) adequate self-care are integral parts of all health care provider education and training. The Commission may also want to comment on public training (in schools and pubic health efforts) concerning these issues.

6. Access and payment: Decisions about access and payment for CAM products and services involves a combination of values and evidence. Methods of assuring the quality of products (supplements, drugs and devices) and practitioners (trained, licensed or certified and peer-monitored) are needed and should be standard across disciplines. The evidence and values criteria for deciding on reimbursement must be consistently applied. Methods for managing personal bias and judgement flaws should be part of this process. Access for special populations (women, children, minorities, the elderly, the poor, veterans and the military, etc.) must be considered and special efforts taken to assure these populations have access to effective CAM therapies and are protected from dangerous ones.

The Commission's report should build in recommendations to help government agencies effectively implement its recommendations. We don't want the report to just gather dust as can easily happen on recommendations to the government. Some options may include:

1. Develop a special Office for the Integration of CAM that would work with all federal agencies to coordinate implementation of the Commission's recommendations and keep track of new developments.
2. Develop full time liaisons with strategic agencies and congressional offices to help coordinate the commission's recommendations into a coherent health care policy.
3. I think that six special sub-committee's (or more) made up of Commission members and outside consultants and experts should be created to write the core background documents and draft recommendations. Theses subcommittees should each address one of the topics above and perhaps others.
4. States were considerable efforts at CAM integration are already underway (such as Maryland, Washington, California and Minnesota, etc.) should be consulted for their experience and input. See the summary of activities in Washington State as an example.

White House Commission on Complementary and Alternative Medicine Policy
Outreach to Health Care Groups

✓Association of American Medical Colleges
Dave Moore
202 828 0400

Association of Schools of Allied Health Professionals
202 293 4848

American Cancer Society
Dan Smith
202 661 5700

✓ National Breast Cancer Coalition
Jennifer Katz, Government Relations Manager
202 296 7477

American Academy of Pediatrics
Graham Newson, Director Department of Federal Affairs
202 347 8600

Health Insurance Association of America
Marianne Miller, Director Federal Regulatory Affairs and Policy Development
202 824 1600

Association of American Health Plans
Julie Goon, Director
202 778-3200

Washington Business Group on Health
Sally Coberly, Director Public Policy
202 408 9320

PhRMA
Barry H. Caldwell, Vice president for Federal Affairs
202 835 3400

American Medical Association
Richard Deem, Government Affairs
202 789 7400

American Nurses Association
Marjorie Vanderbilt, Director of Government Affairs
202 651 7000

Center for Science and the Public Interest
Gail Shearer, Health Care Government Relations Manager
202 332 9110

Consumers Union
Adrienne Hahn, Legislative Counsel
202 462-6262

Public Citizen
Frank Clemente, Congress Watch Director
(202) 588-1000

American Public Health Association
Sarah Lister, Director of Government Relations
202 682 0100

AMERICAN ACADEMY OF PEDIATRICS

Committee on Children With Disabilities

Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness or Disability

ABSTRACT. **The use of complementary and alternative medicine (CAM) to treat chronic illness or disability is increasing in the United States. This is especially evident among children with autism and related disorders. It may be challenging to the practicing pediatrician to distinguish among accepted biomedical treatments, unproven therapies, and alternative therapies. Moreover, there are no published guidelines regarding the use of CAM in the care of children with chronic illness or disability. To best serve the interests of children, it is important to maintain a scientific perspective, to provide balanced advice about therapeutic options, to guard against bias, and to establish and maintain a trusting relationship with families. This statement provides information and guidance for pediatricians when counseling families about CAM.**

ABBREVIATION. CAM, complementary and alternative medicine.

STATEMENT OF THE PROBLEM

The use of complementary and alternative medicine (CAM) is increasing in Western countries. Indeed, more than one third of the adults in the United States have used CAM in recent years.[1,2] Pediatric use of CAM is especially likely among children with chronic illness or disability. Up to 50% of children with autism in the United States probably are using some form of CAM.[3] In many instances, the physician providing medical care is unaware of the concurrent use of CAM. Increasingly, pediatricians providing care for children with chronic illness or disability are discussing CAM with families or are asked to prescribe such treatments. Pediatricians' expertise in biomedicine may not adequately prepare them for discussion of CAM.

BACKGROUND INFORMATION AND DEFINITIONAL ISSUES

CAM has been defined as "a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historic period."[4] An enormous array of unconventional therapies may be used as alternative therapies (instead of conventional treatments) or as complementary therapies (in addition to conventional treatments) (see Fig 1).

Currently, courses on CAM approaches are offered in the majority of US medical schools.[5] The US government established the Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine) in the National Institutes of Health to carry out scientific study of CAM.[6]

Biomedicine is based on laws of science and the rigorous applications of the scientific method. It may aptly be called scientific medicine or evidence-based medicine. Disease is explained by pathophysiologic processes, and treatments are designed to affect these processes. The term *biopsychosocial medicine* has long been used to describe a biomedical model that recognizes the importance of psychosocial factors.[7] Biomedical treatments are based on accumulated evidence of effectiveness from peer-reviewed scientific research. There is a hierarchy of research evidence, at the top of which is the controlled clinical trial. Many accepted biomedical treatments lack evidence of effectiveness from controlled clinical trials (eg, the use of physical therapy in the care of the premature infant). Unproven therapies also may be based on pathophysiology and limited research, but they lack accepted standards of proven effectiveness (eg, the use of immunoglobulins in the treatment of autism).[8] Alternative therapies are based on a variety of nonbiomedical beliefs and usually have not been subjected to clinical research. Most are supported by anecdotal evidence, but some alternative therapies have proven effectiveness. For example, preliminary studies of acupuncture in addiction treatment show positive results.[9] In time, such proven therapies may come into wider use and lose their "alternative" status.

Biopsychosocial medicine and CAM have at least one thing in common: both recognize that the relationship between physician-healer and patient is integral to the success of treatments offered. This is part of the age-old "art" of medicine and is a basis of the placebo response.[10] The emphasis of biomedicine on pathophysiology and on technical outcomes has reinforced the perception among some families that physicians undervalue their relationships with their patients. The failure of biomedicine to recognize and respond adequately to individual differences among patients is one reason families turn elsewhere and has contributed to the increasing use of CAM.

The distinctions among unproven therapies, CAM, and biomedicine may become especially blurred in the care of children with chronic illness or disability.

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

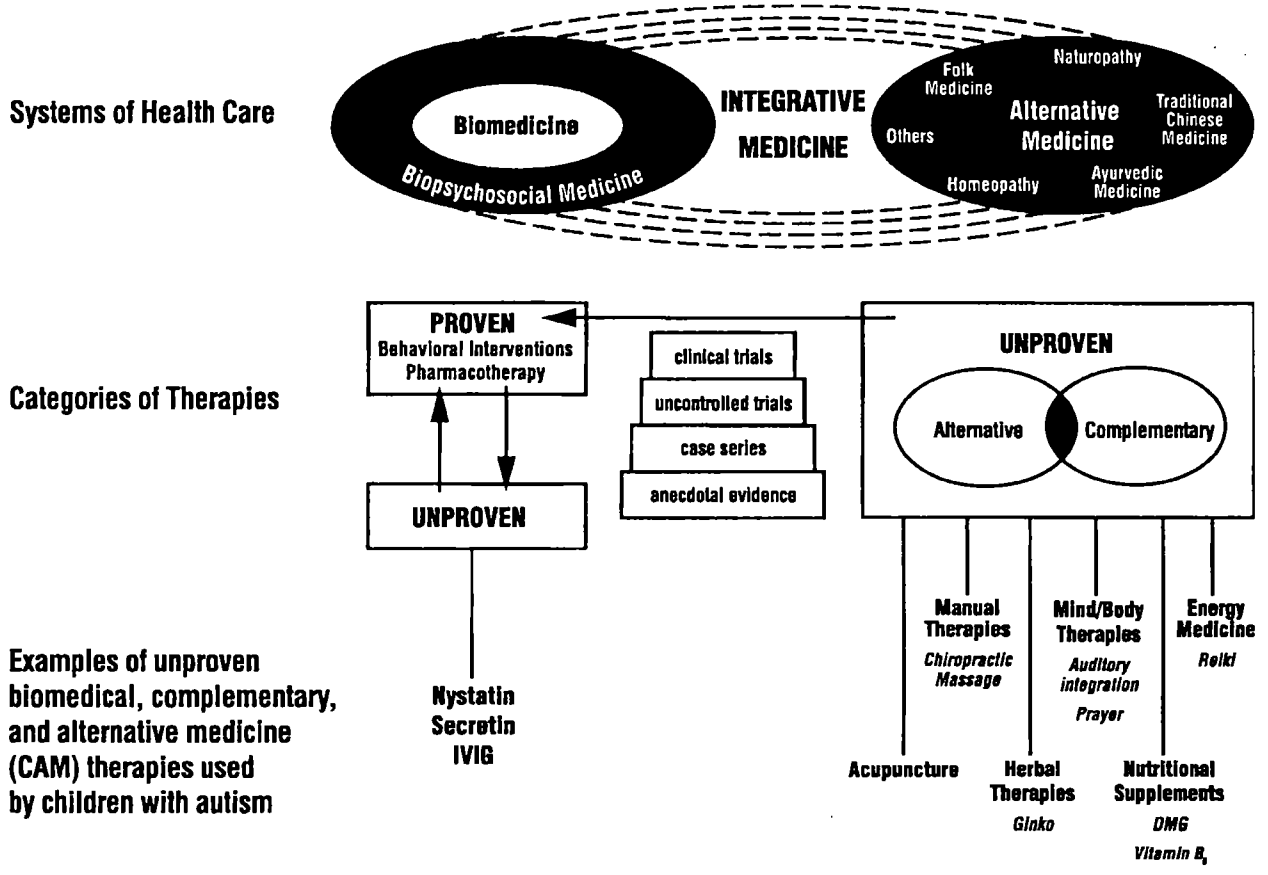

Fig 1. Biopsychosocial medicine and alternative medicine are broad systems of health care that encompass theories, practices, and therapies. Integrative medicine is a term loosely used to describe these systems used in combination. Therapies (whether biomedical, complementary, or alternative) are considered proven or unproven based on a hierarchy of evidence.

