Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Louise Tiranoff to Stephen Groft (partial) (1 page)	10/26/2001	b(6)

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

OA/Box Number: 43233

FOLDER TITLE:
WHCCAMP, December 6-7, 2001 [1]

2011-0568-S
kc839

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]
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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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

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

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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Steering Cmte
Matt Russell
Michael O'Donnell

Talk c Jim
Gordon

[illegible]
to [illegible] value
[illegible]

11/9/01 8:30 Pre Meeting

meeting format
Group – Forum

410-763-9366

Meeting Format

Procedure to
Contact Agencies/Dept

CAMTAC

Format for Sections of Final Report

I. Introduction to General Issue A, B, C, D, E

Issue

1. Specific Issue (2.) Background Information
2. Challenges, obstacles needs
3. Recommendations (s)
4. Strategies for Implementation
5. References for each Section/Issue

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Revised Outline for WHCCAMP Report (11-28)

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- From the Secretary, DHHS to the Congress
  - From the Secretary to the President of the Senate
  - From the Secretary to the Speaker of the House
- From the Chair, WHCCAMP to the Secretary, Department of Health and Human Services

Prologue – Chairman's Summary – 1 page vision
Commission Members
Commission Staff
Working Groups (Planning)
Acknowledgements

Table of Contents

List of Tables and Figures

Executive Summary

Part I: Introduction

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Part V: Education and Training of Health Care Practitioners in CAM

Part VI: Access and Delivery of CAM

Part VII: Coverage and Reimbursement of CAM

Part VIII: CAM Information Development and Dissemination

Part IX: CAM Coordinating Office

Part X: Vision for the Future

Part XI: List of Recommendations and Suggested Implementation Strategies

Part XII: Glossary and Acronyms:

Part XIII: Appendices:

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1. List of Commissioners and Affiliations
2. List of Commission Meetings and Topics
3. List of Commission Meeting Invited Panelists
4. List of Open Public Session Presenters
5. List of Town Hall Meetings, Questions Addressed, and Participants

Appendix B

1. Executive Order 13147 and Amendment
2. Appropriation Language Creating the Commission
3. WHCCAMP Charter

Appendix C

1. List of Organizations Responding to WHCCAMP Requests for Information

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[001]

LOUISE TIRANOFF PRODUCTIONS

October 26, 2001

Stephen C Groft
Executive Director
White House Commission On Complementary and Alternative Medicine Policy
2 Harvard Court
Rockville, MD 20850-1148

Dear Dr. Groft,

It was great getting to meet you and thank you for your thoughtful and thorough review of The Angelman Project/Genetica Pro. I so much appreciated your feedback and we are now at the point of very much in need of this kind of help. I am in the process of putting together a letter with reminders and questions related to our meeting which I will send to Dr. Hyatt-Knorr and cc. to you. I am also forwarding to you a copy of the video "Ben's Story" -- we looked at part of it in our meeting. But in the meantime, thank you so much for all your attention and helpful suggestions!

(b)(6)

Again, thanks so much for all your thoughtful suggestions. Let me know if you need any further information on The Angelman Project or our other proposals. Also, we hope have a beta site in the next few weeks, if all goes well. I will let you know as soon as this us up and running. Look forward to talking with you again soon.

Sincerely,

Louise Tiranoff

attachments:
1) email to Dr. Hyatt-Knorr
2) email from Leigh Sutherland.

488 14TH STREET • BROOKLYN, NY • 11215
PHONE: 718 788 6403 • FAX: 718 3692387

LOUISE TIRANOFF PRODUCTIONS
488 14th STREET
BROOKLYN, NEW YORK 11215

Henrietta Hyatt-Knorr
Acting Director
Office Of Rare Diseases
National Institutes of Health
31 Center Drive, Building 31
Room 1B19
Bethesda,
MD. 20892-2084

10/26/01

Dear Dr. Hyatt-Knorr,

It was great to meet you at Dr. Groft's office on Tuesday, October 16th. We have been working non-stop for two years now on The Angelman Project and we have had very little chance to demo our results. So it is great to finally get feedback and suggestions!

Also, an update on our beta site. It has been sent to The University of California and our contact there, Pat Neill, is going to try to get it online possibly this weekend. It will be similar to the demonstration I had for the meeting -- I'll let you know how this is going.

We would be very interested in participating in a workshop related to parent support, by supplying media elements, etc., as you mentioned. I am forwarding you a copy of the film "Ben's Story" which we started to watch at the end of the meeting. Please let me know if you might be interested in watching any other documentaries.

Also, as we looked at the prototype and discussed the films, you mentioned that I should remind you of some of the points raised, in case you might have further information in your office, so I'm forwarding questions about those flagged items now.

Here are some of the points that I wanted to remind you of in case you had had any further thoughts in since our meeting:

A. Pierre Birabaut - (sp?) in France. I was not able to find additional information on him so I might not have the correct spelling. A mention was made of contacting him by email ...

B. A contact mentioned was Joe Valenzano, editor. "a businessman with a heart" Yes! We would like to contact him!

C. The possibility of obtaining a list of newly approved orphan drug products was mentioned and the contact Debbie Lewis. I will call the office of public information at FDA for this. I think I have also found an orphan drug products listserve.

D. I could not find any additional information on The INTERNATIONAL CONGRESS ON DISABILITIES and (EXCEPTIONAL PARENT a sponsor?)... in Atwater or Daytona. You mentioned that we should think about going there and giving a demonstration.

E. You mentioned the possibility of a referral list of research investigators in the area of rare disorders. This will be helpful -- especially as we progress further into our various applications and proposals. Right now we are focusing on Rett, Morquio and Autism.

F. The Genetic Alliance - Mary Davidson, Executive Director. You mentioned that I should try to meet her. I've looked up the Alliance and I see they are in Washington, D.C. so I will try to arrange that meeting on my next trip in early December.

G. You mentioned a pediatric research report that might be good to look at.

H. Donald A.B. Lindberg, MD, Director National Library of Medicine: Not sure if there was anything to follow up yet on this contact. I believe Dr. Groft suggested that once we begin to expand and have funding for an additional rare disorder (we have one new phase one application already submitted for Morquio, and we are putting proposals together for Autism and Rett syndrome at the moment), then it might be possible to set up a meeting with Dr. Lindberg, and include Dr. Spinella and Dr. Oster-Granite.

I. Also I noticed on one of the websites that there was information provided on NHGRI (National Human Genome Research Institute). I am not sure what stage that is in right now and whether or not our efforts are relevant...I think you might have mentioned this new initiative in our meeting in discussing the relationship of the Human Genome Research Institute to the Office of Rare

Diseases. Perhaps this is something that should be discussed when we have made a little more progress at our end.

I appreciate so much all the guidance and suggestions offered during the meeting.

Another suggestion offered in the meeting: that we should make contacts in the UK. As Angelman syndrome was discovered in England, we have actually done some filming there with Dr. Jill Clayton-Smith at St. Mary's Hospital in Manchester. So I will be in touch with her.

As we discussed in the meeting, our materials can be used in many different contexts -- we have an approach that can follow subjects over time and provide case studies over 5 years or more which will bring out the spectrum and progression of the disorders. Also we can provide support for workshops. One thought for the future: to think about pre-natal diagnosis. We also discussed various types of business plans for the company, as well as the consideration of a non-profit status. We talked about working with pharmaceutical companies -- for example, discussing the possibility of documenting Fabre or Gauche's disease with Genzyme. We would have to maintain creative and content control and offer ads and a certain number of copies for their contribution.

Dr. Groft mentioned, I believe, the possibility of asking for a business school to assist us with the completion of our business plan (we have one, but it is in-progress). Now, coincidentally, we have an offer from a Masters student at NYU and this project will begin in January, 2002.

Thanks so much for all your help! Let me know if you need additional materials. Look forward to talking with you soon again.

Sincerely,

Louise Tiranoff

cc.
Dr. Stephen Groft

Date:
Wed, 24 Oct 2001 13:31:42 EDT
From:
LSutherlnd@aol.com | Block Address | Add to Address Book
Subject:
Angelman Project to CDC
To:
tiranoff@yahoo.com

Louise:

Just reading about how the information about anthrax is getting out to doctors and dermatologists. Seems like the photos available showing anthrax are limited and only show full-blown anthrax. Since I'm sitting at NBC and following every single notice about infections, it occurs to me that the problems with initial diagnosing of bioterrorism-related illness are very similar to diagnosing Angelman Syndrome. Most medical information is written and pictures are limited. Anthrax is similar to flu. It's the start of the flu season. Is it a spider bite or what?

Why not apply your Angelman model of documentation to documenting anthrax and future biological terrorism?(Obviously, this is something you would have to propose to the CDC.) You could have a camera/producer person document each case as it occurs, post it quickly on the web site so that it is available to health officials. It would quickly grow into a data base that would help in diagnosing other cases.

As in the case of the postal workers who died in DC and as in the case of Angelman Syndrome, the health care system varies, depending on class and race. Some doctors are less prepared than others.

I think you should figure out a way to show the Angelman Project to the CDC and propose to document each case as it occurs. These cases should be posted as video on CDC website. This could be especially important if smallpox breaks out. I could go on. You get the picture.

More soon,
Leigh

Louise Tiranoff Productions
488 14th Street
Brooklyn, New York 11215

The Future:
Development of GeneticaPro –

ABSTRACT: Within the last decade there have been significant advances in all areas of research on genetic and low incidence disorders such as Down syndrome, Prader-Willi, Rett, Angelman syndrome (AS) and others. Even with these advances, patients with low incidence disorders are frequently misdiagnosed or not diagnosed at all, compromising the quality of the treatment and care. Diagnosis is hampered by a lack of visual data and information about the specific symptoms related to each of these disorders. Commonly used reference manuals contain very little visual or textual information. In addition, much of the work of leading healthcare professionals and researchers is often not available to professionals and families in need of it. GeneticaPro is designed to bridge the gap between families of individuals with these disorders and those professionals involved in their treatment and education.

BACKGROUND: There are over 500 low incidence disorders that affect individuals worldwide. Angelman syndrome, has at least 1,500 cases documented in the U.S. alone. Many of these disorders have only recently been discovered and described and previous to recent advances, there were few treatments. Diagnosis is difficult, sometimes impossible. Children born with these disorders encounter symptoms that can be extreme, even life threatening: severe mental retardation, brain malformations, difficulties in walking, seizures, gastrointestinal disorders, to name but a few. Yet when families turn to their family physician, they are often told that the disorder their child is experiencing is unknown and that there is little to be done other than managing the symptoms in a palliative way. Ideally, children with low incidence & rare genetic disorders should be managed by a multidisciplinary team in a medical center with access to the latest research. In most cases, such children are treated by a general practitioner, (sometimes at some distance from the medical centers), who does not have access to the specialists or to information about the diagnosis and treatment of many rare and low incidence disorders. Years go by without the proper diagnosis and treatment, sometimes exposing children needlessly to irreparable harm.

PROTOTYPE for GENETICA PRO -- THE ANGELMAN PROJECT: The first in a series of multi-media databases on low incidence disorders and the model/prototype for the various projects within GeneticaPro is *The Angelman Project*.. Working collaboratively with the experts in the disciplines related to the study of Angelman syndrome in education, medicine, and science, *The Angelman Project* makes use of the latest advances in communication technology to acquire current data on AS individuals, illustrating the main features of their appearance, as well as the essential aspects of their behaviors and abilities. In the course of the investigation and filming, the network of people, ideas and information has expanded greatly. We have learned from families and professionals alike. Many of those we have met introduced us to either new subjects or other professionals who have done related work that can contribute to the database. We have distributed a sample CD-ROM with a video segments-in-progress reel to professionals, families, organizations and health care providers and have received many positive responses. We have had requests to expand our database to include additional disorders. We are becoming more and more aware of how much this tool is desired and how much it will be utilized.

GENETICA PRO: The expansion of the database to include other low incidence genetic disorders would assist in making differential diagnoses. For example, Rett Syndrome and AS are often confused with each other in female individuals. Video data and textual examples of such related disorders will further help to establish appropriate diagnoses. Physicians, as well as parents, would be given more accurate information regarding the natural history of the condition(s), including genetic counseling, and potential therapies. It will be an invaluable resource for professionals -- physicians, therapists, and researchers – providing them with a base of technical and clinical information. Providing extensive databases with video on an interactive digital format such as the internet will advance the important task of documenting and categorizing rare disorders and disseminating information about these low incidence disorders across the globe. *GeneticaPro*, which will eventually include a broad selection of databases on different rare disorders, will result in

a) lower healthcare costs due to the reduction in mistaken diagnoses and treatments;
b) the expansion of the education and training of professionals and families;
c) an improvement in quality of life for individuals & families resulting in greater economic productivity for these families and the communities surrounding them.

(718) 788 6403 tel (718) 369-2387 fax Tiranoff@yahoo.com

Finished Documentaries

Code	Title	Description	Keywords	Duration	Subject
HAM8d	Sharon Puts On Her Sweater 3/16/2001	With House Manager Tonjala Tyson's help, Sharon puts on her sweather and hat. Commentary by staff member Doris Simmons	Daily Living Skills, Receptive	00:01:46	HAMILTONS
BEN2d	Ben Communicates Although this sequence is an extract of the overll "Life with Ben" interview of Ben's parents, it has added photos of Ben's expressions	Ben expresses many emotions through expressions: happy, sad, and the "ride" face, a very pensive face when in the car. We used to think that he did not experience fear but a picture was taken after a roller coaster ride (we have the pic) and he was terrified. Includes an amuzing story: when on a plane, he would put his hands up thinking he was on a roller coaster ride	communication, fear, pain	00:02:46	BEN 87
ALE2d	Communication	Shows Alex's use of the picture voice box at mealtime. Footage from 1995 is also shown. It contains Alex's mother (Leigh) explaining how to use the voice box. Leigh also explains how they have returned to a simple system of pictures to identify basic concepts, type of food, bathroom etc.	communication, picture	00:02:49	ALEXANDRA 87
JONM20d	Jonathan, Age 7: Getting Therapies 5/10/2001			00:03:04	JONATHAN 93
JONM21d	Jonathan, Age 7: Sleep Management 5/10/2001 NOTE: This mini-doc was lifted as-is from the			00:03:17	JONATHAN 93
HAM18d	Lisa Toileting	Lisa uses the bathroom with the help of one of her aides; then goes and gets a treat for doing a good job. Some by Lisa's Mom	toileting, about toilet training	00:03:46	HAMILTONS
KEL18d	Kelly's Circle Time	Ms. Kadash includes Kelly in all lessons. They include, number recognition, day of week, and spelling. Teacher adapts each lesson to Kelly's level. For example, the students are saying "Tuesday", Kelly is asked to touch a sign that says "Tuesday"..	educational programs	00:03:56	KELLY 93
HAM1d	Sharon Goes Bike Riding CLINICAL REEL.Good.	Observational documentary of Sharon's favorite activity, bike riding. Staff comments.	Favorite Activities Sign Language	00:04:09	HAMILTONS
JOSW13d	Progress In Gym Class	Gym class where phys ed. teacher works with Josh using a balance beam, jumping on air mattress, and climbing. The teacher also has a race with Josh and Stacy (another AS child)	Gross motor skills, gait,	00:04:15	JOSHUA 92
ABB330-2d	Abbie, Age 4: Communication Abilities of a Child CLINICAL REEL. DEMO CD TWO.	Abbie demonstrates verbal communication, as well as sign language. She understands the conversation going on around her, and participates. Abbie asks for more food using sign language, and she signs "thank you" after being prompted.	receptive language, sign sign language	00:04:27	ABBIE 96 Alvares
HAM17d	Lisa Brushes Her Teeth 3/16/2001	Lisa brushes her teeth with the help of one of her aides. Some commentary by Lisa's Mom.	oral hygiene, oral motor	00:05:03	HAMILTONS
HAM4d	Life with Sharon 3/16/2001	Observational documentary of Sharon's life around the yard at Bessent Group Home. Commentary about this and what Sharon is like	Keywords: Communication,	00:05:06	HAMILTONS
KAS108d	Kasey's Behavior at School	Short documentary on Kasey's behaviors at school. Commentary by Kasey's special needs teacher, Gutede Foruks. Good.	behaviors	00:05:44	KASEY 86

