White House Commission on Complementary and Alternative Medicine Policy

Meeting Site: Academy for Educational Development
1825 Connecticut Avenue, N.W., Academy Hall, 8th Floor
Washington, DC

May 15-16, 2001

AGENDA II

DAY TWO: TUESDAY, MAY 15, 2001

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges

12:30 p.m. **Opening Remarks**

◆ *Dr. James S. Gordon, M.D., Chair*
White House Commission on Complementary and Alternative Medicine Policy

12:40 p.m. **Panel Session I: Overview of CAM Research Challenges**

20. *David Eisenberg, M.D.*
Harvard University
{ 25-minute talk
20-minute discussion

◆ Discussion

1:25 p.m. **Panel Session II: Foundation Support for CAM Research**

21. *M. Bridget Duffy, M.D.*
Medtronic Foundation

1:35 22. *Doriane C. Miller, M.D.*
Robert Wood Johnson Foundation

1:45 23. *Susan Braun*
Susan G. Komen Breast Cancer Foundation

1:55 24. ~~*Ronald Chez, M.D.*~~ Susan Samueli
Samueli Institute for Information Biology

2:40 ◆ Discussion (30 min)

2:35 – 2:50 p.m. **BREAK**

2:50 p.m. **Panel Session III: Approaches to Evaluating Research Literature**

25. *Donald A. Lindberg, M.D.*
National Library of Medicine, NIH

3:00 26. *Douglas B. Kamerow, M.D., M.P.H.*
Agency for Healthcare Research and Quality @AHRQ

3:10 27. *Brian Berman, M.D.*
University of Maryland

{ 20-minute talk
- 10 for Cochrane Collab.
- 10 for CAM Integration into Academic Health Care centers

3:30 ◆ Discussion (40 min)

4:10 p.m. **Panel Session IV: Concerns about CAM and CAM Research**

28. *William M. London, Ed.D., M.P.H.*
National Council Against Healthcare Fraud

4:20 29. *Simeon Margolis, M.D., Ph.D.*
Johns Hopkins University

4:30 30. *Arthur P. Grollman, M.D.*
State University of New York at Stonybrook

4:40 ◆ Discussion (50 min)

5:30 p.m. **ADJOURN**

DAY THREE: WEDNESDAY, MAY 16, 2001

7:30 a.m. **Registration Opens**

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges (continued)

8:00 a.m. **Panel Session V: Research Methodology**

31. *John A. Chabot, M.D.*
Columbia University

8:10 32. *Marcia Angell, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

8:20 33. *Jennifer Jacobs, M.D., M.P.H.*
American Institute of Homeopathy

8:30 34. *B. Alex White, D.D.S., Dr.P.H.*
Kaiser Permanente Center for Health Research

8:40 35. *Bruce Rabin, M.D., Ph.D.*
University of Pittsburgh

8:50 ◆ Discussion (35 min)

9:25 a.m. **Panel Session VI: Training of Conventional and CAM Investigators**

36. *Nancy Pearson, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

9:30 37. *Neal West, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

{ Sharing 10-minute slot 5 minutes each

9:35 38. *Robert H. Blanks, Ph.D.*
University of California at Irvine

9:45 39. *Russell Phillips, M.D.*
Harvard University

9:55 40. *Richard Hammerschlag, Ph.D.*
Oregon College of Oriental Medicine

10:05 ◆ Discussion (30 min)

10:35 – 10:50 a.m. **BREAK**

10:50 a.m. **Panel Session VII: Publication of Peer-Reviewed CAM Research Results**

41. *Edward W. Campion, M.D.*
New England Journal of Medicine

11:00 42. *Jackie C. Wootton, M.Ed.*
Journal of Alternative and Complementary Medicine

11:10 43. *Phil B. Fontanarosa, M.D.*
Journal of the American Medical Association

11:20 44. *David Riley, M.D.*
Alternative Therapies in Health and Medicine

11:30 45. *Christine Laine, M.D., M.P.H.*
Annals of Internal Medicine

11:40 46. *Arnold Relman, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

11:50 ◆ Discussion (40 min)

12:30 – 1:30 p.m. **LUNCH BREAK**

1:30 p.m. (1:50) **Breakout: Small Group Discussion (CAM Research Challenges)** 1.40

2:50 p.m. **Group Reports and Discussion/Adjourn Meeting Topic II** 65

4:00 p.m. **BREAK**

4:15 p.m. **Public Comment Session: 3-Minute Oral Statements**

47. James Sensenig, American Association of Naturopathic Physicians
48. Candace Campbell, American Preventive Medical Association
49. Diane Davis Cole, University of Virginia Cancer Center
50. ~~Katherine Jane Gorton~~, American Dietetic Association Susan Pitman
51. Audrey Di Maria, Art Therapy Credential Board
52. Judy Simpson, American Music Therapy Association

