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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Martha Eddy to WHCCAM (partial) (1 page)	02/13/2001	b(6)
002. list	American Preventive Medical Association board members/addresses (2 pages)	nd	b(6)

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

OA/Box Number: 43234

FOLDER TITLE:
CAM Articles 2000-2001 [2]

2011-0568-S
kc854

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
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[001]

Martha Eddy, Ed. D., CMA, R.M.T

(b)(6)

New York, NY 10027

February 13, 2001

Dear Dr. Gordon and other members of the WHCCAM:

On January 23, 2001, I had the opportunity to speak at the WHCCAM Town Hall meeting held in New York City (Panel 17). I was representing the International Somatic Movement Education and Therapy Association's (ISMETA) view that NCCAM's classification of CAM practices has not specifically and accurately classified the practices represented by ISMETA. At the meeting you requested that we inform WHCCAM how we would like to be classified. The following is our proposal.

Currently many of the practices within our profession are listed under **Category V - Manipulative and Body-based Systems – Massage and BodyWork.** While we understand the affiliation with other manual hands-on/touch methods, as movement professionals we do not feel this is an appropriate classification for us.

We strongly urge you to review the recommendations that were sent by a number of somatic practice professional associations to the US Department of Education (DOE) as public comment for their final draft of the publication Classification of Instructional Programs (CIP – 2000).

I have included this document for your review, as well as another copy of my statement made on January 23.

As mentioned at the Town Hall meeting, ISMETA has already been in active dialogue with the DOE on this project for over one year. They have struggled to make sense out of the proliferation of educational programs that prepare individuals to become CAM professionals. This past summer, in (what was supposed to be) the eleventh hour for their final draft, they decided to adopt the NCCAM's taxonomy. As you see in our letter to them, we find there to be a difference between a classification system for research purposes and a classification system for educational training.

Proposal I

The professions represented by ISMETA would rather be listed under **Category II – Mind-Body Interventions** – of the NCCAM classification, which states:

Mind-Body medicine involves behavioral, psychological, social, and spiritual approaches to health. It is divided into four subcategories: Mind-Body Systems; Mind-Body Methods; Religion and spirituality; Social and contextual areas.

In the **Mind-Body Intervention** Category the professions which ISMETA represents would like to be listed under **Mind-Body Methods** as ***Somatic Practices of Movement Education and Movement Therapy***

Rationale:
Somatic practices of movement education and movement therapy are not solely based in the body. These practices are intrinsically educational in that they consciously engage cognitive and emotional processes. Their theoretical framework includes perceptual-motor, neuro-developmental, and behavioral theory. Thus, we feel it is best that we are listed under Mind-Body Interventions as a CAM practice instead of under Massage and BodyWork as a Body Based Therapy. Furthermore, Yoga, Tai Chi, and Internal Qigong are practices listed under Mind-Body Methods that have already set a precedent for movement based practices in this category.

If it is helpful please consider the following definition of our field.

Somatic Practices of Movement Education and Movement Therapy are practices that promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. The scope of practice includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication. These practices include but are not limited to the following: The Alexander Technique, Bartenieff Fundamentals ™, Body-Mind Centering ®, Dynamic Anatomy ®, Halprin Life Art Processes, Laban Movement Analysis, Phoenix Rising Movement Therapy, Rolf Movement Integration, Rubenfeld Synergy ®, Somatic Movement Coaching, Somatic Movement Education, Somatic Movement Therapy, The Topf Technique®, and could theoretically include Aston Patterning, Feldenkrais Method®, and the Trager® Approach, if they desired.

In summary, and for clarity, ISMETA would like to have all the above listed Somatic Movement Practices listed under **Category II Mind-Body Interventions – Mind Body Methods – CAM Practices**, as ***Somatic Practices of Movement Education and Movement Therapy.***

If it is absolutely impossible for this suggestion to be implemented please consider its alternative, **Proposal II.**

Proposal II
Re: the new/added program title and definition ***Somatic Bodywork: Under Manipulative and Body Based Systems.***

We request that you consider a re-categorization to include the following three categories

Somatic Bodywork.
Somatic Practices of Movement Education and Movement Therapy.
Energy-Based Therapies.

Rationale:
A range of individual systems, modalities and practices is included under this title. The educational providers and movement specialists of some of the systems listed do not identify their instructional programs as Somatic Bodywork.

For your information please consider these alternative definitions:

Somatic Bodywork. promotes physical and emotional balance and well being through the application of skilled touch principles and techniques. Methods include hands-on methods, anatomy and physiology, structural integration and various holistic health systems, practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, and others).

Somatic Practices of Movement Education and Movement Therapy are practices that promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. The scope of practice includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication. These practices include but are not limited to the following: The Alexander Technique, Bartenieff Fundamentals ™, Body-Mind Centering ®, Dynamic Anatomy ®, Halprin Life Art Processes, Laban Movement Analysis, Phoenix Rising Movement Therapy, Rolf Movement Integration, Rubenfeld Synergy ®, Somatic Movement Coaching, Somatic Movement Education, Somatic Movement Therapy, The Topf Technique®, and could easily include Aston Patterning, Feldenkrais Method®, and the Trager® Approach.

Energy-Based Therapies. A program that prepares individuals to promote health and well being through the application of techniques intended to affect the human energy system. Instruction may include a combination of theory and basic principles of orthodox and energetic anatomy and physiology, energetic evaluation and integration, skilled touch, communication and facilitation skills, energetic nutrition, movement, stretching postures, practice management, professional ethics, and service delivery, as appropriate to each practice. (Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qigong, and others).

In summary, we strongly urge you to accept **Proposal I** as detailed above. If upon giving **Proposal I** careful consideration, its adoption is simply not possible, then we ask you to accept **Proposal II**. In summary, **Proposal II** would entail a **re-categorization** to more appropriately separate several diverse modalities into three distinct sub-categories: 1) ***Somatic Bodywork***, 2) ***Somatic Practices of Movement Education and Movement Therapy***, and 3) ***Energy-Based Therapies***.

ISMETA would also like to state that it is in support of the letter from Missy Vineyard of the American Society for the Alexander Technique (AmSAT) to Dr. Kaczmarcyzk on February 10, 2001. In particular ISMETA shares her skepticism towards "creating one big CAM amalgam, complete with a single regulatory system that attempts to be appropriate for all." However, we would also like to state that whereas some somatic movement practices (most notably those Teachers of the Alexander Technique represented by AmSAT) may not want to work toward receiving third party payments, this is not a monolithic view. There are some practitioners that may seek to work as part of HMO's or in conjunction with the insurance system in order to provide greater access of this work to more diverse people, in particular those people unable to afford, 'out of pocket' services.

Again, thank you for your extraordinary efforts to consider this update of the classification of CAM practices under the NCCAM and all that you do to support a greater understanding of the wide range of holistic practices that are being used in our country.

Respectfully yours,

Martha Eddy/KH

Martha Eddy, Ed.D.
Board of Directors
International Somatic Movement Education & Therapy Association (ISMETA)
mhe4@columbia.edu

THE ROLE OF SOMATIC MOVEMENT EDUCATION & THERAPY IN COMPLEMENTARY AND ALTERNATIVE MEDICINE WITH AN EXPRESSION OF OPINION ABOUT LICENSURE, STANDARDS, AND ACCESS.

Hello, thank you for inviting this diversity of dialogue. I am Dr. Martha Eddy, a Professor at Columbia University - Teachers College. I am currently involved in developing research models for the qualitative analysis of movement. I am here to represent the International Somatic Movement Education & Therapy Association otherwise known as ISMETA. ISMETA is a self-regulating board that registers individual somatic practitioners of movement education and movement therapy. Somatic movement education and therapy aims to enhance movement behavior. The eleven ISMETA approved training programs that teach disciplines such as The Alexander Technique, Rubenfeld Synergy®, Laban Movement Analysis, BodyMind Centering®, and Rolf Movement Integration, among others, train our registered practitioners. Each individual and professional organization in our field shares skills in assisting people to gain greater awareness of their movement habits and movement's role in communication, vitality, and self-expression.

ISMETA wishes to assert four ideas about regulation, access, and research. Firstly, access to somatic practices is currently threatened in New York State. *The massage board is challenging in particular, somatic practices that use touch.* **This has included even those somatic movement practices that use movement**

re-patterning to support the facilitation of new awareness and proprioception. The assumption that one field can establish standards for another completely different field needs to be challenged.

Secondly, we realize that the NCCAM classification of CAM practices has been developed for research purposes. However, we are aware that it is being used by other governmental agencies, such as the Department of Education as a model for their classifications of instructional programs (which in turn influences the O*NET categories). **Even without intention the NCCAM is setting a precedent for other organizations and, in our case, our practices are not specifically or accurately classified. Thus, viable and successful Somatic Movement Practices are being omitted, or inappropriately classified with other practices affecting the legitimacy of these fields.**

This furthermore can create problems when licensing is being discussed because the requirements for one discipline may not be appropriate or applicable to every other discipline. What is the solution? A licensing board for each modality? Of course not, this would be a costly and inefficient task to accomplish, however it is also unlikely that any one set of standards will be suitable for the diverse modalities classified by WHCAM. We need to find another solution.

ISMETA has developed a Scope of Practice, Standards of Practice, a Code of Ethics, and Grievance Procedure, which are agreed upon by all of its registered members. ISMETA believes strongly that this model of self-regulation not only benefits our profession, but also enhances the possibility of any individual to have access to somatic movement disciplines of their choice.

Thirdly, the notion of "uniform standards to all CAM practices" also concerns us. ISMETA would like to see regulatory standards be developed by practitioners from specific fields or by committees inclusive of these practitioners. These standards must be true to the model they represent. The somatic paradigm is not necessarily best represented by either allopathic or traditional 'hard science' models.

Fourthly, the diversity of types of CAM also raises issues about research appropriate to somatic movement. Double blind experimental research may prove too reductionistic for the types of questions about movement choices and behavior that we are addressing.

We can glean much from the quantitative studies on biomechanical aspects of movement as well as from the studies of applied physiology. In the work of somatic movement education and therapy the client's movement experience involves an understanding of motor functioning but also reaches into the arena of human expression and communication. Improved movement comes not only from exercise but also through gaining awareness by increased proprioception, enhanced motivation, and applied

understanding of movement principles. (E.g., that there is a constant interplay between mobility and stability; function and expression...etc) The skills employed by such a practitioner are highly individualized and the benefits may vary widely from one client to the next. Thus, standards developed from double-blind placebo studies will not always accurately represent Registered Movement Educators or Registered Movement Therapists. The case study work of neurologists Oliver Sacks and Jonathan Cole may be a useful model. Inclusion of Qualitative research methods allows for holistic, rich and in-depth analysis of these processes.

Increasing the variety of research models accepted by NCCAM to include qualitative studies, (e.g. case studies, cross case analyses, ethnographic analyses, and historical reviews) **combined quantitative and qualitative approaches, and single subjects analyses as well as multivariate analyses could better inform the public about complex and overlapping aspects of human behavior. This type of research can, in turn, support the visibility of holistic therapies and thereby the process of giving the public access to a full spectrum of alternatives.**

Thank you for your consideration of the needs of the public and the specific nature of somatic disciplines concerned with human movement in meeting these needs.

U.S. Department of Education

December 8, 2000

Dear Dr. Morgan and Ms. Korb,

As authorized representatives from the organizations below, we have reviewed the second draft of the *Classification of Instructional Programs (CIP - 2000)* and respectfully submit the comments and corrections in this letter.

We can only begin to imagine the work involved in your overwhelming job of updating this document. Our professions, categorized in Series number ***51.43 Alternative, Complementary and Somatic Practice Health and Therapeutic Services*** have wrought big classification challenges. We sincerely hope you understand our firm commitment to support your efforts with accurate, current information that best represent our educational programs in the growth areas of health and wellness. This in turn will provide a truly updated document for public use.

First, we'd like to put our comments and suggestions in context. It is our understanding that it was your group's decision to apply a classification system developed at the National Institutes of Health, National Center for Complementary & Alternative Medicine (NCCAM) to our professions' educational training programs for the *CIP - 2000*.

The purpose of the NCCAM's *Classification of Complementary and Alternative Medical Practices*, now referred to as the *Major Domains of Complementary & Alternative Medicine* is to provide a reference tool in evaluating research grant applications. While it has other related purposes, all center on expanding research outcomes. This classification system was not arrived at to describe instructional programs preparing professionals to practice these modalities.

We, as representatives from instructional programs listed in the NCCAM's classification system of CAM modalities, and, therefore, the second draft version of the *CIP - 2000*, urge you to evaluate this framework's use for its intended purpose, and consider our suggested adaptations inclusive of educational purposes rather than based on research science purposes alone.

We are eager to assist you in clarifying the criteria for categorizing, entitling and defining our educational training programs, and would welcome engaging NCCAM staff and advisory council members as well. Because you have been through a number of reviews and revisions already, we hope our input can directly serve to integrate the final feedback you receive regarding Series ***51.43***.

Guided by the review instructions and request for feedback on the second draft of the *Classification of Instructional Programs (CIP - 2000)* "...comment on the appropriateness of the titles and definitions used for the new programs and provide corrections or alternative titles or definitions, where needed", we strongly urge you to consider the following two proposals and choose one in accordance with your overall review of ***51.43.***

Proposal I

Re: the new/added program title and definition ***51.4307 Somatic Bodywork:***

> A range of individual systems, modalities and treatments is included under this title. The educational providers of some of the systems listed do not identify their instructional programs as Somatic Bodywork. We request that you consider a re-categorization in ***51.43*** to include the following

Alternative category titles:

> ***Somatic Bodywork.***
> ***Movement Education and Movement Therapy.***
> ***Energy-Based Therapies.***

Alternative definitions:

> ***Somatic Bodywork***. A program that prepares individuals to promote physical and emotional balance and well-being through the application of skilled touch principles and techniques. Instruction includes hands-on methods, anatomy and physiology, structural integration and various holistic health systems, practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, and others).
> ***Movement Education and Movement Therapy.*** A program that prepares individuals to promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. Instruction includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication, practice management, professional standards and ethics. (Alexander Technique, Aston Patterning, Body-Mind Centering, Feldenkrais Method®, Laban Movement Analysis, Trager Approach, Yoga Teacher Training, Yoga Therapy and others).
> ***Energy-Based Therapies.*** A program that prepares individuals to promote health and well-being through the application of techniques intended to affect the human energy system. Instruction may include a combination of theory and basic principles of orthodox and energetic anatomy and physiology, energetic evaluation and integration, skilled touch, communication and facilitation skills, energetic nutrition, movement, stretching postures, practice management, professional ethics, and service delivery, as appropriate to each practice.

(Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qi Gong, and others).

Proposal II

Re: the new/added program title ***51.4307 Somatic Bodywork:***

Somatic Bodywork does not convey a broad enough title for the range of individual systems and modalities included under this title. If you do choose to retain this grouping of instructional programs under one category, then we suggest the following

Correction of title:

Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies

Re: the definition used for ***51.4307 Somatic Bodywork*** :

1) Massage Therapy and Therapeutic Massage are listed as a program in ***51.4304***.

Correction:
Delete these terms from ***51.4307***. The generic term used for entry level instruction in hands-on methods, applied educationally and/or therapeutically, is "skilled touch". Skilled touch principles and techniques are taught in all Somatic Bodywork, Movement, and Energy-Based Therapy modalities.

Replace with:
"A program that prepares individuals to promote physical and emotional balance and well-being through a combination of skilled touch principles and techniques and other somatic healing arts and modalities. Includes instruction in skilled touch;" etc.

2) The word "hypnotherapy" is listed as a program in ***51.4303***.
Correction:
Delete "hypnotherapy" from this section.

3) The word "aromatherapy" is listed as a program in ***51.4301***.
Correction:
Delete "aromatherapy" from this section.

4) Reiki is one of many methods of energy-based therapies.
Correction:
Include with list of other energy-based therapies.

5) Cranio-sacral therapy is a program area best associated with Somatic Bodywork.

Correction:
Move from ***51.4304*** to ***51.4307***

6) Yoga teaching and yoga therapy are forms of movement education and movement therapy instructional programs.
Correction:
Include with other movement education and movement therapy programs.

7) Colon Hydrotherapy is a body cleansing modality, quite distinct from any approach to somatic bodywork, movement, or energy-based therapies. If anything, it has more connection with Nutritional Counseling, although it is different from that as well.
Correction:
Delete under category ***51.43.07***. Include under the category ***51.4309 (..., Other)***.

Correction of definition used for

Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies. A program that prepares individuals to promote physical and emotional balance, health and well-being which may include a combination of principles and techniques of skilled touch, kinesthetic awareness, movement evaluation and patterning methods, techniques intended to affect the human energy system, mind-body healing methods and other somatic healing arts. Instruction may include skilled touch, anatomy and physiology; kinesthetic awareness processes; movement observation, assessment, and guidance methods and verbal, touch and movement communication; structural, functional and expressive integration; energetic evaluation and integration; practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, Alexander Technique, Aston Patterning, Body-Mind Centering, Feldenkrais Method®, Laban Movement Analysis, Trager Approach, Yoga Teacher Training, Yoga Therapy, Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qi Gong, and others.)

In summary, we strongly urge you to accept **Proposal I** as detailed above. This would entail a **re-categorization** to more appropriately group together several diverse modalities into three distinct categories: 1) ***Somatic Bodywork***, 2) ***Movement Education and Movement Therapy***, 3) ***Energy-Based Therapies***.

If upon giving this proposal careful consideration, its adoption is simply not possible, then we ask you to accept **Proposal II**. This would involve **an expansion of the title** ***Somatic Bodywork*** to ***Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies***. This expanded category title would more accurately represent the diversity of systems and modalities included under this one category.

Again, thank you for your extraordinary efforts to update the *CIP – 2000.*

Respectfully yours,

Ellen M. Barlow
Board of Directors
International Somatic Movement Education & Therapy Association (ISMETA)
Ebarlow@gateway.net

James L. Oschman, Ph.D.
Advisory Council member, ISMETA
Academic scientist, researcher of Complementary and Alternative Medicine (CAM)
Joschman@aol.com

Ron Dennis, Ed.D.,
Representative to ISMETA, American Society for the Alexander Technique (AmSAT)
Rondennis@compuserve.com

Pat Nicholson
Representative to ISMETA, Alexander Technique International (ATI)
703 – 978-9499

LaRose S. Daniels, MS, RPP
President, American Polarity Therapy Association (APTA)
larose@earthlink.net

Henry Bornstein
President, United States Trager Association (the U.S. national membership association of the Trager Institute)
henryborn@cs.com

Ginger Carney, MA, PT
Joint Government Relations Committee
The Federation of Therapeutic Massage, Bodywork and Somatic Practice Organizations
gingercarneypt@earthlink.net

Andrea Wiener
Assistant Director, THE FELDENKRAIS GUILD® of North America
andreaww@aol.com

CC: National Center for Complementary & Alternative Medicine (NCCAM), NIH

Albrecht, Joan (NCCAM)

From: Alternative Mental Health News [ezine@alternativementalhealth.com]
Sent: Tuesday, March 20, 2001 3:38 PM
To: Whccamp (NCCAM)
Subject: Alternative Mental Health News -- Issue 9

A L T E R N A T I V E M E N T A L H E A L T H N E W S

An ezine brought to you by AlternativeMentalHealth.com and Safe Harbor, a nonprofit corporation.

Dan Stradford, Editor
Alan Graham, Assistant Editor:
SafeHarborProj@aol.com
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Contact info:
Safe Harbor
P.O. Box 37
Sunland, California 91041-0037

U.S.A.
(818) 890-1862
SafeHarborProj@aol.com
www.AlternativeMentalHealth.com

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EDITOR'S COMMENT

Times they are a-changin'. Just a few years ago when we established AlternativeMentalHeatlh.com, the phrase "alternative mental health" was scarcely known. But now it seems to be an unstoppable juggernaut. In this month's lead article we find that 1 in 5 people suffering from anxiety or depression now go to an alternative practitioner for help.

Additionally, we get regular reports of alternative physicians taking on the role of mental healers because so many people come to them looking for alternatives to the psychiatric medication they are taking. While compiling our internet directory of practitioners at AlternativeMentalHealth.com, we found that so many alternative physicians now receive children on Ritalin that taking kids off the medication has become a mini-industry in itself.

On May 3 of this year in Toronto, probably the continent's largest gathering of alternative mental health advocates and practitioners will occur at the annual meeting of the International Society for Orthomolecular Medicine. (For more information, they can be reached at 416-733-2117.) I'll be there. Along with a number of others who have called us. I believe the time is ripe to organize our forces and combine our strengths to speak as one voice and make our message known to the world. I'll be there. Let's talk.

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ACCEPTANCE OF ALTERNATIVE MENTAL THERAPIES CONTINUES TO RISE

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In the August 2000 issue of Alternative Mental Health News, we reported a trend toward broad acceptance of complementary and alternative mental therapies by the American public. New survey evidence shows that the trend is even more pronounced than before.