Finished Documentaries

Code	Title	Description	Keywords	Duration	Subject
JONM22d	Jonathan, Age 7: Sibling Relations 5/10/2001 NOTE: This mini-doc was lifted as-is from the			00:05:52	JONATHAN 93
ALE14d	Swimming Instruction	Kathy Osburn describes Alex's swim instruction while working with Alex. This is at the Gedulsky swim center in Washington.	aquatic therapy , swimming,	00:06:01	ALEXANDRA 87
HAM2d	Sharon Speaks Good.	Observational documentary of Sharon's speech and understanding skills. Celena P. Desue, staff at Bessent Group Home talks about how	Speech, Receptive Communication	00:06:22	HAMILTONS
HAM3d	Sharon's Behaviors CLINICAL REEL.	Observational documentary of some of Sharon's behaviors such as hugging, and dancing. Also shows some of her communication skills, vocal	Behaviors, Signing, Making Communication hugging	00:06:26	HAMILTONS
HAM10d	Sleepless Sharon	Observational documentary of Sharon's sleeping problems. Commentary by staff members Dora Simmons, Toniala Tyson	Sleep, About Sleep, Speech,	00:06:49	HAMILTONS
JOSW10d	Occupational Therapy	Teacher does putty, slits in can, sifting thru pebbles and balance on swing to aid in finger dexterity and balance	OT	00:07:04	JOSHUA 92
HAM5d	Dora Simmons, Staff Member, Describes Sharon 3/15/2001 Numbers after	Observational documentary showing some of Sharon's communication skills, including vocalizations (with a few words), signing, and gestures. We are also able to observe her receptive language skills. We also see Sharon hugging various people and Sharon bike riding along the driveway. Filmed at Bessent Group Home with a commentary by staff member Dora Simmons	speech, signing, receptive signing speech	00:07:09	HAMILTONS Alvares
ALE6d	Horseback Riding	Filmed on location at a riding stable, Alex rides a horse and works with her riding therapist, who also explains the principles and techniques behind horseback riding therapy.	Keyword: Horseback riding,	00:08:11	ALEXANDRA 87 Osburn
ALE9d	Seizures	A documentary detailing Alex's history of seizures. Tells about the search for proper medication, coping with the ER and footage of her at 2.5 years having a seizure.	Seizures	00:08:42	ALEXANDRA 87
KAT12d	Kate's Toilet Training	Pam, Kate's parents, Ms. Hendricks and Sue Gray all talk about toilet-training Kate. Footage of Pam's home video, new at pam's house before bath, and at Holz. Kate's parents and Pam talk about the difficulties of Kate's toilet training. Two of Kate's teachers mention that she used to hide the bathroom picture symbol because she didn't want to go into the room and the bathroom sign to get attention. But the	toilet-training, behaviors,	00:08:47	KATIE 88
KAS109d	The Importance of Signing DEMO CD THREE. Good. (Mike note) Need to find The Journey of Kasey!!!! Doc	Short documentary on Kasey walking, signing, and at play. Filmed at Kasey's school. Special needs teacher, Cathy, works with Kasey on her signing. Commentary by special needs teacher, Cathy, on Kasey and the importance of her signing.	signing, communication,	00:09:00	KASEY 86 Alvares
JONM9doc -	Dealing With Seizures and Poor Medical	A mini doc examing Jonathan's seizure control through the use of medications and a discussion of the side effects caused by the medications. Interview material as well as observational footage from Jonathan at home and at an examination with Dr. Hutchison at Valley Children's Hosptital.	seizures, medications, sleep	00:09:01	JONATHAN 93
JOSW12d	Speech & Language Class	Teacher uses articles of clothing to animate a scary Halloween book. Josh is very engaged and anticipates the role of each piece of clothing.	Communication, speech	00:09:09	JOSHUA 92

Finished Documentaries

Code	Title	Description	Keywords	Duration	Subject
BRY35d	Adaptations Around The House To Facilitate	Dad shows Bryan's room and how it is outfitted for Bryan's safety and comfort. i.e. TV mounted on ceiling, blinds sealed behind plexi glass etc. He also shows special bikes, wagons and joggers.	special deaccommodations	00:09:35	BRYAN 91
ALE7d	Aquatic Therapy	Alex's aquatic therapy - ages 5 and 13. Two sessions are shown. The first is of Alex, mom and instructor in the water doing exercises. Mom does a good job explaining how the therapy addresses Alex's issues. The second session is 8 years later and shows a marked improvement. She is independent in the water. Her instructor,	Water therapy scoliosis physical therapy	00:09:52	ALEXANDRA 87
JASKd2	Jason: Scoliosis and Surgery	This is a collection of interview footage (10 minutes long) of Jane describing Jason's history with scoliosis and surgery.	scoliosis, surgery	00:10:00	JASON 75
JOSW5d	Home Sweet Home, Sibling Reflections 3/28/2001	Josh's siblings, Charlie, Jonathan, and Katy talk about coping with Josh at home.	siblings, coping	00:10:12	
BEN6d	Ben's Inclusion Program DEMO CD ONE.	Parents discuss the Inclusion program. Featured clips are computer-based learning, pi symbs, choice making, lunchroom, socialization, acceptance by peers with v/o from parents.	inclusion	00:10:43	BEN 87 Ferguson
KAT10o	Communication and Receptive Language Skills made ID stills for Pam; need consent from Pam's Uncle Ray	Montage of Kate demonstrating receptive language skills, using picture symbols, signing, vocalizing, etc. all clips divided by titles describing the situation.	receptive language skills,	00:11:09	KATIE 88
HAM19d	Eating Breakfast 3/16/2001	With the help of a walker, Lisa walks in; sits down in dining room to have	eating, drinking, daily living	00:11:44	HAMILTONS
KAS40d	The Music Class with Kasey and Monica Primo Documentary.DEMO CD THREE.	A documentary of the music therapy class of Monica and Kasey with commentary by the music therapy teacher, Rachel Bons. Filmed at a special education school.	music therapy, peers,	00:12:21	KASEY 86
JUL1d	Nordoff Robbins Documentary	This is a medium length documentary showing Ju-li's music therapy session. Music therapist Matthew Dixon discusses the methodology of music therapy: how it is not like a lesson with particular goals and aims but rather a means for emotional fulfillment.	music therapy,	00:12:25	JU-LI 00
FR3d	Schayne's Sleep Disorder	This sequence contains footage mainly from the counseling session with Schayne and Tim. It also includes excerpts both from Tim's as well as Schayne's parents' interviews that pertain to sleep. It shows what a huge problem the sleep disorder is, and Tim gives Michelle advice as to what she can do to get Schayne to stay in his	sleep, behavior modification,	00:13:00	SCHAYNE 93 Freeman
KAT2d	Kate's Visit to the Orthodontist Link to KAT55sp (sequence of X-rays and before-and-after pix).	Footage of Kate at Dr. Taylor's, where she has her braces taken out. After the procedure, Dr. Taylor meets with the parents to recap the entire story (what made them decide to try it, how it went, specific problems/issues...). Starts with title cards explaining the situation, interspersed with before-and after-shots. 2-camera	orthodontics, dental care, Communication	00:15:53	KATIE 88 Taylor
LUC92d	Lucy'sPhysical Therapy Session w/ Marie Hudson DEMO CD ONE. Mike evaluation GOOD BROWSER IS LOST!!!!	Lucy's PT session w/ Marie Hudson is shown. Filmed at school. Includes interview and observation of the session. Shows a wide range of PT excercises.	gait, follows instructions,	00:16:34	LUCY 90 Osburn
KEL17d	Kelly's Inclusion Program	Kelly gets off bus, interacts with students, and has a variety of inclusion classes, and relationship with aide, Karen. Voice overs are used from parents, OT and pt teachers and aide.	inclusion	00:18:42	KELLY 93

Finished Documentaries

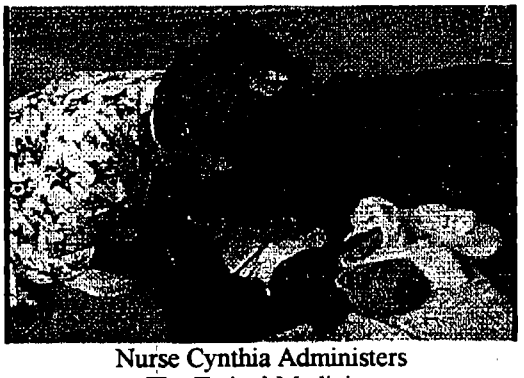
Code	Title	Description	Keywords	Duration	Subject
HAM16d	Lisa's Work Program 3/16/2001	At the Tacachale institution, Lisa waits; then wheels her self to work, to Designs Unlimited. With the help of two aides, Lisa sorts papers	work program, institutional	00:19:21	HAMILTONS
KAS9d	The PE Class with Kasey and Monica	Short Documentary about Kasey and Monica's adapted PE class. With their classmates, they go through an obstacle course, cheering each other on. Also, some ball passing. Jennifer Walker, the adapted PE teacher narrates.	peers, physical therapy, gait,	00:20:22	KASEY 86
FR2d	A counseling session with child psychologist DEMO CD ONE. note from Anita However, there's no	This is a documary of the session with Dr. Timothy Freeman, child psychologist, and Schayne taped at a clinic. It has two parts: the first one deals with Schayne's screaming at school, the second with his sleep disorder. The first part consists mostly of the session at Dr Freeman's office, with some observational examples of	sleep, behaviors, crying,	00:22:00	SCHAYNE 93 Freeman
BRY6d	Changing Behavior: The Intervention Process Audio could use work. Catherine to ask Anita.	This doc shows highlights from all stages of the intervention process. Sections include the observation, the intake, establishing motivators, the trials and an interpretation of the progress of the trials.	Intervention	00:22:08	BRYAN 91 Freeman
STEB1d	A Father's Reflections	The story of Mike Booth and his daughter Stephanie. Sometimes there are dark moments, but one should look for the "wild strawberries" in life. He and his daughter		00:25:37	STEPHANIE 86
CL1d	Diagnosing Angelman Syndrome with Dr. Jill GENETICS FOR WAGSTAFF.	Dr. Jill Clayton-Smith explains how to make a diagonosis of AS. There are three elements to identifying AS - examining a patient's medical history, identifying their clinical features, and performing laboraory investigations such as EEG, DNA and Cytogenetic analysis. A clinic appointment with Lauren, a 22 month old girl with a	clinical features, examination Diagnosis	00:27:00	Clayton-Smith
JASK1d	Jason	Jason was placed in a Training Center at the age of three and a half. His mother talks about what led her to this decision and why Training Centers can be a real necessity to those who can't take care of their disabled children at home. Includes footage of Jason in his home and at work.		00:38:00	JASON 75
KAT5d	Pamela Wilson: The Story of an Aide Important!!! we should write some explanatory blurp in the database that people will see before	2 parts: the first one shows Pam working w/ Kate at school, and she tells the story from the beginning until now (progress, etc.), second part is about training daily living skills at Pam's house, also about Joe and Ashlee. We have A LOT of footage of Pam w/ Kate: at school, at Pam's house, on the playground, plus Pam's home video	aide, inclusion, daily living	00:38:10	KATIE 88
HU1d	An Appointment with Dr. Terry Hutchison, Child LINK information on EEG (talk to Stuart Boyd) --address confusion over the	*The first section sets-up the harried pace of the hospital, as short scenes of the various patients waiting for Dr. Hutchison are inter-cut with glimpses of his interaction with them. The second section formally introduces the five patients and their families. Among the many issues illustrated by each family are : Nicole, age 11 – parent*	Seizures, seizure medications,	00:40:52	Hutchison
CL3d	From Adolescence to Adulthood GENETICS FOR WAGSTAFF.	This is a documentary about how individuals with Angelman Syndrom change during and after adolescence.	adolescence, scoliosis, scoliosis Community and Social	00:44:00	Clayton-Smith
ALE15d	Alex Lance ... see us when return from holiday	Full documentary on Alex detailing her life. The story begins with Alex's birth and continues the impact of the diagnosis on the family, search for a diagnosis, therapies addressing seizures, scoliosis, and other disfunctions.	Family, seizures, community,	00:59:00	ALEXANDRA 87
WAG10d	Dr Wagstaff and His Lab	A short documentary on the work of Dr. Wagstaff and his assistants on diagnosing and searching for a cure for Angelman. Using the interview / observations of assistants Julie, Hayley, and Val plus Dr. Wagstaff's interview as voice-over, along with shots of Dr. Wagstaff overseeing the project; the work at Boston Hospital could	Diagnosis, Genetics, DNA	01:00:00	Wagstaff
HAM35d	The Hamilton Story 3/16/2001 This will undergo one more revision w/ additional family photos added, and names edited out. 4/2001 Revisions complete	A long documentary, told by Veronica and Dwight Hamilton, about their family history of raising four, maybe 5 Angels. Incorporated are	about diagnosis, about	01:09:59	HAMILTONS

Finished Documentaries

Code	Title	Description	Keywords	Duration	Subject
KAI1d	Portrait of Kaitlyn, Then and Now: Ages 5 & 10 3/13/2001 PART 1 NOT COMPRESSED YET	A 70-minute documentary in 2 parts, about Kaitlyn, whose diagnosis is UPD.		01:10:00	KAITLYN 90

Adrian & Riley

SYNOPSIS

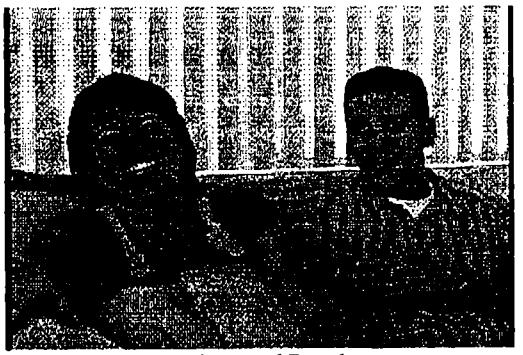


Nurse Cynthia Administers
The Twins' Medicine

Kristy Is Put On Hold When She
Orders Prescriptions

It was not until their twin boys were nine months old that Kristy and Randy discovered that something was wrong. Adrian and Riley have a rare genetic disorder called Angelman syndrome. Affected individuals are unlikely to ever talk and, without appropriate therapies, may never walk. This film tells the story of the challenges faced by this young couple as they come to terms with the devastating impact of their sons' disability upon their lives.

Three year old twins are a handful at the best of times, but because they have Angelman syndrome, Adrian and Riley need constant one-on-one attention. Their mother Kristy is helped on a daily basis by Cynthia, one of two nurses who has worked with the twins for some time. Together they wash, dress and feed the children. Cynthia prepares their daily medications while Kristy, chases down prescriptions on the telephone. The rarity of Angelman syndrome means that it is especially hard to receive government support and Kristy and Randy have had to fight for all that they can for their children.