4:20 (15) ◆ Discussion

4:35 53. Richard Goldberg, Private Practice
54. Nancy Kristine Haller, Feldenkrais Guild of North America Julie Merrill, Amer. Assoc. of Oriental Medicine
55. ~~Christina Herlihy, National Certification Commission for Acupuncture and Oriental Medicine~~
56. Su Liang Ku, Florida Institute for Traditional Chinese Medicine
57. ~~Sharon Stevenson~~, National Center for Homeopathy
Sandra Chase

4:55 ◆ Discussion

5:10 58. ~~Barbara Moquin, National Navel Medical Center~~ Edward Owens
59. Matt Ward Russell, National Integrative Medicine Council
60. Carolyn Jones Sabatini, Pharmavite Corporation
61. Christina Walker, The Shenk Human Energetic Institute
62. Alan Dumoff, Private Practice

5:25 ◆ Discussion

~~5:30 p.m.~~ **MEETING ADJOURN**

5:40

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland, 20817-7707
tel: 301-435-7592, fax: 301-480-1691, e-mail:whccamp@mail.nih.gov
Website: whccamp.hhs.gov

Greetings, Commissioners!

Welcome to our final issue-specific meeting! Please find attached the briefing book, which includes materials for this meeting. The background information sent to you has been reproduced in this binder for your convenience.

Please note that there will be three breakout groups during this meeting. The task for all the breakouts is the same - to discuss and develop a list of draft recommendations for that topic.

Breakout Session I, is scheduled for Monday, May 14th, at 4:15 p.m. and revisits Access and Delivery, the topic of the December 4-5, 2000 meeting. Information from the December 4-5 meeting and other discussion is presented under the Access and Delivery tab. This was sent to you earlier. (Staff contact Dr. Joseph Kaczmarczyk)

Breakout Session I - Group IA: Access and Barriers to CAM Practices and Products (Main Conference Room)
Chair: Julia Scott
Members:
George Bernier, David Bresler, Effie Chow, George DeVries, Wayne Jonas, Linnea Larson, Dean Ornish, Conchita Paz, Joe Pizzorno

Breakout Session I - Group IB: Delivery of CAM Practices and Products (Breakout Room)
Chair: Tom Chappell
Members:
Joe Fins, Bill Fair, Veronica Gutierrez, Sr. Charlotte Kerr, Tieraona Low Dog, Buford Rolin, Ming Tian, Donald Warren

Breakout Session II, is scheduled for Tuesday, May 15 at 9:25 a.m. It will focus on draft recommendations for Coverage and Reimbursement of Complementary and Alternative Medicine Practices and Products. (Staff Contact Maureen Miller)

Breakout Session II - Group IIA: Employer, Health Insurers/Plans, and State (Breakout Room)
Chair: George DeVries
Members: George Bernier, David Bressler, Effie Chow, William Fair, Veronica Gutierrez, Wayne Jonas, Charlotte Kerr, Linnea Larson, Donald Warren

The questions for this group to consider include the following:

- What principles should be considered in developing policy recommendations related to coverage and reimbursement?
- What ideas for recommendations do you have with regard to employers? Health insurers/health plans?
- Are there recommendations that could be considered by State governments?
- What ideas of suggestions do you have for health services research?

Breakout Session II - Group IIB: Federal Agencies, States, and National Organizations (Main Conference Room)

Chair: Conchita Paz

Members: ThomasChappell, Joe Fins, Tieraona Low Dog, Dean Ornish, Joe Pizzorno, Buford Rolin, Julia Scott, Xiaoming Tian

The questions for this group to consider include the following:

- What principles should be considered in developing policy recommendations related to coverage and reimbursement?
- What recommendations regarding coverage and reimbursement could be made to Federal agencies (as purchasers, sources of health services research, tax policy, etc.)?
- Are there recommendations that could be considered by State governments?
- Are there recommendations that could be made regarding the activities of national organizations?