Common alternative therapies include oral medication, physical treatments, specific dietary changes, vitamin and mineral supplementation, exercise programs and the elimination of environmental stress factors. A growing number of complementary and alternative therapies are subject to insurance reimbursement and span a wide variety of such options.

In 1996, a Medical Expenditure Panel Survey of over 16,000 respondents found in 1996 that a total of 4.5% of those reporting a mental condition visited an alternative or complementary practitioner for treatment of the condition.

For a survey published in the February 2001 issue of the American Journal of Psychiatry, data was collected from more than 2,000 respondents on 24 complementary and alternative therapies for specific chronic conditions. Among participants, more than 9 percent reported experiencing "anxiety attacks" in the past 12 months and 7.2 percent felt they suffered from "severe depression."

A key finding of this study, say Harvard Medical School researchers, was the supplementation of conventional forms of treatment with the

alternative methods. Investigators found that more than 65 percent of those seeing a conventional provider for anxiety attacks and 66.7 percent seeing a conventional practitioner for severe depression were also pursuing complementary and alternative methods of treatment.

It was found that 20 percent of those experiencing anxiety attacks and 19 percent of those severely depressed had sought a complementary or alternative therapist. This is 400% increase over the 4.5% in the 1996 study. Additionally, 34 to 37 percent of anxiety and depression groups used complementary and alternative treatments without visiting an alternative practitioner.

The researchers advised conventional providers to be up front in discussing alternative therapies with patients. According to the report's authors, "Opening up lines of communication could help prevent adverse clinical effects, as well as maximize the usefulness of any complementary and alternative therapies subsequently proven to be effective."

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LESS TV, MORE HOBBIES PREVENTS ALZHEIMERS

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Recent research reported by the BBC and USA Today reveals that people who lead inactive lives and watch more television are more likely to get Alzheimer's disease.

The study, carried out by Dr. Robert Friedland of Case Western Reserve University and associates, showed that those who regularly participated in hobbies that were intellectually challenging during their younger adult years tended to be protected from Alzheimer's disease. The finding supports other studies that show the "use or lose it" principle definitely applies to the intellect.

"Television watching is not protective and may even be a risk factor for Alzheimer's disease," said Friedland He and his team studied the leisure activities in young and middle adulthood of 193 Alzheimer's patients and of 358 controls, people who did not have symptoms of the disease. The study participants were in their 70s when the survey was conducted.

The research was hailed by Dr. Zaven Khachaturian, senior medical adviser to the Alzheimer's Association, who claims the study supports other research showing that the onset of Alzheimer's is delayed by education and by intellectually demanding life activities.

The survey centered on three types of activities: Passive, intellectual, and physical. Passive included items such as watching television, talking on the phone or listening to music. Intellectual covered such things as reading, jigsaw or crossword puzzles, playing musical instruments, chess or other board games, knitting or woodwork. Physical included activities such as baseball, football or other sports, bike riding, swimming, walking or skating.

"The Alzheimer's patients were less active in all these activities except for television watching," said Friedland. He also noted that intellectual activities seemed particularly protective. Those who spent their leisure time on mentally stimulating hobbies were approximately 2.5 times less likely to develop Alzheimer's.

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ACTRESS MARGOT KIDDER BECOMES SAFE HARBOR NATL. SPOKESPERSON

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The world will always know her as Lois Lane from the Superman movies. And indeed, she is a highly versatile actress with more than 40 feature

films and 100 television shows to her credit. But those in the alternative mental health field recognize Ms. Kidder as one of the most courageous voices in America.

After curing herself of "manic depression" through personal research and nutrient therapy, Ms. Kidder has chosen not to take the easy road and stay silent. Instead, she has become a powerful advocate for the use of drug-free treatments in mental health, particularly through the use of full physical exams and nutritional therapy.

After years of personal struggles, she was shocked to discover that nutritional mental health treatments had been around for decades but none of her mainstream doctors ever told her about them. Unwilling to stand by and let others suffer needlessly, the vivacious actress has since lent her voice many times to the cause of drug-free alternative treatments.

In January of this year she received the Courage in Mental Health Award from the California Women's Mental Health Policy Council in recognition of her work.

In February 2001, Ms. Kidder added her support as spokesperson for America's fastest-growing alternative mental health organization: Safe Harbor and AlternativeMentalHealth.com.

More than just a pretty face, she is well-read and very articulate on the subject of nutritional brain chemistry, as can be seen by the new article she has contributed at www.AlternativeMentalHealth.com.

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BIOCHEMICAL INDIVIDUALITY AND MENTAL HEALTH
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Nutritional supplementation can be effective in treating mental conditions, but only to the degree that the unique biochemistry of each individual body is taken into account, explains William Walsh, Ph.D, chief scientist of the nonprofit Health Research Institute in Naperville, Illinois.

"I am amused by supplement manufacturers who attempt to develop the ideal combination of vitamins, minerals, and amino acids for the general population," writes Walsh (http://www.hriptc.org/binres.htm). "This is a bit like trying to determine the ideal shoe size for the population."

Shakespeare's statement, "One man's meat is another man's poison," was scientifically sound. Even siblings do not necessarily have the same biochemical balances and needs. In the genetic lottery, variables come from many ancestors on both sides of the family. An astonishing 42 million genetic combinations are possible in children of the same two parents.

A vegetarian diet is suitable for some, but not all, Walsh points out. Some persons can satisfy their nutritional needs by diet alone and others must have nutritional supplements to overcome genetic aberrations. But indiscriminate supplementation can be as bad as no supplementation. "After studying the biochemistry of 10,000 persons, I've learned that the greatest mischief is usually caused by nutrients that are stored in excessive amounts, rather than those at depleted levels. The most common nutrients in overload include copper, iron, folic acid, calcium, methionine, manganese, choline, and omega-6 fatty acids."

The role of neurotransmitters in behavior and mood disorders is acknowledged, if not fully understood, by most of today's practitioners. Genetically-aberrant levels of specific neurotransmitters may predispose individuals to such disorders.

Neurotransmitters such as serotonin, dopamine, and norepinephrine used by the brain are built by the brain cells from available nutrients, including amino acids, vitamins, and minerals.

CALCIUM CUTS PMS SYMPTOMS IN HALF

Calcium carbonate -- an inexpensive, widely available supplement -- seems to lessen the symptoms of premenstrual syndrome (PMS), according to a study by Susan Thys-Jacobs, M.D., funded by SmithKline Beecham, maker of Tums. As reported in the August 1998 issue of American Journal of Obstetrics and Gynecology, the controlled study was conducted on 441 women, ages 18 to 45, at 12 health centers nationwide.

The women took either 1,200 mg chewable calcium supplements or placebo daily for three months and measured 17 symptoms including mood swings, irritability, water retention, food cravings, headache and cramping.

Thys-Jacobs and colleagues at Columbia University in New York studied 466 premenopausal women with moderate-to-severe PMS at 12 locations around the U.S. Each woman was randomly assigned to take either 600 mg of calcium carbonate or a calcium-free look-alike placebo twice a day for three menstrual cycles.

At the end of the study, the calcium group experienced an overall 48 percent reduction in symptom severity during the third cycle, while those taking the placebo had a 30 percent reduction.

Nearly all the symptoms improved significantly in the group taking the calcium supplement. Emotional symptoms dropped by 45 percent (vs. 28 percent for placebo), water retention by 36 percent (vs. 24 percent), food cravings by 54 percent (vs. 34 percent) and pain by 54 percent (vs. a 15 percent pain increase). The only symptoms that didn't improve were insomnia and fatigue.

"The concept is that if you are not consuming enough calcium, the regulating hormones increase and go berserk," says Thys-Jacobs, an endocrinologist. The elevated levels of calcium-regulating parathyroid hormone, as well as a form of vitamin B, interact with the hormones estrogen and progesterone, which are more abundant during the latter half of the menstrual cycle. This prompts PMS symptoms.

"It's better to take calcium with meals," she adds, "because it's better absorbed and because there's less risk of kidney stones."

The study corroborates recent evidence that abnormal calcium regulation may be responsible for PMS.

NUTRITIONAL APPROACHES TO AUTISM

The term "autism" is used for a spectrum of mental disorders with a common set of symptoms. An estimated 400,000 children in the U.S. are affected, and figures just released by the California Department of Developmental Services (DDS) point to a 38% increase in professionally diagnosed autism cases entering the system over the last two years.

Unlike mental retardation and cerebral palsy, which are recognizable in infancy, autism strikes toddlers who were apparently normal infants. At one and a half to two years of age, developmental milestones cease to be met, and communication with parents becomes all but nonexistent. Autistic children may be prone to explosive tantrums or repetitive mechanical behavior, like rocking or shutting off all the lights in a

room again and again.

While autism varies in severity, its key features are improper sensory integration, lack of subtlety of emotional expression ("flatness" can quickly give way to agitation) and limited communication ability. Autistic children are seldom able to lead independent lives.

No effective drug therapy for autism has been found. At best, medications can suppress some of the symptoms, and behavior modification techniques have met with mixed results. The early claims of autism pioneer Dr. Bernard Rimland -- that autism could be substantially ameliorated with diet changes and nutrients -- were met with skepticism by professionals.

A mainstay of Rimland's approach was the elimination of sugar and artificial ingredients, coupled with supplementary nutrients, especially B6 and magnesium. To this he later added dimethylglycine (DMG) and treatment for candida (yeast) infection. There has been no shortage of anecdotal evidence, such as parents' success stories, but not until recent developments in metabolic testing and the dissemination of standardized protocols did physicians begin to endorse the nutritional approach.

Researchers have long believed that autism was neurologically "hard-wired" into the brain circuitry of afflicted children. Most guessed that a complex tangle of mixed up switches in the brain were part of the genetic inheritance of autistic kids. But a new model is helping us understand how certain susceptible children may develop autism, why Dr. Rimland's therapies seem to help some of them, and how we can extend hope and help to still others.

The model arises from medicine's new understanding of the relationship between the nervous system and the immune system. Autistic children are thought to suffer from "sensory integration" problems. New findings suggest that their immune systems, too, may be suffering from overload. Increasingly, the nervous system and the immune system are viewed as components of a continuous network that senses and responds to stimuli. Perceptions of stress factors and other sensory input can have an immediate impact on the immune response. Immune system events such as allergic reactions or the fever accompanying an infection have an impact on concentration, level of fatigue, and moods.

Studies now reveal that autistic children, while not all alike, suffer from a wide array of immune system and metabolic abnormalities. The vast majority possess blood profiles that show a high state of immune system activation and dysregulation. Many show numerous food allergies, especially to wheat gluten and milk, and symptoms respond to elimination diets in such cases. In other cases, antibiotics or immunization shots, commonly laced with mercury, have triggered the onset of symptoms.

Immunologist Sudhir Gupta of the University of California at Irvine. infused willing subjects with intravenous gamma globulin, an immune-enhancing formula derived from donated blood plasma. Many of the children experienced profound improvements in mood, concentration, and speech. One child returned to regular classes and team sports. Few subjects failed to respond at least partially to this immune "fix," and plans are underway for further testing at the University of California and Harvard Medical School.

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U.N. REPORT: DEPRESSANTS OVERPRESCRIBED, ABUSED

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International experts say developed countries are using too many prescription drugs, warned the UN International Narcotics Control Board in its 2000 report (BBC News Online, 21 February 2001).

The board examined the use of mood altering drugs like benzodiazepines (such as Xanax and Valium), a family of often addictive prescription sedatives or tranquilizers that suppress the symptoms of anxiety. (Side effects include drowsiness, dizziness, headache, nausea, impaired memory, hallucinations, and confusion.)

It said the drugs were often given for what amount to social problems, such as unemployment or relationship difficulties, in rapidly developing countries such as Malaysia and Singapore as well as established industrial powers.

A survey by the INCB found many patients were prescribed the mood-altering stimulants to treat mental and psychological disorders, even without a diagnosis of mental illness. Loose prescription regulations, aggressive marketing and unethical prescribing were cited as causes.

INCB president Professor Hamid Ghodse said an oversupply of drugs can be as big a problem as the under-supply of pain-relieving drugs to developing countries which last year's report highlighted. "Up to 70% of long-term use of psychotrophic drugs is irrelevant and often prescribed for social reasons."

Online trafficking of drugs on the internet was also cited as a growing problem by the board, which is urging governments to set up regulatory controls for online pharmacies.

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YEAST, ADHD AND EAR INFECTIONS
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According to William G. Crook, M.D., eliminating candida yeast and making dietary changes may offer the longest-lasting cure.

In an article published on healthwell.com, Crook analyzed the phenomenon that many young American children diagnosed as hyperactive are also troubled by recurrent middle ear infections called "otitis media with effusion," or OME. (Otitis media means inflammation of the middle ear, while effusion denotes the escape of a fluid from its natural vessels into a body cavity.)

The usual treatments include broad-spectrum antibiotics -- powerful enough to destroy many good bacteria along with the bad -- and ear tubes. It may take weeks or even months of antibiotic treatment to stave off further infections. Small plastic ear tubes are inserted through the eardrum to ventilate the middle ear when fluid accumulations persist.

The connection between ear infections and hyperactivity was first suggested by a study by researchers from the University of Colorado and Yeshiva University (Hagerman & Falkenstein, Clinical Pediatrics, May 1987). The study of 67 children ages 6-13 who were failing in school showed that children with repeated ear infections are 3.5 times more apt to develop hyperactivity than other children.

In the group, 94% of those medicated for hyperactivity had a history of three or more otitis infections, as compared to 50% of the nonhyperactive children; 69% of the hyperactive children had had more than 10 ear infections, as compared to only 20% of the nonhyperactive ones.

Dr. Crook notes that when "friendly bacteria" in the gastrointestinal tract are killed by antibiotics, an overgrowth of candida albicans is a common consequence. The candida yeast release toxins that weaken the immune system and lead to repeated infections - and, in some cases, wide systemic and nervous system effects.

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ABOUT AlternativeMentalHealth.com
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AlternativeMentalHealth.com is the world's largest web site devoted exclusively to alternative mental health treatments. It includes a directory of over 150 physicians, nutritionists, experts, organizations, and facilities around the U.S. that offer or promote safe, alternative treatments for severe mental symptoms. Many of the physicians listed do in-depth examinations to find the physical causes behind mental problems.

Also included on the site are an array of articles on topics ranging from the medical causes of schizophrenia to the effects of toxic metals on mental health.

A bookstore page lists top books that cover many areas of alternative treatments with titles like Natural Healing for Schizophrenia and Other Common Mental Disorders and No More Ritalin.

AlternativeMentalHealth.com has been created to educate the public, practitioners, and government officials on the medical conditions that create "mental illness" and the many safe resources available for addressing and often curing severe mental symptoms.

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Mary Ann Liebert, Inc.

EDITORIALS

Rigor and Compassion: The Paradoxical Challenge of Peer Review

In the evaluation of what are currently regarded as complementary and alternative medicines (CAMs), there are some things about which there should be no argument. One of these is that the objective evaluation of therapeutic interventions can and must be rigorous, whatever the nature of the treatment modality or system. Certain criteria can and should apply equally across the board, whether the treatments be orthodox or alternative. At all times, investigators must seek to acquire wherever possible and as nearly as possible, complete sets of raw data with pathologic or other confirmations of clinical diagnoses. Missing and/or inadequately defined data is irritating, not only for the meticulous researcher but especially to those people who are trying to understand and interpret what might be occurring, to ponder the imponderables, the unexpected, the hitherto unthought of, the unexplained: the truth. Missing data can make a mockery of hypotheses and interpretations, rendering statistical analyses misleading. Equally, misquoted data, abbreviated reports, or injudicious literature references of statements, figures, and interpretations, can profoundly influence whole generations of care and vast amounts of funding, research policy, and governmental initiatives. This issue of the Journal, the first of 2001, addresses all of these concerns in some controversial, challenging, and forceful papers.

Richardson et al. (pp. 19–32) reveal data-collection discrepancies between two cancer care clinics, one in Mexico and one in San Diego, both offering nonorthodox cancer treatment protocols involving herbal and other dietary supplements. Although there are very interesting and potentially significant survival data regarding patients who had attended either one of the clinics, the data missing from the records of the Mexico center demonstrate that this makes it impossible to draw any conclusion other than that more work needs to be done. The pathologic certification of diagnoses in the cases in the San Diego clinic, however, demonstrate the added value of such confirmation/verification to objective assessment. Until and unless these principles of accuracy and meticulous record keeping are embraced in the evaluation of any intervention, anecdotal evidence will continue to be used against new ideas, rather than being the forerunner and argument for more rigorous exploration. The Richardson et al. study (pp. 19–32) also endorses the cry from many people that longitudinal, pragmatic follow-up studies of patients with careful documentation of their treatment and dietary choices are long overdue. It is heartening that such prospective outcomes monitoring systems are a priority for the National Center for Complementary and Alternative Medicine in the United States. There have been calls for this in the United Kingdom and in Europe for some time now.

These fundamental prerequisites for useful data collection and research are mirrored in the requirements for meaningful peer review and publication. The paper by Morley et al. (pp. 65–78) suggesting misrepresentation and misapplication of the literature on chiropractic, and the response of Professor Ernst (pp. 79–82), the author accused in Morley et al.'s paper, raises very serious questions about the peer-review process, publication bias, and the responsibility of journal editors and their editorial boards. The authority, integrity and objectivity of people who are involved in the peer-review process, especially in the CAM arena where prej-

udice, emotion and preconception run consistently high, is a continual concern. The paper by Morley and his colleagues, all senior practicing chiropractor educators (pp. 65–78), the reply from Professor Ernst (pp. 79–82) as Chair of Complementary Medicine at Exeter, United Kingdom, and the editorial from Marc S. Micozzi, M.D., Ph.D., Chief Executive of the College of Physicians and Surgeons in Philadelphia, PA, (pp. 13–14) all make very serious, hard-hitting, and far-reaching statements and assertions. These authors ask insistent and critical questions, the answers to which are, and will prove to be, unpalatable to many different audiences. But they must be faced. Increasingly, the opinion is that misinformation, misrepresentation, or distortion of the literature is a form of professional misconduct. At a time when the medical profession and medical science in general, particularly the pharmaceutical industry, are undergoing something akin to an inquisition, great care will need to be taken in developing the arguments and proceeding with evaluation.

All agencies are in fact in the dock, and lest there be any misconception among members of the CAM community, moving to center stage will expose all concerned to the spotlight of scrutiny, rigor, and peer pressure. One is reminded of the admonition that people "without blame be responsible for throwing the first stone." However, if stoning be necessary at all, it is perhaps not individuals at all but rather that within us that balks and rejects, or, at best, struggles with evidence that challenges our preconceptions, our "Weltanschauung." CAM is this challenge to medical science and clinical practice in our time. What are emerging are fundamental questions about our humanity and our integrity, for one might argue that the very analogy of stoning only serves to endorse a violent and confrontational paradigm. What is needed is to understand both stoner and stoned. Such a shift would represent a change in consciousness, which, *of itself*, would change outcomes in research and practice.

Michael McIntyre (pp. 9–11), in his editorial, brings to our attention the landmark report from the House of Lords Select Committee on Science and Technology in the United Kingdom (House of Lords, 2000). Although this meticulous and detailed report focuses on what the responses of government, medical science, and the public might be to CAM in the U.K. National Health Service, and educational and research institutions in particular, there can be no doubt that the report's sphere of action and influence will be global. This is a document of international significance. It merits reading by all people who are concerned with the development and practice of patient-centered health care.

However, as McIntyre, carefully demonstrates, their Lordships rendered the report less potent than it might have been by altering their criteria and parameters for evidence once the process of taking evidence was completed (or perhaps even while it was under way) without informing the people to whom the call for evidence had gone. Many who had eagerly awaited the report, knowing of the seriousness, commitment, and scientific credentials of their Lordships, were deeply disappointed. It is a stark reminder of a cardinal rule which all would-be researchers are taught, which is that the parameters to be evaluated and the criteria for evaluation should be determined in advance and then adhered to, because the outcome will be invalid if deviation or alteration takes place in midevaluation. It is to be hoped that there will be a clear, robust, and credible response to the comments that many thoughtful and committed people have made, so that the full scope of the very carefully thoughtout proposals contained within the document might be appreciated and, for the sake of our patients, its positive impact not undermined.

Wiesendanger et al (pp. 45–51) in their paper on the impact of spiritual healing in chronically ill patients take up the issue of pragmatic, meaningful evaluation of highly complex interventions in clinical practice. Not only does their paper, and Wayne Jonas's incisive and informative accompanying editorial (pp. 5–7) raise questions about the nature of the healing encounter, these authors suggest that even the very simplest human contact might have significant consequences on outcome and well-being at what might be very low cost. While it might well be said that all this shows is that good bedside manner works, the question nevertheless remains: "How?"