Kristy and Randy

Aided by the use of home video this film not only exposes the problems experienced by families of children with severe disabilities but also illustrates the often lonely struggle, and the emotional strength needed to make the most of their situation. As the world around them changed so unexpectedly, Kristy and Randy were forced to look at life from a different perspective and draw on strengths they never imagined they had.

Christmas

This piece is just one of many documentaries made for *The Angelman Project*, a comprehensive digital database of videos, text and photographs, designed to facilitate the diagnosis, treatment and education of individuals with Angelman syndrome.

Funded by the National Institutes of Health, *The Angelman Project* is a unique collaboration between multi-media producers and professionals involved in the diagnosis and treatment of Angelman syndrome.

Adrian and Riley's Physical Therapy

We have filmed over 70 subjects in the US and England. We have filmed over 350 hours of video on these subjects (ranging in age from 3-41) and their families, as well as video on many physicians, teachers, therapists, research scientists and other experts. From this footage, as well as home video and photos submitted by the families, we have completed 401 video clips, documentaries and an additional 495 are nearly complete.

Of this group, we have 55 documentaries and nine are over 1/2 hour. These videos along with chapters written by outstanding researchers in AS, will be published in an interactive format (CD-ROM, DVD-ROM and the Internet), within the next year.

For more information please contact: Louise Tiranoff Productions, 488 14th Street, Brooklyn, NY 11215. Tel: 718 788 6403

White House Commission on Complementary and Alternative Medicine Policy
October 4-6, 2001

Draft Recommendations

CAM Information Development and Dissemination

Issue 1: Accuracy, quality, accessibility, and timeliness of CAM Information on the internet

1. The Commission recommends that a) a public-private partnership be formed to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest; and b) an ongoing process be developed to review participating websites to determine compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.

2. The Commission recommends that a) a public education campaign be conducted that teaches people how to evaluate CAM information on the internet; and b) partnerships be formed with schools that use computers to develop students' skills at evaluating internet information on health care.

3. The Commission recommends that the privacy of individuals using CAM internet sites be protected by a) encouraging CAM sites to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), and b) assessing if current legislation or regulations are adequate to assure the protection of privacy of CAM health information seekers on the internet, and if not, amending or developing new legislation.

Issue 2: Adequacy and accessibility of CAM information from the Federal Government

4. The Commission recommends that an inter-agency task force of Federal agencies be formed to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.

5. The Commission recommends that a centralized source of CAM information be established in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers

6. The Commission recommends that, in partnership with the National Library of Medicine and the American Library Association, training materials be developed to assist librarians in guiding people to find CAM information on the internet.

7. The Commission recommends that a) CAM information materials be developed at a reading level that the general public can understand and utilize, and b) CAM information be developed that is targeted to different population groups.

Issue 4: Availability of CAM information from other countries and in other languages

8. The Commission recommends that barriers to identifying and translating relevant articles, reports, and other materials be identified; strategies be developed to overcome these barriers; and that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Issue 5: False and deceptive health claims on the internet

9. The Commission recommends that additional support be provided to the FTC to a) identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

10. The Commission recommends that national and local leaders of communities of special populations be brought together to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 6: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices

11. The Commission recommends that health professionals be required to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

12. The Commission recommends that States and local governments make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 7: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner

13. The Commission recommends that the AER system be strengthened by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing

outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Issue 8: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits appropriate use, and potential risks

14. The Commission recommends that the availability of consumer information of dietary supplements be increased through a) improved labeling, package inserts, and information at points-of-sale; b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products; and c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

15. The Commission recommends that claims of standardization be limited to products with industry-approved standards.

Issue 9: Quality control of dietary supplements to assure consumer safety

16. The Commission recommends that the FDA's Good Manufacturing Practices (GMP) be implemented to help assure the purity of dietary supplements.

17. The Commission recommends that a) the DHHS, USDA, Environmental Protection Agency (EPA), US Customs Services, and other appropriate Federal departments and agencies work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace; and b) DHHS, USDA, EPA, and others work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

Issue 10: Federal oversight to assure public access to and safety of dietary suppplements

18. The Commission recommends that there be an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

Coordination of Complementary and Alternative Medicine Research

Issue 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners;

research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

Issue 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

21.a. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

21.b. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.c. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.d. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

Issue 3: Research Training and Infrastructure

21.e. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21.f. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

21.g. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

Issue 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities

21.h. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

21.i. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.j. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

Issue 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process

22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research–neither lower nor higher.

22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research.

23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities.

Issue 5: Publishing literature oj CAM research and systematic reviews of the literature

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

25. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date-summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

Education and Training of Health Care Practitioners in Cam

Issue 1: Access to funding and other resources for CAM faculty, curricula, and program development

26. The Commission recommends that appropriate access to funding and other resources for CAM faculty, curricula, and program development at accredited institutions and by licensed professions should be made possible by amending Titles VII and VIII of the PHS Act to authorize Health Resources and Services Administration, Bureau of Health Professions to provide this type of support.

27. The Commission recommends that joint research and educational programs involving CAM practitioners and conventional practitioners should be established and financial support for these programs should be identified.

Issue 2: National Educational Standards to Practice CAM

28. The Commission recommends that national educational standards for CAM modalities, therapies, and practices should be established by professional and educational institution organizations linked with the proposed Federal CAM Coordinating Office.

Issue 3: Basic or core conventional health care health care curriculum for CAM students and practitioners

29. The Commission recommends that a basic curriculum in conventional health care and medical sciences for CAM students and practitioners should be developed to facilitate recognition of limits of clinical expertise and potential complications of interventions and appropriate referrals to conventional health care providers.

30. The Commission recommends that collaboration between CAM and conventional health care institutions should be encouraged and funded.

Issue 4: Traditional Healing Education and Training

31. The Commission recommends that Traditional healers who practice within a community which provides traditions and oversight should be provided appropriate access to educational funding and allowed to continue to practice without State censure, providing:

a. Their clients are fully informed of their training (or lack thereof)
b. They do not mislead their clients by use of titles of licensed professions
c. They have not been censured by their community.

Issue 5: Participation of CAM Students in Scholarship and Loan Programs

32. The Commission recommends that CAM students should be eligible for State and where appropriate national fiscal support based on service to designated areas. Eligibility would apply to loans, loan forgiveness, and scholarships. The next reauthorization of Titles VII and VIII of

the Public Service Act should be amended to include enabling legislation making CAM students eligible.

Issue 6: Basic or core CAM curriculum for conventional health care professionals at professional school, postgraduate, and continuing education levels.

33. The Commission recommends that a basic curriculum which surveys the CAM modalities and ensures basic skills in collaborating with or supervising CAM professionals should be developed for conventional health care professionals in professional schools, postgraduate training programs, and continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

34. The Commission recommends that curricula in CAM fundamentals and principles should be developed at conventional health care professional schools in conjunction with CAM experts and CAM institutions.

35. The Commission recommends that conventional health care providers interested in practicing a CAM modality or system of healing should obtain the necessary education in postgraduate or continuing education programs or at accredited CAM institutions.

36. The Commission recommends that opportunities and funding for postgraduate and continuing education resembling that of conventional health care providers should be developed for CAM practitioners providing primary care to enhance the competency and quality of healthcare.

Issue 7: Postgraduate and continuing education for CAM practitioners resembling that available to conventional health care providers

37. The Commission recommends that combined or joint continuing education and residency programs which include different types of CAM practitioners and conventional health care providers should be developed to improve their mutual understanding and enhance their collaborative interaction.

Access and Delivery of Cam

Issue 1: The Effects of Rugulation on Access

38. The Commission endorses the Report of the Taskforce on Health Care Workforce Regulation, *Reforming Health Care Workforce Regulation,* finding it especially relevant to the regulation of CAM practitioners. States are encouraged to use these recommendations as guidance in developing regulations for CAM practitioners.

39. The Commission recommends that CAM practitioners who demonstrate appropriate competency based on established standards (such as training and education) should have the legal authority to practice.

40. The Commission urges States to include a diversity of qualified CAM practitioners on any workgroup, taskforce or regulatory body established to review regulations and clinical practices. To make the regulatory process accountable and transparent to the public, the Commission urges States to utilize a broad base of representation, including allopathic clinicians, consumers, and payers of health care, as appropriate.

41. The Commission recommends that the Federal Government set up projects in States to develop and evaluate competency-based regulatory mechanisms, and the effects of exclusive scopes of practice on access and delivery of care.

42. *(Placeholder for possible recommendation regarding the interaction of state medical boards and CAM practitioners, to be reviewed and discussed for Final Report Draft in December.)*

43. *(Placeholder for possible recommendation regarding the interaction of state medical boards and CAM practitioners, to be reviewed and discussed for Final Report Draft in December.)*

Issue 2: Delivery of CAM

44. The Commission recommends the Secretary of Health and Human Services expand current models of integrated services networks to incorporate safe and effective CAM services as appropriate. Special attention should be directed to address the needs of vulnerable or underserved populations.

45. The Commission recommends that the Health Care Financing Administration (HCFA) examine proposals to enable services for qualified CAM practitioners in all States to be paid for under its programs. For example, the Medicare Medical Wellness Act and the Medicare Medical Nutrition Act provide the sole right to have nutrition services reimbursed to registered dieticians. While registered dietitians should receive this coverage for services, this legislation could be expanded to include all CAM regulated professions whose training scope of practice provides regulated nutrition services. *(This recommendation to be referred to Group D: Coverage and Reimbursement for consideration)*

46. The Commission recommends that the Secretary of Health and Human Services authorize and fund detailed and expanded epidemiologic surveys of CAM patterns of use, with special attention to ethnic populations. This information is essential to inform public policy and to protect particularly vulnerable populations.

47. The Commission concurs with the 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project), which suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care, and recommends that the Federal Government establish an institute to address the needs of seriously ill and dying patients, and their families. The Commission believes that the collaborative integration of many CAM approaches is both appropriate and will add critical value.

48. The Commission recommends the Secretary of Health and Human Services convene a strategic planning conference to address the needs of seriously ill and dying patients, and their families that includes all relevant Federal and State agencies, non-governmental organizations, professional societies and a broad base of palliative care professionals, including qualified CAM providers.

49. The Commission recommends that the Secretary of Health and Human Services report within 3 years on the use of indigenous healing traditions in the United States to identify common use, best practices, and challenges and potential areas for collaborative learning between such traditions and conventional care. The Commission urges the Secretary's report to include recommendations for the future as regards appropriate protection of such traditions, as well as research and development of such practices as part of community-based health care.

Coverage and Reimbursement

Issue 1: Medical Effectiveness – Fair and impartial consideration of safe, efficacious CAM therapies

50. The Commission recommends that a public-private body (DHHS; DOD; VA; representatives of the research community, insurance industry, and managed care organizations, employers, etc.) be convened to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The Commission recommends that DHHS work within the partnership to target public and private resources on research priorities, maintain public-private coordination, and build cooperation.

51. The Commission recommends that public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system. The Commission encourages funding bodies to cooperate with the priorities established in Recommendation 1.

52. The Commission encourages health care purchasers including insurers, managed care organizations, Federal and State agencies, and other health plan sponsors to develop and maintain a process, as conducted for conventional therapies, for incorporating safe and efficacious CAM interventions into health benefit packages.

53. The Commission encourages

- Federal agencies that provide health benefits (CMS, DOD, VA, etc.) to include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
- Insurers and managed care organizations to include CAM experts on coverage advisory bodies, and related working groups.
- Professional associations, health policy institutions, and foundations to consider

advice, consultation, and information from CAM practitioners and other CAM experts.

- CAM practitioners to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects

Issue 2: Cost Effectiveness – Information on the utilization, costs, and cost-effectiveness of CAM therapies

54. The Commission recommends that public and private entities (DHHS; DOD; VA; research organizations, foundations, insurance industry, managed care organizations, employers, etc.), as with conventional medicine, fund or jointly fund health services research on the cost-effectiveness of CAM interventions, including the specific interventions for various conditions, and the impact of CAM on health care costs. The Commission recommends funding to study the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies on the costs and benefits of CAM practices, wellness programs, and self-care on health status are encouraged.

55. The Commission recommends that purchasers, insurers, managed care organizations, and other health plan sponsors consider coverage of CAM interventions shown to be safe and cost-effective.

56. The Commission recommends Federal agencies responsible for healthcare coverage and services investigate and report to their respective administrators on how safe, cost-effective CAM therapies may be integrated into federal programs.

57. The Commission recommends that DHHS, working in partnership with representative from the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), conduct a study of current coding processes and CAM, consider the issues associated with appropriate coding for CAM, and report to the Secretary of DHHS.

Issue 3: Licensure as a requirement for coverage and reimbursement

58. In order to increase access to and coverage of CAM therapies shown to be safe and cost-effective, the Commission encourages State governments to grant legal authority to practice to those CAM professions seeking licensure, or equivalent stature, within the State.

Issue 4: Determining when to pay for or provide CAM

59. The Commission encourages DHHS to support private sector efforts to develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

60. The Commission encourages insurers, managed care organizations, and benefit experts to work cooperatively with CAM professions to develop criteria for appropriate coverage of CAM benefits.

Issue 5: Supporting coverage and reimbursement through information

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Cam in Wellness, Self-care, and Prevention

Issue 1: Utilization of CAM in schools and the community to facilitate learning, improve behavior, ad optimize well-being

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71. The Commission recommends that DHHS, in consultation with the American Academy of Pediatrics, American Academy of Family Physicians, National Association of Community Health Centers, and others, including CAM professionals and consumers, develop guidelines and provide training and information on CAM and wellness to clinicians in Federally-funded health programs (e.g. community and migrant health centers, maternal and child health programs, school health programs, etc.) that provide clinical services to children and their families.

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77. The Commission recommends that DHHS identify Federal programs (e.g. Head Start, Meals on Wheels, Women Infants and Children, State Children's Health Insurance Program, etc.) that could benefit from the addition of CAM in wellness, prevention, or self-care, and develop strategies to incorporate these into the programs as appropriate.

Coordinating and Centralizing Federal Cam Efforts

Issue 1: Coordinating and Centralizing Federal CAM Efforts

78. The Commission recommends that The President, Secretary of the Department of Health and Human Services, or Congress should create an Office at the highest possible and most appropriate level with sufficient staff and budget to perform functions that include, but are not limited to, coordination of Federal CAM activities; Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning and convening conferences, workshops, and necessary advisory groups, centralized Federal media point of contact; and facilitation of implementation of the WHCCAMP recommendations.

White House Commission on Complementary and Alternative Medicine Policy
October 4-6, 2001

Draft Recommendations

CAM INFORMATION DEVELOPMENT AND DISSEMINATION

Issue 1: Accuracy, quality, accessibility, and timeliness of CAM Information on the internet

1. The Commission recommends that a) a public-private partnership be formed to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest; and b) an ongoing process be developed to review participating websites to determine compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.

2. The Commission recommends that a) a public education campaign be conducted that teaches people how to evaluate CAM information on the internet; and b) partnerships be formed with schools that use computers to develop students' skills at evaluating internet information on health care.

3. The Commission recommends that the privacy of individuals using CAM internet sites be protected by a) encouraging CAM sites to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), and b) assessing if current legislation or regulations are adequate to assure the protection of privacy of CAM health information seekers on the internet, and if not, amending or developing new legislation.