Some conventional biomedical therapies lack proof of effectiveness, and some unproven and alternative therapies may in time prove effective. Also, some alternative therapies conceivably may have placebo effects, which confer additional therapeutic gain and enhanced quality of life. These factors may present significant challenges to the health care professional. Moreover, there are no published clinical guidelines regarding the use of CAM in the care of children with chronic illness or disability.[11]

WHY PARENTS OF CHILDREN WITH CHRONIC ILLNESS OR DISABILITY CHOOSE CAM

Parental questioning of a child's diagnosis, treatment, and prognosis reflects a normal process of adjustment to the permanence or chronicity of the condition and the desire to ensure the best possible outcome for their child. Many parents become frustrated with biomedical therapies because of complexity, discomfort, bewildering technology, or uncertainty of cure. Indeed, for some conditions, biomedicine has little or nothing to offer. Also, families may be frustrated because they have not been sufficiently involved in the development of a care plan. The media, condition-specific publications, and parent-to-parent contacts provide essential opportunities for families to learn about resources, including CAM. Furthermore, the Internet has dramatically increased exposure of families to sophisticated marketing, testimonials, and unproven claims. Some parents are attracted to simple explanations of causality, some by an approach perceived to be more "natural." Many try a succession of alternative therapies, believing that any approach that does no harm is worth a trial. For almost all, CAM approaches represent an attempt to gain a sense of control over their child's chronic illness or disability and to improve quality of life.

BALANCING FAMILY-CENTERED CARE WITH THE ETHICAL RESPONSIBILITY OF THE PEDIATRICIAN

The "medical home" concept emphasizes that care should be compassionate and family-centered. Mutual participation in decision making and informed consent are essential elements of respectful care.[12] Decisions and plans should be made through a process of collaborative decision making in which the family receives complete and unbiased information needed to understand and make informed decisions. The quality of the relationship between the health care professional and patient with chronic illness has been shown clearly to affect outcomes.[13] Honest and supportive relationships with health care professionals can help parents cope[14] and promote the child's independence.[15] Such relationships are strengthened when health care professionals understand the perspectives of the family, provide care with flexibility, and attempt to meet the family's needs and expecta-

tions. Clearly, it is optimal for children with chronic illness or disability to receive health care in a setting that is family-centered. At the same time, pediatricians have an ethical responsibility to guard the welfare of children by ensuring that any treatment they endorse is "in accordance with science and proven experience."[16,17] Dilemmas may arise when families ask their pediatrician to endorse or to provide a therapy that is considered by the pediatrician not to be in the best interests of the child. There may be evidence of the possibility of direct harm, unknown risks, or concerns about indirect harm to the child. The pediatrician is in a position to balance a commitment to family-centered care with the ethical responsibility to guard the welfare of children.[18,19]

SUMMARY/CONCLUSION

The use of CAM approaches in the United States is increasing, especially among children with chronic illness or disability. Distinctions among unproven therapies, CAM, and biomedicine may become blurred, presenting special challenges to the pediatrician. To best serve the interests of children, it is important to provide balanced advice about therapeutic options, to guard against bias, and to establish and maintain a trusting relationship with families. Although the focus of this statement is chronic illness or disability, the recommendations that follow also may apply to the use of alternative medicine in other pediatric domains.

RECOMMENDATIONS FOR PEDIATRICIANS WHO DISCUSS ALTERNATIVE, COMPLEMENTARY, AND UNPROVEN THERAPIES WITH FAMILIES

1. Seek information for yourself and be prepared to share it with families.

   Families are likely to be appreciative of information you have obtained through literature searches. Reviews of CAM discuss currently popular alternative approaches and their attendant risks.[3,20-22] Also, Appendix I shows several Web sites that may be useful resources.
2. Evaluate the scientific merits of specific therapeutic approaches.

   Critical evaluation of claims of effectiveness requires training in the scientific method and an understanding of processes of disease. This training is equally important for evaluating conventional biomedical treatments and alternative therapies. Many CAM approaches are based on inconsistent or implausible biomedical explanations, and claims of effectiveness rest on anecdotal information and testimonials. The pediatrician can be uniquely helpful to parents seeking an assessment of the merits of specific therapies by evaluating such therapies and providing guidance.
3. Identify risks or potential harmful effects.

   Alternative therapies may be directly harmful by causing direct toxic effects, compromising adequate nutrition, interrupting beneficial medications or therapies, or postponing biomedical therapies of proven effectiveness. Indirect harm may be caused by the financial burden of the alternative therapy, other unanticipated costs (eg, the time investment required to administer the therapy), and feelings of guilt associated with inability to adhere to rigorous treatment demands. If a child receiving alternative therapy is at direct or indirect risk of harm, the pediatrician should advise against the therapy. In some circumstances, it may be necessary for the pediatrician to seek an ethics consultation or to refer to child welfare agencies. If there is no risk of direct or indirect harm, a pediatrician should be neutral.
4. Provide families with information on a range of treatment options (avoid therapeutic nihilism).

   Although effective treatments to cure the underlying condition or restore function may be lacking, there may be adjunctive treatments to improve quality of life, address specific concerns of the child or family, or modify environmental conditions that may be causing additional problems. Consultation with pediatric specialists may suggest therapeutic options. Discussion of a range of treatment options may avert feelings of frustration and powerlessness that drive families to alternative sources of care.
5. Educate families to evaluate information about all treatment approaches.

   Families should be informed about placebo effects and the need for controlled studies. The pediatrician should explain that anecdotal and testimonial evidence is very weak. Families also should be advised to be vigilant for exaggerated claims of cure, especially if such claims are for treatments requiring intense commitment of time, energy, and money on the part of the family.
6. Avoid dismissal of CAM in ways that communicate a lack of sensitivity or concern for the family's perspective.

   Some alternative therapies considered by families may warrant independent review and evaluation of scientific merit by the pediatrician. Respectful family-centered care rests on the pediatrician's willingness to listen carefully and to acknowledge the family's concerns, priorities, and fears, including social and cultural factors that may affect their choice of therapies. If CAM is chosen against the advice of the pediatrician, he or she should continue to offer care to the child.
7. Recognize feeling threatened and guard against becoming defensive.

   Families may express their opinions in ways that challenge the professional expertise of the pediatrician. They may bring to the discussion of CAM a number of biased assumptions that contribute to an atmosphere of distrust and an adversarial relationship. It may be helpful for the pediatrician to make empathic statements that acknowledge the families' deep concerns, thereby avoiding angry or defensive reactions.
8. If the CAM approach is endorsed, offer to assist in monitoring and evaluating the response.

   The pediatrician can help to establish clinical outcomes and target behaviors or symptoms that can be observed and measured. Sometimes, the

pediatrician and family can agree on a time-limited trial of the proposed approach.

9. Actively listen to the family and the child with chronic illness.

The pediatrician should be aware of their concerns, their understanding of the condition, and their needs for support. Support groups and community networks can greatly enhance family comfort with the management of the chronic illness or disability.

APPENDIX I

Helpful Resources on the Internet

1. University of Texas Center for Alternative Medicine Research, http://www.sph.uth.tmc.edu/utcam/default.htm
2. The National Institutes of Health Office of Alternative Medicine, http://altmed.od.nih.gov/
3. The National Council for Reliable Health Information, http://www.ncahf.org
4. The Consumer Federation of America, http://www.quackwatch.com

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Recommendation

Groft, Stephen (NCCAM)

To: Colleen Nee
Subject: RE: Monday's meeting, 3/26/01

Colleen,

Please thank Jacki for the comments. She makes some valid points. We try not to restrict the Commission members in their questions to panelists. At times, some do appear repetitive despite efforts to bring all Commission members to the same level of understanding before the meeting. We, as the staff to the Commission, try to clarify issues after we hear of the concerns expressed at the meeting rather than spending time at the meeting itself. It doesn't always work as well as we would like. I wil visit the website to review the information . Corinne's assessment was correct and I particularly appreciate Jacki's comments on a proposed recomendation. I traditionally like to keep the Government away from activities that the private sector could or should be doing. However, I have found it useful for the Government staff to act as a coordinator or broker to get many parties together to foster advancements or to provide seed money for workshops, symposia, or planning meetings.

Jim Gordon's e-mail is jsgordon@mindspring.com and phone number is 202-537-6837.

Again, thank you for the comments and I welcome more. Best wishes,

Steve Groft

-----Original Message-----
From: Colleen Nee [mailto:colleen.nee@onemedicine.com]
Sent: Thursday, March 29, 2001 9:07 AM
To: Groft, Stephen (NCCAM)
Subject: Fw: Monday's meeting, 3/26/01

As Jacki Hart mentioned in her email to you yesterday, she would like you and Dr. Gordon to have access to our online database. Would you be able to provide me with an email address for Dr. Gordon so I can create his account? I have created an online account so you can view this information. Please follow the steps below to logon to our site.

-Go to http://www.onemedicine.com/logon.asp

-Log on by entering your email address, GroftS@mail.nih.gov and your password, groftsl

You will be able to review all of the material found on our Members Menu, as well as our online product demonstrations found on our Licensing page.

If you have any problems accessing the site, please let me know.