Alfano et al. (pp. 53–64) present data on the significant impact of two different kinds of magnetic mattress (one with a uniform static negative polarity field and the other with a uniform low static magnetic field, which varied spatially and in polarity) on the pain intensity suffered by patients with fibromyalgia. One wonders to what extent the impact of the interaction of the electromagnetic fields, the "auras," of the healers and patients in Walach's study, or in any good therapeutic consultation, might be responsible for some part of both placebo and nocebo effects. Far too little is known among members of the medical profession as a whole about the effects of magnetic fields, which is perhaps significant in the light of the massive sales of magnetic devices, gadgets, and clothing to the public, as evidenced in the United States $5 billion market referred to by the Nikken group (Nikken, Inc., Irvine, CA). Once again, a potentially powerful confounding variable in the evaluation of clinical trials of orthodox and CAM treatments is emerging; something that we should be taking note of and adding to questionnaires and evaluation protocols immediately.

Shang picks up these themes in his discussion paper about emerging paradigms in mind–body medicine (pp. 83–91). This paper is food for thought and debate, as is the comprehensive report by Gerard Bodeker, Ed.D., the Chairman of the Global Initiative for Traditional Systems (GIFTS) of Health, on the International Conference on Health Research for Development Symposium on Traditional Medicines, hosted by the World Health Organization, the World Bank, The Global Forum for Health Research, and the Council on Health Research for Development (pp. 101–108). The fact that this symposium was requested by the agencies involved as part of its development strategy clearly emphasizes the fact that traditional health systems are now center stage in the exploration of health care development and evaluation. They are a major political issue in the face of escalating Western health care costs. In the last U.S. administration, a task force on Complementary and Alternative Medicine was established by former President Clinton. One wonders how the incoming administration will respond to the phenomenon of CAM. In the light of the policies debated in public, there is evidently concern that industrial biotechnology and pharmaceuticals will dominate the agenda in the face of the public demand for humanizing medical science. Integrated health care is not about "cherry picking," technique acquisition, and medical appropriation. It is to be hoped that the United States under its new leadership will not lose the momentum it has established in exploring these issues, an exploration of which is influencing developments elsewhere in the world.

In the light of globalization and enhanced communications, we are always in danger of, and already are victims of, information overload. The potential to perpetrate misinformation on a massive scale is enhanced with global communications systems and unfettered access to data sources. This is, of course, nothing new. It is simply a matter of scale and extent in this electronic age. The task now must be to fight with all our might to preserve the fundamental tenets of science in expressing and researching the art of practice, to preserve academic and personal integrity, to debate energetically, with passion, as far as possible, with an open mind, and to stand as stoner and stoned in learning to observe with compassion.

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Kim A. Jobst, M.A., D.M., M.R.C.P., M.F.Hom.
Editor- in-Chief

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Assessment of Outcomes at Alternative Medicine Cancer Clinics: A Feasibility Study

MARY ANN RICHARDSON, Dr.Ph.,[1] NANCY C. RUSSELL, M.P.H.,[2]
TINA SANDERS, M.S.,[3] ROBERT BARRETT, Ph.D.,[4] and
CATHERINE SALVESON, R.N., Ph.D.[5]

ABSTRACT

Objective: This pilot study tested the feasibility of performing outcomes and more advanced research regarding cancer patients at two complementary and alternative (CAM) clinics. The primary objectives were to determine the feasibility of (1) obtaining and collecting data from medical records, (2) determining 5-year survival, and (3) comparing 5-year survival to that of conventional treatment. In addition, in this paper we present the barriers and recommend strategies to facilitate high-quality research.

Settings/Location: The Bio-Medical Center in Tijuana, Mexico, and the Livingston Foundation Medical Center in San Diego, California.

Subjects: New patients who were treated for cancer during 1992 at the Livingston Foundation Medical Center and during the first quarter of 1992 at the Bio-Medical Center.

Results: Charts were available for 89.6% of the 307 new patients treated at the Bio-Medical Center; 149 (54%) patients were treated for cancer and 65 (43.6%) cases were confirmed by pathology reports. In contrast, all records were available for 193 new patients treated for cancer at the Livingston Clinic; 152 (78.8%) cases had pathology confirmation. At both clinics, patients were equally divided by gender and were predominantly Caucasian, were married, and were U.S. residents. On average, patients were 51–54 years old and within 1 year of diagnosis for breast, colorectal, lung, or male genital cancer. Most patients (61.1%–63.7%) arrived with distant or regional disease after conventional surgery and/or chemotherapy/radiotherapy. Survival at 5 years was determined for 57.0% at the Bio-Medical Center (11.4% were alive and 45.6% were deceased) and 94.8% at Livingston (14.5% were alive and 80.3% were deceased). The limited number of cases by cancer site prevented comparison to conventional treatment.

Conclusions: Historical, widespread use of clinics such as these with anecdotal reports of extraordinary survival merit prospective, systematic monitoring of patient outcomes. For data to be meaningful, however, disease status must be pathologically confirmed and patient follow-up improved.

[1]University of Texas—Center for Alternative Medicine Research, The University of Texas—Houston Health Science Center School of Public Health, Houston, TX.
[2]Department of Symptom Control and Palliative Care, The University of Texas M.D. Anderson Cancer Center, Houston, TX.
[3]Center for Health Promotion, Research and Development, The University of Texas—Houston Health Science Center School of Public Health, Houston, TX.
[4]Executive Director, Livingston Foundation Medical Center, San Diego, CA.
[5]School of Nursing, Oregon Health Sciences University, Portland, OR.

INTRODUCTION

Cancer is accompanied by fear and hope (Durant, 1998; Hoey, 1998), reflecting the well-known toxicities and sometime limited efficacy of conventional cancer treatment. Although patients may seek alternative approaches before conventional treatment, most patients turn to alternatives after the disease progresses or recurs despite conventional treatment or when conventional approaches have nothing further to offer. Two established clinics that have provided alternative cancer treatment for more than three decades are the Livingston Foundation Medical Center in San Diego, California, and the Bio-Medical Center in Tijuana, Mexico. Neither clinic offers surgery, radiation, or chemotherapy, but both recommend conventional treatments on occasion.

As many as 69% of cancer patients in the United States use complementary/alternative medicine (Richardson et al., 2000), most in combination with conventional therapies (Burstein et al., 1999; Lerner and Kennedy, 1992; McGinnis, 1991). Generally, users tend to be more affluent, better-educated, younger women and are patients who are currently receiving or post-chemotherapy or surgery (Lee et al., 2000; Lerner and Kennedy, 1992; Richardson et al., 2000). In surveys across 13 countries, the prevalence of complementary and alternative (CAM) use by cancer patients ranges from 7% to 64% (Ernst and Cassileth, 1998). According to the world literature, many patients do not begin CAM treatments until 4–6 months after diagnosis at a time when treatment outcomes may be uncertain (Risberg et al., 1995; Verhoef et al., 1999). However, other patients seek alternatives at later stages of advanced disease (Fernandez et al., 1998; Grothey et al., 1998; Lerner and Kennedy, 1992; Risberg et al., 1995; Sollner et al., 1997) or when the risk of death at diagnosis is higher (Sawyer et al., 1994), after recurrence or progression (Lerner and Kennedy, 1992; Sawyer et al., 1994; Sollner et al., 1997), or when palliation is the only option (Risberg et al., 1995).

The concern that patients abandon conventional treatment in favor of CAM arose in the early 1980s when a study reported that 40% of patients discontinued conventional care after using CAM treatments for 8 months (Cassileth et al., 1984). However, the sample was not representative of cancer patients in general because half of the patients were recruited at CAM clinics. In sharp contrast, the literature confirms that few patients abandon conventional care (McGinnis, 1991) and 60%–80% combine CAM with conventional cancer treatment (Arkko et al., 1980; Fernandez et al., 1998; Grothey et al., 1998; Jirillo et al., 1996; Lerner and Kennedy, 1992; Liu et al., 1997; Mottonen and Uhari, 1997; Neogi and Oza, 1998; Richardson et al., 2000; Sawyer et al., 1994; Verhoef et al., 1999; Weis et al., 1998).

The established medical community is demanding regulations and insisting that the promotion and sale of alternative therapies be subjected to the same standards of evaluation as other therapies (Angell and Kassirer, 1998; Levin et al., 1997). Because interest in these approaches is here to stay, scientific testing is the next logical step (Hoey, 1998; Jonas, 1998; Richardson, 1999). Therefore, our center (University of Texas Center for Alternative Medicine Research [UT-CAM]) visited two popular alternative health clinics to determine the feasibility of conducting outcomes and more advanced research.

BACKGROUND OF THE CLINICS

Bio-Medical Center

Since 1963, the Bio-Medical Center has treated cancer patients with an herbal tonic, external powders, and diet. The story of Harry Hoxsey (1901–1974), developer of the treatment, provides a historical perspective of the controversy and mistrust between the conventional and alternative communities. His story has been documented in a film (Ausubel, 1987), an autobiography (Hoxsey, 1956), books (Ausubel, 2000; Moss, 1998), articles (Brinker, 1995), and government reports (Office of Technology Assessment [OTA], 1990; Workshop on Alternative Medicine, 1992).

Although a similar tonic was used in the 1800s to treat syphilis, Hoxsey promoted his tonic as a cancer cure in the 1920s (Brinker, 1995). By the mid-1950s, the treatment was available at 17 clinics across the United States.

When the Food and Drug Administration closed the facilities, the head nurse of the Hoxsey operation, Mildred Nelson, R.N., established a clinic in Tijuana to provide the treatment to cancer patients. Ms. Nelson had initially believed that Hoxsey was a fraud; however, she became an advocate after observing her mother recover from advanced, untreatable uterine cancer with his tonic.

This proprietary tonic reportedly contains potassium iodide, red clover (*Trifolium pratense*), licorice (*Glycyrrhiza glabra*) root, burdock (*Arctium lappa*), stillingia (*Stillingia sylvatica*) root, pokeroot (*Phytolacca americana*), cascara (*Cascara sagrada*), barberry (*Berberis vulgaris*), prickly ash bark (*Zanthoxylum americanum*), and buckthorn (*Rhamnus catharticus*) bark. However, at least one reference does not include the prickly ash bark, and buckthorn bark (Brinker, 1995). As part of a comprehensive treatment plan, patients must follow a special diet that may be supplemented with yeast tablets, vitamins, garlic (*Allium sativum*), thymus-gland extract, liver, superoxide dismutase, dimethylsulfoxide, bacille Calmette-Guerin (BCG) vaccine, vitamins, *Aloe vera*, and bovine cartilage (Brinker, 1995; Duke, 1988–1989); Moss, 1992; OTA, 1990). Topical powders and pastes are sometimes prescribed for patients who have melanomas or tumors that are near the surface of the skin (Brinker, 1995).

Approximately 1200 patients are treated annually, but many of those are being treated for conditions other than cancer or are receiving follow-up cancer care. The first visits are 1–3 days, and follow-up visits are scheduled at 3–6-month intervals. Patients complete laboratory assessments in the mornings prior to meeting physicians in the afternoons. The staff at this outpatient facility includes four physicians, four nurses, and a radiologist. The clinic site houses a laboratory for standard blood analyses, an X-ray machine, computed axial tomography (CAT) scan equipment, and a facility for preparing the tonic and salves.

Several herbs in the formula contain anticancer or immune-stimulating properties (Bodger et al., 1979; Hoshi et al., 1976; Kitagawa et al., 1986; Kupchan and Karim, 1976; Morita et al., 1984; Pineyro-Lopez et al., 1994). Favorable historical and laboratory evidence of anticancer activity for several components of the tonic was summarized in an Office of Technology Assessment (OTA) report by historian, Patricia Spain Ward, Ph.D. (Ward, 1988). Furthermore, external caustic pastes were once part of a conventional treatment for skin cancer (i.e., Moh's chemotherapy) before being replaced by surgical excisions (OTA, 1990).

No clinical trials have been conducted with the Hoxsey approach; however, an observational study conducted in 1983–1984 followed 39 consecutive cancer patients for 5 years (Austin et al., 1994). Follow-up was monitored annually by questionnaires that were mailed to the patients, but 58.9% of patients were lost to follow-up by the fifth year. For the 16 patients who were monitored, 6 patients (37.5%) lived 58 months with cancers of the lung, melanomas, bladder cancers, and labial cancers. The authors concluded that these cancer sites might be candidates for further evaluation. In contrast, the 10 deceased patients had survived 15.4 months.

Livingston Foundation Medical Center

The Livingston Foundation Medical Center was established in 1969 to offer an immune-based treatment developed by Virginia Livingston-Wheeler, M.D. Approximately 250–400 patients are treated annually, primarily for cancer. Patients are required to complete an intake questionnaire, sign a patient-care consent form, and provide copies of all medical records (i.e., operative, pathology, laboratory, and ultrasound, CAT scan, and magnetic resonance imaging [MRI]).

According to Dr. Livingston-Wheeler, cancer is associated with the *Progenitor cryptocides* bacteria (Wheeler and Wheeler, 1977). She developed vaccines to enhance natural immunity and supplemented them with the BCG vaccine and a multifaceted treatment including a vegetarian diet, vitamins, antioxidants, detoxification, nutritional counseling, and support groups or individualized counseling. The center is an outpatient facility but contains a laboratory certified by the Clinical Laboratory Improvement Act (federally mandated oversight certification) and the California State Depart-

ment of Health Services. Routine clinical assessments are contracted to SmithKlein Beecham (San Diego, CA) Laboratories, and specific assessment of immune function, antioxidant capacity, and vitamin levels are contracted to Immunoscience Laboratories in Los Angeles, California.

Although more than 10,000 patients have been treated at this clinic in the past 30 years, only two studies have assessed the efficacy of the regimen. Dr. Livingston-Wheeler conducted a retrospective review of 62 patients who were treated for pathologically confirmed cancer between 1972 and 1982. Most of the patients had distant metastases and recurrent colorectal, breast, or lung disease; however, she reported an 82% success rate in her review entitled "100 Random Case Histories" (Livingston-Wheeler and Addeo, 1984). If one excludes 38 patients who did not have cancer or arrived after the cutoff date, however, only 39 of the 62 eligible cancer patients were followed for a 5-year survival of 64% (n = 25/39).

A prospective cohort study evaluated survival and quality of life for 78 pairs of patients who had extensive disease and an expected survival of less than 1 year. Patients at the Livingston clinic were matched for gender, race, age, diagnosis, and time from diagnosis of metastatic or recurrent disease with external controls from the University of Pennsylvania Cancer Center, Philadelphia. All patients were followed at intervals of 2 months until death. Survival did not differ for the groups; however, quality of life was lower for the Livingston patients at pretest and posttest and deteriorated at an equal rate for both groups (Cassileth et al., 1991).

PURPOSE

Given the limited data on clinical outcomes at these widely used CAM clinics, the aim of this pilot study was to determine the feasibility of conducting a historical cohort study. Specifically, this study assessed the feasibility of (1) collecting demographic, diagnostic, treatment, and other clinical data from the patient records. By targeting a cohort of patients treated in 1992, we assessed the feasibility of (2) determining 5-year survival, and ultimately (3) comparing survival to that of patients who were treated solely with conventional therapy in the United States. Survival of patients, rather than tumor response, symptomatic improvement, or quality of life was selected as the outcome variable because this outcome was the only one expected to be uniformly available.

MATERIALS AND METHODS

The UT Houston Health Science Center's Institutional Review Board (IRB) approved the study, and both clinics provided written approval as part of the IRB approval process. The study was initiated in June of 1997 by the UT-CAM research team, consisting of the center's director and two research assistants. The director has a doctorate in Public Health, experience in data collection, and expertise in research methodology. The senior research assistant has a master's degree in Public Health, expertise in oncology research, and more than 15 years of experience working in the tumor registry at the University of Texas M.D. Anderson Cancer Center, Houston, Texas. The third member of the team has a master's degree in biometry with training in data management and analysis. At the Livingston clinic, a certified tumor registrar and member of the California tumor registry reviewed charts to determine stage of disease at the time of initial diagnosis, but all other data were collected previously by this registrar as part of standard reporting procedures required by the state of California. At the Bio-Medical clinic, a professor of nursing research at the Oregon Health Sciences Center, who is experienced in all phases of research, identified new patients, supervised the collection of charts, and assisted with the data-extraction process.

At both clinics, we collected data items that are routinely collected by cancer registries that are accredited by the Commission on Cancer and the Surveillance Epidemiology and End-point Results (SEER), a U.S. population–based cancer registry maintained by the National Cancer Institute (Commission on Cancer, 1995;

Miller et al., 1993). These data items include demographics (i.e., age, gender, ethnicity, and residence), disease status (i.e., date of diagnosis, pathology, grade, stage, site of primary tumor, metastases), and types of previous treatment (i.e., surgery, chemotherapy, radiotherapy, immunotherapy, endocrine therapy). We also collected contact information and clinical outcomes (i.e., verification of cancer status, date of last contact, and vital status at last contact) from the medical records. All data were collected from history and physical documents; progress notes; laboratory, pathology, or cytology reports; and diagnostic imaging reports (i.e., X-rays, CAT scans, or MRIs). Information on compliance with the alternative treatment was not available.

We relied on reports by physicians and other sources for stage of disease documentation and on pathology reports for confirmation of cancer diagnosis. For information on prior treatment, we relied on our review of the medical charts; however, treatment response prior to conventional or current treatment at the Bio-Medical Center was not consistently available. For patients who had a known cancer status at the time of their last visits to the clinic, we recorded the type(s) of diagnostic verification. At the Livingston clinic, the California Tumor Registry had collected data on the status of residual tumors after initial surgery but not on response to subsequent treatment. Therefore, the registrar conducted a second review to determine the stage of disease at arrival to the Livingston clinic.

To determine clinical and vital status outcomes at 5 years, UT-CAM first searched the computerized 1998 Social Security Death Index to identify patients who were deceased. Then, the clinic director mailed a letter to each patient who was thought to be alive. The letter introduced the UT-CAM study and informed former patients that a member of that research team would be contacting them to discuss their medical treatments and health status. Attempts were made to contact all patients who were considered to be alive. During the interviews of patients, we asked about their compliance with the alternative treatments, current health and cancer status, and date of their most recent check-ups, type of diagnostic tests, and concurrent and/or subsequent conventional or other alternative treatments.

Analysis

The Kaplan-Meier survival method provided by SPSS Base 9.0 (SPSS for Windows 9.0, 1998) was used to calculate the risk analysis and summarize the time between initial diagnosis and death or last contact. According to SEER, at least 25 cases are needed to calculate valid survival rates (Miller et al., 1993). Survival time for cancer patients is usually calculated from the time of diagnosis until death or last contact when alive. This method was used for patients who had a known diagnosis date. However, survival should also be calculated from the time of arrival at the CAM clinic to eliminate the possible "lag time" bias that occurs from diagnosis to CAM treatment. Information on the lag time from diagnosis to initial conventional treatment was unavailable from the SEER database, so we were unable to make this comparison. The problem associated with lag time is usually eliminated at oncology centers by restricting the analysis to patients who have had no prior treatment. Because most patients who seek CAM services have received prior conventional treatment, such an approach is not feasible. Therefore, we assessed survival time as the time from admission to the CAM clinic until last contact. With enough cases, the lag time from diagnosis to treatment can be controlled by a statistical procedure. When information on date of death was limited to the year only, we assigned July as the month of death to reflect a midpoint.

RESULTS

Feasibility of collecting information from patient records

The Bio-Medical Center maintains a patient registry and medical charts with information on diagnostic test results and treatment summaries, including notes by Bio-Medical physicians, appointment schedules, and other con-

tacts. Many of the charts were incomplete, handwritten notes were illegible, and outside reports were not consistently collected.

A total of 307 new patients were treated during the first quarter of 1992. Of those, 275 records were available, and 149 patients (54.2%) were treated for cancer. The clinic contained limited documentation on patient outcomes, and most charts did not have social security numbers or birth dates. Thus, patient follow-up was limited to 65.9% or 64 of the 97 patients who were last known to be alive. This follow-up represents an unacceptably low percentage in comparison to the 80% standard set by most tumor registries (Commission on Cancer, 1995).

In contrast, charts for all 193 new patients treated for cancer at the Livingston clinic were available and contained all data required by the California Cancer Registry. Specifically, the tumor registry requires demographic data and information on the method of diagnosis, site and type of cancer, stage of disease, previous and current treatment, and cancer status after initial treatment. The charts also contained social security numbers and birth dates that allowed us to identify patients in the Social Security Death Index.