Breakout Session III, is scheduled for Wednesday, May 16 at 1:30 p.m. It will focus on Research Challenges and incorporate the discussions of this meeting with those held earlier in October 2000. Please review the summary of suggested recommendations listed by panel from the October research meeting, which is included in the Research meeting section of the briefing book behind the Recommendations tab. (Staff contact: Geraldine Pollen)

Breakout Session III - Group IIIA: (Breakout Room)
Evaluating Research Literature (May meeting - Panel III)
Publication of Research Results (May meeting - Panel VI)
Foundation (Not-for-Profit) Support (May meeting - Panel II and October meeting-Panel IX)
Private Sector Support (October meeting-Panel VIII)
CAM Research and Regulatory Process (October meeting-Panels V, VI, VII)

Chair: Tieraona Low Dog / Maureen (E)
Members: Dean Ornish, George Bernier, Conchita Paz, Donald Warren, Tom Chappell, Linnea Larson, Julia Scott, Joe Pizzorno

Breakout Session III - Group IIIB: (Main Conference Room)
Methodology (May meeting - Panel V)
Training (May meeting - Panel VI)
Concerns about CAM (May meeting - Panel IV)
Federal Agency Support (May meeting and October meeting-Panels II, IV, XI)
Academic Health Centers and CAM Support (October meeting-Panel III)
Research and Experimental Design (October meeting-Panel X)

Chair: Wayne Jonas / Ken Lunch room
Members: David Bresler, George DeVries, Xiaoming Tian, Effie Chow, Buford Rolin, Veronica Gutierrez, Joe Fins, William Fair

As always, speakers' testimonies and bio-sketches are included for your reference. We have numbered the speakers for this meeting so that materials submitted to you during the meeting can be more easily added to your briefing books. Please keep in mind your breakout session topics when reading the briefing book materials and while taking notes during the meeting.

We will take some time at lunch to continue our discussions about the interim and final report process, in particular our plans for the upcoming July meeting. The July meeting will focus entirely on draft recommendations and will not include any invited speakers, however, a public comment session will be held as usual.

No shuttles will be provided because our new meeting site is located only three blocks from your hotel. Feel free to walk or take a taxi to the site. By metro subway exit Dupont Circle station on the Red Line, Q street exit, and walk 3 blocks north to The Universal South Entrance of 1825 Connecticut Avenue (Academy for Education Development). The meeting will be held in the Academy Hall on the eight floor.

Dr. Gordon has invited you and your guest to an informal dinner at his home after the meeting on Tuesday, May 15, at 7:00 p.m. Dr. Gordon's home is located at 2934 Macomb Street, NW Washington, DC, a quick ride up the Red Line from Dupont Circle to Cleveland Park, or by taxi. At the Cleveland Park Station, exit Connecticut Avenue west and walk south (away from the EXXON station) two blocks, turn right on Macomb Street. Please let Doris know by Monday, May 14, how many guests you will be bringing.

We look forward to this meeting. Maureen Miller (Reimbursement and Coverage) and Gerry Pollen (Coordination of Research), and Dr. Joseph Kaczmarczyk (Access and Delivery), who have provided the staff lead for these two topics, are available to answer any questions that you might have. Maureen can be reached at 301-435-2211, Gerry at 301-435-6233 and Joe at 301-435-6197.

Sincerely,

Stephen C. Groft, Pharm.D.
Executive Director

Michele M. Chang, CMT, MPH
Executive Secretary

Julie Merrill

American Association

of Oriental Medicine

410-367-1126

Reimbursement

Education

3:45 - 4:00

4:15 p.m. **Public Comment Session: 3-Minute Oral Statements**

~~47.~~ James Sensenig, American Association of Naturopathic Physicians -?-
4:18 ~~48.~~ Candace Campbell, American Preventive Medical Association
4:21 ~~49.~~ Diane Davis Cole, University of Virginia Cancer Center
4:24 ~~50.~~ Katherine Jane Gorton, American Dietetic Association
4:27 ~~51.~~ Audrey Di Maria, Art Therapy Credential Board
4:30 ~~52.~~ Judy Simpson, American Music Therapy Association

◆ Discussion

4:15 - 4:30 4:45 ~~53.~~ Richard Goldberg, Private Practice
4:48 ~~54.~~ Nancy Kristine Haller, Feldenkrais Guild of North America
4:51 ~~55.~~ Christina Herlihy, National Certification Commission for Acupuncture and Oriental Medicine
4:54 ~~56.~~ Su Liang Ku, Florida Institute for Traditional Chinese Medicine
4:57 ~~57.~~ Sharon Stevenson, National Center for Homeopathy 703. 548. 7809 Regis. form
Left message w/ Secty.

◆ Discussion

5:15 ~~58.~~ Barbara Moquin, National Navel Medical Center
5:18 ~~59.~~ Matt Ward Russell, National Integrative Medicine Council
5:21 ~~60.~~ Carolyn Jones Sabatini, Pharmavite Corporation
5:24 ~~61.~~ Christina Walker, The Shenk Human Energetic Institute ✓
5:27 ~~62.~~ Alan Dumoff, Private Practice 301. 984. 8020

5:30 ◆ Discussion

~~5:30 p.m.~~ 5:45 p.m. **MEETING ADJOURN**

ALAN DUMOFF
Attorney at Law
Master of Social Work

Licensed in the District of Columbia and the State of Maryland

11140 Rockville Pike · Suite 530 · Rockville, MD 20852 · (301) 984-8020 · *Fax:* (301) 984-2215

February 15, 2001
Originally sent by mail January 3, 2001

James Gordon, M.D.
Chairman

Stephen Groft, Pharm.D.
Executive Director
White House Commission on
Complementary and Alternative Medicine Policy
6701 Rockledge
Room 1010
Bethesda, MD 20817-1813

Re: Request to testify at Commission meeting
regarding credentialing and licensure issues.