Thank you,
Colleen Nee
Integrative Medicine
1029 Chestnut Street
Newton, MA 02464
877-426-6633
----- Original Message -----
From: "Jacki Hart" <jacki.hart@onemedicine.com>
To: "Colleen Nee" <colleen.nee@onemedicine.com>
Cc: "Julia Goldrosen" <julia.goldrosen@onemedicine.com>; "Tamara Swain" <tamara.swain@onemedicine.com>
Sent: Wednesday, March 28, 2001 7:05 PM
Subject: FW: Monday's meeting, 3/26/01

> > -----Original Message-----
> > From: Jacki Hart
> > Sent: Wednesday, March 28, 2001 7:01 PM
> > To: 'GroftS@mail.nih.gov'; 'WHCCAMP@mail.nih.gov'
> > Subject: Monday's meeting, 3/26/01
> >
> > James S. Gordon, M.D.
> > Director
> > The Center for Mind-Body Medicine
> > 2934 Macomb Street, N.W.
> > Washington, D.C. 20008
> >
> > Dear Dr. Gordon,
> >
> >
> > As both a physician and a medical editor, I am writing to
> > express a few of my impressions and ideas stemming from the WHCCAM
> > conference on information dissemination which took place on Monday
> > 3/26/01.
> >
> > First, it was a pleasure to see a well organized operation with
> > the conference running very close to on time throughout the day - no
> > easy feat with such significant ground to cover. Secondly, I was quite
> > impressed with your style, Dr. Gordon, in presiding over the
> > Commission. You were clear, direct, and insightful; in addition, you
> > were able to keep both panelists and committee members focused and on
> > track during the discussion, redirecting them appropriately and doing
> > so in a kind manner. Not being involved in the political arena, it
> > was fascinating for me to watch government in action. Both you and Mr.
> > Groft clearly had a hand in the agenda, punctuality, and choices for
> > the panelists.
> >
> > However, I did have a few concerns. One was that there seemed to
> > be a lack of awareness on the part of several committee members
> > regarding existing mechanisms to help evaluate information and
> > facilitate its dissemination. My hope is that the level of some of the
> > questions may not reflect a lack of knowledge but, rather, a desire to
> > hear how the panelists responded. There were several questions that
> > prompted me to express this concern. The first example arose in the
> > morning regarding how to search for and uncover data about herb-drug
> > interactions and adverse events from herbs and supplements. I found it
> > quite surprising that this particular committee member did not seem to
> > realize that there is (a) a mechanism through the FDA for making such
> > data public via press releases and warnings posted on their website,
> > (b) several well researched, well written, and well presented
> > commercial sources of such data, and (c) that a simple search in
> > MEDLINE and/or EMBASE would uncover this data directly. Similarly, in
> > the afternoon, there was a series of questions regarding the FDA and
> > the FTC and when a supplement becomes a drug. I do realize that the
> > jurisdiction of the two separate agencies often becomes muddled and
> > that it is confusing to keep the bureaucracy straight; however, I felt
> > that some of the questions were basic and repetitive. It was as if the
> > answers would change if they continued to be asked, simply because the
> > particular committee member inquiring did not like the response.
> >
> > I was also concerned that several of the suggestions made in the
> > subcommittee group on Internet and the Media seemed neither logical
> > nor feasible. The suggestion to have a site that hosts "pros and cons"
> > of all CAM related information, for example, is a huge, extremely
> > unrealistic (not to mention unbelievably expensive) undertaking that
> > will not contribute to lessening consumer confusion but, rather, will
> > increase this perplexity. From my perspective, what seemed to be
> > stated by several different panelists throughout the day is a need for
> > consumers to have some help in determining reliable, dependable
> > sources of health related information, particularly in the area of CAM
> > and integration, not to recreate information that already exists in

> > other sources. I thoroughly agree with this need.
> >
> > Within the industry, there has actually been an attempt to try to set
> > standards for health information on the web. One non-profit
> > organization is called Hi-Ethics, Inc; there may be others. Health
> > information sites that market directly to consumers can voluntarily
> > join Hi-Ethics, Inc. by paying a membership fee (albeit sizeable at
> > $20,000 annually) and meeting a set of criteria defined by the
> > organization. I work for a company called Integrative Medicine
> > Communications. (Dr. Gordon, you are scheduled to be our keynote
> > speaker at an upcoming meeting.) We license both professional and
> > consumer databases to internet companies, hospitals, health centers,
> > HMOs, etc. Our clients, in turn, provide information directly to
> > individuals either through the internet, other electronic media, or
> > print. We are proud to say that several of our web based clients are
> > members of Hi-Ethics including allHealth.com/iVillage, AmericasDoctor,
> > Discoveryhealth.com, HealthGate, and InteliHealth. This means that
> > they, and therefore we, must meet the current industry standards.
> >
> > I believe that a potentially valuable recommendation by the WHCCAM
> > might be to set up a short-term subcommittee to evaluate the existing
> > criteria initiated by the industry (e.g. Hi-Ethics, Inc.), determine
> > if these criteria are adequate for consumer protection, and set
> > government standards including evaluation of sites to see if they meet
> > these standards. This could be achieved through either a government
> > fund or a nominal fee to the companies so that a greater number of
> > health information websites would be able to participate in the
> > evaluation process compared to the limitation of Hi-Ethics due to
> > their steep price. Then, a website, via either NCCAM or a separate
> > organization, could have a section describing those standards with
> > links to companies that meet the criteria.
> >
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> > integrative perspective, CAM modalities, supplements, herbs, herb-drug
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> >
> > Sincerely,
> > Jacki Hart, MD
> >
> > Jacqueline A. Hart, MD
> > Senior Medical Editor
> > Integrative Medicine Communications
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> > Newton, Ma. 02464
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> >
> >
> > CC: Stephen C. Groft, Pharm D
> >
> >
> >

Current Outline of the

SHEN Therapy Internship and Certification Program

March 1, 2000

North American Version

Certification in SHEN

The Certification Program serves two equally important and interrelated goals. The first is to teach you to become truly proficient in SHEN techniques and procedures so that you can provide high quality SHEN to others who may wish your services. The second is to deepen and intensify your own internal growth process that you began in your first SHEN workshop -- not only for you but for your clients, because we firmly believe that you can take those you work with no further than you have gone yourself.

THE SHEN CERTIFICATION PROGRAM

Overview

The Internship Program and Certification of Practitioners are regulated by and conducted under the auspices of The International SHEN Therapy Association. ISTA sets and maintains standards of competency in SHEN, standards of ethics, and basic standards of practice throughout the world. ISTA is the sole certifying authority. However you may give SHEN to friends/family on a no fee basis. Candidates for the program must have completed the Personal Empowerment Workshop twice before submitting their application.

The comprehensive Internship Program includes: a Clinical Skills Development Seminar (formerly called Sections C and D), a three-day Personal SHEN Intensive which the Intern receives from his or her Mentor, assisting at Sections A and B, and the successful completion of a minimum of 200 supervised SHEN client sessions.

Your personal journey during your Internship will take you on an internal exploration well beyond what you have already experienced during your previous SHEN Workshops.

The Program is not easy, but neither is it impossible. You will have a Mentor who will be your guide throughout your Internship. Your Mentor wants you to successfully complete the course and will be there to help you over any obstacles that occur. The majority of those who begin complete the Program within 18 to 24 months.

To Enroll as an Intern

1. You must have successfully completed and re-taken both sections of the SHEN Personal Empowerment Workshop. You may retake the workshop from any Instructor.

2. You must complete an application to enter the Internship Program, which includes a personal, and employment history and identifies your emotional growth issues you intend to work on through SHEN,

3. You must be able to receive SHEN well,

4. You must have participated appropriately when you took the SHEN Workshops,

5. You must have no drug or alcohol addictions,

6. You must have no major irresolvable emotional conditions which might affect your ability to maintain a reasonable neutral emotional stance when giving SHEN to your clients, or that might otherwise affect your professional practice,

7. You must join and maintain membership in ISTA. Membership in ISTA is required to maintain your Certification.

The Acceptance Process

The ISTA Intern Selection Review Committee for your region will review your application and decide whether you can be admitted.

You may request a specific Mentor, but assignment cannot be guaranteed as many are over-loaded. Available Mentors will discuss the possibility of working with you, and together, you will make a choice. Enrollment is limited by the availability of Mentors.

Applicants who are admissible when no Mentor is available will be placed on a prioritized waiting list.

If you are not accepted, you will be advised why you were not accepted and what you will need to do to re-apply at a later date.

Provisional Acceptance

If you have clear and specific issues that are not sufficient to prohibit entrance into the Program, but will need to be overcome before Certification, the ISTA Selection Review Committee will recommend that acceptance be provisional. Your letter of admittance will state the conditions of provisional admittance.

When you complete the Program, your Mentor will need to verify that the identified issues have been successfully resolved before Certification can be granted.

Deferred Acceptance

If you have been away from SHEN for an extended period you will need to repeat the Personal Empowerment Workshop before your application will be considered.

Candidates in question because of doubt as to their eventual success may be asked to retake the Personal Empowerment Workshop with a different Instructor or receive additional SHEN before being reconsidered.

The Selection Review Committee will then consult to see whether the questions that prevented whole-hearted recommendation have been resolved. If they do not feel confident that the applicant is ready, the applicant's request will not be forwarded.

Re-application

Applicants who are not admissible at the time the application is made are encouraged to re-apply when the reasons for rejection have been rectified.

After Certification

You will be required to take a Continuing Education course or review C &r D every two years to maintain your certification.

THE COURSE CURRICULUM

Upon Acceptance

Upon acceptance you will be sent a complete set of masters for the client and record-keeping forms along with basic instructions in how to begin your Internship. Other materials to help you begin your internship will be included.

Classroom Training in SHEN skills

The SHEN Clinical Skills Development Seminar comprises lectures, group practice, and a series of monitored individual SHEN sessions that will be planned during class practice assessments. Some of the subjects covered are listed below.

The Seminar lasts nine days and consists of two, four-day sections (formerly called C & D) with a day in between. Interns joining the program after January 2000 are required to take the full seminar at one time, within the first six months of their Internship. (Interns who enrolled prior to January 2000 may, if necessary, take the two sections separately but it is much to your benefit that you take them consecutively. If you do not, you must take Section C within the first six months of internship and Section D within the first year.)