TABLE 1. CHARACTERISTICS OF NEW CANCER PATIENTS BY CLINIC DURING 1992

Demographics	*Bio-Medical Center*[a] *(n = 149)*	*Livingston Foundation Medical Center (n = 193)*
Gender		
Men/boys	67 (45.0%)	92 (47.7%)
Women/girls	82 (55.0%)	101 (52.3%)
	At treatment	*At diagnosis*
Age		
Mean (SD, range)	51.0 years (SD 16.3; 3–83)	54 (SD 14.5; 2–85)
Ethnicity		
Caucasian	129 (89.0%)	181 (93.8%)
Hispanic	8 (5.5%)	5 (2.6%)
African-American	6 (4.1%)	2 (1.0%)
Asian	2 (1.4%)	4 (2.1%)
American Indian	0 (0.0%)	1 (1.0%)
Missing	(n = 4)	–
Marital status		
Single	9 (8.7%)	15 (7.9%)
Married	79 (76.7%)	143 (75.3%)
Separated	2 (1.9%)	1 (0.5%)
Divorced	7 (6.8%)	12 (6.3%)
Widowed	6 (5.8%)	19 (10.0%)
Missing	(n = 46)	(n = 3)
Residence		
U.S.	124 (83.2%)	167 (86.5%)
Other	25 (16.8%)	26 (13.5%)
Religion		
Protestant	39 (28.7%)	–
Jehovah's Witness	32 (23.5%)	–
Catholic	23 (16.9%)	–
Jewish	3 (2.2%)	–
Amish	1 (0.7%)	–
Quaker	1 (0.7%)	–
Other	24 (17.6%)	–
None	13 (9.6%)	–
Missing	(n = 13)	–

[a]Treated during the first quarter only.
SD, standard deviation.

Patient characteristics

Bio-Medical Center. Of the 149 patients who were treated for malignant disease during the first quarter for 1992, the average age was 51 years (standard deviation [SD] 16.3; range 3–83) and 55% were women. Most patients were Caucasian (89.0%), married (76.7%), and residents of the United States (83.2%). The clinic director stated that many patients refused chemotherapy and radiotherapy because of religious beliefs. This anecdotal report was supported by the following documentation on religious affiliation: Jehovah's Witness (23.5%), Amish (0.7%), and Quaker (0.7%). (See Table 1.)

Most (93.9%) patients had one malignant primary tumor, specifically breast (18.1%), colorectal (10.0%), respiratory (10.1%), male genital (8.7%), or central nervous system (8.8%). (See Table 2.)

Less than half (43.6%) of the records contained pathology reports, but 4.0% had cytology reports, and 0.7% contained hematology reports. According to the SEER staging guidelines, 40.3% of patients arrived at the clinic with distant and 20.8% with regional disease; the remainder of patients presented with local (22.1%) disease, an unknown stage (10.7%), or no evidence of disease (6.0%). Of the 109 patients with a known date of diagnosis, 66.1% arrived within 1 year of diagnosis. (See Table 3.)

Information on previous treatment was available in 94.0% of the records. Overall, 53.7% (n = 80) were treated via surgery and 48.3% (n = 72) received chemotherapy and/or radiotherapy. For patients treated via surgery, 15.0% received radiation, 23.8% chemotherapy, and 18.8% received radiation and chemotherapy. For the 60 patients who were not treated via surgery, 11.7% received radiation, 16.7% received chemotherapy, and 10.0% received radiation and chemotherapy. Of the 9 patients (6.0%) for whom previous surgery was unknown, 2 received chemotherapy and 1 received radiation and chemotherapy.

To determine 5 year survival status of the 149 cancer patients treated at the Bio-Medical center, we documented 52 deaths by either the Social Security Death index (n = 40) or clinic sources (n = 12). For the remaining 97 patients last known as alive, we were able to contact 33 patients or family members to learn the patients' vital status in the past or current year (1997–1998). Thus, we were able to verify the 5-year vital status for 85 (57.0%) of the Bio-Medical patients. We determined that 17 (11.4%) were alive, 68 (45.6%) had died, and 64 (42.9%) were unknown. Survival analysis was

TABLE 2. CANCER SITE AT ADMISSION BY CLINIC

Cancer Site Group	*Bio-Medical Center*[a] *(n = 149)*	*Livingston Foundation Medical Center (n = 193)*
	N (%)	*n (%)*
Breast	27 (18.1%)	43 (22.3%)
Reproductive Tract	22 (14.8%)	34 (17.6%)
(n = women/men)	(n = 9/13)	(n = 10/24)
Lymphoma/leukemia	17 (11.4%)	15 (7.8%)
Colorectal	15 (10.1%)	26 (13.5%)
Respiratory	15 (10.0%)	25 (13.0%)
Brain/eye/nervous system	13 (8.8%)	3 (1.6%)
Skin	10 (6.7%)	5 (2.6%)
Endocrine	5 (3.4%)	3 (1.6%)
Pancreas	3 (2.0%)	12 (6.2%)
Stomach/small intestine	5 (3.4%)	3 (1.6%)
Bone including multiple myeloma	3 (2.0%)	5 (2.6%)
Head/neck	2 (1.3%)	2 (1.0%)
Liver/gallbladder/biliary tract	1 (0.7%)	7 (3.6%)
Urinary system	0 (0.0%)	5 (2.6%)
Ill-defined/unspecified	11 (7.4%)	5 (2.6%)

[a]Includes 4 patients with basal or squamous carcinoma.

TABLE 3. TIME FROM DIAGNOSIS TO CAM TREATMENT BY SEER STAGE OF DISEASE AT ARRIVAL

Time: Diagnosis to CAM Treatment	*SEER stage of disease at arrival*				
	Local	*Regional*	*Distant*	*No evidence of disease*	*Total n (%)*
Bio-Medical Center (missing diagnosis date and/or stage of disease n = 40)					
0–6 months	24	17	21	5	67 (61.0%)
7 months–1 year	2	2	3	1	8 (7.3%)
13 months–2 years	1	6	5	1	13 (11.9%)
25 months–4 years	3	2	9	1	15 (13.8%)
More than 4 years	0	2	4	0	6 (5.5%)
Total n (%)	30 (27.5%)	29 (26.6%)	42 (38.5%)	8 (7.3%)	109 (100%)
Livingston Foundation Medical Center (missing diagnosis date and/or stage of disease n = 26)					
0–6 months	11	14	30	6	61 (36.5%)
7 months–1 year	3	3	19	1	26 (15.6%)
13 months–2 years	1	6	26	1	34 (20.4%)
25 months–4 years	0	6	24	0	30 (17.9%)
More than 4 years	0	1	15	0	16 (9.6%)
Total	15 (9.0%)	30 (17.9%)	114 (68.3%)	8 (4.8%)	167 (100%)

not possible because of the large number of patients with an unknown vital status in the fifth year. (See Figure 1.)

Livingston clinic. Of the 193 new patients treated at the Livingston clinic during the 1992, the average age was 54 years (SD 14.5; range 2–85), and 52.3% were women. Most patients were Caucasian (93.8%), married (75.3%), and residents of the United States (86.5%). Religion was not required by the California Cancer Registry, recorded by the Livingston clinic, or indicated as a reason for seeking this treatment. (See Table 1.)

The majority (78.8%) of the records contained pathology reports. Most patients (91.2%) had

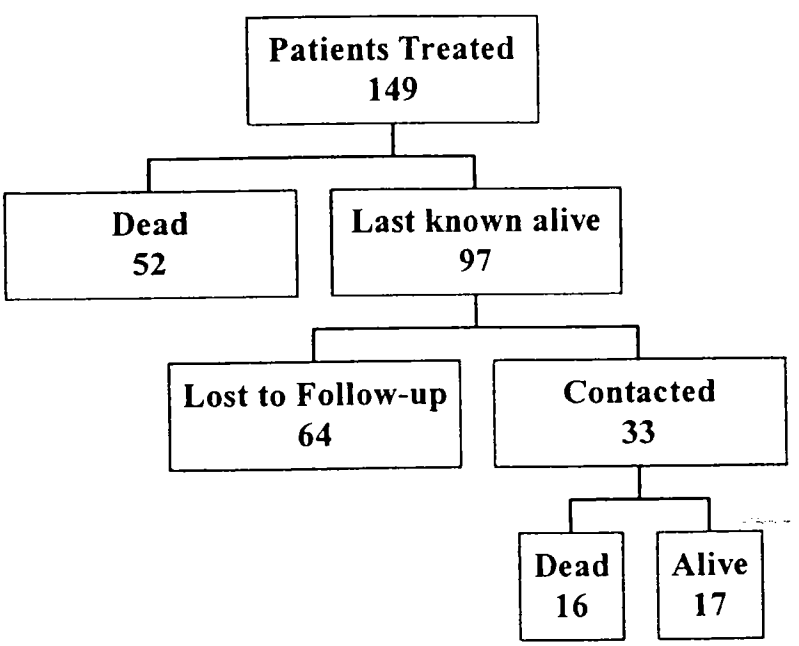

FIG. 1. Follow-up status of cancer patients treated at the Bio-Medical Clinic—first quarter of 1992.

TABLE 4. RESIDUAL TUMOR AFTER SURGICAL RESECTION OF PRIMARY TUMOR BY STAGE AT ADMISSION TO LIVINGSTON FOUNDATION MEDICAL CENTER (n = 82)[a]

	Stage group					
Residual tumor after first surgery	*Local*	*Regional*	*Distant*	*Tumor removed, NED*	*Unknown*	*Total*
None						
Count	4	14	47	6	2	73
Row %	5.5%	19.2%	64.4%	8.2%	2.7%	100.0%
Column %	80.0%	87.5%	92.2%	85.7%	66.7%	89.0%
Microscopic						
Count	0	1	1	1	1	4
Row %	0%	25.0%	25.0%	25.0%	25.0%	100.0%
Column %	0%	6.3%	2.0%	14.3%	33.3%	4.9%
Macroscopic						
Count	1	1	37	0	0	5
Row %	20.0%	20.0%	60.0%	0%	0%	100.0%
Column %	20.0%	6.3%	5.9%	0%	0%	6.1%
Total						
Count	5	16	51	7	3	82
Row %	6.1%	19.5%	62.2%	8.5%	3.7%	100.0%
Column %	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

[a]Tumor status unknown (n = 34); no surgery for primary (n = 77). NED, no evidence of disease.

one malignant primary tumor, specifically breast (22.3%), colorectal (13.5%), male genital (12.4%), or lung (13.0%). (See Table 2.) The tumor registrar recorded the residual tumor status following initial surgery for the 82 patients who received surgical resection of their primary tumors. Residual tumor status was unknown for 34 patients, and the remaining 77 patients did not receive surgery for primary tumors. After surgery, 73 patients had no evidence of tumors, 4 patients had microscopic tumors, and 5 patients had macroscopic tumors. (See Table 4.)

At the time of arrival to the Livingston clinic, the stage of disease had changed for most patients. According to SEER staging guidelines, 63.7% of patients arrived with distant disease; the others arrived with local (8.3%) or regional (16.1%) disease post-surgery, no evidence of disease (4.1%), or unknown stage (7.8%). For the 167 patients with known diagnosis date and stage, 54.1% arrived at the clinic within 1 year of their cancer diagnoses. (See Table 3.)

Overall, 55.4% of the patients were treated via surgery, and 50.3% had received chemotherapy and/or radiotherapy prior to attending the Livingston clinic. Specifically, 107 patients (55.4%) received prior surgery and, of those, 24.3% received chemotherapy, 15.0% received radiation, and 13.1% received radiation and chemotherapy. Of the 79 patients (40.9%) who were not treated via surgery, 15.2% received chemotherapy, 19.0% received radiation, and 11.4% received radiation and chemotherapy. Of the seven patients (3.6%) for whom previous surgery was unknown, one received chemotherapy and four received radiation and chemotherapy.

In order to assess 5-year survival, we documented 131 deaths by either the Social Security Death index (n = 37) or clinic sources (n = 94). For the remaining 62 patients last known as alive, the clinic contacted 24 patients or family members (17 dead and 7 alive) and UT-CAM contacted 28 patients or family members (7 dead and 21 alive). Thus, the 5-year vital status was verified for 183 (94.8%) of the 193 Livingston patients. We determined that 28 (14.5%) were alive, 155 (80.3%) had died, and 10 (5.2%) were unknown. (See Figure 2.) Because 9 of the 10 patients lost to follow-up were from outside the United States, we limited the survival analysis to the subset of 167 residents of the United States, yielding a known vital status for 99.4%. An unknown year of death for one patient could only be estimated within the last 4 years; therefore, this individual was cen-

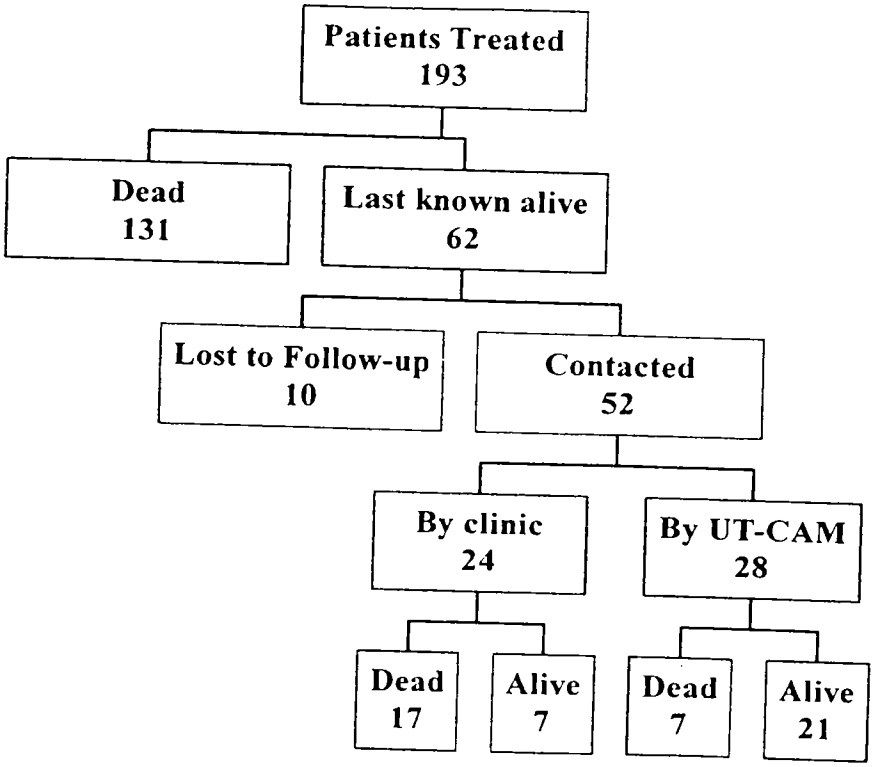

FIG. 2. Follow-up status of cancer patients treated at Livingston Foundation Medical Center in 1992.

sored (i.e., designated as being alive as of the last contact).

Interviews of patients and families

Although we could not assess survival for the overall group of patients treated at the Bio-Medical Center, responses from the 17 patients and 16 families of deceased Bio-Medical Center patients that we were able to contact indicated that the treatment was beneficial (n = 11), not beneficial (n = 11), or too late to help (n = 3). However, two patients did not use the tonic, and six family members would not comment. Among patients, nine reported definite benefits. One patient with melanoma of the eye experienced a regression after using the tonic for 10 months whereas two patients reported dramatic drops in prostate specific antigen (i.e., 98–0.1 and 13.9–0.4) with the tonic only. One patient did not use the tonic because she feared that it was harmful, and seven reported no benefits. The Bio-Medical Center recommends a special diet and the tonic indefinitely; however, only four patients were complying with this recommendation, and two were following a modified diet. Among family members, two reported the tonic extended survival, four reported no benefits, three believed the tonic was started too late, and one stated that the tonic was not used.

Although the Livingston clinic contacted 24 patients and family members, the clinic did not conduct interviews to assess perceived benefit or compliance. Therefore, we present the findings from the interviews conducted by UT-CAM. Responses from 21 patients, six family members, and one neighbor of deceased patients treated at the Livingston clinic indicated that the treatment was beneficial (n = 18), not beneficial (n = 4), or uncertain of benefit (n = 4), too late to help (n = 1), or unknown (n = 1). Of the 21 patients contacted, two patients had been told by conventional physicians that they had only a few months to live but were alive at 5 years; one had been treated for a grade III, local-stage astrocytoma of the brain and the other for colon cancer. For the remaining patients, three reported the treatment was of no benefit and three were uncertain of a benefit. Ten patients were following the Livingston diet, and five had adopted a modified diet. Of

TABLE 5. MEDIAN AND PROPORTIONAL 5-YEAR SURVIVAL FROM DIAGNOSIS AND ADMISSION TO LIVINGSTON FOUNDATION MEDICAL CENTER (n = 167)[a]

Site by stage at arrival n = known diagnosis date/total	*Median survival: Months (95% CI)*		*5-Year Survival % (n = surviving/total)*	
	Diagnosis	*Admission*	*Diagnosis*	*Admission*
Overall	29 (22, 36)	8 (5, 11)	17% (27/155)	17% (28/167)
Distant disease				
Prostate (n = 8/9)	34 (22, 46)	20 (0, 43)	25% (2/8)	33% (3/9)
Breast (n = 22/25)	42 (33, 51)	10 (8, 12)	36% (8/22)	12% (3/25)
Colorectal (n = 12/13)	22 (15, 29)	5 (3, 7)	0% (0/12)	0% (0/13)
Lung (n = 18/18)	12 (8, 16)	4 (3, 5)	6% (1/18)	0% (0/18)

[a]167 of 193 patients were U.S. citizens for whom it was possible to follow-up for survival status.
CI, confidence interval.

the family members contacted, three reported a benefit and one each cited no benefit, uncertainty of a benefit, or that the tonic was started too late.

Survival for the Livingston patients

For the 167 U.S. patients, the cumulative proportion with 5-year survival from the time of treatment at the Livingston clinic (not diagnosis) was 18.9%. The only cancer site adequately represented with sufficient cases to allow stage-specific survival analysis was distant breast disease (n = 25); however, survival for patients with prostate (n = 9), colorectal (n = 12), and lung (n = 18) cancers are also presented.

The proportion of breast-cancer patients with distant stage who were surviving at 5 years from time of arrival at the Livingston clinic was 12%, and 36% from time of diagnosis. For prostate-cancer patients, 25% of eight patients with known diagnosis dates had survived 5 years from diagnosis and 33% of nine patients survived 5 years from admission. No patients with distant colorectal cancer survived 5 years from either diagnosis or admission. Only one patient with lung cancer survived beyond 5 years from diagnosis, and none survived five years from admission. (See Table 5.)

Of the 101 patients who presented with distant disease, 7.9% (n = 8) survived 5 or more years from admission with carcinomas of the prostate (n = 3), breast (n = 3), non-Hodgkins' lymphoma (n = 1), and cystadenocarcinoma of the ovary (n = 1). One patient with advanced pancreatic cancer survived 19 months from admission and 21 months from diagnosis.

DISCUSSION

As part of the first step towards assessing CAM approaches scientifically, this feasibility study represents one of the first field investigations to document systematically clinical outcomes at the Bio-Medical and Livingston clinics. Based on our review of the medical records, this feasibility study determined that demographic, clinical, and treatment data could be collected from the medical records maintained by Livingston, but not from those of the Bio-Medical Clinic. The Livingston clinic has an excellent record-keeping system. At the Bio-Medical Center, however, data required for outcomes follow-up was not complete. Furthermore, vital status at 5 years was determined for only 57.0% of the patients, indicating a need for improved patient follow-up at the Bio-Medical Center. In contrast, 5-year follow-up was 94.8% at the Livingston clinic and may reflect, in part, reporting requirements of the California Tumor Registry. Survival status of Livingston patients could not be compared to those of SEER because of the limited number of patients with each cancer site.

Information on additional conventional and/or unconventional medical use following treatment at the clinics was missing but should be collected. Furthermore, our telephone interviews determined that 7 of the 21 patients had

been treated with conventional medical approaches after receiving treatment at the Livingston clinic; however, the extent of additional conventional treatment among deceased patients was unknown. Such a problem is not unique to CAM clinics. Patients in conventional cancer treatment centers often receive subsequent conventional or unconventional treatment after initial treatment. Nevertheless, documentation of subsequent treatment must be monitored by the CAM clinics. We acknowledge that such a time-intensive effort is rarely achieved at most conventional cancer centers, but this level of documentation is necessary to eliminate confounding factors and critical to assess the benefit of CAM.

Furthermore, the CAM clinics must assess stage of disease at arrival rather than rely on stage of disease at diagnosis and confirm disease status (i.e., pathological reports). Although the majority of patients are in the first year of diagnosis, many have received prior conventional treatment before arriving to the CAM clinics and therefore, their disease stages have changed. The timing of treatment at the CAM clinics presents a potential lag time bias; however, the Cox proportional hazard model can control for time from diagnosis to CAM treatment (i.e., lag time) by using time-dependent covariates.

To facilitate outcome assessment, CAM clinics such as the Bio-Medical Center will need to collect complete information at intake using recognized cancer data items (i.e., date of diagnosis, pathology, grade, stage, site of primary tumor and metastases, prior treatment). In addition, information such as birth dates and social security numbers will be necessary to allow patient follow-up. An assessment of patient outcomes will not be possible until a system is established to collect admission and follow-up data consistently and systematically. Such a monitoring system is necessary because more than 600 new cancer patients travel to Tijuana each year to seek treatment at this clinic.