Issue 2: Adequacy and accessibility of CAM information from the Federal Government

4. The Commission recommends that an inter-agency task force of Federal agencies be formed to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.

5. The Commission recommends that a centralized source of CAM information be established in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers

6. The Commission recommends that, in partnership with the National Library of Medicine and the American Library Association, training materials be developed to assist librarians in guiding people to find CAM information on the internet.

7. The Commission recommends that a) CAM information materials be developed at a reading level that the general public can understand and utilize, and b) CAM information be developed that is targeted to different population groups.

Issue 4: Availability of CAM information from other countries and in other languages

8. The Commission recommends that barriers to identifying and translating relevant articles, reports, and other materials be identified; strategies be developed to overcome these barriers; and that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Issue 5: False and deceptive health claims on the internet

9. The Commission recommends that additional support be provided to the FTC to a) identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

10. The Commission recommends that national and local leaders of communities of special populations be brought together to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 6: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices

11. The Commission recommends that health professionals be required to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

12. The Commission recommends that States and local governments make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 7: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner

13. The Commission recommends that the AER system be strengthened by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing

outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Issue 8: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits appropriate use, and potential risks

14. The Commission recommends that the availability of consumer information of dietary supplements be increased through a) improved labeling, package inserts, and information at points-of-sale; b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products; and c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

15. The Commission recommends that claims of standardization be limited to products with industry-approved standards.

Issue 9: Quality control of dietary supplements to assure consumer safety

16. The Commission recommends that the FDA's Good Manufacturing Practices (GMP) be implemented to help assure the purity of dietary supplements.

17. The Commission recommends that a) the DHHS, USDA, Environmental Protection Agency (EPA), US Customs Services, and other appropriate Federal departments and agencies work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace; and b) DHHS, USDA, EPA, and others work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

Issue 10: Federal oversight to assure public access to and safety of dietary suppplements

18. The Commission recommends that there be an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

COORDINATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE RESEARCH

Issue 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation,

and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

Issue 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

21.a. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

21.b. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.c. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.d. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

Issue 3: Research Training and Infrastructure

21.e. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21.f. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

21.g. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

Issue 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities

21.h. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

21.i. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.j. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

Issue 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process

22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research–neither lower nor higher.

22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research.

23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities.

Issue 5: Publishing literature oj CAM research and systematic reviews of the literature

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

25. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date-summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

EDUCATION AND TRAINING OF HEALTH CARE PRACTITIONERS IN CAM

Issue 1: Access to funding and other resources for CAM faculty, curricula, and program development

26. The Commission recommends that appropriate access to funding and other resources for CAM faculty, curricula, and program development at accredited institutions and by licensed professions should be made possible by amending Titles VII and VIII of the PHS Act to authorize Health Resources and Services Administration, Bureau of Health Professions to provide this type of support.

27. The Commission recommends that joint research and educational programs involving CAM practitioners and conventional practitioners should be established and financial support for these programs should be identified.

Issue 2: National Educational Standards to Practice CAM

28. The Commission recommends that national educational standards for CAM modalities, therapies, and practices should be established by professional and educational institution organizations linked with the proposed Federal CAM Coordinating Office.

Issue 3: Basic or core conventional health care health care curriculum for CAM students and practitioners

29. The Commission recommends that a basic curriculum in conventional health care and medical sciences for CAM students and practitioners should be developed to facilitate recognition of limits of clinical expertise and potential complications of interventions and appropriate referrals to conventional health care providers.

30. The Commission recommends that collaboration between CAM and conventional health care institutions should be encouraged and funded.

Issue 4: Traditional Healing Education and Training

31. The Commission recommends that Traditional healers who practice within a community which provides traditions and oversight should be provided appropriate access to educational funding and allowed to continue to practice without State censure, providing:

a. Their clients are fully informed of their training (or lack thereof)
b. They do not mislead their clients by use of titles of licensed professions
c. They have not been censured by their community.

Issue 5: Participation of CAM Students in Scholarship and Loan Programs

32. The Commission recommends that CAM students should be eligible for State and where appropriate national fiscal support based on service to designated areas. Eligibility would apply

to loans, loan forgiveness, and scholarships. The next reauthorization of Titles VII and VIII of the Public Service Act should be amended to include enabling legislation making CAM students eligible.

Issue 6: Basic or core CAM curriculum for conventional health care professionals at professional school, postgraduate, and continuing education levels.

33. The Commission recommends that a basic curriculum which surveys the CAM modalities and ensures basic skills in collaborating with or supervising CAM professionals should be developed for conventional health care professionals in professional schools, postgraduate training programs, and continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

34. The Commission recommends that curricula in CAM fundamentals and principles should be developed at conventional health care professional schools in conjunction with CAM experts and CAM institutions.

35. The Commission recommends that conventional health care providers interested in practicing a CAM modality or system of healing should obtain the necessary education in postgraduate or continuing education programs or at accredited CAM institutions.

36. The Commission recommends that opportunities and funding for postgraduate and continuing education resembling that of conventional health care providers should be developed for CAM practitioners providing primary care to enhance the competency and quality of healthcare.

Issue 7: Postgraduate and continuing education for CAM practitioners resembling that available to conventional health care providers

37. The Commission recommends that combined or joint continuing education and residency programs which include different types of CAM practitioners and conventional health care providers should be developed to improve their mutual understanding and enhance their collaborative interaction.

ACCESS AND DELIVERY OF CAM

Issue 1: The Effects of Rugulation on Access

38. The Commission endorses the Report of the Taskforce on Health Care Workforce Regulation, *Reforming Health Care Workforce Regulation,* finding it especially relevant to the regulation of CAM practitioners. States are encouraged to use these recommendations as guidance in developing regulations for CAM practitioners.

39. The Commission recommends that CAM practitioners who demonstrate appropriate competency based on established standards (such as training and education) should have the legal authority to practice.

40. The Commission urges States to include a diversity of qualified CAM practitioners on any workgroup, taskforce or regulatory body established to review regulations and clinical practices. To make the regulatory process accountable and transparent to the public, the Commission urges States to utilize a broad base of representation, including allopathic clinicians, consumers, and payers of health care, as appropriate.

41. The Commission recommends that the Federal Government set up projects in States to develop and evaluate competency-based regulatory mechanisms, and the effects of exclusive scopes of practice on access and delivery of care.

42. *(Placeholder for possible recommendation regarding the interaction of state medical boards and CAM practitioners, to be reviewed and discussed for Final Report Draft in December.)*

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Issue 2: Delivery of CAM

44. The Commission recommends the Secretary of Health and Human Services expand current models of integrated services networks to incorporate safe and effective CAM services as appropriate. Special attention should be directed to address the needs of vulnerable or underserved populations.

45. The Commission recommends that the Health Care Financing Administration (HCFA) examine proposals to enable services for qualified CAM practitioners in all States to be paid for under its programs. For example, the Medicare Medical Wellness Act and the Medicare Medical Nutrition Act provide the sole right to have nutrition services reimbursed to registered dieticians. While registered dietitians should receive this coverage for services, this legislation could be expanded to include all CAM regulated professions whose training scope of practice provides regulated nutrition services. *(This recommendation to be referred to Group D: Coverage and Reimbursement for consideration)*

46. The Commission recommends that the Secretary of Health and Human Services authorize and fund detailed and expanded epidemiologic surveys of CAM patterns of use, with special attention to ethnic populations. This information is essential to inform public policy and to protect particularly vulnerable populations.

47. The Commission concurs with the 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project), which suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care, and recommends that the Federal Government establish an institute to address the needs of seriously ill and dying patients, and their families. The Commission believes that the collaborative integration of many CAM approaches is both appropriate and will add critical value.

48. The Commission recommends the Secretary of Health and Human Services convene a strategic planning conference to address the needs of seriously ill and dying patients, and their families that includes all relevant Federal and State agencies, non-governmental organizations, professional societies and a broad base of palliative care professionals, including qualified CAM providers.

49. The Commission recommends that the Secretary of Health and Human Services report within 3 years on the use of indigenous healing traditions in the United States to identify common use, best practices, and challenges and potential areas for collaborative learning between such traditions and conventional care. The Commission urges the Secretary's report to include recommendations for the future as regards appropriate protection of such traditions, as well as research and development of such practices as part of community-based health care.

COVERAGE AND REIMBURSEMENT

Issue 1: Medical Effectiveness – Fair and impartial consideration of safe, efficacious CAM therapies

50. The Commission recommends that a public-private body (DHHS; DOD; VA; representatives of the research community, insurance industry, and managed care organizations, employers, etc.) be convened to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The Commission recommends that DHHS work within the partnership to target public and private resources on research priorities, maintain public-private coordination, and build cooperation.

51. The Commission recommends that public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system. The Commission encourages funding bodies to cooperate with the priorities established in Recommendation 1.

52. The Commission encourages health care purchasers including insurers, managed care organizations, Federal and State agencies, and other health plan sponsors to develop and maintain a process, as conducted for conventional therapies, for incorporating safe and efficacious CAM interventions into health benefit packages.

53. The Commission encourages

- Federal agencies that provide health benefits (CMS, DOD, VA, etc.) to include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
- Insurers and managed care organizations to include CAM experts on coverage advisory bodies, and related working groups.
- Professional associations, health policy institutions, and foundations to consider

advice, consultation, and information from CAM practitioners and other CAM experts.

- CAM practitioners to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects

Issue 2: Cost Effectiveness – Information on the utilization, costs, and cost-effectiveness of CAM therapies

54. The Commission recommends that public and private entities (DHHS; DOD; VA; research organizations, foundations, insurance industry, managed care organizations, employers, etc.), as with conventional medicine, fund or jointly fund health services research on the cost-effectiveness of CAM interventions, including the specific interventions for various conditions, and the impact of CAM on health care costs. The Commission recommends funding to study the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies on the costs and benefits of CAM practices, wellness programs, and self-care on health status are encouraged.

55. The Commission recommends that purchasers, insurers, managed care organizations, and other health plan sponsors consider coverage of CAM interventions shown to be safe and cost-effective.

56. The Commission recommends Federal agencies responsible for healthcare coverage and services investigate and report to their respective administrators on how safe, cost-effective CAM therapies may be integrated into federal programs.

57. The Commission recommends that DHHS, working in partnership with representative from the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), conduct a study of current coding processes and CAM, consider the issues associated with appropriate coding for CAM, and report to the Secretary of DHHS.

Issue 3: Licensure as a requirement for coverage and reimbursement

58. In order to increase access to and coverage of CAM therapies shown to be safe and cost-effective, the Commission encourages State governments to grant legal authority to practice to those CAM professions seeking licensure, or equivalent stature, within the State.

Issue 4: Determining when to pay for or provide CAM

59. The Commission encourages DHHS to support private sector efforts to develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

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Issue 5: Supporting coverage and reimbursement through information

61. The Commission recommends that DHHS sponsor, or co-sponsor with external partners, an easily accessible, continuously updated website that provides information on CAM practices and products proven to be safe, clinically efficacious, and cost effective. The Commission believes that information should be provided for both consumer and professional use. The Commission encourages an out-reach effort be made to inform purchasers, such as employers and community health centers, of the availability of this website.

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COORDINATING AND CENTRALIZING FEDERAL CAM EFFORTS

Issue 1: Coordinating and Centralizing Federal CAM Efforts

78. The Commission recommends that The President, Secretary of the Department of Health and Human Services, or Congress should create an Office at the highest possible and most appropriate level with sufficient staff and budget to perform functions that include, but are not limited to, coordination of Federal CAM activities; Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning and convening conferences, workshops, and necessary advisory groups, centralized Federal media point of contact; and facilitation of implementation of the WHCCAMP recommendations.

OVERARCHING DRAFT RECOMMENDATIONS and ACTION ITEMS

Education and Training of Health Care Practitioners

1. **The Commission recommends that the education, training and credentialing of CAM and conventional practitioners be improved to assure public safety, and to increase the availability of qualified CAM practitioners and knowledgeable conventional practitioners.**

Action Items

1.1 The Commission recommends that appropriate support should be made available through competitive award processes for CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

1.2 The Commission recommends that joint research, education and training programs involving CAM and conventional institutions should be supported to focus research on clinically relevant topics, improve the quality of research conducted, and link research with evidenced-based education and training.

1.3 The Commission recommends that conferences should be convened by the proposed Federal CAM Coordinating Office to assemble the leadership of professions, educational institutions, and appropriate organizations to determine the feasibility of and possible mechanisms for establishing national CAM education and training standards.

1.4 The Commission recommends that all CAM and conventional education and training programs should develop curricula and other methods to facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions and organizations.

1.5 The Commission recommends that core elements of a biomedical science and conventional health care curriculum for CAM education and training programs should be determined along with methods for incorporation into existing curricula through demonstration projects and conferences with subsequent results, models, and recommendations compiled and available on the internet.

1.6 The Commission recommends that traditional healers should be educated and trained in accordance with their respective established traditions to ensure that culturally appropriate access to traditional healers and healing is maintained.

1.7 The Commission recommends that demonstration projects should be developed to determine the feasibility of expanding the role of appropriately trained CAM practitioners becoming primary care providers, so that the eligibility of CAM students to participate in existing loan and scholarship programs and CAM practitioners to participate in loan forgiveness programs can be evaluated.

1.8 The Commission recommends that a core curriculum of knowledge about CAM systems, modalities, therapies, approaches, fundamentals, and principles should be developed in conjunction with CAM experts and CAM institutions, based on minimal knowledge-related competencies, and designed with maximal latitude for easy and cost-effective implementation at conventional health professional schools, in postgraduate training programs, and in continuing education programs to increase knowledge and understanding of CAM, so that conventional health professionals can discuss and provide guidance for the appropriate use of CAM.

1.9 The Commission recommends that demonstration projects of joint primary care residencies for appropriately educated and trained CAM practitioners and conventional physicians should be conducted to determine the feasibility of such residencies and their impact on collaboration, clinical competency, and quality of health care.

Access and Delivery of CAM

2. The Commission recommends that regulatory oversight of CAM practitioners be improved to assure public safety, provide for accountability to the public, and maximize access to safe and effective CAM practitioners and services.

Action Items

2.1 No later than 6 months following the receipt of the White House Commission on Complementary and Alternative Medicine Policy's report, the Secretary of Health and Human Services should establish a national policy advisory board that will support and coordinate efforts with a designated Federal office for CAM to develop policy guidelines on issues related to the access and delivery of CAM.

2.2 Within 18 months of being established, the national policy advisory board appointed by Health and Human Services (HHS) will research, develop and publish a set of national standards for the practice of CAM. These standards will establish minimum educational, ethical and practice guidelines for any practitioner wishing to provide health care via CAM approaches, and focus on ensuring patients with necessary safeguards.

2.3 With guidance from the HHS' national advisory board on CAM policy, the designated Federal office for CAM should actively promote the development of consensus and practice standards that are specific to a wide variety of CAM practices.

2.4 With the support and facilitative efforts of the designated Federal office for CAM, CAM practices and professions should establish a single, voluntary, national organization to register, regulate, and represent its members.

2.5 States strongly are encouraged to use and implement the national practice standards developed by the HHS's advisory board, and to acknowledge and recognize the self-regulating authority of single, national, voluntary CAM organizations by requiring that CAM practitioners be registered through such organizations, and by providing broad legal authority and limited uniform protection for CAM practitioners who qualify under the national practice standards and who register with a self-regulating organization.