Professional & clinical skills covered in the Seminar

Starting and advancing the Intern's SHEN Practice, Record Keeping:

Supervision, Client Session, Assessment, Consent, and other Forms,

Personal Journal keeping,

Observing body motion and postural clues,

Development of good session plans,

Initial and Pre-Session SHEN Interview techniques,

Techniques for drawing out clients,

Broaching delicate subjects,

Proper use of the Registered Service Mark, SHEN® and the logos incorporating the Service Mark,

Criteria when writing articles, and when making public statements,

Establishing and maintaining appropriate Intern/Client boundaries,

Differences between SHEN and psychotherapy approaches.

Handling the Intern's responses to the client: judging, rescuing, wanting to be liked, and/or feeling attracted,

Handling the client's responses to the Intern: criticism, anger, guardedness, undue praise, and/or controlling, wanting to be rescued, and/or feeling attracted,

Interfacing with other health professionals,

Table coaching: facilitating client experience during the session,

Following the client's changes on the table,

Work in the outer portion of the biofield,

Functional vs. Organic Conditions,

What can and cannot be expected of SHEN,

Chronic Pain Evaluations,

The Intern's and the Client's Expectations,

Presenting SHEN to Health Care Institutions.

Assisting at a Personal Workshop

After completing the Clinical Skills Development Seminar and when your Mentor thinks you are ready you are required to assist with at least one Personal Growth Workshop (both A & B), During the Workshop you will monitor table work for a section of the class, joining the sessions as required and answering students' questions that arise at the table or later during discussion. The Instructor will correct and/or amplify these answers as required. The Instructor will advise your Mentor of your level of knowledge of SHEN and your expertise when assisting the students with their sessions.

Mentor Supervised Activities

The main activities fall into two broad categories: clinical sessions performed by the Intern under either direct or telephone supervision of the Mentor, and an extensive, focused three-day therapeutic SHEN Intensive given to you by your Mentor or by another Instructor if your Mentor so designates. You may undertake these elements in any order that you and your Mentor agree upon

Supervision: You are required to initiate and complete at least one supervision consultation with your Mentor each month during the Internship. This may be in person or by telephone. You are expected to learn to recognize when you feel unsure about your work, and to seek supervision, over and above the minimum. The individual Mentors determine their mentoring fees

Clients: You will need to provide your own paying and/or non-paying clients. Most sessions will be organized, planned and performed in your own workspace without your Mentor being present. But this does not preclude sessions performed at a hospital or at a health clinic being counted towards the required sessions.

Client Fees: You are not allowed to charge your clients a fee before completing the Clinical Skills Seminar. After completing the Seminar and when your Mentor approves, you may charge one-third of the usual CSP rates in the area. As you progress, your Mentor's may allow you to increase this to a maximum of two-thirds of the area CSP rates. (Recipients such as family members, close friends or persons who are hospitalized are usually not charged.)

Disclosure: You must advise each person you give SHEN to during your Internship of your status as a Supervised Intern, and that some of their client sessions and interviews will be discussed with your Mentor and may be reviewed by the Certification Committee.

Your clients are required to sign a Consent Form that includes:

1. A Statement of your fees,
2. The Client's Acceptance of Limited Confidentiality,
3. The Mentor's name and telephone number, and
4. ISTA's address and instructions for complaints.

If your client declines to sign this form, you may not give this person SHEN during your Internship. (This does not apply to family members or close friends, but their sessions cannot be used to fulfill the Internship requirements.)

Cautionary Procedures

1. You are required to notify your Mentor, with all possible haste, of client sessions aborted for any reason, or when the client has been left in physical pain or in a debilitated emotional state.

2. You are required to consult with your Mentor before accepting clients from the Precautionary List that you will be given.

Required Records

You will submit a brief record of all SHEN sessions given, whether included in those submitted as part of the requirements, whether successful or unsuccessful, whether completed or uncompleted to your Mentor at the end of each month.

Criteria for the Required Clinical Sessions

You must perform, and keep comprehensible records for a minimum of 200 SHEN sessions according to the following.

You may include up to 50 supervised client sessions given before you take Section C of the Professional Skills Intensive.

The 200 sessions are to include:

1. At least three successful therapeutic series, of a minimum of ten sessions each, for different clients who receive SHEN for emotional unfolding, growth and empowerment.

The first is to be a series spaced over a few days and is to be completed during the first six months.
The second, also a spaced out series, should be completed midway through the internship.
The third is to be a two and one half or three-day Intensive and is to be given only after taking Sections C & D, having logged a minimum of 100 supervised sessions, and with the Mentor's permission.

2. At least three sessions given to your Mentor.

The ISTA Certification Committee or your Mentor may assign additional clinical sessions when it is deemed necessary.

3. You must have demonstrated your ability to successfully complete a pivotal client session - during which the recipient experiences previously blocked anger, fear, grief or shame and leaves it to enter the emotion that underlies the surface emotion - without becoming unnerved and/or withdrawing. This is to be observed by the Mentor or another Instructor and may occur during a private session, a Personal Empowerment Workshop or a Clinical Skills Development Seminar.

Restrictions

While you are an Intern you may not combine any other health, psychotherapeutic or counseling modality you may otherwise be using in your general practice into any SHEN session, or between the sessions of any series, that you submit as part of your Internship requirements.

This does not restrict you from performing any other health, or counseling modality you may normally practice, with clients receiving SHEN at times other than those specified.

Interns are prohibited from giving anyone a Personal Intensive without consulting with their Mentor prior to starting the series.

You are restricted from giving SHEN to anyone on the precautions list you will be given unless you have your Mentor's permission.

Your Personal Growth Sessions

During Internship you will receive a therapeutic Personal SHEN Intensive from your Mentor. This will be a three-day Intensive of no fewer than three sessions each day. Your Mentor may determine that you need additional sessions to complete any issues that become identified prior to, during or after the series.

Pace of Participation

Your pace through Internship will necessarily be determined by your available time and your Mentor's timetable, scheduling of the two Training Sections, and availability of the necessary clients. Minimum time allowed for completion is 12 months and the maximum is 36 months. Extensions will be granted for Interns who can show good cause. The majority of Interns complete their Internship within 18 to 24 months. You will be expected to maintain reasonably consistent progress during your Internship.

Reporting: You must contact your Mentor at least once a month, if only to report that you have had no activity during the month.

Inactive Status: You may request being placed on the Inactive List for a maximum of 12 months, if your situation requires. You may apply for reinstatement without prejudice when your circumstances have changed. When you are Inactive you continue to receive mailings and must keep your ISTA dues current. NOTE: You may not give SHEN to clients until you resume active status. However you may give SHEN to friends/family on a no fee basis.

Lack of Progress without due cause: Your Mentor will counsel you and if the situation does not improve or if you have no clear plan to resume when progress has entirely halted, your Mentor will notify ISTA and your internship will be suspended. If you do not resume within six months you will be dropped from the program.

All reinstatement requests are subject to review.

Dismissal for cause

Interns are dropped from the program if:

1. There are incidents of gross misconduct.

2. There is consistently poor performance with clients, fellow interns or other students.

3. Overwhelming emotional difficulties arise.

4. Other issues manifest that interfere with the Intern's ability to give and receive SHEN appropriately or to complete the curriculum requirements.

Appeal

Interns who have been suspended, or asked to resign for cause, may appeal to the ISTA Appeals

Committee. The Intern will suspend all Internship activities while the appeal is being considered.

Your Mentor

Your Mentor's primary task is to be your friend and guide. Within the Mentor's role are elements of teacher, parent, guide, cheerleader, confidant, judge, sheriff, record keeper and confessor. All of these will likely come into play to one degree or another with every Intern.

Completion of your Internship

Certification is not automatic. When all your requirements have been completed, you will submit all necessary documentation including a typewritten narrative of your progress during your Internship, of no more than two pages in length, and a self-assessment of your strengths and weaknesses as a practitioner to your Mentor. Your narrative should detail evidence of having gone into and through a significant portion of your own internal fear, grief or shame and come to resolution as a result of your personal SHEN sessions. It should include any changes in behavior and in social and/or professional relationships. Your Mentor will review the material and, when able to recommend you, will forward your materials to the Certification Committee. The Committee will review the materials presented and will either approve or may ask that you or your Mentor clarify elements of the work you present, or may require that you complete additional requirements when it deems necessary. When the Committee is satisfied, you will receive your Certificate.

Expect the Certification process to take a minimum of 60 days. The members of the Committee are all Instructors; many travel for their classes and have other time constraints as well. All of them are just as interested as you are in completing the process as rapidly as possible.

After Certification

After you become a Certified SHEN Practitioner you are allowed to use the Registered SHEN Service Mark on your stationery, business signs, etc. As a CSP, you are allowed to incorporate SHEN into your health practice as you see fit. Your Certificate will remain in force as long as you fulfill ISTA's Continuing Education requirements, are not under suspension by the Ethics and Standards of Practice Committees and maintain your membership in ISTA.

Continuing Education Requirements

You will be required to take a Continuing Education course or review C & D every two years to maintain your certification.

Teaching SHEN

Interns and CSPs are not authorized to teach SHEN.

Certifying Authority

Certification is under the auspices of The International SHEN Therapy Association, 3213 West Wheeler Street, Suite. 202, Seattle. WA 98199, ISTA's Member Services office is at 20 YFH Gate 6 Road, Sausalito, CA, 94965. Phone 415/332-2595, fax 415/331-2455. or email at: KyleSHEN_ISTA@hotmail.com

There are no governmental licensing requirements for SHEN as it is not regulated by any governmental regulatory body.

Clinical Skills Development Seminars are organized for ISTA by the regional authorities on the left. Please contact the appropriate regional authority for schedules.