A best-case series or prospective monitoring of patients is justified not only because of the public health issue and investment of many patients in this course of treatment, but also because of several noteworthy cases of survival. One such case involved a patient from Australia who met with the research team while being treated for recurrent melanoma of the leg. For the past 7 years, she had used the tonic and powder only. In a small observational study, skin melanoma was cited as one cancer site for possible monitoring based on a limited number of cases (Austin et al., 1994). The recommendation to monitor patients with melanoma also was confirmed anecdotally by Mildred Nelson, R.N., Clinic Director, who stated that these patients respond to a treatment consisting of the tonic and external paste only.*

For patients treated at the Livingston clinic, we did not attempt a comparison to SEER because of the small number of patients in each stage and site-specific group. To achieve adequate numbers, an expanded cohort of patients treated over multiple years will be necessary. In the one cited study of the Livingston therapy, patients for whom conventional treatment has failed and who were treated at the clinic were compared to external controls who were treated with conventional treatment only. Survival rates were comparable for both groups, but the results have been misinterpreted to suggest that quality of life was lower after treatment at the Livingston clinic. Instead, the findings clearly demonstrated that patients who sought CAM after conventional treatment reported a lower quality of life at pretest than patients who were willing to receive standard care only. During the course of treatment, however, quality of life declined at a similar rate for both groups.

Between 1992 and 1995, most patients who sought treatment at the Livingston clinic had regional or distant disease, were in the first year of their cancer diagnoses and had received conventional treatment (i.e., surgery, radiotherapy, and/or chemotherapy). The demographics may have changed during the past 5 years, however. Given the volume of patients who have visited this CAM clinic over the past three decades, it is critical to establish a monitoring system to determine the relative merits of the treatment approach, including quality of life.

One possible approach to monitor the treatment benefit is with a Prospective Outcomes

*Personal communication, Mildred Nelson, R.N.

Monitoring System (POMES). The approach was first proposed by the National Center for Complementary/Alternative Medicine and assessed in a workshop cosponsored by the National Cancer Institute. According to the process, documents that could confirm the cancer diagnosis, compliance with the unconventional treatment, and follow-up clinical status and course of the disease would be necessary. Although the Livingston clinic is committed to additional research to document outcomes, the Bio-Medical Clinic's ability and commitment to establish a prospective monitoring system, standardize the herbal tonic for clinical research, or assemble a best-case series is unclear since the death of Ms. Nelson in 1998.

CONCLUSION

In summary, this feasibility study found that quality survival analysis or any other qualitative assessments of clinical benefit at these clinics will require improved record-keeping systems. We have documented the process and procedures necessary to assemble this data, discussed barriers, and presented strategies to facilitate future outcome assessment and data analysis. Given the current interest in CAM and the growing demand by patients for reliable information on the benefit of these treatments, documentation and outcome assessment are critical. With systematic evaluation of clinical outcomes, we can move the field of alternative medicine into evidence-based medicine for the twenty-first century.

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Address reprint requests to:
Mary Ann Richardson, Dr.Ph.
The National Institutes of Health
Center for Alternative and Complementary
Medicine 6707 Democracy Boulevard, #106
Bethesda, MD 20892-5475

E-mail: marich@mail.nih.gov

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Mary Ann Liebert, Inc.

The White House Commission on Complementary and Alternative Medicine Policy: Meeting on the Access to, and Delivery of, Complementary and Alternative Medicine Services

JACQUELINE C. WOOTTON, M.Ed.

The second full meeting on Access and Delivery of Complementary and Alternative Medicine (CAM) Services took place in Washington, D.C., on Monday and Tuesday, December 4th and 5th, 2000. The White House Commission was established by President Clinton in March 2000 to develop a set of legislative and administrative policy recommendations to maximize the benefits of CAM practices and products for the general public. The Commission has a charge to submit a report to the new President and Congress by March 2002. Information about the Commission, the now nineteen commissioners, and the future schedule of full meetings and Town Hall meetings can be found on the Commission's Web site at: http://www.whccamp.hhs.gov/ A final appointment, bringing the number of commissioners to twenty, will shortly be announced and posted on the Web site. All meetings are open to members of the public.

There cannot be many Capitol Hill meetings that start with a period of meditation. The basic structure of the room and the proceedings followed the usual committee format but, at the meeting I attended, there was no sense of constrained formality. Jim Gordon, M.D., is a sensitive and empathic chair who initiated the meditation. Steven Groft, Pharm.D., the Executive Director, was the first acting director of the Office of Alternative Medicine at the National Institutes of Health (NIH). He and his team knowledgeably, yet unobtrusively, ensure a smooth, focused operation. The commissioners are warm, caring, and dedicated.

During the 2 days, expert witnesses were called to make written and verbal presentations. In an open session, preregistered members of the public had an opportunity to comment. Some familiar wrangles and long-standing tensions were aired at this gathering but the mood was positive. Gone were the acrimonious exchanges of the early years of the NIH Office of Alternative Medicine. There was a new feeling of tolerance, compassion, and good humor rather than a jaded sense of "here we go again."

Therapists frequently feel squeezed out of the process of integration. Those who spoke at this meeting argued persuasively that the art of, for example, an acupuncturist is a result of long, high-level training and cannot be learned or understood in a few weeks by a physician. Many expressed the view that the M.D.s are dominating the movement to integrate. On the other hand, some physicians were sensitive to the CAM practitioners views and eager to work with the therapists on an assumption of parity. It was clear from the commissioners' reactions that they do not believe that "one size fits all" and that there is need and room in the future for a pragmatic mix of therapist-led integrative centers employing some conventional physicians, to physician-led centers with referrals to practitioners.

There was strong recognition from testimo-

Alternative Medicine Foundation, Bethesda, MD.

nials that the public spearheaded the campaign for health freedom, and that it is demanding choice; that it needs clear, impartial information and access to research results, and that it is quite capable of making its own health decisions. Nonetheless, there seemed to be a degree of consensus that health freedom depends on agreed standards of delivery, accreditation, and recognition.

Health insurance and managed care organizations are aware of the public pressure. Representatives who spoke admitted that the economics of provision are still being worked out. There were interesting examples of coverage and state schemes to study as prototypes for future policy directions. Wellness practices were also recognized as a crucial element of any health plan and a future meeting of the commission will be devoted entirely to the topic of wellness.

ACCESSIBILITY—AFFORDABILITY—ACCOUNTABILITY

The commissioners include therapists, physicians, educators, trainers, businessmen, and businesswomen, and represent different ethnic groups and interests. Their questioning of experts and public, interspersed with their input throughout the day, was respectful but incisive, emanating from their own expertise rather than promoting personal agendas. There was just 1 hour left at the end of the 2-day meeting for the Commission to discuss, barely enough time for each to make a brief final comment. There was no time for any indepth discussion and debate. It is to be hoped that time is allotted elsewhere for this.

In the final discussion, there was a plea for spreading the mission wider to consult with environmentalists, economists, large companies, and schools. How, one asked, is it possible to talk about wellness while we have "sick building" syndrome? The theme was echoed. How can children learn healthy habits if wellness is not on the curriculum? How can families and communities be healthy without access to health care as a right? It was agreed to explore the issue of universal health coverage and cost in future meetings.

However, the concept of access was seen as broader than a set of legal rights. Accessibility, they agreed, is about creating a caring, sharing system, in which patients can enter into a partnership in decision making, and in which there is recognition of spirituality and diverse ethnic values. When modern health care is perceived as cold and uncaring, one opined, the wide interest in CAM may be, in part, a symptom of the problems of the system.

Affordability, likewise, was seen as not just a question of reimbursement systems. It was felt that cost accounting is counterproductive if there is no time for a healing relationship. Health education, wellness practices, and prevention were seen as crucial elements of a truly cost-effective system and reimbursement policies as a function of the values and needs of the consumers.

Accountability can sound cold and legalistic. One discussant put the concept in the context of a consumer-centered health support system, pointing out that there is a need to respect and to protect both consumers and providers by defining standards and ensuring the quality of products, services, and information. A final comment was that exploring and defining these underlying philosophical principles will help to articulate the specific recommendations for policy and practice.

I was left with a warm glow despite the lack of substance. One commissioner spoke for all in saying that it was time to take a major step forward. However, this message was in the medium, the format, and the style, rather than in any clear action agenda. I look forward to further meetings and a strong report with clear and feasible recommendations.

Address reprint requests to:
Jacqueline C. Wootton, M.Ed.
Executive Editor
Journal of Alternative and Complementary Medicine
5411 West Cedar Lane, #205A
Bethesda, MD 20814

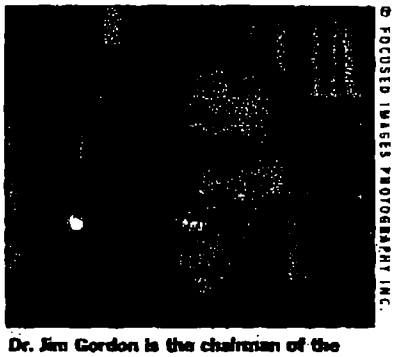
E-mail: jacm@amfoundation.org

Examining alternative medicines

3-2001

By Lauran Neergaard SENIOR BEACON

The 55-year-old sinus cancer patient refused surgery and instead bought unregulated pills touted on the Internet to fight tumors. Four months later, he was dead — not from his still-present cancer, but from



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Dr. Jim Gordon is the chairman of the White House Commission on Complementary and Alternative Medicine Policy. He is a psychiatrist with the Center for Mind/Body Medicine in Washington.

liver and kidney failure that an autopsy blames on those pills.

An estimated four in 10 Americans use some form of alternative medicine, from acupuncture or hypnosis, to herbs or Internet-touted wonder remedies. Some may work; in fact, some of the nation's best-known hospitals have begun offering certain alternative remedies.

But others can be quackery or outright dangerous. How is a patient to know the difference?

A presidential commission is traveling the country on a two-year quest to determine how to help doctors and consumers sort out what works, what doesn't, and what's too risky — and to integrate alternative remedies that do prove effective into mainstream health care.

Stacking the deck?

It's an ambitious effort, funded with $2 million in taxpayer dollars, designed to recommend to Congress a national policy on alternative therapies.

But it's drawing fire from some critics who complain the White House Commission on Complementary and Alternative Medicine Policy is packed with proponents of the unconventional.

That doesn't mean they champion all alternative remedies, insists commission chairman Dr. James Gordon, a psychiatrist whose Center for Mind/Body Medicine in Washington often works with local doctors.

"What I'm interested in is what works for people . . . what has the fewest harmful side effects," said Gordon, who offers everything from well-tested acupuncture to the admittedly "far-out, strange treatment" of putting a rheumatoid arthritis sufferer on a week long watermelon-only diet.

"We want to protect the public health," said Dr. Joseph Fins of New York-Presbyterian Hospital, one of three commissioners who doesn't practice or promote alternative therapies. "There is a healthy amount of skepticism."

But doctors who are reluctant to learn about alternatives "need to appreciate that there is this other parallel universe out there," Fins said. Millions of Americans are currently using remedies without their physicians' knowledge and do so with no source of unbiased information about safety and effectiveness.

Sometimes those choices prove fatal. In January, doctors reported in the *Annals of Internal Medicine* about the 55-year-old who died from hydrazine sulfate, a controversial, unregulated chemical. While such severe toxicity seems rare, National Cancer Institute studies say hydrazine sulfate doesn't fight cancer.

Other studies suggest certain treatments may work, but are risky if used the wrong way. For example, the herb St. John's wort, widely used to treat mild depression, can dull the effectiveness of birth control pills as well as drugs for cancer, AIDS and organ transplants. But how many U.S. doctors are trained enough about alternative remedies to know that?

Combining therapies

Some top hospitals have begun offering certain unconventional remedies as "complementary therapy" — add-ons to traditional medicine, when studies show they help.

Boston's Beth Israel Deaconness Hospital, for instance, recently reported that patients suffer significantly less pain during surgery when using self-hypnotic relaxation. And the University of California, Los Angeles, employs acupuncturists to treat children's pain.

But there is little science behind other alternative remedies. The National Institutes of Health is spending tens of millions of dollars this year testing some of them, including the first U.S. multicenter study of the effectiveness of glucosamine/chondroitin for arthritis.

It is also systematically reviewing the clinical evidence for other alternative treatments, such as the use of milk thistle for liver disease and cirrhosis.

Proof may be years in coming, but the White House commission is charged with determining how to ensure doctors and patients learn about the available evidence — and if something works, to explore how to pay for it.

Indeed, at meetings in Seattle, San Francisco and Washington, alternative practitioners — including a controversial cancer doctor who has faced scrutiny for pushing coffee enemas and pancreatic enzymes — have touted untested remedies and begged for funds.

But don't expect a push to pay for alternative remedies before getting Medicare to pay for proven disease-fighting medications, cautioned Fins. Will other commissioners agree? The panel's first draft report to Congress is due in July.

Learn more about the White House Commission on Complementary and Alternative Medicine Policy by visiting its Web site: www.whccamp.hhs.gov. The National Center for Complementary and Alternative Medicine at NIH can be reached toll-free at 888-644-6226 or online at http://nccam.nih.gov.

—AP

NCCAM

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

TO	Dr Stene Graft
ORGANIZATION	White House Commission
FAX NUMBER	480-1691
PHONE	435-7592
DATE	3/14/01
FROM	*B. Anita Greene* *Press Communications Program Officer* *Telephone: 301-496-1712* *Facsimile: 301-480-0311* *Email: ag19d@nih.gov*
PAGES (INCLUDING THIS PAGE)	
NOTES/COMMENTS	FYI Stene, Lauran Neergaard is a reporter with the Associated Press. She has traditionally been very critical of CAM. I've dealt with her a few times

OFFICE OF SCIENCE POLICY, COMMUNICATIONS AND PUBLIC LIAISON
31 CENTER DRIVE, BUILDING 31, ROOM 5B38, BETHESDA, MD 20892
TELEPHONE: 301-496-6701, FACSIMILE: 301-480-3519

Groft, Stephen (NCCAM)

From: Greene, Anita (NCCAM)
Sent: Friday, March 30, 2001 10:05 AM
To: Straus, Stephen (NCCAM); Groft, Stephen (NCCAM); Hussey, Doug (NCCAM); Sabatos, Charles (NCCAM); Hoover, Camille (NCCAM)
Subject: State Legislation and the Use of CAM

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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AMERICAN PREVENTIVE MEDICAL ASSOCIATION

P.O. Box 458 • Great Falls, Virginia 22066 • 703.759.0662 • Fax 703.759.6711 • www.apma.net

copy to Steve

February 27, 2001

Dr. James Gordon
White House Commission on Complementary
And Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010
Bethesda, Maryland 20892

Dear Jim:

As you requested, I have given considerable thought to specific legislative recommendations that we would like the Commission to propose. Dozens of action steps were suggested in the *National Plan to Advance Integrated Health Care,* of course, and it is difficult to choose from among so many worthwhile issues. On behalf of the American Preventive Medical Association, I would like to suggest the following top three:

1. First and foremost, we would like to see passage of the Access to Medical Treatment Act. I included a copy of last year's version (S. 1955) with my testimony. It will be reintroduced early in the 107th Congress, with only minor revisions. This legislation would, in one fell swoop, dramatically increase the health care options of Americans and, at the same time, expand consumer protection. The bill creates a federal statutory right for consumers to use whatever therapy or device they prefer, even if it is not approved by the FDA. This would give Americans access to therapies approved and used overseas, but not available here. It would also allow U.S. physicians to offer therapies they know to be safe and effective, without fear of losing their licenses. In addition, it would ensure that patients see authorized health care practitioners and benefit from informed consent procedures, instead of resorting to black market products or having to travel to other countries for medical attention that may or may not be regulated.

2. We would also like to see non-discrimination clauses included in all federal health care initiatives to ensure that patients have access to a broad array of practitioners, products and services. If, for instance, diabetics are eligible for nutrition counseling under Medicare/caid, they should not be restricted to getting that counseling only from registered dietitians. Medical doctors, nutritionists, osteopaths, naturopaths and chiropractors may all be capable of providing that service, but the Federal Government

actually prohibits it by restricting coverage to one practitioner type. This selective approval works against the integration of CAM practitioners into the health care system, marginalizes well-trained individuals, and serves only to support a monopoly by one practitioner group instead of guaranteeing the intent of the legislation, which is access to a desirable, beneficial and cost saving service.

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Sincerely,

Candace Campbell

Candace Campbell
Executive Director

cc: Stephen Groft , Pharm.D.
Executive Director

D/A (CRO)

Marc Blumenthal,

Groft, Steve (NCCAM)

From: Stoneberger, Amanda (NICHD)

Sent: Wednesday, August 30, 2000 7:13 AM

To: Groft, Steve (NCCAM)

Cc: Plummer, Mary (NICHD)

Subject: Linnea Larson

Hi, Steve. Has a CV come in for ~~Linnea Larson~~? We have no information on her and can't find her on the internet searches.

Thanks,
Mandy

Freddie Ann Hoffman

1150 Conn Av

www.CHPA-info.org

o Consumer Health Care Products Industry Assoc

202-429-9260

Bill ~~Soller~~ Soller Ph.D CHPA Senior VP, Dir

CRN = Council for Responsible Nutrition / Dietary

Annette Dickinson Ph.D

202-872-1488

o American Herbal Products Assoc

Joe Betz, Ph.D Dir VP Sci Aff

301-588-1171

o Grocery Manufacturers Assoc

Natl Food Assoc

Floyd Leaders

Varro E Tyler

American Health Prod

Samuel Nixon

Loren Israelson - Utah -

Daniel Eskey 212-551-2523

Floyd Leaders

301-840-3930

Tony Martinez

Am Botanical Council

512-926-4900 x102

Marc Blumenthal

East Earth Herb Company

Peggy Brevoort -

73512.133@compuserve.com

CAM Grey

Am Cancer Society

404-329-7785

Terri Ades RN

* Pfizer — Dr Jasjit Bindra (Ph.D) medicinal Chem
Groton Ct 860 441 3815 (nutraceuticals)

Smith Kline Beecham —
(alum/Valerian Product) entire to do Better Products

Novartis —

* J + J — Debra Bowen
(McNeil) OTC

Whitehall Robbins
All Products / Bayer - Herbal

Monsanto
Dupont
Boehringer Ingelheim

AMERICAN PREVENTIVE MEDICAL ASSOCIATION

P.O. Box 458 • Great Falls, Virginia 22066 • 703.759.0662 • Fax 703.759.6711 • www.apma.net

February 27, 2001

Dr. James Gordon
White House Commission on Complementary
And Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010
Bethesda, Maryland 20892

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Executive Director

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Working DRAFT

Complementary and Alternative Medicine Laboratory Tests

JUNE GIBBS BROWN
Inspector General

DECEMBER 2000
OEI-05-00-00250

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452 as amended by Public Law 100-504, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Chicago Regional Office prepared this report under the direction of William Moran, Regional Inspector General and Natalie Coen, Deputy Regional Inspector General. Principal OEI staff included:

REGION

John Traczyk, *Team Leader*
Susan Otter, *Lead Analyst*
Dennis Tharp, *Analyst*

HEADQUARTERS

Bambi Straw, *Program Specialist*

EXECUTIVE SUMMARY

PURPOSE

To examine how the Health Care Financing Administration (HCFA) regulates laboratories conducting Live Blood Cell Analysis and other complementary and alternative laboratory tests.

BACKGROUND

Complementary and alternative medicine (CAM) encompasses a broad range of philosophies and treatments not widely accepted by western medicine. In the 1990's, HCFA began to identify laboratory sites doing complementary and alternative medicine laboratory tests. One such test, Live Blood Cell Analysis (LBA), uses a drop of blood from a patient's finger. The blood is placed on a slide and viewed under a specialized microscope connected to a video monitor. Testing of this type is regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and HCFA is responsible for its implementation. This report discusses the problems encountered in trying to regulate complementary and alternative medicine laboratory testing, particularly LBA.

FINDINGS

Complementary and Alternative Medical Laboratory Testing Cannot Meet CLIA Requirements

An unknown, but perhaps significant, number of complementary and alternative medicine laboratories may be operating without CLIA certification. Of the 200 CAM laboratories, we identified during this study, 80 percent do not have a CLIA certificate. The HCFA has difficulty identifying laboratories that perform complementary and alternative medicine tests. Getting these laboratories to comply with CLIA requirements is difficult. The program relies on laboratories to identify themselves for enrollment voluntarily but CAM laboratories have few, if any, incentives to do so. The HCFA has no administrative remedies that would permit them to take action against laboratories that refuse to enroll or comply with the Federal law.

To date, laboratories conducting Live Blood Cell Analysis have not been able to meet all CLIA requirements. Many LBA providers are nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. Laboratories performing LBA are also unable to meet requirements pertaining to the

establishment and verification of test method. Consequently, the remaining laboratories identified as offering LBA may be improperly operating outside their CLIA certificate.