2.6 Within 8 months of being established, the HHS' national policy advisory board should begin a process to develop national uniform scopes of practice for CAM practices, primarily to address those practices deemed to present the most potential risks to patients. States are encouraged to use these scopes of practice to provide the necessary legal authority and licensure of such practitioners.

2.7 State medical boards strongly are encouraged to work closely with HHS' advisory board through the designated Federal office for CAM to develop standard operational guidelines for the regulation and oversight of licensed physicians practicing CAM, which are based on national uniform scopes of practices developed by the HHS board.

2.8 The Commission recommends that nationally recognized accrediting bodies assume leadership roles to review the most commonly used and evidence-based CAM modalities, especially those with particular relevance to a coordinated care approach, with respect to establishing accreditation standards.

3. The Commission recommends that access to affordable, safe and effective CAM services be better facilitated for all Americans.

Action Items

3.1 The Federal Government, including but not limited to HHS, should fund and support efforts by the designated Federal office on CAM to coordinate detailed and expanded epidemiologic surveys of CAM patterns of use, with special

attention to ethnic and vulnerable populations.

3.2 The Federal Government, including but not limited to HHS, should fund and support efforts by the designated Federal office on CAM to collaborate with private sector studies and demonstration projects that evaluate the usefulness, effectiveness and cost-benefits of collaborative care models at three delivery levels: global health care systems, such as hospitals, community health centers, and managed care settings; specialized health care systems, such as hospice care; and small clinical settings, such as individual and group practices.

3.3 Based on studies and demonstration projects evaluating the effectiveness and cost benefits of collaborative care models at three delivery levels, the Federal Government, including but not limited to HHS, should fund and support efforts by the designated Federal office for CAM to convene strategic planning conferences addressing the needs of seriously ill and dying patients, as well as other special populations, to determine best practice guidelines that incorporate conventional palliative care with appropriate and effective CAM approaches.

3.4 Within 3 years of being established, the designated Federal office for CAM shall report to the Secretary of HHS on the use of indigenous healing traditions in the United States to identify common use, best practices, and challenges and potential areas for collaborative learning between such traditions and conventional care. The Commission urges this report to include recommendations for the future as regards appropriate protection of such traditions, as well as research and development of such practices as part of community-based health care. Members from such traditions should be involved closely in this endeavor.

3.5 The Federal Government, including but not limited to the Department of Agriculture and HHS, should fund and support efforts by the designated Federal office on CAM to evaluate the feasibility, costs vs benefits, and overall impact on allowing Food Stamp Program Participants to use food stamps to purchase specified single or multiple vitamin-mineral products that do not exceed the nutrient recommendations of the Food and Nutrition Board of the Institute of Medicine.

Coverage and Reimbursement of CAM

4. The Commission recommends that coverage and reimbursement of safe and effective CAM services and products provided by qualified practitioners be facilitated as quickly as possible.

Action Items

4.1 The Commission recommends that purchasers and other health plan sponsors, insurance companies and managed care organizations offer coverage of safe and effective CAM interventions in a manner and through a process equivalent to that used for conventional medicine.

4.2 The Commission recommends that purchasers and other health plan sponsors, insurance companies, managed care organizations, and health care organizations which influence health policy and interventions open their processes to CAM, such as maintaining an expertise regarding CAM and including CAM experts on appropriate advisory bodies and working groups related to health benefits plans, health care coverage, reimbursement, and applicable processes including coding.

4.3 The Commission recommends that professionals working in complementary and alternative health care actively seek opportunities to advise and participate on public and private bodies that address issues related to health services research (for CAM or, where appropriate, health care generally), CAM-related demonstration projects, coverage and payment for health services and products, and improvements to coverage-related processes, such as coding.

4.4 The Commission recommends the Secretary, Department of Health and Human Services (DHHS), convene a public and private task force to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The task force should convene within 3 months of its appointment, and submit its report to the Secretary within 18 months of its appointment.

4.5 The Commission recommends that Federal agencies, states, and private organizations fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, the use of CAM in underserved and vulnerable populations, and the efficacy of various models for providing CAM services, including integration and collaboration, within the U.S. health care system.

4.6 The Commission recommends that Federal agencies, state, and private organizations fund health services research and demonstrations on the costs and cost-effectiveness of CAM interventions and wellness programs.

4.7 The Commission recommends that the Secretary, Department of Health and Human Services, support the development of coding for CAM services and products and, specifically, conduct a study analyzing nationally-used coding

systems (including current CAM systems) and the issues associated with integrated versus separate CAM coding systems, and make recommendations.

4.8 The Commission recommends that state governments recognize and address barriers to third-party coverage of safe and effective CAM services related to the legal authority to practice CAM interventions within the state.

4.9 The Commission recommends the Secretary, Department of Health and Human Services, through the National Institutes of Health and other appropriate agencies, identify CAM interventions of importance to patients, health care providers, and the general public that need an assessment of the state-of-the-science, and conduct conferences to produce consensus statements.

4.10 The Commission recommends that the National Center for Complementary and Alternative Medicine, through its clearinghouse, provide information on safe and effective CAM services and products including information on health services research and demonstrations, models of providing CAM, costs and cost-effectiveness.

4.11 The Commission recommends that appropriate Federal departments report to the President and Congress on the status, coverage and reimbursement, and impediments to coverage and reimbursement of CAM services and products for their respective beneficiaries or through their respective sponsorships.

4.12 The Commission recommends that health care entities that influence health policy and the delivery of health care services, such as insurance and managed care associations, integrate information regarding safe and effective CAM interventions into appropriate professional meetings.

4.13 The Commission recommends that the Secretary, Department of Health and Human Services, provide support for the development of informational programs on safe and effective CAM services and products which are targeted to purchasers, insurers managed care organizations, health care professionals, and providers of health care services.

Information Development and Dissemination

5. The availability of reliable CAM information to the general public and to health care practitioners be increased to improve public awareness and understanding of their health care options.

Action Items

5.1 The Secretary, DHHS, should establish an inter-departmental task force to identify and eliminate existing gaps in the development and dissemination CAM information in the Federal government, and resources should be increased to centralize CAM information for the public and the media. This should include a toll-free telephone number that directs callers to the appropriate department, agency, and/or person for specific CAM information.

5.2 Resources should be made available to a) develop CAM informational materials at a level that most of the adult general public can understand and utilize; and b) support national and local community leaders and organizations in identifying strategies and developing materials to enhance the availability of CAM information to the communities they represent and help prevent special populations from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

5.3 Current efforts of the National Library of Medicine and the American Library Association should be expanded to develop training materials and provide training to librarians in guiding people to find CAM health information.

5.4 The Secretary, DHHS, should form a public-private partnership to review new and existing websites and develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of sources of support and any conflicts of interest. Sites reviewed and found in compliance with the standards could publicize this achievement and display a logo identified with this level of merit.

5.5 Funding should be provided to the Secretaries, DHHS and Department of Education, to jointly conduct a public education campaign that teaches people, including students, how to evaluate health care information, including CAM information, particularly on the internet.

5.6 Congress should protect the privacy of individuals using CAM internet sites by a) requiring all health information sites, including CAM sites, to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), and stored; and b) expanding existing legislation or regulations to assure that the privacy of CAM health information seekers on the internet is protected.

5.7 Barriers to identifying and translating relevant articles, reports, and other materials should be identified; strategies should be developed to overcome these

barriers; and relevant and high quality, scientific materials should be made available to researchers, clinicians, policymakers, and others.

5.8 States and local governments should require all persons providing any kind of health services or products, including CAM, to make information easily available to consumers that explains their level and scope of training so that consumers can make informed choices.

5.9 States and local governments should make information on state guidelines, requirements, licensure, certification, and disciplinary actions of health providers, including CAM providers, readily available to the public.

6. The Commission recommends that regulatory oversight of CAM products be improved to assure accurate information on quality and safety.

Action Items

6.1 Efforts of both the public and private sectors to assure the development, validation, and dissemination of analytical methods and reference materials for well-characterized dietary supplements to the public should be enhanced and accelerated.

6.2 Information on benefits, appropriate use, and potential risks should be made more easily available at the time of purchase through improved labeling, package inserts, and information at points-of-sale. When significant interactions with prescription or OTC drugs, foods, or other health products are known, this information should be on the label. In addition, labels or information provided to consumers should identify possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems, All information on labels should be in English, even if another language is also included.

6.3 Additional support should be provided to the Federal Trade Commission to a) expand efforts to identify false and deceptive CAM- related health claims and take appropriate enforcement action; and b) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

6.4 Good Manufacturing Practices for Dietary Supplements should be implemented to help assure the quality and composition of dietary supplements, and a study should be commenced 12 - 18 months after the full implementation of the GMPs

by an external organization to evaluate current efforts and provide recommendations for improvement.

6.5 Appropriate Federal entities should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements to identify and prevent products that are contaminated or adulterated from entering the U.S. marketplace.

6.6 DHHS and other appropriate Federal Departments and Agencies should work with the Codex Alimentarius Commission, World Health Organization, Agency for International Development, and other international organizations to establish standards to help assure the quality of imported dietary supplements and prevent products that are contaminated or adulterated from entering the U.S. marketplace.

6.7 The FDA and other agencies with regulatory responsibilities should be provided with the necessary funds to employ additional professionals with expertise in dietary supplements to assure appropriate oversight.

6.8 Congress should require dietary supplement manufacturers and suppliers to register their products with the FDA and the FDA should encourage voluntary registration until such a requirement is in effect. This information is for the purpose of notifying manufacturers and suppliers in the event that a problem is identified with a product.

6.9 The FDA should develop guidelines to assist the dietary supplement industry in understanding and complying with the FFDCA sections of 201(n) and 403(a)(1) which require that material facts be included on labels of all products regulated by the FDA.

Coordination of Research

7. The Commission recommends strengthening the emerging dialogue between practitioners and researchers in both CAM and conventional health care fields to facilitate the integration of CAM into the health care system.

Action Items

7.1 The emerging dialogue between conventional medicine and CAM should be strengthened by continuing to develop ways to enhance communication, cooperation, and collaboration among conventional and CAM research and clinical professionals, research centers and accredited institutions, professional

organizations, and Federal and state research, health care, and regulatory agencies, the private and nonprofit sectors, and the general public.

7.2 Standards of quality for all aspects of research and related activities should be the same for CAM as for conventional medicine and health services.

7.3 Trained, experienced and properly qualified CAM and conventional professionals should be included as needed on research, journal, regulatory, and health insurance advisory and/or review committees in both the public and private sectors, and regulations should be adapted, as appropriate, to avoid impeding such representation.

7.4 The public, private, and nonprofit sectors should support and organize independently or collaboratively multidisciplinary conferences on CAM research and related activities to increase opportunities for CAM and conventional medical practitioners, clinicians, researchers and others to exchange ideas on research programs and policy, research planning, and methodological approaches to studying CAM questions.

8. The Commission recommends increasing collaboration among public, private and nonprofit sectors in the support of CAM research.

Action Items

8.1 The Federal and private sectors should provide support for workshops to discuss research needs for regulatory review and approval of CAM products and devices, as well as for other purposes.

8.2. The Federal, private, and nonprofit sectors should support research on practices that build on lifestyle and self care; and on new, innovative and sometimes controversial CAM research in emerging areas of scientific study that might expand our understanding of health and disease; and basic research on core questions described in many CAM systems, such as bioenergy.

8.3 NCCAM should conduct a review assisted by the National Science Foundation, the Institute of Medicine, the World Health Organization, or other Federal or non-Federal bodies on methods to study in a credible manner emerging areas of scientific investigation associated with CAM.

8.4 Public and private resources should be increased to strengthen the CAM research infrastructure at strategically located conventional medical and CAM sites to expand the core of researchers knowledgeable about CAM, who have received

rigorous research training in basic, clinical, and health services research.

8.5 Public and private resources should support, conduct, and update systematic reviews of current evidence in high quality, peer-reviewed research literature on the safety (including contraindications) and efficacy of CAM practices and products. These reviews should be written in understandable English and other languages, and should be easily obtained from multiple publicly available information services, including the National Library of Medicine's MedlinePlus database, which is accessible directly and through public libraries.

8.6 Summary reports of current clinical evidence on CAM should be produced by public and/or private organizations and updated at appropriate intervals.

9. The Commission recommends that government agencies increase CAM research and related activities according to their missions.

Action Items

9.1 All Federal agencies with research or related health care responsibilities should increase CAM activities relevant to their biomedical or health services missions in a more proactive manner, including the consideration of special initiatives, to ensure that CAM is properly integrated into the health care system.

9.2 Adequate public funding should be continued for research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.

9.3 The Federal government should provide incentives to stimulate private sector investment in research on CAM products and NDA development, and on developing analytical methods for producing better quality CAM products.

9.4 State professional regulatory boards should develop processes that will allow practitioners who have developed scientifically acceptable preliminary data to move successfully to clinical investigation of a non-approved treatment while maintaining their ethical and professional responsibilities toward their patients and the public and therefore their right to practice.

9.5 NIH Institutes and Centers and other Federal agencies, as appropriate, should develop programs to evaluate practice-based data for potential research support, communicate the availability of such initiatives in a proactive manner to CAM and conventionally-trained practitioners who believe they have promising data on non-approved treatments, and provide training in data collection, protocol

development, and ethical guidelines and human subject protection.

9.6 Enhanced support for research training should be offered by all Federal health agencies with research training programs and responsibilities that encompass CAM-related questions.

9.7 Existing resources, such as NCCAM-supported centers and the National Center for Research Resources' General Clinical Research Centers, should be utilized to increase opportunities to conduct clinical research and training on CAM and examine the integration of CAM into the clinical setting.

9.8 Strong support for career development awards that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators should be continued.

9.9 The Agency for Healthcare Research and Quality should expand its Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

CAM in Wellness and Prevention

10. The Commission recommends that CAM interventions that improve wellness, self-care, health promotion and disease prevention be utilized broadly to reduce health disparities and enhance the health status of all Americans.

Action Items

10.1 The Commission recommends that DHHS review the 10 leading health indicators and, where appropriate, develop strategies to encourage the use of safe and effective CAM principles and practices in these areas.

10.2 The Commission recommends that questions on specific CAM usage be included in the national surveys that are the sources of the HP 2010 data including the National Health Interview Survey, National Health and Nutrition Examination Survey, and the Medical Expenditure Panel Survey.

10.3 The Commission recommends that CAM become part of a national focus to improve the health behaviors of children. Where appropriate, CAM practices should be incorporated into national guidelines on wellness and prevention practices for children, and a media campaign be should be conducted that

includes public service announcements and involvement of public figures to teach and encourage healthy behaviors among children

10.4 The Commission recommends that CAM wellness and prevention activities be included in all Federal worksite wellness and health promotion programs and Federal health coverage plans.

10.5 The Commission recommends that the Secretary, DHHS, establish a task force to develop strategies to incorporate CAM wellness and prevention in health care delivery programs such as the Department of Veterans Affairs Hospitals, community and migrant health centers, maternal and child health programs, and school health programs.

Coordinating and Centralizing Federal CAM Efforts

11. The Commission recommends that the Federal Government establish a CAM office to coordinate activities that maximize the benefits of safe and effective CAM to all Americans.

12/6/01

VIA FAX to MAUREEN MILLER (301) 402.7549

The Commission recommends that the Internal Revenue Code should be amended to provide equitable tax treatment of health insurance coverage of various CAM health care services and products. Specifically, the Commission recommends that Congress hold a hearing and consider legislation on equitable tax treatment and the Executive branch consider administrative relief for employers who include coverage for Dietary Supplements and for other CAM healthcare services and products that have been shown to be safe and beneficial.