CANADA

The SHEN Center
644 27th Ave Northwest
Calgary, Alberta T2N 2T1
403/282-7888 Fax 403/210-2875

IRELAND

The SHEN Therapy Training Centre
73 Claremont Park,
Circular Road, Galway
091-525-941 Fax 091-529-807

ITALY

SHEN Italia
Corso Vittorio Emanuele 154
00187 Roma
Tel./Fax. 0039-6-6385843
SHENit@hotmail.com

NORWAY

SHEN Sentret I Norge
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larsen-e@online.no

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Tel/Fax 0131-478-4780
info@shentherapy.abel.co.uk

London
SHEN Therapy Centre
PO Box 115,
Beckenham BR3 4ZF
Tel/Fax 020-8658-6505

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SHEN Therapy Institute
20 YFH Gate 6 Road,
Sausalito, CA 94965
415/332-2593 Fax 415/331-2455
SHENmaker@MSN.com

Groft, Stephen (NCCAM)

From: SHENmaker [SHENmaker@email.msn.com]
Sent: Wednesday, December 13, 2000 9:27 AM
To: Groft, Stephen (NCCAM)
Subject: Certification

Hi Steve,

As we discussed I am attaching the outline of our Certification Program in SHEN. As I mentioned, it will be modified next month and I will replace it with the new version then. This is the Certification Program of the International SHEN Therapy Association and is in effect in the Canada, the United Kingdom, Norway, Sweden, Ireland, Italy, Denmark and Greece, as well as in the United States.

I neglected to mention that the U.S. Department of Labor assigned SHEN Practitioners an Occupational Title and Code Number in August of 1989. This was one of a series of earlier steps on the path towards (hopefully) eventual state licensure as a stand-alone profession. It will be a long time before we have enough numbers for that, that is why recognition of national certification programs are so vital for us, as well as for some of the other CAM disciplines.

Later in that day after I left you I had the privilege of working with a recent rape victim who was unable to work and suffering from intense pain from chest to groin alternating with no feeling there at all. There is more to be done but normal sensation has begun to return and she was able to return to work the next day and is still working. SHEN is really remarkable with posttraumatic stress disorders. We had some most gratifying results in Dunblane Scotland following the shooting of the school children three years ago.

It was good to visit with you, even if only briefly,

Richard

Whccamp (NCCAM)

From: Jacki Hart [jacki.hart@onemedicine.com]
Sent: Wednesday, March 28, 2001 7:01 PM
To: Groft, Stephen (NCCAM); Whccamp (NCCAM)
Subject: Monday's meeting, 3/26/01

James S. Gordon, M.D.
Director
The Center for Mind-Body Medicine
2934 Macomb Street, N.W.
Washington, D.C. 20008

Dear Dr. Gordon,

As both a physician and a medical editor, I am writing to express a few of my impressions and ideas stemming from the WHCCAM conference on information dissemination which took place on Monday 3/26/01.

First, it was a pleasure to see a well organized operation with the conference running very close to on time throughout the day - no easy feat with such significant ground to cover. Secondly, I was quite impressed with your style, Dr. Gordon, in presiding over the Commission. You were clear, direct, and insightful; in addition, you were able to keep both panelists and committee members focused and on track during the discussion, redirecting them appropriately and doing so in a kind manner. Not being involved in the political arena, it was fascinating for me to watch government in action. Both you and Mr. Groft clearly had a hand in the agenda, punctuality, and choices for the panelists.

However, I did have a few concerns. One was that there seemed to be a lack of awareness on the part of several committee members regarding existing mechanisms to help evaluate information and facilitate its dissemination. My hope is that the level of some of the questions may not reflect a lack of knowledge but, rather, a desire to hear how the panelists responded. There were several questions that prompted me to express this concern. The first example arose in the morning regarding how to search for and uncover data about herb-drug interactions and adverse events from herbs and supplements. I found it quite surprising that this particular committee member did not seem to realize that there is (a) a mechanism through the FDA for making such data public via press releases and warnings posted on their website, (b) several well researched, well written, and well presented commercial sources of such data, and (c) that a simple search in MEDLINE and/or EMBASE would uncover this data directly. Similarly, in the afternoon, there was a series of questions regarding the FDA and the FTC and when a supplement becomes a drug. I do realize that the jurisdiction of the two separate agencies often becomes muddled and that it is confusing to keep

the bureaucracy straight; however, I felt that some of the questions were basic and repetitive. It was as if the answers would change if they continued to be asked, simply because the particular committee member inquiring did not like the response.

I was also concerned that several of the suggestions made in the subcommittee group on Internet and the Media seemed neither logical nor feasible. The suggestion to have a site that hosts "pros and cons" of all CAM related information, for example, is a huge, extremely unrealistic (not to mention unbelievably expensive) undertaking that will not contribute to lessening consumer confusion but, rather, will increase this perplexity. From my perspective, what seemed to be stated by several different panelists throughout the day is a need for consumers to have some help in determining reliable, dependable sources of health related information, particularly in the area of CAM and integration, not to recreate information that already exists in other sources. I thoroughly agree with this need.

Within the industry, there has actually been an attempt to try to set standards for health information on the web. One non-profit organization is called Hi-Ethics, Inc; there may be others. Health information sites that market directly to consumers can voluntarily join Hi-Ethics, Inc. by paying a membership fee (albeit sizeable at $20,000 annually) and meeting a set of criteria defined by the organization. I work for a company called Integrative Medicine Communications. (Dr. Gordon, you are scheduled to be our keynote speaker at an upcoming meeting.) We license both professional and consumer databases to internet companies, hospitals, health centers, HMOs, etc. Our clients, in turn, provide information directly to individuals either through the internet, other electronic media, or print. We are proud to say that several of our web based clients are members of Hi-Ethics including allHealth.com/iVillage, AmericasDoctor, Discoveryhealth.com, HealthGate, and InteliHealth. This means that they, and therefore we, must meet the current industry standards.

I believe that a potentially valuable recommendation by the WHCCAM might be to set up a short-term subcommittee to evaluate the existing criteria initiated by the industry (e.g. Hi-Ethics, Inc.), determine if these criteria are adequate for consumer protection, and set government standards including evaluation of sites to see if they meet these standards. This could be achieved through either a government fund or a nominal fee to the companies so that a greater number of health information websites would be able to participate in the evaluation process compared to the limitation of

Hi-Ethics due to their steep price. Then, a website, via either NCCAM or a separate organization, could have a section describing those standards with links to companies that meet the criteria.

The overriding message that I am trying to deliver is that there is no need (nor is it in anyone's best interest given the time, expense, difficulty, etc.) for the Commission to reinvent the wheel. Becoming a content provider as well as a content deliverer (both of which are inherent in the suggestion to "host a site with pros and cons on CAM related topics") is a massive undertaking from every angle; this is not, in my opinion, the charge of your Commission. It seems much more reasonable to use existing databases and effectively point consumers and professionals toward the best researched, best supported, and best presented data in both the private and the public sectors.

One very interesting issue raised by both Lee Raines, M.S. and Susan Detwiler, M.B.A. is the question of how most consumers are accessing websites today. Using this to help direct how best to deliver recommendations to the consumer regarding assessment of the quality of health information is very important.

Thank you for taking the time to listen to me. I hope that this is of some help. If I think of additional suggestions, I will forward them on to you. I wish you, Mr. Groft, and the committee tremendous success in this very difficult task. From my experience on Monday, it appears that you, the staff, and several of the committee members are doing a wonderful job. Plus, despite my concerns mentioned here, I had a heartening conversation with Corinne Axelrod, M.P.H. who was quite reassuring that extremely impractical ideas and concepts will not make their way into the final report.

Dr. Gordon, we have been very excited at Integrative Medicine that you will be our keynote speaker for the upcoming Summit conference in May. Having met you briefly and watching how seamlessly you conducted the meeting on Monday 3/26/01, I am even more enthusiastic given that you are a dynamic speaker. I will send a message to our Customer Service Manager, Colleen Nee, so that she may set up complementary accounts for you and Mr. Groft to have access to our databases on Integrative Medicine. These include the English translation of the Commission E as well as an expanded version of Comm E (called Herbal Medicine) with explanations of that Committee's recommendations and references. Another important database is our comprehensive fully integrated product called Access, which is available in both consumer and professional versions and includes monographs on conditions from an integrative perspective, CAM modalities, supplements, herbs, herb-drug interactions for any of the botanical medicines in our database, and supplement depletions by the most commonly prescribed medications. Two of our most recently updated monographs on the website

include Hypertension and Prostate Cancer which contain a very interesting
section entitled Integrative Treatment Strategy, a unique feature that we
created to teach readers how to bring complementary and conventional
healthcare together.

Thank you again for your time and attention.

Sincerely,
Jacki Hart, MD

Jacqueline A. Hart, MD
Senior Medical Editor
Integrative Medicine Communications
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CC: Stephen C. Groft, Pharm D

Groft, Stephen (NCCAM)

From: NewsAlert Email Account [newsalrt@burrelles.com]
Sent: Thursday, March 29, 2001 4:35 PM
To: Greene, Anita (NCCAM); O'Donnell, Ellen (NCCAM); Groft, Stephen (NCCAM)
Subject: NewsAlert

10960 0329 CNNfnNYNY State legislation and the use of complementa
10967 0329 TimesofIndiaNewD Anorexic teens use herbal remedies to lose w

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--------- 10960 ----------
CNNfn (NY,NY) via World Wide Web 03/29/2001
Profile:
complementary and alternative medicine
Alternative Medicine
Alternative \\Medicine
Complementary Medicine
Complementary Medical

State legislation and the use of complementary and alternative medicine

Source Website: http://www.cnnfn.com

Source: Inquiry - Blue Cross and Blue Shield Association

Publication date: 2000-01-01

Arrival time: 2001-03-29

There are increasing attempts at the federal and state levels to change regulations for [complementary and alternative medicine] (CAM). We use data from a new survey of about 10,000 individuals to examine CAM use and insurance coverage and their relationship to state regulations. We find that insurance mandates to cover CAM providers are significantly associated with increased coverage of CAM, but not with increased use of CAM providers. Liberalization of physician licensure to practice CAM is associated with significantly increased CAM use, as are practice laws authorizing nonphysician CAM providers. In states with multiple CAM practice laws, insurance coverage for CAM visits among users is significantly lower than in states without CAM practice laws.