Some Laboratories Performing Live Blood Cell Analysis May Have Been Improperly Issued CLIA Certificates

The HCFA may be unaware that laboratories with waived or provider-performed microscopy CLIA certificates are conducting complementary and alternative laboratory testing. Obtaining these types of certificates is relatively easy. Applications from laboratories do not require disclosure of CAM testing, and laboratories seeking waived and provider-performed microscopy certificates are not routinely visited. Consequently, HCFA may never discover that these laboratories are performing LBA and that they may have been improperly issued a CLIA certificate.

Laboratories that perform LBA and other CAM testing and apply for a certificate of compliance to conduct complex testing are more likely to be detected and have their certificate revoked because CLIA surveyors routinely visit them. However, this process is resource intensive and may take up to 3 years to complete. All CLIA laboratories that conduct complementary and alternative medicine tests do so outside the scope of their certificate. These certified laboratories should not be performing LBA and may be violating the law.

State Agency and Complementary and Alternative Medicine Respondents Believe Testing Should Be Regulated, but They Differ on How this Should Be Accomplished

Most State agencies believe that CLIA regulation of LBA laboratories would help to ensure the quality of testing and help protect patients from unscrupulous providers. Two-thirds of State agencies believe that HCFA should change CLIA policies to better address CAM testing. Most complementary and alternative medicine providers agree that LBA should be regulated to protect patients, but feel that the CLIA program is the wrong entity to do this.

Few States Restrict Complementary and Alternative Medicine Laboratory Testing and Oversight by Other Federal Agencies Is Limited

The CLIA program plays the primary role in oversight of laboratories. State laws and other Federal regulations may affect laboratories, but only HCFA is responsible for overseeing the quality of testing performed at every laboratory. Many States place restrictions on who can order and receive laboratory test results, but only a few have laws that prohibit non standardized laboratory testing. Other Federal agencies enforce regulations that affect the marketing of laboratory equipment, advertising claims, and disposal of biohazardous materials but these agencies have no direct impact on tests provided to patients.

OPPORTUNITIES FOR IMPROVEMENT

The growth and acceptance of complementary and alternative medicine poses challenges not only to HCFA but also to other Department of Health and Human Service (HHS) regulatory bodies. Conflict exists between established rules and regulations inherent in HHS systems and the public's desire for access to complementary and alternative medicine.

The Department, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health and the Health Care Financing Administration, will need to decide how best to protect consumers in a changing health care arena.

If the Department determines that CLIA is the appropriate structure for regulating complementary and alternative medicine laboratory tests it should:

Take action to improve and enforce current CLIA policies and procedures for addressing laboratories performing complementary and alternative medicine tests.

If the Department does not wish to enforce CLIA compliance and wishes to allow access to complementary and alternative medicine laboratory testing while still protecting the public, it must consider approaches such as the following:

Change the current law or regulations to create a special regulatory category within CLIA for complementary and alternative medicine laboratory tests, or

Establish a new regulatory agency and program to oversee complementary and alternative medicine laboratory testing.

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INTRODUCTION

PURPOSE

To examine how the Health Care Financing Administration (HCFA) regulates laboratories conducting Live Blood Cell Analysis and other complementary and alternative laboratory tests.

BACKGROUND

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). The CLIA law establishes "quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed." The HCFA is responsible for implementing CLIA, including laboratory registration, fee collection, onsite surveys and enforcement. The HCFA contracts with State Agencies and professional organizations to carry out the provisions of the law.

Under current law, all laboratories except those specifically exempted by law, must be CLIA certified to perform testing on human specimens. The CLIA regulations define a laboratory as:

> *"[A] facility for the . . . examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body."*

The CLIA regulations exempt some laboratories from regulation. Forensic laboratories, drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration and some Federal laboratories are exempt from CLIA regulation. Research laboratories that do not report patient test results to physicians and patients are also exempt from CLIA regulation.

As of July 2000, nearly 170,000 laboratories were registered under CLIA. About 86,500 laboratories have been issued a certificate of waiver. These laboratories only perform simple laboratory procedures cleared by the Food and Drug Administration. Laboratory surveyors do not make routine visits to them to ensure compliance with CLIA requirements.

Approximately 36,000 laboratories hold provider performed microscopy certificates. These certificates are issued to physicians and other approved providers who meet CLIA requirements to perform certain moderate level microscopic procedures. In addition to specified microscopic procedures, providers issued this type of certificate can also perform waived tests. As with laboratories issued a Certificate of Waiver, laboratories issued a Certificate for Provider-Performed Microscopy Procedures are not routinely visited under the CLIA program.

The remaining 41,500 laboratories conduct moderate or high complexity testing. They have been issued a Certificate of Compliance or a Certificate of Accreditation. All laboratories conducting moderate and high complexity testing are required to meet specific CLIA requirements. When these laboratories apply for certification they are issued a Certificate of Registration that enables them to participate in the Medicare and Medicaid program until an onsite visit can be conducted to verify compliance with CLIA standards. They are then issued a Certificate of Compliance. State and accrediting agency surveyors revisit these laboratories at least every 2 years to ensure continued compliance with CLIA requirements.

Types of CLIA Certificates

Certificate of Waiver
This certificate is issued to laboratories that only perform tests approved for home use or that employ methodologies that are so simple and accurate the likelihood of erroneous results is negligible or they pose no reasonable risk of harm to the patient if the test is performed incorrectly. These laboratories are not routinely visited.

Certificate for Provider-Performed Microscopy (PPM) Procedures
This certificate is issued to laboratories where a physician or other qualified provider performs specific microscopic procedures permitted by CLIA. Laboratories with PPM certificates are also permitted to perform waived tests. These laboratories are not routinely visited.

Certificate of Registration
This certificate is issued to laboratories that conduct moderate or high complexity testing or both. This certificate is issued when a laboratory's application is accepted by CLIA and is valid until the laboratory is surveyed.

Certificate of Compliance
This certificates is issued after a laboratory is surveyed and found to be in compliance with all applicable CLIA requirements. Onsite visits to these laboratories are routinely made to ensure compliance.

Complementary and Alternative Medicine

The National Institutes of Health (NIH) defines complementary and alternative medicine (CAM) as "those treatments and healthcare practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies." According to NIH, complementary and alternative medicine covers a "broad range of healing philosophies, . . . approaches, and therapies that mainstream Western

(conventional) medicine does not commonly use, accept, study, understand, or make available."

Studies estimate that between ten and 40 percent of the population uses some form of CAM treatment. One study asserts that more than 42 percent of Americans used an alternative therapy in 1997, up from about 33 percent in 1990. This study also claims that, in 1997, Americans spent more than $27 billion on these therapies. A more recent study argues that only 10 percent of Americans use CAM treatments and that expenditures are lower than previous studies suggest.

The number of providers that promote complementary and alternative medicine may be increasing. Most CAM providers are largely unregulated by States or the Federal Government. Little data exists about the types of complementary and alternative medicine treatments and services being provided to the public. Even less is known about the use of complementary and alternative medicine laboratory services. Information suggests that complementary and alternative medicine laboratory tests are a very small segment of the overall CAM marketplace.

Federal Efforts to Address Complementary and Alternative Medicine

There has been a growing Federal interest in complementary and alternative medicine. Except for HCFA's efforts, the Federal focus had not been on CAM laboratory services but on broader issues such as public access to complementary and alternative medicine treatments, patient protection and evaluation of CAM treatments.

In 1992, NIH established the Office of Alternative Medicine to facilitate and coordinate "the evaluation of alternative medical treatment modalities through research projects and other initiatives." In 1998, that office became the National Center for Complementary and Alternative Medicine through Congressional mandate.

The Congress has also expressed an interest in consumer access to complementary and alternative medicine treatments and in ensuring patient safety. In 1999, the House proposed the Access to Medical Treatment Act (H.R.2635), and a similar bill (S.1955) was introduced in the Senate. The Access to Medical Treatment Act would establish provisions to allow consumers freedom to choose alternative therapies while protecting patients from dangerous and ineffective treatments. Both of these bills have been referred to committee.

On March 7, 2000, the President established The White House Commission on Complementary and Alternative Medicine Policy. The Commission was established "to develop a set of legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine practices and products for the general public."

Live Blood Cell Analysis

The HCFA has identified several complementary and alternative medicine laboratory tests that use blood, urine and saliva. One such laboratory test, Live Blood Cell Analysis, uses a drop of blood from a patient's finger. The blood is placed on a slide and viewed while the cells are alive using a specialized microscope connected to a video monitor.[1] The video monitor allows patients to view their blood cells while the provider describes substances found in the blood sample. Some providers use results to assess nutritional deficiencies, to outline a course of treatment or to assess the effects of treatment. Other providers may use LBA for other purposes.

Under current regulations, meeting all CLIA requirements for certification is virtually impossible for a laboratory performing LBA. Many LBA providers are nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. Facilities performing Live Blood Cell Analysis must also meet CLIA requirements for high complexity testing including patient test management, proficiency testing, quality control, and quality assurance.

Every high complexity laboratory must establish and verify every test method used in the laboratory. Establishing and verifying a test method is usually demonstrated, in part, by 1) comparing the new test results with the results obtained from established methods, 2) testing samples of known value, and 3) testing the same sample multiple times to see if the results are comparable.

Laboratories are required to run quality control samples to ensure that a test is working correctly from day to day. The laboratory must also verify test accuracy by participating in a proficiency testing program. Because LBA is performed on freshly drawn blood samples, it is much more difficult to comply with these CLIA quality assurance requirements.

HCFA's Efforts to Address Live Blood Cell Analysis

In 1995, HCFA created a work group to address regulation of Live Blood Cell Analysis and other CAM laboratory tests. The work group asked their Office of General Counsel and the Centers for Disease Control and Prevention (CDC) for assistance in understanding what role, if any, the program should play in regulating laboratories conducting Live Blood Cell Analysis. The Office of General Counsel advised HCFA that laboratories conducting LBA are subject to all CLIA requirements. The CDC determined that laboratories performing this test must meet all of the requirements for laboratories conducting high complexity testing. The HCFA posted the CDC and Office of General Counsel findings in a Special Alert on their website.

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[1] The laboratory method used for LBA is also used in CAM tests with the following names: Peripheral Blood Assessment, High Resolution Blood Morphology, High Resolution Microscopy, Live Cell Analysis, Live Blood Demonstration, Unchanged Blood Analysis, Vital Hematology, darkfield microscopy and nutritional microscopy.

The work group developed guidelines for State surveyors to help them apply CLIA regulations to laboratories conducting LBA. The work group has also asked States and their regional offices to provide them with information on laboratories identified as providing LBA and other complementary and alternative medicine tests.

METHODOLOGY

For the purposes of this study, we will use the phrase "complementary and alternative laboratory tests" (or "CAM tests") to mean laboratory testing procedures that are not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies. Although we collected some information on other complementary and alternative medicine laboratory tests, we focused this report on LBA because it is the CAM test most often encountered by CLIA personnel, and because HCFA has made an effort to address how this test should be regulated by the program.

This inspection examines how HCFA addresses laboratories performing LBA and other complementary and alternative medicine tests. This study does not address the validity or accuracy of LBA or any other CAM laboratory test. Nothing in this report should be construed as an endorsement or condemnation of any CAM laboratory test.

We reviewed CLIA regulations, policies and procedures to determine how they relate to laboratories conducting Live Blood Cell Analysis and other CAM tests. We interviewed HCFA central office staff and regional office staff in five regions. We discussed CLIA enrollment and certification processes, and staff experiences relating to LBA testing and CAM laboratory sites. Similar discussions were held with representatives from the College on Office Laboratory Accreditation, the Joint Commission on Accreditation of Healthcare Organizations and the College of American Pathologists. These accrediting organizations were contacted because they have contracts with HCFA to provide survey and certification services for some laboratories.

We contacted the State agencies responsible for carrying out the CLIA provisions in all 50 States, the District of Columbia and Puerto Rico. We conducted in-person interviews with State CLIA staff in the District of Columbia and 11 States: Arizona, California, Delaware, Illinois, Kansas, Maryland, Missouri, New Jersey, New York, Pennsylvania and Wisconsin. We discussed CLIA enrollment and certification processes and obtained information and opinions about CLIA regulation of CAM laboratories. The remaining 39 States and Puerto Rico completed written surveys. Overall, we have 52 State agency respondents.[2]

[2] Collectively, the respondents from the 50 States, the District of Columbia, and Puerto Rico will be referred to as "State Agencies" or "States" in this inspection report.

To identify facilities offering LBA, we solicited information from HCFA central and regional offices, State agencies and the three accrediting organizations. We also used Internet searches to identify manufacturers, instructors, promoters and practitioners of LBA. We were unable to obtain reliable data to determine the total number of laboratory sites performing LBA or other CAM laboratory tests. From the information we obtained, we compiled a list of laboratory sites conducting LBA in the United States.

To obtain the perspective of those involved in complementary and alternative medicine, we interviewed people involved in LBA laboratory testing. We contacted industry representatives identified as manufacturing, promoting or offering Live Blood Cell Analysis. Of the 38 potential respondents that we attempted to contact, 18 agreed to participate in this study. Others could not be contacted or were unable to meet with us.

We also interviewed staff at CDC, NIH, the Food and Drug Administration, the Federal Trade Commission, and the Occupational Safety and Health Administration. These agencies were identified by State agencies and HCFA staff as playing a role in regulating CAM laboratory tests. We conducted these interviews to determine what, if any, oversight responsibility each agency has in relation to laboratory testing.

FINDINGS

Complementary and alternative medical laboratory testing cannot meet CLIA requirements

An unknown, but perhaps significant, number of LBA sites operate without CLIA certificates

We identified 200 laboratories in 38 States that purport to offer Live Blood Cell Analysis or other complementary and alternative laboratory tests. One hundred fifteen sites were identified using information we received from HCFA and State CLIA surveyors. We believe that the remaining 85 sites have not been identified by HCFA and State survey staff.

We asked industry representatives to estimate the number of laboratories offering LBA. One respondent claims to have trained 300 to 400 American physicians to conduct LBA. Another respondent stated that he had trained about 3,000 practitioners. Based on his knowledge of the industry, this respondent estimates that between 10,000 and 15,000 sites may be conducting LBA in the United States.

We checked the names and addresses of the 200 CAM laboratory sites we identified during this inspection against CLIA enrollment records. We found that nearly 80 percent did not have a CLIA certificate. The remaining sites were certified by the CLIA program. They had been issued Certificates of Waiver, Certificates for Provider-Performed Microscopy Procedures and Certificates of Compliance. Some of these certificates were revoked when HCFA discovered that they were doing LBA. Other certificates remain in effect because the laboratory has assured HCFA that it has ceased performing LBA.

When a non-certified CAM laboratory is identified, the laboratory is sent a letter advising them to cease testing and to apply for CLIA certification if they wish to resume testing. State agency respondents suspect that some CAM laboratories continue testing despite agreeing to cease and desist. Other laboratories claim they are exempt from CLIA because they are conducting LBA as research. To qualify for this exemption laboratories must agree not to provide test results to patients. Some State agency respondents have expressed concern that these facilities may be providing test results to patients.

Complementary and alternative medicine laboratories cannot meet all CLIA requirements

All laboratories that perform LBA must meet regulatory requirements for laboratories performing high complexity testing. To date, no laboratory performing LBA has successfully met these requirements. Many complementary and alternative medicine providers often do not meet CLIA personnel requirements. Those laboratories that can

meet the personnel requirements cannot meet other CLIA requirements. Meeting the regulatory requirement concerning the establishment and verification of test methods has been particularly problematic for the LBA test method. To meet this requirement each laboratory must prove that LBA is accurate, precise and an analytically sensitive test. The laboratory must also establish reference ranges to distinguish normal or acceptable results from abnormal or unacceptable results.

Getting complementary and alternative medicine laboratories to enroll in the CLIA program is difficult

Laboratories conducting LBA have little or no incentives to enroll in the CLIA program. The main incentive for traditional laboratories to enroll under CLIA is reimbursement by Medicare or Medicaid. Nearly all CAM providers bill patients for CAM laboratory tests. Medicare, Medicaid and most other insurance programs do not cover complementary and alternative medicine laboratory tests.

Most State agencies believe that at least 95 percent of all laboratories in their State voluntarily identify themselves for CLIA enrollment. States report that laboratories operating without CLIA certificates often decide to enroll when Medicare and other insurance payers deny their claims.

The CLIA program's reliance on laboratories to identify themselves for enrollment is problematic when it comes to laboratories conducting LBA and other CAM tests. Some complementary and alternative medicine providers have heard that HCFA forces laboratories conducting Live Blood Cell Analysis to close; consequently, laboratories that perform LBA and other CAM tests may seek to avoid HCFA detection.

Chiropractors, herbologists, naturopaths, nutritionist, therapists, health food store owners and other CAM providers may be unaware of the CLIA program. These practitioners may not be associated with such schools or organizations that offer a laboratory curriculum. Physicians (medical and osteopathic) who perform or offer their patients LBA and other CAM laboratory tests appear more likely to be aware of CLIA. Traditional medical schools and professional organizations help to keep physicians informed about CLIA and other Federal and State regulations that affect laboratories. Training programs, schools and organizations for complementary and alternative medicine practitioners may not inform their clients about CLIA and CLIA requirements.

HCFA cannot take administrative actions against laboratories that refuse to enroll in CLIA and must rely on other agencies to take action

According to HCFA staff, CLIA's enforcement provisions work well for CLIA certified laboratories, but are problematic for laboratories not enrolled in the program. When a State agency or HCFA discovers that a laboratory is operating without a CLIA certificate, they send the laboratory a letter advising them that they must cease and desist from testing until the laboratory is CLIA certified.

There are no administrative remedies available to HCFA when a laboratory refuses to enroll in CLIA and refuses to cease testing. The HCFA cannot impose monetary or other administrative penalties on laboratories that defy the law. The only course of action available to HCFA is to refer cases to other Federal or State agencies for civil suit or criminal prosecution. There are no intermediate remedies with more proportionate administrative penalties. The only recourse available to HCFA is to convince an outside agency that a laboratory has intentionally violated the law and that the agency should take criminal or civil action that may result in fines or imprisonment. Under Federal law, a criminal conviction can result in a fine of up to $10,000 and up to 1 year in prison or both.

The HCFA can refer a case for an injunction if they can prove there is a "significant hazard to the public health." It may be difficult for HCFA to establish that LBA and other CAM tests pose a significant hazard to patients or the public. During our in person interviews, we asked State and Federal respondents whether LBA had harmed any patients. We found no evidence that would suggest that LBA or any other CAM test has harmed patients. As with some traditional laboratory test methods, the LBA test method itself appears to pose little harm to patients. Harm to patients is more likely when providers fail to recognize and take appropriate action based on test results and other non-test related factors.

Some laboratories performing Live Blood Cell Analysis may have been improperly issued CLIA certificates

The number of laboratories that perform LBA and other CAM tests is unknown. We do know that some laboratories doing these tests have been issued CLIA certificates. In some cases, a laboratory applied for a CLIA certificate because they were performing traditional laboratory procedures. They subsequently added LBA or other CAM tests and did not notify CLIA. Others stopped doing the traditional laboratory tests that they were approved to perform under CLIA and only offer LBA and other CAM tests.

Laboratories doing complementary and alternative medicine tests can easily obtain a CLIA certificate

Any laboratory, including complementary and alternative medicine laboratories, can easily obtain a Certificate of Waiver or a provider-performed microscopy (PPM) certificate. Applications from laboratories for these types of certificates may be approved and CLIA numbers issued because the CLIA application does not ask laboratories if they are doing LBA or any other CAM testing. Since laboratories with waived and PPM certificates are not routinely visited, HCFA may never know that they are performing Live Blood Cell Analysis and that they have been improperly issued a CLIA certificate.

Laboratories that do CAM testing and apply for a certificate of compliance are more likely to be detected and have their certificate revoked. However, the process may take

up to 3 years to complete. Despite their inability to meet CLIA requirements, HCFA requires that surveyors complete a full site visit of LBA laboratories that submit correctly completed applications. Surveyors examine and determine which CLIA requirements the laboratory meets. Deficiencies noted during onsite surveys are documented on Statements of Deficiency. Statements of Deficiency for some laboratories conducting LBA have approached 30 pages in length - significantly more than most laboratories. One LBA laboratory response to CLIA survey findings exceeded 200 pages, and we have seen other complex responses to Statements of Deficiency. The HCFA must respond to each laboratory response and the laboratory has the opportunity to reply again. Laboratories may not be visited for 2 years and are given up to 1 year to correct deficiencies before their CLIA certificate is revoked.

All CLIA laboratories that conduct complementary and alternative medicine tests do so outside the scope of their certificate. These CLIA certified laboratories *should not be performing LBA* and may be violating the law.

State agency and complementary and alternative medicine respondents believe testing should be regulated, but they differ on how this should be accomplished

More than two-thirds of the State agencies believe that laboratories conducting LBA create difficulties for CLIA enrollment and certification. State agencies reported several difficulties including: identifying laboratories conducting LBA, enforcing CLIA requirements for certification for all laboratories, and fitting LBA to CLIA standards. Several States reported that extensive amounts of time are spent on LBA laboratories that attempt to comply with CLIA.