CLINICAL CENTER SETS NEW POLICY ON USE OF HERBAL AND OTHER ALTERNATIVE SUPPLEMENTS BY CC PATIENTS

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The escalating use of dietary supplements in the United States over the past few years, with herbal products representing the most rapidly growing segment, has generated new concerns related to patient safety.

These supplements are consumed by 30–40 percent of Americans, and an estimated 15 million adults are taking herbal products concurrently with prescription medication.[1] As a result, there has been a dramatic increase in published reports on adverse consequences of herb-drug interactions, including loss of drug efficacy, physiologic disturbances, skewed laboratory results, and compromised perioperative care.

These concerns for patient safety are reflected in specific questions posed by the Joint Commission on Accreditation of Healthcare Organizations to hospitals seeking accreditation. They ask how patients who bring herbal products from home are handled, whether herbs are on the hospital formulary, and whether physicians are required to assess the use of herbals during the hospital stay.[2]

Impact on Research

The effect of herbal and alternative supplement use by people participating in biomedical research protocols has been a concern of NIH's.[3]

Recently, NIH investigators reported a significant reduction in the bioactivity of the protease inhibitor indinavir—up to a 75 percent decrease—in HIV-infected patients who were prescribed indinavir and were also taking St. John's wort.[4, 5] The studies also showed that low plasma concentrations of protease inhibitors are a cause of antiretroviral resistance, treatment failure, and cross-resistance among members of this class of compounds. Such findings demonstrate that in some contexts, herbal supplements may not be the harmless agents some health-care workers take them to be.

How prevalent is the use of these natural products by patients enrolled in NIH clinical trials? In surveys conducted at the Clinical Center (CC), 25–42 percent of patients reported taking herbal and other supplements.[6, 7, 8, 9, 10]

Herb Research Foundation

Two of the more popular herbal products, St. John's wort (above) and echinacea

Encouraging Patient Disclosure

A major theme in complementary and alternative medicine literature is the communication barrier between physicians and their patients.[11] Though slowly changing, health professionals still do not routinely question their patients about use of herbals and other kinds of alternative supplements.

Understanding why patients seek out and use these products can help physicians and investigators detect such practices and discuss them more openly. Patients may have accepted anecdotal evidence or slick marketing as sufficient information for use and they may be unaware of the potential effect of supplements on research results, not to mention potential complications or adverse effects on their own health.

Furthermore, patients eager to be selected for a clinical trial may be hesitant, even if asked, to disclose anything that may threaten their acceptance into a protocol. They may be less reluctant once a clinical trial is under way.

Assessment of herbals and other alternative supplements may be omitted in a biomedical research setting, where significant focus is on the clinical trial. For an investigator to venture into these uncharted areas is to have to consider many issues not addressed in

protocol development nor routinely raised during the institutional review board (IRB) process. However, there is a trend beginning to include questions about patient use of these natural products in protocols.

It is incumbent upon health-care providers at the CC to provide a safe environment for disclosure and to understand the strong beliefs many patients have in the value of alternative approaches. Questions must be direct, open, and specific to avoid underreporting.[12] Furthermore, to maintain a trusting credible relationship with their patients, physicians need to become educated about herbal and dietary supplements.[13] Only through a combination of patient disclosure and availability of reliable information can there be informed decisions.

Clinical Center Policy

Understanding the complexity of the issue and recognizing the need for guidelines, the CC moved forward in early 2000 with an initiative to construct a policy to guide hospital staff in the management of patient use of herbal and alternative supplements.

An interdisciplinary task force was formed by the CC Quality Committee to assess physician, nurse practitioner, and physician assistant understanding of this issue. Further goals were to examine and benchmark practice and policy in other hospitals, draft a policy based on findings, engage focus groups throughout the CC to assist in shaping the final form of the policy, and gather input on how to achieve successful implementation.

On May 15, 2001, the CC's Medical Executive Committee approved a policy on the "Use of patient's own dietary supplements and alternative consumable products brought into the Clinical Center." The policy took effect June 28, 2001.

The underlying basis of the policy was that "Patients shall use their own dietary supplements and alternative consumable products only upon authorizing orders by their CC physician." This would be accomplished by the following procedures:

■ Through the established admission assessment process, within 8 hours of admission the nurse will screen all inpatients for current use of dietary supplements and alternative consumable products.

■ Products currently being used by a patient will be promptly reported to the physician in order to determine whether inpatient use is allowed. If inpatient use is allowed, the physician will generate MIS orders to authorize use of each product by name. If the physician does not specifically authorize usage, the patient will not be allowed to take the product.

■ Patients will be responsible for the initial and ongoing supply of these products during

the course of the hospital stay.

In the focus groups held prior to policy approval, medical staff strongly voiced their need for resources to support decision-making in clinical practice—the tools to learn about these products and easy access to existing scientific evidence on risk. In response, the CC secured a site license for an online database of herbal monographs. The selection of the *Natural Medicines Comprehensive Database* was based on its scientific integrity, completeness, ease of navigation, timely updating of existing data, and ongoing addition of new products as they become popular.[14] The database became available on desktops throughout the CC on August 1, 2001.

Policy Implementation

The standards of practice for nurses were changed to incorporate use of herbal and alternative supplements as a mandatory area of inquiry during the admission assessment process, and computerized nursing documentation screens were modified accordingly. A new set of physician order screens was also constructed to document approval of continued use by a patient of his or her own supply of such a supplement during hospitalization.

It was also decided that the same process would be applied in the outpatient setting: Outpatient nurses would use the same standard of practice and documentation pathway, ascertaining whether patients on protocol were using herbal or other supplemental products and then alerting the physician to the findings. The physician would then determine whether the patient should continue use—and, ideally, engage in open dialogue with the patient about the issues that informed that decision.

Around the Corner

The implementation of the Herbal and Alternative Supplement Policy will inevitably lead to other necessary steps within the CC to help raise awareness and to ensure compliance. IRBs might contemplate including a section on patient use of herbal and alternative supplement products in all protocols; expectations that patients will disclose and discuss such use with their physician might be included in the written informed consent.

The challenge to clinical investigators and biomedical research facilities is to create policies and follow practices that respect the choices of individuals participating in clinical trials while ensuring patient safety and preserving the scientific integrity of the study■

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Return to *Table of Contents*

GUIDING PRINCIPLES OF THE COMMISSION

Based on its mission and responsibilities, the Commission endorsed 10 basic principles to both guide its process for making recommendations and the recommendations themselves. These Guiding Principles, include a commitment to:

1. **A wholeness orientation in healthcare delivery.** Health involves all aspects of life – mind, body, spirit, relationships and environment - and quality health care must support care of the whole person in this context.

2. **Evidence of safety and efficacy**. The Commission it committed to promoting the use of science and the appropriate scientific methods to help identify safe and effective CAM services and products and generating the evidence that will enhance the development and delivery of these services and products.

3. **The healing capacity of the person.** The body has a remarkable capacity for recovery and self-healing and a major focus of health care is to support and promote this capacity.

4. **Respect for individuality.** Every person is unique and has the right to have healthcare customized to that uniqueness, respecting their preferences and preserving their dignity.

5. **The right to choose treatment.** People have the right to choose freely among safe and effective therapies and qualified practitioners who are responsive to their needs and accountable for their claims and actions.

6. **An emphasis on prevention.** Good health care emphasizes early intervention and self-care for maintaining health and preventing disease. There is overwhelming scientific evidence that it is significantly more humane and cost-effective to prevent illness and disease compared to treating people once they become ill.

7. **Partnerships as essential for integrated healthcare.** Good health care requires collaborative teamwork between conventional and complementary practitioners, researchers, and patients committed to the creation and delivery of optimal healing environments. Any potential benefits of CAM for the public can best be maximized through promoting collaborations between conventional and CAM healthcare professionals and researchers. These collaborations can best be encouraged by the integrated delivery of CAM and conventional medicine, where CAM practitioners work side-by-side with conventional practitioners. Integrated delivery, however, does not mean the distillation of CAM services that are then offered by conventionally trained practitioners.

8. **Education as a fundamental healthcare service.** Education about prevention, healthy lifestyles, and the power of self-care and healing capacity should be made an integral part of curricula for both health care professionals and the public at all ages. Quality health care can be enhanced by promoting efforts that thoroughly

and thoughtfully examine the current evidence base for CAM systems and practices and make this evidence base widely and easily available in a timely fashion. The Commission recognizes the need to enhance this evidence base by advocating for high-quality research.

9. **Self Healing.** [THIS IS REDUNDANT WITH ABOVE. I SUGGEST IT BE DELETED]

10. **More integral public involvement.** Public and consumer views and participation must be included in all research and health care prioritizations and decisions. This includes the development of public advocacy specialists who participate on advisory councils, approval and review boards and in teams that implement integration acitivities.

Match 10/23/01

GRAS - Joe Levitt

SBIR Phase I
II

Mede Johnson

Ross
Wyeth Ayerst

Omega 3 - Fatty Acids
Rockefeller DHA
Mt Sinai

UCSF - Peds

Galileo - Greg Miller
Gamma E

γE

Joe Nourn
Hilbert Salem - Dyspraxia

IQ -
Sight
Vision
Auditory -

WIC Availability
Political ⊕ /
Low Income - ⊖

- WIC Who is Responsible
- Ag for Programs
- Defense

- Intellectual Property
- Patent

- Use Patent Claims for Use

Pocal Center -
workshop
mental acuity
A-DHD

U.S. Department of Health and Human Services
Office of the Secretary
Office of Public Health and Science

Director, Office of HIV/AIDS Policy

The U.S. Department of Health and Human Services (HHS) is accepting applications for the senior executive service position of Director, Office of HIV/AIDS Policy until November 1, 2001. **All applications must be received by close of business November 1, 2001.** This position will be located in Washington, D.C. The incumbent will report to the Assistant Secretary for Health (ASH) and will provide supervision and guidance for staff operations within the Office of HIV/AIDS Policy. In this capacity, the incumbent will be expected to provide leadership on all aspects of the planning, development, and implementation of HIV/AIDS policy throughout HHS. Other assigned duties include serving as the personal advisor and confidant to the ASH on all matters pertaining to HIV/AIDS and representing the ASH and the Office of Public Health and Science (OPHS) in relationships with Public Health Service (PHS) agencies, other HHS and Federal organizational components, State and local entities and health organizations in the public/private sector on matters related to HIV/AIDS. The incumbent reviews and makes recommendations on Departmental research, prevention, services, and infrastructure priorities pertaining to HIV/AIDS-related matters. In addition, serves as the HHS liaison with the Office of the National AIDS Policy Coordinator (NAPC) in the Executive Office of the President, and represents HHS as the official staff liaison to the United Nations Program on AIDS, the Pan American Health Organization (PAHO), the Department of the State, and the Agency for International Development (AID). Candidates must demonstrate knowledge of scientific advances in biomedical, behavioral, and epidemiological research in HIV/AIDS and have experience in applying administrative or analytical methods and techniques to carry out public health programs providing health care and/or services specifically targeting people living with HIV/AIDS.

The salary range for this position will be $120,261 to $133,700 per annum. If a physician is selected, the appointee may be entitled to a Physicians Comparability Allowance of $10,000 to $20,000 per annum.

This vacancy is posted as EX-01-03X. A copy of the announcement for this position, which provides detailed information about mandatory qualifications and application requirements, can be obtained by calling (202)619-0146 or by accessing the following Internet address: www.psc.gov/spo/swhtml.

FEDERATION OF STATE MEDICAL BOARDS
OF THE UNITED STATES, INC.

October 23, 2001

Dear Colleague:

In April 2000, under the leadership of then President Alan E. Shumacher, MD, the Federation's Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine) was charged with developing model guidelines for state medical boards to use in educating and regulating physicians who use complementary and alternative medicine (CAM) in their practices. The Special Committee is comprised of physician and non-physician members representing the Federation and state medical boards.

The Committee met in August and December 2000, and then again in March and August 2001 to thoroughly examine the current status of CAM in the practice setting, determine which states have formal policies/guidelines in place for regulating the practice of CAM, develop definitions crucial to the document's composition, and solicit advice from consultants with varied expertise and professional experience. Additionally, the Committee analyzed the standards used in regulating the use of conventional medicine and evaluated the responsibilities required of both state medical boards and physicians to assure public protection.

A draft of the Special Committee report is being circulated to state medical boards and other interested parties for input in developing a final document. A copy of the draft report is enclosed.

Comments must be in writing and may be returned to Pat McCarty by mail, email at pmccarty@fsmb.org, or fax to 817-868-4167. Comments will be accepted until Friday, December 7, 2001. If you have any questions, please call Lisa Robin at 817-868-4053 or Pat McCarty at 817-868-4067.

Sincerely,

Paul M. Steingard, DO

Paul M. Steingard, DO, Chair
Special Committee for the Study of Unconventional Health Care Practices
(Complementary and Alternative Medicine)

Enclosure as stated
PS/pcm

Model Guidelines for the Use of Unconventional Health Care Practices (Complementary and Alternative Medicine)

Physicians, indeed all health-care professionals, have a duty not only to avoid harm but also a positive duty to do good – that is, to act in the patient's best interest[s]. This duty of beneficence takes precedence over any self-interest.[1]

Introduction

In 1995, the Federation of State Medical Boards' Special Committee on Health Care Fraud was established and charged with developing strategies for recommendation to state medical boards for the regulation and discipline of physicians who engage in unsafe and/or deceptive practices. The Federation's House of Delegates adopted the Committee's recommendations as policy in April 1997. In February 1997, then Federation President James E. West, MD assigned the Committee a new charge – to provide objective information to medical boards for their use in educating licensees, the public and state legislators on issues surrounding health care practices that may be potentially harmful and/or deceptive. In February 1999, the Federation's Board of Directors approved a recommendation by the Committee to modify the title of the Committee to "Special Committee on Questionable and Deceptive Health Care Practices" in order to more appropriately reflect the Committee's work. In April 2000, then Federation President Alan E. Shumacher, MD expanded the Committee's charge to include the development of guidelines for state medical boards to use in educating and regulating physicians who use complementary and alternative medicine (CAM) in their practices. Subsequently, the Committee's name was changed to reflect its new charge. The name of the Committee is the "Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine)."

Because of the increasing interest in and use of CAM practices, state medical boards have a responsibility for assuring that licensees utilize these practices in a manner consistent with safe and responsible medicine. To do this, boards must first understand how CAM is defined.

CAM is a fluid concept that has been defined differently by various organizations and groups. CAM, which may also be termed *unconventional* medical practices, has been described as "medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals."[2] *Conventional* medical practices can then

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[1]Schneiderman L. Medical ethics and alternative medicine. *The Scientific Review of Alternative Medicine*. Spring/Summer 1998;2,(1):63-66.

[2]Eisenberg et al. Unconventional medicine in the United States – prevalence, costs, and patterns of use. *New England Journal of Medicine*. 1993;328,(4):246-252.

be defined as medical interventions that are taught extensively at U.S. medical schools, generally provided at U.S. hospitals, or meet the requirements of the generally accepted standard of care. For the purposes of these guidelines, the Committee has chosen to use the terms *conventional* medical practices (as described above and further defined in Section II of this report) and *unconventional* medical practices (which would include CAM).