The use of [complementary and alternative medicine] (CAM) has risen substantially in the last 10 years, largely due to an increase in the number of people seeking alternative therapies, rather than more intensive use by prior patients (Eisenberg et al. 1998). The growing acceptance of CAM by the general public has caught the interest of policymakers and, consequently, seen the development of public policies regarding CAM. As in other areas of medicine, most of the pioneering legislation has been at the state level. Up to now, however, there has been no evaluation of the association among use of [complementary and alternative medicine], insurance coverage, and state legislation of CAM. The primary reason for this gap may have been the relatively small sizes of prior surveys. For example, the most recent study by Eisenberg et al. (1998) included 2,000 responses nationwide. In this paper, we provide the first estimates of the association between state legislation and utilization of CAM using data from a new national survey with almost 10,000 respondents (Sturm et al. 1999).

State Legislation Affecting CAM

We distinguish three types of legislation in this study. The first type mandates that insurance policies cover CAM. Mandates regarding

health care services have been popular in other areas of health care, and more than 600 different mandates were in effect in various states in 1998 (Blue Cross/Blue Shield of America 1998). In the area of mental health and substance abuse alone, Blue Cross/Blue Shield lists more than 200 mandates affecting coverage of specific services or providers. We rely on the Blue Cross/Blue Shield data for CAM mandates. At the time of the survey, only two states had insurance mandates for massage therapists and naturopaths, and seven states had mandates for acupuncturists.1 Eight states had at least one mandate for CAM: Alaska, California, Florida, Montana, New Mexico, Nevada, Oregon, Washington. Only two states (Florida and Washington state) had mandates covering at least two types of CAM providers. Washington had a particularly stringent mandate, which required every health plan to cover treatments by all categories of providers regulated by the Department of Health.

The second type of legislation is liberalization of physician practice acts that expands the scope of physician practice to CAM, primarily through limiting a state medical board's authority to discipline physicians who practice CAM. In California, for example, a physician currently is not allowed to treat cancer with anything except surgery, radiation, or chemotherapy. There is a strong "medical freedom" lobby that advocates liberalizing the scope of treatment by physicians; the lobby also has influential supporters in Congress, including many of the cosponsors of the recently introduced Access to Medical Treatment Act (H.R. 2635). That proposed bill would allow physicians to provide unapproved drugs or medical devices that a patient desires. Until now, however, such physician practice acts only have been passed in a relatively small number of states. This type of legislation primarily affects the supply of CAM, since it allows physicians to enter this market. In addition, if CAM services provided by a physician were at least partially reimbursable by insurance (because of billing using standard visit codes and diagnoses), demand for CAM could increase, due to an effective price drop for CAM among insured patients.

We used two sources to identify legislation dealing with liberalization of physician practice (Sale; Foundation for the Advancement of Innovative Medicine 1999) and then checked the actual statutes. We excluded states with legislation that affected only a specific type of treatment (e.g., South Dakota) and states that passed only a regulation (e.g., Texas). We included only those states that passed legislation up to and including 1997. Those states, and the year the legislation was enacted, include: Alaska (1990), Colorado (1997), Georgia (1997), North Carolina (1993), New York (1994), Oklahoma (1994), Oregon (1995), and Washington (1991).

The third set of laws is alternative provider practice acts that establish and regulate the practice of certain CAM treatments, such as acupuncture, homeopathy, massage, and naturopathy. Some treatment modalities, such as homeopathy, have practice acts in only a few states, whereas other modalities, such as acupuncture, have specific practice acts in the majority of states. The absence of a practice act does not necessarily preclude this treatment, as some practice rights may be recognized within the scope of practice for other health care professions. Nevertheless, the existence of a formal practice act that gives nonphysicians specific rights to deliver certain services is likely to substantially increase the supply of providers practicing this modality.

We used three sources to identify potential legislation: the National Acupuncture Foundation (1995), Sale (website), and Health World (1999). For acupuncture, which is regulated in the majority of states, we selected only states where the law authorizes nonphysician providers to practice independently, because several statutes explicitly limit the practice of acupuncture to licensed physicians. Rather than expanding the supply of providers, practice laws that explicitly prohibit nonphysicians from providing such services are

more likely to restrict the supply, and we excluded those states. The variable we use in the quantitative analysis is an indicator equal to 1 for states that have practice acts for at least two out of four CAM modalities (acupuncture, naturopathy, homeopathy, massage therapy). Those states are: Alaska, Arizona, Colorado, Connecticut, Florida, Idaho, Maine, Montana, New Hampshire, New Mexico, Nevada, New York, Oregon, Rhode Island, Tennessee, Texas, Utah, Washington, and the District of Columbia. The limitation is that we consider only formal laws for specific alternative therapies. These laws do not address differences in the scope of such legislation, such as how easy or difficult it is to become certified, which can vary widely.

Survey Data and Methods

The data on CAM utilization comes from a new national survey, Health Care for Communities (HCC), funded by the Robert Wood Johnson Foundation (Sturm et al. 1999). The HCC household survey is a supplement to the Community Tracking Study (CTS) (Kemper et al. 1996), and it reinterviewed 9,585 CTS participants. While the two surveys constitute a panel for insurance and general health care, questions about CAM were asked only in the HCC. Thus, our study is a cross-sectional analysis based on data collected in surveys between September 1997 and November 1998. The HCC study was clustered in 60 sites, usually defined as Metropolitan Statistical Areas (MSAs), with a smaller geographically dispersed sample. Except for Vermont and Hawaii, all states (plus the District of Columbia) were represented. Details are described in Sturm et al. (1999).

The HCC survey asked: 1) whether an individual used any alternative or folk medicine in the past 12 months; 2) the number of visits to alternative practitioners in the past 12 months; 3) whether visits were covered by the regular health plan; and 4) the individual's out-of-pocket expenses for these alternative therapies. Table 1 provides the exact wording for our questions; the precise wording is necessary because the estimated use depends on the definition of CAM. Our survey did not prompt for the use of chiropractors, which results in lower estimates of CAM use than studies that consider chiropractors to be CAM providers and explicitly ask about the use of chiropractors.

To analyze effects of the three different types of legislation on use of CAM, we estimate logistic regression models. We include an indicator variable for each type of legislation (insurance mandate, liberalization of physician practice acts, and alternative provider acts). For sensitivity analyses, we consider several alternative definitions of the legal variables. We also control for other confounding factors. Previous research has found that use of alternative treatments is more common among women, less common among blacks, and more common among people aged 35 to 49 than among younger or older people (Eisenberg et al. 1998). Better educated and higher-income individua\ls also reported higher use. Regarding geographic variation, western states had substantially higher utilization rates (Eisenberg et al. 1998).

Other independent variables in the models include: age, in three groups (younger than 35 and at least 50 years old, with the middle group as the comparison group), female, years of schooling, log of family income, race (white is the omitted category), insurance status (private insurance and no insurance, with public insurance as the omitted group), and census region (West, Midwest, Northeast, with South as the omitted group). We also consider health status, including the mental health inventory from the Medical Outcomes Study (Wells et al. 1996) and a count of chronic medical conditions. The multivariate analyses use weighted data and standard errors are adjusted nonparametrically to account for the clustered sampling design.

Results

Table 2 contains descriptive statistics for the nation and for states with specific CAM legislation on the probability of use, number of visits to CAM providers, insurance coverage for CAM, and out-of-pocket payments for CAM users. About one respondent in seven reports having used any "alternative or folk medicine" in the previous year, which is similar to usage rates reported in two other recent studies (MacLennan et al. 1996; Paramore 1997), but substantially lower than the rate in the survey by Eisenberg and colleagues (1998). The rate of CAM use in states with liberalized physician practice acts or CAM practice acts is significantly higher than in the nation. It is highest in states with CAM insurance mandates, and increases with the number of CAM modalities covered by insurance mandates. In states with an insurance mandate for at least one CAM modality, CAM use is 8 percentage points higher than in the nation. In states with insurance mandates for at least two CAM modalities, CAM use is 11 percentage points higher. The state of Washington has the most comprehensive CAM insurance mandate, and CAM use in that state is 16 percentage points higher than in the nation.

Table 1.

Table 2.

About half the users report at least one visit to an alternative provider, and the average number is slightly less than 10 visits among users with at least one visit in the previous year. There are no statistically significant differences in the average number of visits among the nation, states with CAM insurance mandates, states with liberalized physician practice acts, and states with CAM practice acts. The number of visits in states in the West (9.0) or in Washington state (8.8) does not differ significantly from the national average either.

The rate of insurance coverage for CAM is similar in states with and without CAM legislation; the only exception is in states with insurance mandates for two or more CAM modalities, where insurance coverage for CAM visits is significantly higher ($p = .01$). No clear pattern emerges in out-of-pocket costs for people in states with and without CAM legislation, but standard deviations for such costs are very high.

These descriptive statistics clearly indicate differences by the existence of state legislation, but states also differ substantially in their populations. The multivariate analysis tries to disentangle the effects of sociodemographic characteristics that could lead to different utilization and insurance patterns from the effect of state legislation.

As Table 3 shows, after controlling for individual characteristics and geographic area, all three types of legislation are associated with higher CAM use or visits to providers. Regarding any CAM use, the effects of insurance mandates and liberalized physician practice laws are significant (p Urban Institute for comments on an earlier version.

1 Most states (42) have mandates for chiropractors, but chiropractors are now considered mainstream, not alternative, providers. The survey did not prompt for chiropractor use and we therefore do not cover chiropractor legislation either.

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Roland Sturm, Ph.D., is a senior economist at RAND. Jurgen Unutzer, M.D., is an assistant professor at the University of California, Los Angeles, and is affiliated with NPI Health Services Research Center. Funding for this study came from the Robert Wood Johnson Foundation. Address correspondence to Dr. Sturm at RAND, 1700 Main St., Santa Monica, CA 90401.