Laboratory surveyors and CAM providers disagree on the validity of Live Blood Cell Analysis. They also disagree as to whether CLIA is the appropriate program to regulate LBA and other complementary and alternative medicine laboratory procedures. Most State agency respondents and complementary and alternative medicine providers do, however, agree that LBA should be regulated.

Most of our State agency respondents believe LBA should be regulated under CLIA to protect the public

Most State agency respondents believe that CLIA regulation of laboratories performing LBA and other CAM tests is needed to protect the public. State surveyors protect the public by verifying that laboratories meet CLIA requirements designed to ensure accurate laboratory testing. The CLIA surveyors cannot ensure that LBA laboratories conduct quality testing if the laboratory fails to enroll in CLIA.

State surveyors are not convinced that LBA provides quality diagnostic information. Many State surveyors generally believe that LBA tests yield results that are inconsistent

with basic principles of biology, chemistry and physics. One State respondent said that the scientific application of LBA is limited to what performance characteristics the laboratory can actually validate. This respondent and others believe that complementary and alternative medicine practitioners often make claims about LBA testing that cannot be supported.

Some State respondents also believe that laboratories should be regulated because the public assumes that some governmental agency is ensuring that their laboratory tests are reliable and accurate. One State said, "If the public is led to believe that any test, whether standard or alternative, is one on which they could or should base some lifestyle adjustment, then there should be accountability of the testing person and the site. . . ." Another State respondent said that "the general public operates under the assumption that anyone in a laboratory coat is a professional and will operate in a professional manner."

A majority of States believe HCFA should change CLIA processes rather than the law to address complementary and alternative medicine laboratories

Two out of three States believe CLIA regulations, policies and processes should be adapted or changed to better address LBA and other CAM procedures. Some respondents believe that clarification of processes and better guidelines would help them determine whether CAM laboratories can comply with current CLIA requirements. Others believe that changes to regulations, policies and processes are needed to better address CAM laboratories and complementary and alternative medicine testing.

State agency respondents are divided as to whether the CLIA law needs to be changed to address CAM laboratories and CAM testing. Some State respondents believe that the current law is adequate. Other State respondents believe that any changes would dilute the existing law and encourage exceptions for other procedures. Of the States that would like to see a change in the law, many mentioned stronger enforcement authority. A few would like to see language that would specifically exclude complementary and alternative medicine laboratory tests from CLIA regulation.

Some CLIA surveyors are uncomfortable evaluating LBA test methods

Several State surveyors expressed concern about their ability to evaluate non-traditional tests. Others indicated that CLIA regulations and policies are unclear as to what levels of proof are necessary to meet regulatory requirement concerning validation of test methods. They mentioned that their training is based on traditional laboratory practices and that they often have no experience with complementary and alternative medicine tests. Some State surveyors and HCFA personnel would like another entity, such as CDC or FDA, to determine whether LBA is a reliable and accurate test method. If this question were resolved, CLIA surveyors felt they would be more comfortable evaluating LBA test validity.

Complementary and alternative medicine providers that we spoke with believe LBA should be regulated, but not by the CLIA program

Most complementary and alternative medicine providers with whom we spoke would like to be regulated by their peers and not by the CLIA program. One respondent summarized the sentiments of many LBA providers when he said, "CLIA is not in a position to make definitive statements about LBA technology." They believe that many CLIA surveyors have little or no understanding of LBA. Nonetheless, many CAM providers believe that there needs to be some checks and balances to protect the public from unscrupulous providers.

One CAM provider with whom we spoke believes that there should be no regulation of LBA testing when providers do not bill Medicare or other insurance. Some pathologists and other physicians who perform Live Blood Cell Analysis also shared this viewpoint. They believe that LBA falls within the scope of their license to practice medicine and that it should not be regulated under CLIA.

Half of our CAM respondents believe that an alternative laboratory division should be established. This new division would be responsible for registration and oversight of CAM laboratory tests. It would regulate complementary and alternative medicine testing, set standards and enforce requirements. This new division would protect the public from providers who fail to act in the best interest of their patients while not impeding access to complementary and alternative medicine laboratory tests.

A few complementary and alternative medicine laboratory providers want to comply with CLIA requirements but with some modifications

Three physician respondents who perform LBA said that they are not opposed to CLIA regulation. They are willing to comply with CLIA if standards more applicable to CAM are developed. They believe that the CLIA program needs to provide more guidance on how they can come into compliance. They also believe that HCFA needs to be more reasonable in assessing new technologies. One respondent said, "CLIA is going to drive the legitimate people out of LBA, and the illegitimate ones will prevail underground."

These three physicians operate laboratories certified to perform moderate and high complexity testing. They meet most CLIA requirements for LBA testing, but they cannot establish the validity of the LBA test method to meet HCFA requirements.

Few States restrict complementary and alternative medicine laboratory testing, and oversight by other Federal agencies is limited

The HCFA plays the primary role in oversight of laboratories. Little oversight exists outside CLIA. Half the States require that laboratories obtain a State laboratory license but the requirements for these licenses do not differ substantially from CLIA except in a few States. A few States have laws that may affect laboratories offering LBA or other CAM tests. Other Federal agencies have limited roles in laboratory oversight.

Laboratories, the tests they perform, and the equipment they use may also come under the scrutiny of FDA, CDC, FTC and OSHA.

Few State laws and regulations restrict complementary and alternative medicine laboratories

The CLIA regulations require that laboratories comply with all State laws to receive CLIA certification. Half the States require that laboratories obtain a State laboratory license but the requirements for these licenses do not differ substantially from CLIA. A few States have laws that go beyond CLIA provisions, which may affect laboratories conducting complementary and alternative medicine tests.

Only three States reported that they had State statutes that they believe prohibit laboratories from performing CAM testing. These three laws, while somewhat different, prohibit laboratories from conducting tests that do not have "substantial proof of efficacy," and are not "substantiated by an independently conducted and documented scientifically based clinical trial." The Alabama Administrative Code states that procedures employed in a laboratory ". . . shall be the standard procedures which are generally accepted by leading authorities or are equivalents approved by the Alabama Department of Public Health." Maryland and Pennsylvania have statutes with similar language. These States believe that they have the authority to deny or revoke the State laboratory license of any laboratory doing CAM testing.

Several States reported that they had State laws restricting who can order or receive laboratory test results. Connecticut, Georgia, Hawaii, Oregon, Pennsylvania and Tennessee require that laboratories examine specimens only when requested by a physician or other person authorized by State law to use the findings of laboratory examinations. These States also require that laboratory test results be provided only to physicians or other persons authorized to receive such tests by State law. Some of these State laws also prohibit the reporting of laboratory test results directly to patients.

Three States believe that complementary and alternative medicine providers may not meet State standards governing laboratory personnel. California, Hawaii and Tennessee respondents mentioned that they had State personnel standards that would affect some laboratories doing CAM testing. For example, California law prohibits chiropractors from drawing blood and thus affects chiropractors who conduct LBA.

Federal agencies play a limited role in regulating complementary and alternative medicine laboratory practices

The CLIA provisions are intended to ensure the quality of laboratory testing. These provisions directly affect patient care. Poor test quality can lead to misdiagnosis, inappropriate treatment, and patient harm. No other Federal agency looks at how well laboratories perform tests. However, other Federal agencies play a role in regulating discrete elements of laboratory practice, including manufacturer and provider claims, equipment and employee safety.

The Food and Drug Administration. The FDA's Office of Device Evaluation ensures that medical devices are safe and effective. They ensure that these devices perform as claimed and that valid scientific evidence supports the claims made about a product. New medical devices for use in laboratories must receive FDA approval before manufacturers can market them. The FDA is also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories.

Manufacturers of laboratory equipment and chemical reagents are not required to seek FDA approval to market products that do not substantially differ from products already approved by FDA. The FDA advised us that the microscopes used to perform LBA testing do not differ substantially from microscopes already approved by the FDA for other diagnostic purposes. They indicated that additional FDA approval would only be required if a manufacturer of the microscopes made new claims about the capabilities and uses for their microscope.

Some LBA practitioners make claims as to how this test can be used to assess nutritional deficiencies, diseases and patient health status. These claims are made by the user and not the manufacturer of LBA equipment; therefore, the FDA has no jurisdiction.

The Centers for Disease Control and Prevention. The mission of the CDC is to promote health and quality of life by preventing and controlling disease, injury and disability. The CDC conducts research and provides services to meet public needs and to achieve public health goals. The CDC is responsible for CLIA program and policy evaluation. The CDC has provided support and technical advice to HCFA, and has helped HCFA in the development of CLIA regulations and guidelines. Until this year (when the FDA assumed this task) CDC was also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories. It was CDC that first advised HCFA that laboratories performing LBA would need to meet CLIA requirements for laboratories doing high complexity testing.

We asked CDC if Live Blood Cell Analysis posed any health risks to the population. They advised us that the risk of infection and disease transmission to patients from a finger stick (such as that used in LBA) is low. Our CDC respondents stressed that while the risk of disease transmission was low, it did not mean that no risk existed. They pointed out that anything contaminated with blood poses a potential biohazard. Such products should be properly handled and disposed of to prevent transmission of disease, particularly hepatitis that can remain virulent longer than most other contagious diseases. As with all patient provider encounters, CDC respondents expressed concern about potential harm that might occur when providers fail to recognize seriously ill patients.

The Federal Trade Commission. The Federal Trade Commission is responsible for enforcing Federal antitrust and consumer protection laws. It has enforcement and administrative responsibilities for statutes relating to business competition and consumer protection. The FTC seeks to protect consumers against unfair, deceptive or fraudulent practices by combating actions that threaten consumers' opportunities to exercise

informed choice. The FTC can stop advertisers who are making false claims about products.

The FTC's Bureau of Consumer Protection reviews the advertising claims made by sellers of health care products to consumers. They focus their investigation and prosecution efforts on large providers where they can have a greater impact and where national publicity is likely to have the greatest deterrent effect. Infractions by smaller businesses are usually addressed through more cost-effective, non-enforcement activities, such as consumer education. The FTC remains a potential source for HCFA to use when they find that a CAM provider makes false or misleading claims in their advertising about CAM laboratory testing. False or misleading claims that providers make to their patients are not addressed by the FTC.

As part of its oversight responsibility, the FTC monitors the Internet for sites containing "bogus claims for products and treatments touted as cures for various diseases." This campaign, known as "Operation Cure.all" uses the Internet both as a law enforcement tool to identify bogus claims and as a communication tool to give consumers reliable health care information. Operation Cure.all has identified five areas of interest: dietary supplements, products that make therapeutic claims, medical devices, diagnostic tests (including LBA) and fraudulent foreign clinics. It is too early to evaluate the effect Operation Cure.all will have on laboratories performing complementary and alternative medicine tests.

The Occupational Safety and Health Administration. Some State and HCFA respondents suggested that OSHA could help protect patients from exposure to potentially harmful laboratory tests including CAM tests. We discussed this with OSHA and found that they (OSHA) do not play a role in protecting consumers or patients. The mission of OSHA is to save lives, prevent injuries and protect the health of America's workers. The Agency and its State partners ensure that employers provide safety guidelines and adequate protections for their employees. They ensure that employees are safe and that they are not exposed to hazardous materials or events in the workplace.

The Health Standards Programs Division within OSHA ensures that workers follow universal precautions for drawing blood. They also ensure that laboratories properly equip their staff with the tools to perform their jobs in a safe and sterile environment, and that laboratories properly dispose of blood products and biohazardous wastes. To date, OSHA headquarters is not aware of any laboratories offering LBA that would warrant their intervention. The OSHA would become involved in CAM laboratories if they felt that any of these laboratories exposed their employees to biohazardous wastes or any other potential harm.

OPPORTUNITIES FOR IMPROVEMENT

The CLIA was enacted to improve the quality of laboratory testing and to protect the public from harm that might result from poor quality laboratory testing. It recognizes that the risk of harm to patients differs from test to test. The greater the risk of harm the greater the regulatory requirements.

The Department, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health and the Health Care Financing Administration, will need to decide how best to protect consumers in a changing health care arena.

If the Department determines that CLIA is the appropriate structure for regulating CAM laboratory tests it should:

> **Take action to improve and enforce current CLIA policies and procedures for addressing laboratories performing complementary and alternative medicine tests.**

Laboratories performing LBA and other CAM procedures that do not meet CLIA requirements would be prohibited from doing these tests until they can satisfy all CLIA requirements. In theory, this would force laboratories to stop CAM testing or force them to operate underground.

The Department would need to seek legislation that would give HCFA additional administrative authorities to ensure that laboratories performing LBA and other CAM tests cease this type of testing until they can meet all CLIA certification requirements for these tests. The HCFA should consider: 1) improving its methods for identifying CAM laboratory sites, 2) requiring that all laboratories currently in the CLIA program or seeking CLIA enrollment sign an attestation that they do not perform LBA or any other CAM laboratory test, 3) promoting the use of the surveyor guideline package developed by the LBA workgroup, and 4) requiring that LBA providers who claim they will continue testing as a research facility sign an agreement that they will not give results to patients.

The practical consequence of the above option would be that LBA would never be approved under CLIA without a major scientific breakthrough. However, LBA would probably still exist.

If the Department does not wish to enforce CLIA compliance and wishes to allow access to CAM laboratory testing while still protecting the public, it must consider approaches such as the following:

- **Change the current law or regulations to create a special regulatory category within CLIA for complementary and alternative medicine laboratory tests, or**

- **Establish a new regulatory agency and program to oversee complementary and alternative medicine laboratory testing.**

Both approaches would permit patients who want CAM laboratory tests to have access to such testing and provide a regulatory remedy if patients are harmed. Under both options the Department would need to decide how complementary and alternative medicine laboratories would be distinguished from certified CLIA laboratory sites. It would also need to decide which tests and which providers fit into each category.

AMERICAN PREVENTIVE MEDICAL ASSOCIATION
P.O. Box 458 • Great Falls, Virginia 22066 • 703.759.0662 • Fax 703.759.6711 • www.apma.net

FAX TRANSMISSION

To: Steve Date: 5.3.01

Fax #: Voice #: Pages, including cover: 8

From: Candace

Subject:

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As promised —

National Policy Dialogue To Advance Integrated Health Care: Finding Common Ground

Convened by

The Integrated Healthcare Consortium

Co-hosted by

American Preventive Medical Association
Bastyr University
Georgetown University School of Medicine

November 1-3, 2001

At The
Georgetown University Conference Center
Washington, D.C.

Integrated Healthcare Consortium

Steering Committee

A National Policy Dialogue To Advance Integrated Health Care Policy: Finding Common Ground

Members of the Integrated Healthcare Consortium are convening a conference titled "National Policy Dialogue to Advance Integrated Health Care Policy: Finding Common Ground," November 1-3, 2001, at Georgetown University Conference Center in Washington, D.C. The meeting is being co-hosted by the American Preventive Medical Association, Bastyr University and Georgetown University School of Medicine.

The goal is to create a collaborative report that will help focus the national health care debate and ultimately develop national policy recommendations to ensure that the American public benefits from advancements in the science and understanding of all health care systems, disciplines and modalities. The intent is that the finished report can be used by policy makers, professional associations, academic institutions and others to develop a coordinated national effort to foster appropriate research; to develop appropriate standards for professionals as well as products; to expand and integrate curricula; and to increase consumer access to complementary and alternative therapies. Participants will use several documents as a starting point. These include the *National Plan to Advance Integrated Health Care*;* the draft report of the White House Commission on Complementary and Alternative Medicine Policy, the five-year strategic plan developed by the National Center for Complementary and Alternative Medicine (NCCAM) entitled *Expanding Horizons of Healthcare*, and the findings from the Integrative Medicine Industry Leadership Summit 2001.

The Integrated Healthcare Consortium, as well as the Steering Committee for this National Policy Dialogue, consists of (1) faculty from a number of universities and academic health centers, who have credibility in the academic and professional communities of both conventional and complementary /alternative medicine (CAM), law and public policy, and (2) representatives of the conventional and CAM professions who, along with their organizations, have extensive contacts throughout both communities and a comprehensive understanding of the relevant issues facing them. Members of the Steering Committee and others within their institutions/organizations have also worked with legislators, regulators, providers, payers, educational institutions, professional associations, policy makers and the public on CAM and integration issues for many years. In addition, they are experienced collaborators, who know how to bring diverse constituencies together and create a cooperative spirit and focus on shared goals.

The Steering Committee members and their organizations, listed on the opening page of this program description, have agreed to be conference sponsors. Their task is to oversee the design and implementation of the event, secure adequate funding, and determine an agenda that will ensure that this Policy Dialogue will be a remarkable and productive joint effort of all who come to the table.

Participants

The number of attendees will be limited to ensure optimal participation. Approximately 75 individuals representing major stakeholder groups will be invited to attend. They will include educators from accredited conventional and CAM schools and professional organizations; representatives of regulated conventional and CAM practicing disciplines; payers (Medicare, private insurance companies, HMOs, Indian Health Service); natural health care product manufacturers; major employers; consumer advocacy groups; and government agencies.

All of these stakeholders are active in their own spheres of influence and expertise. They are both impacted by and working to shape federal health care policies regarding CAM; however, many are doing it in relative isolation, with little coordination or communication among other sectors of this massive industry. As the health care paradigm continues to evolve, it will become more and more necessary for all stakeholders to communicate with each other regularly about how the changing paradigm affects them and how they would like to see it develop. Policy makers need guidance from the industry; businesses and practitioners need a livable regulatory environment; educational institutions need to understand the environment for which they are preparing students; and consumers need broader access to qualified providers and to safe and effective alternatives. The National Policy Dialogue will provide an opportunity for experts, industry leaders and stakeholders to collaborate in drafting a position statement outlining a shared vision and specific policy direction for creating the health care environment of the future, in which cooperation, accountability and increased understanding will result in optimal benefits for consumers. Identification of a vision, voice, agenda and policy priorities through this partnership of stakeholders will help identify the emerging consensus that will advance integrated health care.

Structure

The meeting will be held over the course of 2 ½ days, November 1-3, 2001 (an opening welcome reception will take place on the evening of October 31, 2001). Designed to be a working meeting, it will open with a speech from a key government official who can elucidate the need for a more unified vision from the health care community to which policy makers can respond. A large portion of the meeting will be devoted to work in small groups focused on the following areas:

1. Research Issues and Goals
2. Education, Training and Accountability
3. CAM Use in Underserved and Special Needs Populations
4. Regulation and Access to CAM Products and Services
5. Federal Benefits Discrimination against CAM
6. Clinical Practice, Quality of Care, and Delivery Systems

After discussing their respective areas of concern, the working groups will prepare reports that include goal statements and background information; identify barriers in the present health care system; and, if time allows, outline action steps to achieve agreed-upon goals and

establish priorities and sequences for activities. This report will then be presented to a Committee of the Whole for discussion and revision.

Outcome

The six working group reports, with Committee of the Whole revisions, will be combined into a white paper or position statement reflecting the views of the stakeholders. It will be an educational document as well as a blueprint for change, and will be disseminated widely to policymakers, the media and stakeholder groups. It is our expectation that the new and improved *National Plan to Advance Integrated Health Care* will be used by policymakers to determine how the Federal Government can encourage a more integrated health care system; by the media as a guide to the players and the issues; and by stakeholders as a strategic plan for implementing their own piece of the puzzle and for further cooperative activities. Any post-meeting efforts to implement portions of the *Plan* will be the responsibility of individual stakeholders or coalitions formed by participants. While we do not anticipate the formation of an over-arching organization comprised of National Policy Dialogue participants, we do hope to have a follow-up meeting by 2004 to assess progress and to review and revise the *Plan*. It has been suggested that, in subsequent years, similar meetings be convened to discuss discrete aspects of the white paper, such as research or education. At these meetings, stakeholders with a vested interest in a specific area would have an opportunity to flesh out the broad topics identified at the National Policy Dialogue, determine targeted public policy goals, and set collaborative action plans for achieving those goals.

Budget

The budget for the two and a half day event is approximately $60,000. This will cover the cost of the conference facility; supplies; on-site conference costs; pre-conference organizing/administration; printing; breakfast, lunch and break-out sessions for participants each day; audiovisual equipment; a professional facilitator; writing and editing of the final report; and part-time administrative assistance. Attendees will be expected to cover their own travel, hotel and dinner expenses.

Relationship to the White House Commission on Complementary and Alternative Medicine Policy

A legitimate question is how this meeting and end product will differ from or relate to that of the White House Commission. The Commission has been charged with surveying the CAM landscape and reporting to HHS "on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine." In its two-year life span, the Commission will hear testimony from a wide range of individuals to elicit their perceptions on topics ranging from access to research. It will then write a draft report, receive comments, and prepare a final version for presentation to HHS. To date, the Commission has done a tremendous job of reaching out to a wide range of

stakeholders and, we have no doubt, it will produce a thoughtful, thorough and useful report which will help direct policy makers faced with many conflicting demands for changes in the health care system. Its end product, however, will be its own, and may or may not be taken up and implemented by the stakeholder organizations.