On behalf of the Federation and its continued commitment to assist state medical boards in protecting the public and improving the quality of health care in the United States, the Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine), chaired by Paul M. Steingard, DO, undertook its initiative in April 2000 to develop model guidelines for state medical boards to use in regulating the use of *unconventional* medical practices.

This initiative focuses on encouraging the medical community to adopt consistent standards, ensuring the public health and safety by facilitating the proper and effective use of *unconventional* treatments, while educating physicians on the adequate safeguards needed to assure these services are provided within the bounds of acceptable professional practice. The Federation believes adoption of guidelines based on this model will protect legitimate medical uses of *unconventional* practices while preventing the proliferation of medical practices that may be potentially harmful.

The intention of the Federation is to provide guidelines that are clinically responsible and ethically appropriate. These guidelines should be consistent with what the state medical board generally considers to be within the boundaries of professional practice and the accepted standard of care.

Section I: Preamble

The *(name of board)* recognizes that the practice of medicine consists of the ethical application of a body of knowledge, principles and methods known as medical science and that these objective standards are the basis of medical licensure for physicians of the state of *(name of state)*. These standards allow a wide degree of latitude in physicians' exercise of their professional judgment and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk. Furthermore, patients have a right to seek any kind of care for their health problems. The Board also recognizes that a full and frank discussion of the risks and benefits of all medical practices is in the patient's best interest. However, the Board is aware that the use of *unconventional* practices and promotions in the United States has led to the existence of health care treatments that may lack scientific research and clinical validation, or are worthless and likely to harm the public.

There are varying degrees of potential harm that can impact patients who undergo either *conventional* or *unconventional* forms of health care:

- Economic harm, which results in monetary loss but presents no health hazard;

- Indirect harm, which results in a delay of appropriate treatment;
- Direct harm, which results in adverse patient outcome;
- Psychological harm, which results in unreasonable expectations that discourage patients and their families from accepting and dealing effectively with their medical conditions.

Whatever the practice setting, physicians are responsible for practicing good medicine by complying with professional standards and regulatory mandates. In consideration of the above potential harms, the *(name of board)* will evaluate whether or not a physician is practicing appropriate medicine by considering the following practice criteria. Is the physician using a practice that is:

- effective and safe? (having adequate scientific evidence of efficacy and/or safety or greater safety than other established treatment models for the same condition)
- effective, but with some real or potential danger? (having evidence of efficacy, but also of adverse side effects)
- inadequately studied, but safe? (having insufficient evidence of clinical efficacy, but reasonable evidence to suggest relative safety)
- ineffective and dangerous? (proven to be ineffective or unsafe through controlled trials or documented evidence or as measured by a risk/benefit assessment)

Inasmuch as the *(name of board)* is obligated under the laws of the state of *(name of state)* to protect the public's health, safety and welfare and recognizes that the standards used in evaluating health care practices should be consistent, whether such practices are regarded as *conventional* or *unconventional* (a.k.a., complementary, alternative), the Board recognizes that a licensed physician shall not be found guilty of unprofessional conduct for failure to practice medicine in an acceptable manner *solely* on the basis of utilizing *unconventional* practices. Instead, the Board will use the following guidelines to determine whether or not a physician's conduct constitutes a violation of the state's Medical Practice Act with regards to providing *unconventional* practices.

Section II: Definitions

For the purposes of these guidelines, the following terms are defined as indicated:

Conventional Medical Practices

Conventional medical practices refers to those healthcare methods of diagnosis, treatment and interventions that are offered by licensed physicians as generally accepted methods of routine practice, based on current medical education, training, experience and/or peer-reviewed scientific literature.

Unconventional Medical Practices

Unconventional medical practices refers to medical practices not taught widely at U.S. medical schools or generally available at U.S. hospitals, and not included in the above definition of *conventional* medical practices.

Competent and Reliable Scientific Evidence

Tests, analyses, research, studies or other evidence based upon the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

Section III: Guidelines

The *(name of board)* has adopted the following guidelines when evaluating the delivery or co-management of *unconventional* medical practices:

1. Evaluation of Patient

   Parity of evaluation standards should be established for patients whether the physician is using *conventional* or *unconventional* practices.

   Prior to offering any recommendations for *unconventional* practices, the physician shall conduct an appropriate medical history and physical examination of the patient as well as an appropriate review of the patient's medical records. This evaluation shall include, but not be limited to, *conventional* methods of diagnosis and may include other methods of diagnosis as long as the methodology utilized for diagnosis is based upon the same standards of safety and reliability as *conventional* methods, and shall be documented in the patient's medical record. The medical record should also document:

   - what *conventional* medical options have been discussed, offered or tried, and if so, to what effect, or a statement as to whether or not *conventional* options have been refused by the patient or guardian;
   - that proper referral has been offered for appropriate *conventional* treatment;
   - that the risks and benefits of the use of the proposed *unconventional* treatment to the extent known have been appropriately discussed with the patient or guardian;
   - that the physician has determined whether or not the *unconventional* medical treatment could interfere with any other recommended or ongoing *conventional* treatment.

2. Treatment Plan

The physician may offer the patient an *unconventional* treatment pursuant to a documented treatment plan tailored for the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives, such as pain relief and/or improved physical and/or psychosocial function. Such a documented treatment plan shall consider pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals, or the use of other treatment modalities.

The *unconventional* treatment offered should:

- have a favorable risk/benefit ratio compared to other treatments for the same condition;
- be based upon competent and reliable scientific evidence;
- be based upon a logical and reasonable expectation that it will result in a favorable patient outcome, including preventive practices;
- be based upon the expectation that a greater benefit will be achieved than that which can be expected by placebo alone.

3. Consultation and/or Referral to Licensed or Other State-Regulated Health Care Practitioners

The physician may refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives and may include referral to a licensed or other state-regulated health care practitioner with the requisite training and skills to utilize the *unconventional* practice being recommended. However, the physician is responsible for monitoring the results and should schedule periodic reviews to ensure progress is being achieved.

4. Documentation of Medical Records

The physician should keep accurate and complete records to include:

- the medical history and physical examination;
- diagnostic, therapeutic, and laboratory results;
- results of evaluations, consultations and referrals;
- treatment objectives;
- discussion of risks and benefits;
- appropriate informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements;

- periodic reviews

Records should remain current and be maintained in an accessible manner, and readily available for review.

5. Education

All physicians must be able to demonstrate a basic understanding of the medical scientific knowledge connected with any method they are offering or using in their medical practices as a result of related education and training.

6. Financial Incentives

Physicians may distribute products to patients free of charge or at cost in order to make products readily available. Due to the potential for patient exploitation, physicians should not sell, rent or lease health-related products or engage in exclusive distributorships and/or personal branding. Exceptions can be allowed for the sale of durable medical goods essential to the patient's care, as well as nonhealth-related goods associated with a charitable or service organization. If physicians do provide any goods to their patients, even at cost, they have a duty to inform their patients of any financial interests in these products or goods.

7. Clinical Investigations

As expected of those physicians using *conventional* medical practices, physicians providing *unconventional* practices while engaged in the clinical investigation of new drugs and procedures (a.k.a. medical research, research studies) are obligated to maintain their ethical and professional responsibilities. Investigators shall be expected to conform to the following ethical standards:

- Clinical investigations should be part of a systematic program competently designed, under accepted standards of scientific research, to produce data which are scientifically valid and significant.
- A clinical investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.

Furthermore, investigators shall be expected to abide by all federal guidelines and safeguards, such as approval and monitoring of the clinical trial by an Institutional Review Board (IRB), when applicable, to ensure the risks to the patient are as low as possible and are worth any potential benefits.

Section IV: Conclusion

The Federation recognizes that legitimate standards of medical practice are rooted in competent and reliable scientific evidence. These standards are subject to

continual change and improvement as advances are made in scientific investigation and analysis. In addition, standards of medical practice to some degree, and the provision of medical services in individual circumstances in particular, are influenced by psychological, social, political and market forces. It is the responsibility of state medical boards to balance all of these considerations in fulfilling their mission of protecting the public through the regulation of the practice of medicine.

Public protection is carried out, in part, by ensuring physicians in all practices, whether *conventional* or *unconventional*, comply with professional, ethical and practice standards and act as responsible agents for their patients. Accordingly, the Federation encourages state medical boards to adopt these guidelines to assist them in educating and regulating physicians who are (1) engaged in a practice environment offering both *conventional* and *unconventional* forms of treatment; and/or (2) engaged in cooperative therapeutic relationships for their patients with a non-physician licensed or other state-regulated health care practitioner offering *unconventional* practices.

State medical boards need to ensure a balance between the requirements that all medical practices be scientifically based while remaining compassionate and respectful of the dignity and autonomy of patients. This balance should also ensure informed consent and minimize the potential for harm.

The Federation reaffirms its commitment to cooperate with physicians and professional, governmental and other organizations and agencies in supporting the further study of all health care practices that offer promise.

Section V: Bibliography

- AMA. Policy E 2.07: *Clinical Investigation.*
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- Fontanarosa PB, ed. AMA's *Alternative Medicine: An Objective Assessment.* 2000.
- Illinois Department of Professional Regulation Medical Disciplinary Board. Board Policy Statement: *Complementary and Alternative Therapies.* November 1999.
- Kentucky Board of Medical Licensure. Board Policy Statement: *Complementary and Alternative Therapies.* March 1999.
- Nevada State Board of Medical Examiners. *Non-Conventional Medical Treatment Regulations.* August 2000;Section 1:Chapter 630.
- Texas State Board of Medical Examiners. *Standards for Physicians Practicing Integrative and Complementary Medicine.* November 1998;Chapter 200.

Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine): 2001-2002

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The Federation thanks the following consultants for their efforts in providing direction to these guidelines:

- Tammy L. Born, DO – Chair, Michigan Board of Osteopathic Licensing and Regulation; Owner/President, Born Preventive Health Care Clinic

- David M. Eisenberg, MD – Director, Division for Research and Education in Complementary and Integrative Medical Therapies, Associate Professor of Medicine, Harvard Medical School

- Timothy N. Gorski, MD – President, Dallas/Fort Worth Council Against Health Care Fraud; Clinical Assistant Professor, Department of Obstetrics and Gynecology, University of North Texas Health Science Center

- Russell H. Greenfield, MD – Medical Director, Carolinas Integrative Health, Carolinas HealthCare System; Visiting Assistant Professor, University of Arizona College of Medicine

- Kenneth R. Pelletier, PhD – Clinical Professor of Medicine, Department of Medicine, University of Maryland School of Medicine

- Wallace I. Sampson, MD – Editor, *The Scientific Review of Alternative Medicine*; Clinical Professor of Medicine, Stanford University School of Medicine.

Groft, Stephen (NCCAM)

To: Axelrod, Corinne (NCCAM)
ubject: RE: Comments on the Federation

Thank you and I agree (with no editing, either)
Steve

-----Original Message-----
From: Axelrod, Corinne (NCCAM)
Sent: Tuesday, October 30, 2001 11:04 AM
To: Pollen, Geraldine (NCCAM); Groft, Stephen (NCCAM)
Subject: Comments on the Federation

Beyond stating the obvious about this document (its negative, biased, it does not even consider the possibility that CAM could be beneficial in some situations, etc.), I would suggest that they include examples of clinical situations as a guide to practitioners to help them provide "clinically responsible and ethically appropriate" care. Sometimes the boundaries of professional practice and the accepted standard of care are not clear and case scenarios would help.

Also, we should object in the strongest terms to the wording at the end of the 1st paragraph under Preaamble on page 4 that characterizes unconventional practices and promotions (what do they mean by promotions?) as lacking science, worthless, or harmful.

Beyond that, I think the document is pretty useless and serves only as a political statement which will end up making the Federation look totally out of touch with reality and serve to confirm one of the reasons people seek out CAM providers.

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FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC. REPORT OF THE SPECIAL COMMITTEE ON HEALTH CARE FRAUD

SECTION I: PREAMBLE

In April 1995, Federation President Robert E. Porter, MD, established a special committee on health care fraud. The need for such a committee arose from the proliferation of unconventional and unproven medical practices and promotions in the United States, some of which may be questionable and thereby pose a risk to the public health, safety, and welfare. Recent national and state legislative initiatives prompted further concern because they could result in restricting state medical boards' ability to provide appropriate regulation of such practices. The committee was directed to research, review, and evaluate questionable health care treatments, procedures, and promotions which may be worthless and therefore deceptive and/or that pose a risk to the public health, safety, and welfare. The committee was also charged with developing strategies which could be recommended to state medical boards for the regulation and discipline of physicians who engage in unsafe, worthless, and/or deceptive practices.

The committee met several times since its inception and developed recommendations designed to assist state medical boards in evaluating, investigating, and prosecuting physicians engaged in such practices. The committee limited its review to those practices, procedures, and/or promotions which may be offered by allopathic or osteopathic physicians and, therefore, subject to medical boards' jurisdiction and are not widely taught in medical schools nor generally available in hospitals. Additionally, the committee has expanded its charge to include an educational component to develop recommendations for state medical boards in educating licensees, consumers, and legislators on issues regarding unconventional and/or unproven health care treatments, procedures, and promotions.

The committee recognized that the primary responsibility of state medical boards is to protect the public from the incompetent, unprofessional, improper, and unlawful practice of medicine and further that the authority for state medical boards to regulate medical practice is determined by each state's medical practice act. In its capacity as a resource for research, policy development education, and information, the Federation has developed a model medical practice act (A Guide to the Essentials of a Modern Medical Practice Act) to assist state medical boards in developing legislative language necessary to effect regulation of medical practice. Accordingly, the committee's initial recommendations included a proposal to revise pertinent sections of A Guide to the Essentials of a Modern Medical Practice Act in order to strengthen the ability of state medical boards to regulate fraudulent behavior. These recommendations were adopted by the Federation's House of Delegates during its April 1996 meeting and have been incorporated in the policy document. The revisions expand the responsibilities of the medical board to include protection against the fraudulent and/or deceptive practice of medicine and render the unlicensed practice of medicine a felonious offense.

The following objectives were identified by the committee:

* To develop recommendations to assist state medical boards in identifying evaluating, investigating, and prosecuting cases involving questionable health care practices.

* To develop strategies to monitor legislative initiatives supporting increased access to unconventional and unproven treatments and assist state medical boards in responding to such initiatives in the interest of the public health, safety, and welfare.

* To solicit support for the Federation's efforts to control health care fraud from medical professional organizations, governmental agencies, and other interested organizations.

* To develop and implement educational opportunities for state medical board members, executive directors, and investigative staff on effective regulation of questionable health care practices.

The recommendations contained in this final report of the Special Committee on Health Care Fraud are designed to achieve the above objectives.

SECTION II: DEFINITIONS

The committee recognizes the practice of medicine (defined in A Guide to the Essentials of a Modern Medical Practice Act) as - - -

1. advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in the jurisdiction;

2. offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

3. offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any methods, devices, or instrumentalities any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

4. offering or undertaking to perform any surgical operation upon any person;

5. using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., MD, DO, or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction.

Additionally, for the purposes of this report, the terms "alternative medicine/therapy" and/or "complementary medicine" have not been utilized by the committee due to a lack of consensus among both practitioners and the public as to their meaning. The committee has chosen to use the term "questionable health care practices" to include those treatments, procedures, and/or promotions, conventional or unconventional, which may be unsafe and thereby considered a risk to the public's health, safety, and welfare AND/OR which may be worthless and thereby likely to deceive or defraud the public.

SECTION III: IDENTIFICATION

Recommendation One:

State medical boards should develop mechanisms to identify physicians who may be engaging in questionable health care practices.