Publication date: 2000-01-01

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Times of India (The) (New Delhi, India) via World Wide Web 03/29/2001
Profile:
alternative medicine

Anorexic teens use herbal remedies to lose weight

Source Website: http://www.timesofindia.com

NEW YORK: With increasing numbers of American adults turning to herbal supplements and other forms of [alternative medicine], it should be no surprise that adolescents are doing the same. But according to a group of Canadian researchers, some of these young people are using herbal supplements not to improve their health, but to damage it.

``In our study of young people with eating disorders, we found out that these adolescents are using herbal remedies, both for weight control purposes and for non-weight control purposes,'' Dr Debra Katzman of the University of Toronto told Reuters Health.

Katzman and colleagues presented their research findings at the annual meeting of the Society for Adolescent Medicine held in San Diego earlier this month. The study included 47 patients between the ages of 10 and 17, mostly female, who had been diagnosed with an eating disorder such as anorexia or bulimia.

Overall, 37 per cent of the youngsters reported using herbal remedies, and 35% said they used these remedies to induce vomiting or decrease their appetite. Despite this widespread use of herbal products, however, 41% of participants said they knew ``nothing at all'' about

herbal remedies. Furthermore, only 24 per cent reported that their doctors had asked them about use of such products.

``This is a pretty important public health issue,'' Katzman told Reuters Health. ``These medications are associated with health risks, and some of them can be severe. The kids and their parents need to know this.''

Katzman described a study published last year in a prestigious medical journal about the use and health risks of ephedra. Ephedra, also known as ma huang, is used in traditional Chinese medicine to treat upper respiratory problems, but is also a common ingredient in herbal remedies that claim to help users lose weight.

``That article reported 10 deaths and 13 serious disabilities associated with this common weight-loss drug,'' Katzman stated. ``And in our study, 6% of the kids we surveyed had used ephedra, and had no idea it could hurt them.''

What's needed, Katzman stressed, is education. ``As parents, as physicians, we need to educate ourselves and our kids, and give them the best information possible. As physicians, we need to ask our patients, adults and adolescents alike, about whether they use any of these remedies.''

(Reuters)

Motherhood does not protect women from abuse

Anorexic teens use herbal remedies to lose weight

Child cancer survivors at risk later

Study finds tales of ``crack babies'' exaggerated

Quick test can identify depression in new moms

Many heart attack victims do not call ambulance

Women smokers increase; Thompson favors FDA control

Getting tough early makes parenting teens easier

Therapy on horizon for rare brain tumor in young

FDA says anesthetic shortage resolved

Rochester's 'model' health system at risk

Transfusion technique worthless for HIV patients

Hormone therapy can cause colon polyp recurrence

Company gets okay to let patients fill oxygen tank

Abbott to offer AIDS drugs at low cost in Africa

Air sole sneakers linked with ankle injuries

Many Medicaid children get inadequate asthma care

Long-term care insurance Bill introduced

Blood vessel defect found in preeclampsia

Insurance industry ads target tax break for care

Foundation plans $100m faith grant

Health secy likely to change privacy rules

Britain aims to end ageism in healthcare

Hinge device speeds healing after knee surgery

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Groft, Stephen (NCCAM)

To: Jmhelmsmd@aol.com
Subject: RE: Afterthoughts on the February meeting

Joe,

Thank you for the presentation at the meeting and the follow-up at the end. You bring up some interesting points for consideration and possible incorporation into the report language. I think we will stay away from micromanagement of CAM modalities and interventions. This is an endless task that is not the Commission's mandate. (Please note these are my impressions at this time and not the Commission's) Many questions are asked and statements are made that will not be incorporated into the report. We'll atay in touch on the issues before the commission.

Steve groft

-----Original Message-----
From: Jmhelmsmd@aol.com [mailto:Jmhelmsmd@aol.com]
Sent: Sunday, March 25, 2001 5:55 PM
To: jsgordon@mindspring.com; Groft, Stephen (NCCAM); Kaczmarczyk, Joseph (NCCAM)
Subject: Afterthoughts on the February meeting

Dear Jim and Steve and Joe:
A tardy but heartfelt congratulations on the well-selected collection of invited presenters for the commission assembly. You did a good job with the cast of characters, and an excellent job with clustering and balancing their content. Until the last half hour, I thought the time was very well organized and well used.

I especially liked that the reports from the four breakout groups came back with pretty much the same recommendations with respect to each CAM discipline defining its training and practice standards, credentialing and self regulation.

My response to the last half hour on Friday, however, is fully the opposite. I understood that the mantra of these meetings is that no one group of providers has exclusive ownership of any given CAM discipline, that a variety of practitioners are encouraged and entitled to provide the different services. This is a logical starting point in a complex situation where access to multiple levels of qualified providers is important. The breakout groups unanimously recommended creating and maintaining high standards among the practitioners by the various provider groups of the CAM disciplines.

When the challenges came at me from Effie Chow, and earlier from Charlotte Kerr ("What would you say if the commission RULED that 200 hours is insufficient for physicians?"), I think a more appropriate reply from the commission could have been on the order of: "We have defined the two major groups of acupuncture providers as standardized, qualified, credentialed, and regulated unto themselves. It is not the job of the panel to inspect, interfere with, or regulate the details of the different provider groups for each discipline, except to recommend high standards and self-regulation."

If the commission elects to continue its inspection of physician versus nonphysician training in the discipline of acupuncture, then it must also elect to inspect all provider groups of all the CAM disciplines addressed by the commission. Is that its mandate or its interest? If it is, I request that we proceed immediately with the inspection and evaluation of all groups of CAM providers so that this task can be accomplished within the timeframe of the commission. If it is not, I suggest that, rather than the commission micromanaging the CAM modalities, the public would be better served if the

commission transcended its involvement in practitioner turf battles and interacted on the plane of broad policy.

I would appreciate a prompt reply reflecting the commission's position regarding this issue so that, if necessary, I can prepare appropriately and adequately for the next stages of this process. Thank you again for the opportunity to participate as a presenter, and for your consideration of my thoughts.

Respectfully, Joe Helms

Statement to the President's Commission on Complementary and Alternative Medicine Policy – Evaluation of CAM Information

Lucinda L. Maine, PhD, RPh
Senior Vice President, American Pharmaceutical Association

I am pleased to represent APhA, the national professional society of pharmacists, at today's hearing and to have this opportunity to address key issues regarding information available to professionals and consumers to guide their selection and use of complementary and alternative medicine products. Pharmacists largely deal with patient or consumer use of dietary supplements, including vitamins and herbal products, and my comments will in large measure relate specifically to these components of CAM products and services. It is APhA's position that pharmacists have a responsibility to assist consumers with decisions about effectiveness, proper use, indications, safety and potential interactions between alternative medicines and traditional therapy. Their ability to carry out this responsibility depends on the availability of credible, evidence-based information to supplement their professional education and experience.

I will draw upon several sources in framing my remarks, including a publication issued as a joint effort of APhA and the American Dietetic Association last year, which has previously been shared with the Commission. In addition, I have gleaned the highlights from focus groups held just one week ago during the APhA Annual Meeting. These were convened by staff members from the Office of the Inspector General of HHS in the Boston office. They are embarking upon a study of the sufficiency of dietary supplement labeling and the impact of these products and available information on the elderly population specifically. Finally, research results from colleagues at the University of Minnesota College of Pharmacy who addressed the Commission at your open hearing in Minneapolis have been helpful in guiding development of my brief comments.

For perspective, I believe it is important to note several things about pharmacists and dietary supplements. Pharmacists, and especially those practicing in community pharmacy settings, are a highly accessible resource for the public for guidance about selection and use of alternative medicines. The Minnesota survey I just referenced indicated that pharmacists are approached on average approximately 7 times per week by consumers with questions about herbals and/or other natural products. This is a striking increase when compared to a national survey conducted in 1996 which found a rate of only 10 queries a month. In addition, the MN pharmacists surveyed reported receiving questions from other health care practitioners about use of these products.

How comfortable are pharmacists with their knowledge base and their access to scientifically grounded information on these products and their use? By observation and focus group results I would say far less comfortable when compared to other categories of products commonly purchased in pharmacies. Almost 40 percent of the MN pharmacists responded that available clinical and technical information to use in making decisions about herbal/natural products was not adequate and another 57 percent indicated information was only somewhat adequate. For the past several years, standing

room only crowds of practitioners have attended educational sessions held at ours and other association meetings. We feel this reveals an unsatisfied demand for credible information from pharmacists.

In the recent focus group discussions, pharmacists indicated that both they and their patients found dietary supplement labeling confusing and inadequate to guide point of purchase decision-making. Confusion also stems from disclaimers which are too small and suggests something about product review by the FDA but leave many questions in the minds of consumers and pharmacists. Further, while pharmacists find that references on labels to USP is important in judging product quality, references to other "quality reviews" that may also appear on labels is confusing and potentially misleading. Concerns about product quality and purity, in addition to other concerns about combining these products with traditional therapy are prevalent in the thinking of pharmacy practitioners.

There are two important points about the interface of pharmacists and consumers in the CAM arena. First, while many consumers appear to reach for these products in the context of health-seeking and wellness, those who access such products in pharmacies, we believe, are more likely to be individuals who are familiar with the pharmacy setting because they may also have acute or chronic conditions that prompt prescription or nonprescription medication use. Fortunately, when they ask pharmacists for guidance they may be thinking of their need to assure that whatever self-care activities they engage in won't interact with or complicate their other health conditions. But there are limits to what is known about such combinations of therapy and pharmacists do not feel that existing literature, whether primary, secondary or commercial, meets either their needs as professionals or the needs of consumers for safe use.

The second point about sale and labeling of CAM products in the pharmacy environment is that often herbal/natural products are sold very near or integrated with traditional over the counter medicines. Pharmacists are split in their opinion about whether labeling should be modeled more like OTC products or food. Proponents of OTC-like labeling believe consumers are used to that format and would benefit from similar labeling for CAM products. Others feel that it is inappropriate to infer that CAM products are like OTC medications. A third group told the OIG staff that it really didn't matter how products were labeled because consumers ignored product labels anyway.