In contrast, the National Policy Dialogue will provide a collaborative forum on national policy (we believe the first of its kind) in which stakeholders from all parts of the health care community will have a chance to discuss and debate their perceptions about the future of integrative health care and federal policy with individuals who are not normally part of their network. For example, instead of medical schools talking to medical schools about the best way to design an integrative curriculum, they will have the opportunity to speak with professionals in the CAM community, consumers, insurers and others who will have much to contribute to the task at hand. CAM professionals will have an equal opportunity to hear the perspectives of the many stakeholders who have an impact on their ability to practice, but with whom they have not had a useful dialogue. Instead of the Balkan States, we will have the United States. Realistically, if we are to achieve the best integrative system possible, all the stakeholders should be working together or, at the very least, be cognizant of how the rest of the puzzle will affect them.

By launching this landmark dialogue and crafting a broad position paper that recognizes areas of shared concern and mutual goals, we will have succeeded in advancing the debate and helping to create a successful, effective integrated system in a more timely fashion. By getting all the parties to the table, opportunities will exist for new relationships to develop and new coalitions to be fostered, and a sense of ownership of the finished product will be generated by the participants that may lead to more effective implementation.

Summary

These are ambitious goals for such a short meeting. Decision makers (many of whom have never met) are being asked to debate a large and potentially divisive topic and identify common ground. We are confident that we can succeed for two reasons: First, individuals will only come if they want to work to advance integrated health care, so we can assume that participants share at least that overarching goal. Second, participants are being asked to help draft a broad position paper and to identify common ground, not commit to a specific, tailored legislative agenda or formal scientific consensus statement.

It is vital to begin the dialogue and quite appropriate to begin by examining the subject from the widest possible perspective. In contrast, expecting to solve the concerns in one area, such as research, without benefit of the big picture, would necessarily result in a skewed and less successful final product. Each area affects the others. It would be premature to address integrating medical school curricula, for instance, without also considering credentialing. It would be impossible to address issues regarding access without also considering research.

The Integrated Healthcare Consortium members are aware that other groups are also interested in addressing the challenges of creating an integrated health care system. In addition

to this National Policy Dialogue and the White House Commission activity, other efforts are underway in various sectors of the health care community to debate some of the same questions. The Integrative Medicine Industry Leadership Summit, for instance, is focusing for a second year on the business aspects of integration. We view these efforts as mutually supportive. Among our team are conveners of the industry gatherings who also see the need for our National Policy Dialogue. There is no harm in multiple efforts, and no cause to fear duplication. The job is so immense that it will take multiple efforts and diverse perspectives to be successful. Each participant brings a unique perspective to the discussion, and may take separate roads to the same destination. What matters is that we raise the level of the debate and begin the dialogue. With hard work, intention, and some luck, we will all find places at which our paths cross and ways we can work together to achieve mutual goals.

***

* The *National Plan* was drafted at the request of Senator Tom Daschle, Senator Tom Harkin and Rep. Peter DeFazio, who requested an overview of the health care environment and the identification of the barriers to creation of an integrative health care system. The *Plan* is the result of numerous interviews with a wide range of stakeholders over the course of more than a year. The authors of the *National Plan* are: the Hon. Berkley Bedell, former Congressman, Iowa; Candace Campbell, Executive Director, American Preventive Medical Association; Sheila Quinn, Senior Editor, Institute for Functional Medicine (Executive Director, American Association of Naturopathic Physicians at the time the *National Plan* was drafted); and Pamela Snider, N.D., Associate Dean of Naturopathic Medicine, Bastyr University. The goal of the National Policy Dialogue is to broaden the discussion and identify common ground, in an effort to craft national policy which reflects the needs of all stakeholders.

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April 17, 2001

AMERICAN PREVENTIVE MEDICAL ASSOCIATION
P.O. Box 458 • Great Falls, Virginia 22066 • 703.759.0662 • Fax 703.759.6711 • www.apma.net

FAX TRANSMISSION

Whitehouse Commission

To: Jim Gordon Date: 5/7/01

Fax #: 301-480-1691 Voice #: Pages, including cover: 3

From: Taffy

Subject: APMA Board members names + addresses

Notes:

Jim Gordon requested this information when he spoke at our Board meeting on April 27th. (for mailing list.)

Please forward to him.

Thank You

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. list	American Preventive Medical Association board members/addresses (2 pages)	nd	b(6)

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

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RESTRICTION CODES

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

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

C. Closed in accordance with restrictions contained in donor's deed of gift.
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RR. Document will be reviewed upon request.

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

Albrecht, Joan (NCCAM)

From: Maury Silverman [mauryshi@ix.netcom.com]
Sent: Monday, April 09, 2001 10:16 AM
To: Albrecht, Joan (NCCAM)
Subject: Fw: Undeliverable: Fw: Medical Innovation and Treatment Access Act

Medical Innovation and Treatme...

----- Original Message -----
From: System Administrator <postmaster@mail.house.gov>
To: <mauryshi@ix.netcom.com>
Sent: Tuesday, April 03, 2001 11:22 AM
Subject: Undeliverable: Fw: Medical Innovation and Treatment Access Act

> Your message
>
> To: sarahanderson@mail.house.gov
> Subject: Fw: Medical Innovation and Treatment Access Act
> Sent: Tue, 3 Apr 2001 11:51:33 -0400
>
> did not reach the following recipient(s):
>
> sarahanderson@mail.house.gov on Tue, 3 Apr 2001 11:21:58 -0400
> The recipient name is not recognized
> The MTS-ID of the original message is: c=us;a= ;p=u.s. house of
> re;l=IMS04010403152121XRQR0F
> MSEXCH:IMS:U.S. House of Representatives:U.S. House:IMS04 0
(000C05A6)
> Unknown Recipient
>
>
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> -----
> Message-ID: <026001c0bc55$f5c45260$1162f7a5@x5q6o1>
> From: Maury Silverman <mauryshi@ix.netcom.com>
> To: sarahanderson@mail.house.gov
> Subject: Fw: Medical Innovation and Treatment Access Act
> Date: Tue, 3 Apr 2001 11:51:33 -0400
> X-Mailer: Internet Mail Service (5.5.2653.19)
> X-MS-Embedded-Report:
>
>
> ----- Original Message -----
> From: Duncan, William <William.Duncan@mail.house.gov>
> To: Maury Silverman <mauryshi@ix.netcom.com>
> Sent: Tuesday, April 03, 2001 4:53 AM
> Subject: Medical Innovation and Treatment Access Act
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> > <<Medical Innovation and Treatment Access Act Physician Cover.doc>>
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Medical Innovation and Treatment Access Act

The Medical Innovation and Treatment Access Act (MITA) contains the basic concepts that a patient has a right, in consultation with the physician, of choosing and having access to the medical treatment that both the patient and the practitioner feel is beneficial. The MITA Act expressly addresses the issues of changing the enforcement powers of the FDA and providing access to currently restricted treatments. It expressly changes the import restrictions on approved drugs or devices from other countries, changes the interstate shipment restrictions on experimental drugs or devices, and allows researchers to have access to the bulk raw materials (without fillers) from which drugs are manufactured. It provides for comprehensive data collection of research results. It requires a Federal agency (but not FDA) to use an expedited process to ensure that there is no clear and convincing evidence that unapproved drugs and devices are unsafe, and it provides an expedited FDA process when sufficient data has been accumulated to show that a drug or device should be approved for commercial distribution.

The MITA Act does each of these things and also promotes the needed collection of data on the effectiveness and potential medical uses of dietary supplements, as well as allowing surgeons to collect and share data on innovative surgical techniques, while preserving the current protections against the FDA interfering with surgical practices.

This legislation has been warmly received by health care practitioners in a variety of medical disciplines. Many feel restricted in their ability to provide patients with the best treatment. The FDA has prevented them from accessing and utilizing common-sense treatments. Physicians understand that biomedical research is not a linear, cause-and-effect process. It is a dynamic and fluid process which must be allowed to blossom and prosper. We expect substantial support from these physician groups as we move this legislation forward.

The three central themes of the Access bill are (1) The patient and physician have a right to decide their own treatment and (2) they have a right to obtain information and materials to follow the protocol, and (3) the concept of participation by the patient and physician in a mini-clinical trial, with full disclosure, collaborated with others across the nation and coordinated by the Agency for Healthcare Research and Quality (AHRQ).

This clinical trial concept, conducted in individual offices across the nation, removes the need patients to have to have the right connections, or the right "luck" to get innovative treatments, and dynamically increases the quantity and quality of biomedical research. Physicians are protected under malpractice laws because the patient is enrolled in a Federally-registered clinical trial, and patients are protected because they have been fully informed of treatment options, potential hazards and benefits, and legally consented.

For example, one treatment for HIV/AIDS that has been shown to be very beneficial, is under clinical evaluation, and has been for the past 5 years, at the National Institutes of Health. Under this legislation, anyone in America, whose physician complies with the requirements of this act, would have access to the experimental treatment, at cost, and be able to provide it to their patients, as long as the developer was willing to share it, and in turn, the results from these additional patients would further enhance the overall research project, at minimal cost to the project. Information would be gathered much more quickly and efficiently than current practice permits.

Items that are approved products, but have not been approved for off-label uses, are also included in these mini-trials. It currently costs the pharmaceutical company as much to obtain recognition from the FDA for an off-label use as it does for developing a new drug that is not yet patented. This has delayed innovation and approval of some drugs for treatment for years. The systematic data collection system for these off-label protocols, designed by physicians, is a key to obtaining expedited FDA approval for off-labels uses of these approved drugs and devices.

In addition, approved drugs and devices from specific countries are approved for importation to be included in these trials. These countries are: Australia, Canada, France, Germany, Great Britain, Netherlands, Japan, and Sweden. These countries are considered to have drug and device approval systems as scientifically valid as the United States. Many of them have developed products that would save lives in America. Below are two examples.

Antibiotic beads are finally available as a pre-mix kit in the United States after 15 years of research. The kit contains an approved antibiotic and an approved epoxy, but the two cannot be pre-manufactured. The result currently is the physician has to mix the two substances by hand in the operating room, with varying consistencies. The kit contains enough for a hip replacement, even if the joint being worked on is a toe. This is expensive and wasteful. The Germans developed this epoxy-antibiotic combination 15 years ago, and clinical trials were conducted in the United States, with the kit finally allowed by the United States. Physicians would prefer to purchase pre-mixed, sterile beads of the size they need for the type of surgery they are doing. This is especially critical for diabetic patients. Unfortunately current FDA regulations block this product from being developed and manufactured here in the United States, in spite of clear popularity of the product, and the need for it.

The Germans have developed an anti-toxin for mushroom poisoning. A person who consumes a poisoned mushroom has 72 hours to take the anti-toxin before the liver is damaged beyond repair, and the person requires a liver transplant. Every minute counts. In Europe, the German Airforce flies the treatment wherever it is needed, including former communist countries. When the company presented their product to the FDA, with all of the data and usage and acceptance in Europe, they were told they would need to redo all of the research here in America, including doing a double-blind clinical trial. (This means that ½ of the patients would receive no treatment and require liver transplants.) Unfortunately this is not practical, because most of the victims are children, and there are about 4 cases per year. This is not enough cases to warrant a clinical trial, and by the time the children were identified, it would be too late. In addition, we already know what happens without treatment, and with the standard treatment. Rational parents certainly would not want their children in the placebo portion of the trial, and physicians have ethical problems with providing no treatment for patients in this circumstance.

This legislation would allow these two products to be either imported, or manufactured under appropriate license here in the United States, for inclusion in these outcomes-based trials.

The legislation promotes innovation, restores the patient-physician relationship, enables persons in rural areas to receive the most innovative care, allows the medical community to more rapidly communicate medical breakthroughs, while preserving protection for patients and improving and saving their lives.

The Medical Innovation and Treatment (MITA) Bill Summary

1) Findings: The findings cover the concept that improving the health status of the United States is a priority of the Federal government, and that individuals should have the right to choose their methods of treatment, physicians should have the freedom to provide those services, and a physician's mission is to safeguard the health of his or her patients.
2) Title I: (Page 6)
   a) Section 101: Patient and Practitioner Rights:
      i) The patient may use, and the practitioner may provide, unapproved drugs and devices to patients in accordance with the provisions of the Act. There are three ways they could be obtained.
         (1) Under an existing new FDA program[1], he could obtain experimental drugs and from U.S. companies (that program is not changed by this Act);
         (2) He could obtain approved drugs and devices from specified foreign countries[2];
         (3) The physician can make or have compounding pharmacists or other authorized persons make his or her own drugs or devices[3]; and
         (4) He can obtain drugs or devices that other U.S. doctors have made.
      ii) The physician could obtain the raw material ingredients to make approved drugs or devices. (The FDA currently has a policy against this.)[4]
      iii) A practitioner may introduce, deliver, transport, or receive a drug or device in interstate commerce.[5]
      iv) FDA law: This legislation modifies the impact of the Public Health Service Act Section 351, and modifies the impact of sections 501 (a) (2) (B), 501 (c), through (h), section 502(f)(1), section 505, and section 515 of the Federal Food, Drug and Cosmetic Act.[6]
   b) Section 102: General Safeguards [Pages 9 – 11]
      i) The activity may not be in violation of state law.[7]
      ii) Patients will be comprehensively notified that:
         (1) The FDA has not approved the drug or device for the purpose for which it is being used
         (2) There is clearance by the Agency for Health Care Policy Research that there is "no clear and convincing evidence" that the treatment is unsafe
         (3) That the product cannot be distributed commercially
         (4) That it is for experimental use only
         (5) The risks and benefits of the treatment, including any expected possible side effects

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[1] Sec. 561. [21 U.S.C. 360 bbb]
[2] Australia, Canada, France, Germany, Great Britain, Netherlands, Japan, and Sweden [Page 7, Lines 16 - 21]
[3] [Page 7, lines 3 – 15]
[4] [Page 7, lines 3-7]
[5] [Pages 7 – 8, lines 22 – 4]
[6] [Page 8, lines 5 – 14]
[7] [Page 8, lines 22 – 24]

(6) The standard medical practice for the health condition involved, and how this treatment differs from that standard treatment.

iii) The practitioner may not be an employee or agent of any entity that has or has held an approved application for a new drug from the FDA (to help insure that the pharmaceutical industry does not try to use this program as an end run around the FDA approval process.)

iv) There is a restriction on advertising and the physician making or distributing it cannot make a profit other than in regard to his own patients.

c) Section 103: Federal Registration of Unapproved Treatments; Determination regarding safety. [Pages 12 – 17]

i) Submission and Clearance of Registration: In order to obtain a waiver from the FDA law, and enroll the patient in the clinical trial, the physician will register the treatment with the Secretary of Health and Human Services through the Agency for Healthcare Research and Quality. Where the treatment is not already registered with the Agency, the Agency will examine the registration and determine there is no "clear and convincing evidence that the treatment is unsafe." (A provision like this must be provided to protect the public from truly dangerous practices, such as someone who wanted to give a Mercury I.V.) This is a very different standard than FDA efficacy determinations. [Pages 12 – 14]

ii) Registration Requirements:

(1) The name and address of each practitioner

(2) A complete description of the unapproved treatment

(3) The disclosure statement that will be given to the patient

(4) A description of the research protocol, with such samples and components as the Secretary may require. (It is anticipated that many physicians who submit this information may not have a good understanding of the steps necessary to conduct a valid clinical trial. The Agency is experienced with a wide variety of clinical trial methodologies and can help the practitioner determine the best methodology to use for the particular drug or device being utilized. The vast majority of these trials will not be double-blind placebo trials, but instead, outcomes examinations, or some other similar methodology.)

(5) The Agency has 90 days to clear or disapprove a particular registration. If the registration was disapproved, the agency will explain why the registration was disapproved.

iii) Supplemental Notices:

(1) Supplemental notices provide updates of information to show the effects of the treatment on a patient, but submissions may not be made more than quarterly, except for emergency situations, such as adverse reactions reporting.

iv) Standard for Clearance:

(1) The criteria may not be as stringent as criteria under section 505 of the FDA law.

(2) The Agency will take into account the capacity of the practitioners to respond to their requirements, and will make reasonable efforts to avoid

establishing criteria that would present a significant disincentive for such practitioners to develop unapproved treatments.

(3) Section 104: Unapproved Treatments; Forum for Facilitating Exchange of Information in Scientific and Medical Community. [Pages 17 – 22]

(a) A website will be established to create a forum for obtaining and disseminating information, including clinical data, toward the goals of:

(i) Identifying new drugs and devices, and the uses of such drugs and devices that are reasonable candidates for approval under the FDA law.

(ii) Identifying drugs and devices that constitute a threat to public health.

(iii)Obtaining information for use in the development, review, and updating of clinically relevant guidelines, standards of quality, performance measures and medical review criteria.

(b) Patient Confidentiality shall be maintained, while posting the relevant information about the patient, (age, height, weight, treatment protocol, outcomes, etc.) but the name of the patient will not be disclosed. The name of the physician will be disclosed. (This is current AHRQ practice and law.) This will facilitate communication between the professional community, and patients seeking treatments.

(c) The information about how to make a drug or device will not be posted, in order to protect the intellectual property rights of the developer. As covered previously, the physician may provide the drug or device to any other physician who wishes to utilize it, and may recover the costs from the person to whom it is supplied, but may not make a profit.

(d) Clinical Guidelines:

(i) After sufficient evidence from treatments using unapproved drugs or devices, or approved drugs or devices being used for off-label purposes, under sections 352 of the Public Health Service Act, or Section 505 or 515 of the Federal Food, Drug and Cosmetic Act, the Secretary (again through the Agency for Health Care Policy Research), shall

1. Develop clinical guidelines on the treatment
2. Submit those guidelines to the Commissioner of Food and Drugs.

(ii) After these guidelines have been submitted to the FDA, the FDA has 120 days to approve or disapprove an application (which must also be submitted to FDA for the drug or device or use of the drug or device in question.

(iii) If the Commissioner disapproves the application, a report stating the reasons for the disapproval will be made within 30 days after the disapproval.

(4) Section 105: Relation to Other Laws

(a) Controlled Substances Act: All laws regarding controlled substances, including illegal drugs, must be obeyed. This legislation is

not intended to open up use of currently illegal substances such as marijuana, cocaine, etc., by prescription.

(b) State Law: This title does not supersede any law of a State or political subdivision of a state, including rights and duties among practitioners and patients.

d) Authorization of appropriations for the Agency for Healthcare Research and Quality

i) Such sums as may be necessary for FY 2001 through FY 2005

ii) Internet Sites: $25 million for FY 2001 and such sums as necessary for FY 2002 through FY 2005

3) Title II—Additional Forums for Exchange of Health Information

a) Section 201: Forum regarding surgical procedures [Page 23 – 25]

i) An internet site will be set up so that health care practitioners can submit information regarding surgical procedures and outcomes.

(1) This submission process is voluntary, unlike that for drugs and devices. Surgeons requested this site because they would like to coordinate innovations in surgical procedures.

(2) This outcomes data generated will enable them to communicate effective surgical techniques

(3) It will also allow them to have innovative techniques approved more quickly for reimbursement by insurance companies and Medicare, because they will be able to demonstrate outcomes, efficacy and cost differentials, though this is not specifically addressed in the legislation.

b) Section 202: Forum regarding Health Claims for Dietary Supplements and Food [Pages 25 – 29]

i) Forum for Exchange of Information Regarding Health Claims for Dietary Supplement and for Food

(1) Health care practitioners submit information obtained in the course of their professional practices regarding the effects of dietary supplements and food on diseases and disorders.

(2) Submission and participation is voluntary

(3) The purpose of this forum is to identify dietary supplements and food and uses of such items that are of clinical benefit in treating particular diseases or disorders.

(4) This will also assist supplement manufacturers with their labeling claims regarding supplements.

(5) It will also allow accurate information to be collected on threats to public health.

(6) It provides a method of collecting data so that the Agency for Healthcare Research and Quality can develop clinical guidelines, standards of quality, performance measures and medical review criteria.

ii) The key purpose of this data base is to allow the accumulation of data, in an inexpensive manner, that shows the effectiveness of a particular treatment protocol. Just as with the drugs and devices database, clinical trial procedures can be submitted for inclusion on the website. It is conceivable that a particular nutritional regimen could be developed, placed onto the site and

replicated across the nation. Effectiveness could be determined much more quickly than the current system allows. (This could include things such as the National Institute of Arthritis and Muscular Skeletal Disorders at the National Institutes of Health finding that 1500 milligrams of calcium supplementation each day prevents a second vertebral stress fracture in osteoporosis patients.)

iii) Nothing in this section dilutes the protections of DSHEA. The section is designed to enhance DSHEA's effectiveness by collecting accurate information for practitioners who chose to treat their patients, and patients who wish to be treated with these products, so that efforts can be coordinated and disseminated. It also allows for particular regimens to become part of conventional medicine as effectiveness is demonstrated.

4) Title III: General Provisions
   a) This Title specifies the effective dates of the legislation.