In order to offer reasonable protection to the public, state medical boards must be able to identify physicians who engage in questionable health care practices which may endanger the public, either directly or indirectly. Direct harm may result in adverse patient outcomes and indirect harm may result in delay of appropriate diagnoses and/or treatments.

The committee suggests the following mechanisms to facilitate the identification of physicians engaging in questionable health care practices:

* Encourage consumer/patient reporting by increasing awareness among the public through distribution of educational materials and utilizing media sources.

* Encourage and expand reporting from licensees and other health care professionals by increasing awareness of reporting requirements through newsletters, announcements, alerts, advisory opinions, and collaboration with state and local medical professional organizations and societies.

* Expand liaison efforts with regulatory agencies (federal, state, and local), including the Federal Trade Commission, other state licensing authorities, state attorneys general, district attorneys, and public health departments.

* Improve reporting from third party payers and peer review organizations (PROs).

* Periodically monitor health care promotional materials, including random review of newspapers, periodicals, and other advertising mediums.

SECTION IV: EVALUATION AND INVESTIGATION

Recommendation Two:

State medical boards should develop criteria for evaluating any health care practice which has been called into question.

In order to effectively process a complaint or report involving questionable health care practices, state medical boards must determine whether the practice in question is (1) indicated (2) appropriate and (3) reasonably safe as compared to established treatment models. The committee strongly supports the concept that the prevailing standard of care used in evaluating health care practices be consistent, whether such treatment is regarded as "conventional" or "unconventional". Such standards include appropriate documentation, informed consent, appropriate monitoring and follow-up, rationale for treatment, and period review of efficacy of treatment.

The committee suggests the following criteria be utilized in evaluating health care practices:

* Has an adequate patient assessment been conducted, including history and physical examination, laboratory studies, x-rays, and other evaluative measures, to determine that the patient has the condition for which the treatment is being prescribed?

* Is the methodology promoted for diagnosis as reliable as other available methods of diagnosis?

* Is the risk/benefit ratio greater or less than that for other treatments for the same condition?

* Is it based upon competent and reliable scientific evidence, including properly conducted clinical trials, and/or is it supported by a scientific rationale?

* Is there logical and reasonable expectation that the treatment offered will result in a favorable patient outcome?

* Is the practitioner excessively compensated for the service provided?

* Are the practitioner's promotional claims supported by competent and reliable scientific evidence?

* Is the benefit achieved greater d= that which can be expected by placebo alone?

* Has the patient's informed consent been adequately documented in the medical record?

Recommendation Three:

State medical boards should utilize reliable information resources in their evaluation of questionable health care practices.

Reliable information may be obtained by utilizing databases such as Medline, NEXIS/LEXIS or Westlaw by searching the (1) name of the practice/therapy/treatment/promotion (2) provider and/or promoter and (3) organizations involved in the promotion of such practice/therapy/treatment.

The committee suggests state medical boards query the following organizations to provide reliable information regarding specific questionable health care practices:

* Federation of State Medical Boards Library Services, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039; (817) 868-4000; FAX (817) 868-4099;

* National Council Against Health Fraud (NCAHF), P.O. Box 1276, Loma Linda, California 92354; FAX (909) 824-4848;

* Consumer Health Information Research Institute (CHIRI), 300 East Pink Hill Road, Independence, Missouri 64057; (816) 228-4595; FAX (816) 228-4995;

* Food and Drug Administration, Office of Health Affairs; 5600 Fishers Lane, HFY-1, Rockville, NO 20857; (301) 443-6143; and

* Federal Trade Commission, Division of Service Industry Practices, Washington, DC 20580; (202) 326-3291; FAX (202) 326-3392.

Office of Alternative Medicine, National Institutes of Health, 6120 Executive Boulevard, EPS, Suite 450, Rockville, MD 20892; (301) 402-2466; FAX (301) 402-4741.

The committee suggests state medical boards obtain reference materials such as the following to provide a foundation for research into questionable health care practices:

* Reader's Guide to Alternative Health Methods, Zwicky, John F, PhD, Hafner, Arthur W., PhD, Barrett, Stephen, MD, and Jarvis, William T., MD. American Medical Association 1993.

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Recommendation Four:

State medical boards' ancillary staff, including board investigators, should utilize methods to effectively investigate questionable health care practices.

State medical boards must rely heavily on their investigative staff to aggressively develop and present evidence that is thorough, cohesive, sequential, and well-documented. It is necessary for investigators to remain abreast of trends in and promotions of questionable health care practices within the jurisdiction of the agency.

The committee suggests the following guidelines be implemented during the investigative stage:

* Select a reliable expert, familiar with the practice in question, and willing to assist in the investigative stage.

* Gather evidence to include (1) promotional and other materials used to produce patient consent (2) drug samples or medical devices together with manufacturers package inserts and specifications (3) proponent literature describing the practice in question together with medical/scientific justification and (4) competent and reliable scientific evidence on the efficacy/safety of the practice.

* Conduct a thorough review of the Medical Practice Act to determine all applicable breaches to be included in the board's complaint.

SECTION V. DISCIPLINARY ACTION/DISPOSITION

Recommendation Five:

State medical boards should work in conjunction with state prosecutors in the initiation, development, and disposition of cases involving questionable health care practices.

It is necessary to employ procedures to effectively present cases in the disciplinary process. The committee identified elements that are commonly utilized by respondents in cases involving questionable health care practices, specifically the use of testimonials and anecdotal evidence. Proponents of questionable health care practices likely hold strong views and convictions regarding the therapeutic approach and may have a large cadre of devotees, willing to testify on the respondent's behalf. In order to successfully prosecute such cases, it is imperative that state attorneys be familiar with medical practice and terminology and be able to apply and argue case law and rules of evidence in terms of generally accepted scientific standards so that unreliable evidence may be excluded and not used by

respondents in defense of prosecution. Following a determination by the state medical board to prosecute a complaint, the committee suggests the following elements be utilized in the disposition of cases involving questionable health care practices:

* Conduct thorough preheating discovery to obtain additional information and the names and qualifications of defense expert witnesses.

* Conduct careful research of defense experts and their writings.

* Request a prehearing conference or evidentiary hearing to suppress unreliable evidence and exclude testimony of unqualified proponents testifying on behalf of the respondent as unreliable and inadmissible. Review Daubert v. Merrell Dow Pharmaceuticals, Inc. 113 S. Ct. 2786 (1993) and relevant state law to establish legal precedent on admissibility of disputed scientific evidence.

* Strategize trial presentation to not only prove the board's case but to disprove the proponent of the practice in question.

* Utilize expert witnesses who can not only establish the board's case but also who can provide credible rebuttal of the evidence in support of the practice in question.

Recommendation Six:

State medical boards should carefully evaluate all avenues of potential prosecution and coordinate such with appropriate federal, state, and local agencies.

Certain breaches of the medical practice act may be subject to civil action or criminal prosecution in other forums. These breaches may include (1) the unlicensed practice of medicine (2) deceptive advertising (3) violations regarding, controlled substances and/or (4) fraudulent billing practices.

The committee suggests that state medical boards coordinate with and among the following agencies in their respective potential areas of prosecutorial concerns:

* Federal Trade Commission (deceptive/fraudulent health care promotions/claims);

* State Attorney General (consumer complaints/protection and deceptive/fraudulent health care promotions/claims);

* State Insurance Board/Commission (billing practices);

* Health Care Financing Administration (Medicare claims);

* U.S. Postal Service (mail fraud);

* U.S. Customs Service (import of unapproved/illicit drugs/devices);

* Food and Drug Administration (unapproved drugs/devices);

* District Attorney (unlicensed practice of medicine and related criminal offenses).

SECTION VI: LEGISLATIVE STRATEGIES

Recommendation Seven:

State medical boards should review their Medical Practice Acts and pursue legislative support for revisions to strengthen the medical board's ability to regulate physicians engaging in questionable health care practices.

There are increasing political and social pressures to provide the public with access to unconventional medical treatments, as evidenced by various recent federal and state legislative proposals. The committee believes that there may be substantial direct and indirect harm to patients resulting from enactment of such legislation unless appropriate safeguards are included. In order to fulfill state medical boards' responsibility to protect the public from incompetent, unprofessional, improper, unlawful, fraudulent and/or deceptive medical practice, it is necessary for state medical boards to maintain legislative authority adequate to regulate all practices constituting the practice of medicine.

The committee suggests the following elements be included in all state Medical Practice Acts:

* The unlicensed practice of medicine should be deemed a felonious offense.

* State medical boards should be granted authority to use injunctive powers to order physicians and others engaged in questionable health care practices to immediately cease such practice pending hearing.

* State medical boards should be granted authority to monitor physicians engaged in questionable health care practices, including, but hot limited to, requirements that physicians: (1) file treatment plans with the board (2) report patient outcomes and (3) file periodic reports regarding the efficacy of treatment.

Recommendation Eight:

State medical boards should notify the Federation of state Medical Boards of any state legislative initiatives identified that could diminish state medical boards' ability to regulate questionable health care practices.

The committee suggests that the following mechanisms be implemented for monitoring and opposing such legislative measures:

* Request assistance from the Legislative Services Department of the Federation of State Medical Boards in analyzing and developing strategies in opposition to such state legislative measures.

* Identify individuals within the state willing to educate state legislators and legislative staff on the potential effects of such legislative initiatives.

* Assist legislators in soliciting written comments from the Food and Drug Administration and the Federal Trade Commission on the potential consumer health and economic effects of such legislative initiatives (requests are honored only if submitted by legislator).

Recommendation Nine:

The Federation of State Medical Boards should monitor federal and state legislative activities regarding health freedom issues and develop strategies to assure that the authority of state medical boards is maintained.

Through its Legislative Services Department and government relations firm, the Federation monitors federal legislative initiatives to identify proposals that could impact state medical boards, Upon the identification of such measures, the Federation develops strategies to intervene and oppose measures that could negatively affect state medical boards. The committee supports and encourages the Federation in its legislative efforts to protect the authority of state medical boards to regulate the practice of medicine, both conventional and unconventional.

SECTION VI: EDUCATION

Recommendation Ten:

State medical boards, with the assistance of the Federation of State Medical Boards, should develop educational opportunities for licensees regarding the prevalence, risky, and efficacy of questionable health care practices.

In order to contain the proliferation of questionable health care practices, it is necessary to increase awareness among licensees. State medical boards may wish to develop educational programs in cooperation with state and local medical professional societies, organizations , and hospital medical staff organizations The committee supports and encourages education of medical board members and staff, legislators, and consumers. The committee also supports the Federation of State Medical Boards in its continuing development of educational programs through forums such as the Annual Meeting, workshops, and publications as well the dissemination of timely information to its member boards on related issues via the FSMB computer network.

The committee suggests state medical boards use the following methods in developing educational opportunities for their licensees and publics:

* Present educational information at meetings of state and local medical professional societies and associations and other organized physician educational forums.

* Include educational information in board newsletters and other communications with licensees.

* Utilize media sources, public service announcements, consumer advocacy groups, and other means to disseminate information to the public.

SECTION VII: COLLABORATION

Recommendation Eleven:

On behalf of state medical boards, the Federation of State Medical Boards should collaborate with other agencies and organizations in efforts to identify and eliminate questionable health care practices that are adverse to the public health, safety, and welfare.

The committee recognizes that the scope of this issue reaches far beyond the jurisdiction of state medical boards and, therefore, strongly encourages that a network of cooperation and collaboration be established to coordinate efforts to stop the spread of questionable health care practices.

The committee suggests the following forums for collaboration:

* Explore opportunities for mutual cooperation, including information sharing and education, with the American Medical Association and the American Osteopathic Association.

* Develop working relationships with other interested organizations, including, but not limited to, the National Association of Attorneys General, the National Conference of State Legislatures, American Legislative Exchange Conference, the Food and Drug Administration, and the Federal Trade Commission in promoting responsible medical practices.

SECTION VIII: CONCLUSION

It has been estimated that up to $I00 billion is lost to health care fraud in the United States annually (Stern, 1994). Medical interventions that do not conform to prevailing scientific standards are becoming increasingly popular. It is estimated that, in 1990, Americans made 425 million visits to providers of "unconventional" medicine, exceeding the number of visits to all US primary care physicians, at a cost of approximately $13.7 billion (Eisenberg et al. 1993). It may be recognized that some alternative therapies may be beneficial and therefore warrant further investigation and possible integration into mainstream medical practice. However, because of the lack of reliable scientific evidence and clinical validation, safety has not been established for most of these modalities. Questionable health care practices can pose significant risks to the public safety, either by causing direct patient harm, or indirectly, by being needlessly expensive, delaying a more effective treatment, or from being a administered in an incompetent manner. This proliferation of questionable health care practices and promotions will continue if left unchecked and unregulated. State medical boards are charged with protecting the public from the unprofessional, improper, incompetent unlawful fraudulent and the deceptive practice of medicine (Essentials, Section 1) and, therefore, state medical boards must assure that physicians practice responsible medicine.

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INSTITUTE OF MEDICINE
Board on Health Promotion and Disease Prevention

Use of Complementary and Alternative Medicine (CAM) by the American Public

With the increased use and acceptance of CAM, it is becoming increasingly important to develop a systematic and evidence-based understanding of the field and to create a framework to guide decision-making in research, regulatory policy, and in managing the interface between CAM and conventional health care. Although significant advances have been made in developing a research agenda in CAM, barriers to the successful conduct of research are numerous. The challenges in regulation, training, and practice are even more formidable.

The pressure points across the health system will shortly increase in number and intensity. The Presidential Commission on CAM appears likely to propose an ambitious agenda for the inclusion of CAM in health professions education, training, coverage under public and private health insurance, eligibility for federal training grants, and in other domains. No framework currently provides a scientifically based, transparent and publicly accountable approach to addressing the use of CAM therapies.

The results of this project could be used to facilitate and inform the decision-making of scientific and policy-making organizations, educators and practitioners. The results could also provide a logical, evidence-based framework for addressing emerging issues related to use of CAM therapies, including issues related to scientific research, oversight and regulation, reimbursement, medical education, and relationships among the allied health professions.

The IOM proposes to convene a study committee to explore the scientific and policy implications of the use of Complementary and Alternative Medicine (CAM) therapies by the American public. Specifically, the study will:

(1) describe the use of CAM therapies by the American public—providing a comprehensive overview, to the extent data are available, of the therapies in wide-spread use, the populations that use them, and what is known about how they are provided;
(2) identify major scientific and policy issues related to CAM research, regulation, interface/integration with conventional medicine, and training and certification; and
(3) develop a conceptual framework(s) to guide decision-making on these important issues and questions.

The types of questions that might be considered by the committee include:

- **Research:** What are major methodological difficulties in evaluating some CAM therapies and how do these relate to issues in regulation and practice?
- **Regulation:** What is the status of CAM regulation in the U.S. and the major areas of vulnerability that result from current policy? What regulatory approaches are used in other countries?
- **Interface/integration:** What is the current status of third party coverage for CAM, or provision of CAM in public programs? What types of evidence threshold should be established for incorporation of CAM into insurance plans and care programs?
- **Training and certification:** How should health professions' education and training programs incorporate knowledge about CAM into their curricula? How should states approach licensure and certification issues?

11/18/01

- Thank you
- Handouts
- Principle
- Representative Samples of Recommendations
- Questions.

March of Employee Program Assistants

① Practitioner Agreement on Qualifications

ND
LAC no 100 Accountant