There was a feeling that labels should encourage consumers to share information about their use of dietary supplements with their physicians and pharmacists. Further, a warning regarding seeking health care provider input if the symptoms, if any, for which consumers are using the CAM products don't resolve is highly recommended.

My final point is about surveillance of experience with CAM. Pharmacists are perhaps most uncomfortable with what we don't know about actual consumer experience with CAM products. APhA believes it is time for a much more robust system of experience reporting by consumers and health care providers. Ideally such a system could be voluntary and be embraced by manufacturers of CAM products as a key tool for

collecting and analyzing actual use information about their products. A program could be modeled, we believe, after reporting systems used by chemical and related products industries. APhA would support and cooperate in the development of an accessible reporting system that would meet the needs of manufacturers, regulators and providers for information about product quality and consumer experience with dietary supplements and other CAM products.

Thank you for seeking the input of America's pharmacists on these issues before the Commission. I would be happy to provide additional information as time permits.

Groft, Stephen (NCCAM)

From: Colleen Nee [colleen.nee@onemedicine.com]
Sent: Thursday, March 29, 2001 9:07 AM
To: Groft, Stephen (NCCAM)
Subject: Fw: Monday's meeting, 3/26/01

As Jacki Hart mentioned in her email to you yesterday, she would like you and Dr. Gordon to have access to our online database. Would you be able to provide me with an email address for Dr. Gordon so I can create his account? I have created an online account so you can view this information. Please follow the steps below to logon to our site.

-Go to http://www.onemedicine.com/logon.asp

-Log on by entering your email address, GroftS@mail.nih.gov and your password, groftsl

You will be able to review all of the material found on our Members Menu, as well as our online product demonstrations found on our Licensing page.

If you have any problems accessing the site, please let me know.

Thank you,
Colleen Nee
Integrative Medicine
1029 Chestnut Street
Newton, MA 02464
877-426-6633
----- Original Message -----
From: "Jacki Hart" <jacki.hart@onemedicine.com>
To: "Colleen Nee" <colleen.nee@onemedicine.com>
Cc: "Julia Goldrosen" <julia.goldrosen@onemedicine.com>; "Tamara Swain" <tamara.swain@onemedicine.com>
Sent: Wednesday, March 28, 2001 7:05 PM
Subject: FW: Monday's meeting, 3/26/01

>
> > -----Original Message-----
> > From: Jacki Hart
> > Sent: Wednesday, March 28, 2001 7:01 PM
> > To: 'GroftS@mail.nih.gov'; 'WHCCAMP@mail.nih.gov'
> > Subject: Monday's meeting, 3/26/01
> >
> > James S. Gordon, M.D.
> > Director
> > The Center for Mind-Body Medicine
> > 2934 Macomb Street, N.W.
> > Washington, D.C. 20008
> >
> > Dear Dr. Gordon,
> >
> >
> > As both a physician and a medical editor, I am writing to
> > express a few of my impressions and ideas stemming from the WHCCAM
> > conference on information dissemination which took place on Monday
> > 3/26/01.
> >
> > First, it was a pleasure to see a well organized operation with
> > the conference running very close to on time throughout the day - no
> > easy feat with such significant ground to cover. Secondly, I was quite
> > impressed with your style, Dr. Gordon, in presiding over the
> > Commission. You were clear, direct, and insightful; in addition, you

> > were able to keep both panelists and committee members focused and on
> > track during the discussion, redirecting them appropriately and doing
> > so in a kind manner. Not being involved in the political arena, it
> > was fascinating for me to watch government in action. Both you and Mr.
> > Groft clearly had a hand in the agenda, punctuality, and choices for
> > the panelists.
> >
> > However, I did have a few concerns. One was that there seemed to
> > be a lack of awareness on the part of several committee members
> > regarding existing mechanisms to help evaluate information and
> > facilitate its dissemination. My hope is that the level of some of the
> > questions may not reflect a lack of knowledge but, rather, a desire to
> > hear how the panelists responded. There were several questions that
> > prompted me to express this concern. The first example arose in the
> > morning regarding how to search for and uncover data about herb-drug
> > interactions and adverse events from herbs and supplements. I found it
> > quite surprising that this particular committee member did not seem to
> > realize that there is (a) a mechanism through the FDA for making such
> > data public via press releases and warnings posted on their website,
> > (b) several well researched, well written, and well presented
> > commercial sources of such data, and (c) that a simple search in
> > MEDLINE and/or EMBASE would uncover this data directly. Similarly, in
> > the afternoon, there was a series of questions regarding the FDA and
> > the FTC and when a supplement becomes a drug. I do realize that the
> > jurisdiction of the two separate agencies often becomes muddled and
> > that it is confusing to keep the bureaucracy straight; however, I felt
> > that some of the questions were basic and repetitive. It was as if the
> > answers would change if they continued to be asked, simply because the
> > particular committee member inquiring did not like the response.
> >
> > I was also concerned that several of the suggestions made in the
> > subcommittee group on Internet and the Media seemed neither logical
> > nor feasible. The suggestion to have a site that hosts "pros and cons"
> > of all CAM related information, for example, is a huge, extremely
> > unrealistic (not to mention unbelievably expensive) undertaking that
> > will not contribute to lessening consumer confusion but, rather, will
> > increase this perplexity. From my perspective, what seemed to be
> > stated by several different panelists throughout the day is a need for
> > consumers to have some help in determining reliable, dependable
> > sources of health related information, particularly in the area of CAM
> > and integration, not to recreate information that already exists in
> > other sources. I thoroughly agree with this need.
> >
> > Within the industry, there has actually been an attempt to try to set
> > standards for health information on the web. One non-profit
> > organization is called Hi-Ethics, Inc; there may be others. Health
> > information sites that market directly to consumers can voluntarily
> > join Hi-Ethics, Inc. by paying a membership fee (albeit sizeable at
> > $20,000 annually) and meeting a set of criteria defined by the
> > organization. I work for a company called Integrative Medicine
> > Communications. (Dr. Gordon, you are scheduled to be our keynote
> > speaker at an upcoming meeting.) We license both professional and
> > consumer databases to internet companies, hospitals, health centers,
> > HMOs, etc. Our clients, in turn, provide information directly to
> > individuals either through the internet, other electronic media, or
> > print. We are proud to say that several of our web based clients are
> > members of Hi-Ethics including allHealth.com/iVillage, AmericasDoctor,
> > Discoveryhealth.com, HealthGate, and InteliHealth. This means that
> > they, and therefore we, must meet the current industry standards.
> >
> > I believe that a potentially valuable recommendation by the WHCCAM
> > might be to set up a short-term subcommittee to evaluate the existing
> > criteria initiated by the industry (e.g. Hi-Ethics, Inc.), determine
> > if these criteria are adequate for consumer protection, and set
> > government standards including evaluation of sites to see if they meet
> > these standards. This could be achieved through either a government
> > fund or a nominal fee to the companies so that a greater number of

> > health information websites would be able to participate in the
> > evaluation process compared to the limitation of Hi-Ethics due to
> > their steep price. Then, a website, via either NCCAM or a separate
> > organization, could have a section describing those standards with
> > links to companies that meet the criteria.
> >
> > The overriding message that I am trying to deliver is that there is no
> > need (nor is it in anyone's best interest given the time, expense,
> > difficulty, etc.) for the Commission to reinvent the wheel. Becoming a
> > content provider as well as a content deliverer (both of which are
> > inherent in the suggestion to "host a site with pros and cons on CAM
> > related topics") is a massive undertaking from every angle; this is
> > not, in my opinion, the charge of your Commission. It seems much more
> > reasonable to use existing databases and effectively point consumers
> > and professionals toward the best researched, best supported, and best
> > presented data in both the private and the public sectors.
> >
> > One very interesting issue raised by both Lee Raines, M.S. and Susan
> > Detwiler, M.B.A. is the question of how most consumers are accessing
> > websites today. Using this to help direct how best to deliver
> > recommendations to the consumer regarding assessment of the quality of
> > health information is very important.
> >
> > Thank you for taking the time to listen to me. I hope that this is of
> > some help. If I think of additional suggestions, I will forward them
> > on to you. I wish you, Mr. Groft, and the committee tremendous success
> > in this very difficult task. From my experience on Monday, it appears
> > that you, the staff, and several of the committee members are doing a
> > wonderful job. Plus, despite my concerns mentioned here, I had a
> > heartening conversation with Corinne Axelrod, M.P.H. who was quite
> > reassuring that extremely impractical ideas and concepts will not make
> > their way into the final report.
> >
> > Dr. Gordon, we have been very excited at Integrative Medicine that you
> > will be our keynote speaker for the upcoming Summit conference in May.
> > Having met you briefly and watching how seamlessly you conducted the
> > meeting on Monday 3/26/01, I am even more enthusiastic given that you
> > are a dynamic speaker. I will send a message to our Customer Service
> > Manager, Colleen Nee, so that she may set up complementary accounts
> > for you and Mr. Groft to have access to our databases on Integrative
> > Medicine. These include the English translation of the Commission E as
> > well as an expanded version of Comm E (called Herbal Medicine) with
> > explanations of that Committee's recommendations and references.
> > Another important database is our comprehensive fully integrated
> > product called Access, which is available in both consumer and
> > professional versions and includes monographs on conditions from an
> > integrative perspective, CAM modalities, supplements, herbs, herb-drug
> > interactions for any of the botanical medicines in our database, and
> > supplement depletions by the most commonly prescribed medications. Two
> > of our most recently updated monographs on the website include
> > Hypertension and Prostate Cancer which contain a very interesting
> > section entitled Integrative Treatment Strategy, a unique feature that
> > we created to teach readers how to bring complementary and
> > conventional healthcare together.
> >
> > Thank you again for your time and attention.
> >
> > Sincerely,
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> >
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