Dear Drs. Gordon and Groft:

I am writing to request an opportunity to testify before the Commission at its upcoming meeting regarding certification and licensure issues. My testimony would not be on behalf of any particular client or interest, but rather on behalf of the collective interest of numerous clients and the community of CAM physicians, practitioners and patients at-large, to which I have dedicated my professional activities. I originally sent this letter by mail without response, and a colleague suggested that e-mail might be more successful.

I know that Jim is generally familiar with my efforts, but I wanted to briefly highlight the credentialing and licensure experience I bring to these matters, which I believe present a unique combination of experience among those working in the field:

- In 1988-89 I was Acting Director and General Counsel for the National Commission for the Certification of Acupuncturists and Oriental Medicine (NCCAOM).

- I have represented holistic physicians and CAM practitioners before several medical boards.

- As a part-time Senior Professional Editor at IntegrativMedicine, a Boston-based company, I am writing a primer for hospitals on integration that in part addresses these issues.

- I am authoring a guide book on credentialing and privileging CAM practitioners that includes over 80 pages of text describing issues in the field, as well as a large volume of reference material.

- I drafted and assisted in the successful lobbying in the District of Columbia for the *Qualified Massage Therapists Act of 1994,* and assisted in the regulatory development in support of the Act.

My experience representing clients and participating in numerous discussions with those involved in the CAM community suggest to me that there are some serious misunderstandings about licensing matters, particularly about scope of practice and competitive issues, and that there are ways the Commission could assist the field in discerning and documenting quality practice through the further development of credentialing efforts.

Jim, I also wanted to make sure you knew that the article in the Green Journal you read was published in two parts, the latter which you may not have seen and which addresses state issues and was included in the letter I gave you. I noted in that portion a concern about the Federation of State Medical Boards consistent with that raised in testimony at the last public meeting, and agree that there is some serious concern about the approach the Federation takes to CAM. I appreciate your kind words about the article and am certainly available to assist the Commission about the issues I raised there or in any other way that might prove useful.

Sincerely,

Alan Dumoff

Enclosure

Albrecht, Joan (NCCAM)

From: AlanDLMC@aol.com
Sent: Friday, February 16, 2001 1:41 PM
To: Whccamp (NCCAM)
Subject: Request to participate; Alan Dumoff

white house request rtf

Drs. Gordon and Groft:

I understand that the public slots have been filled at the upcoming meeting;
I had written in early January requesting an opportunity to share the benefit
of my experience. I resend that letter (slightly modified) via this e-mail in
hopes that some vehicle for participating might be offered.

Alan Dumoff
301-984-8020

Registration Form

May 14, 2001 – 8:00 am – 6:00 pm
May 15, 2001 – 8:00 am – 6:00 pm
May 16, 2001 – 8:00 am – 6:00 pm
Academy for Educational Development
1825 Connecticut Avenue, NW, Suite 800
Washington, DC

Last/Family Name*	Walker
First Name	Christina
Middle Name	Lee
Degree	RN MA
Organization*	The Schenk Human Energetic In:
Address	220 East 26th St. #1B
City	New York
State	NY
Zip	10010
Telephone*	212-951-7107
Fax	212-684-5692
Email Address	cwalkerrn@aol.com

* Indicates Required Field

Anyone wishing to present oral comment must register by **May 04, 2001**

I wish to: provide oral comment on (•) datefromdatabase or ( ) datefromdatabase

( ) Observe (no oral statement)

NOTE: There is a 5 minute limit for all oral comments - 3 minutes for testimony and 2 minutes for questions

My oral comments will focus on:(check any that apply)

☑ **1. Coordinated Research and Development to Increase Knowledge of Complimentary and Alternative Medicine Practices and Interventions.**

- What can be done to expand the current research environment so that practices an interventions that lie outside conventional science are adequately and appropriately addressed?
- What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?
- How can we move effectively integrate the CAM and conventional research communities to stimulate and coordinate research?

☐ **2. Guidance for Access to, Delivery of, and Reimbursement for Complimentary and alternative medicine Practices and Interventions.**

- Do you have ready access to CAM practices and interventions?
- How can access to safe and effective CAM practices and interventions be improved?
- What types of CAM practices and interventions should be reimbursable through federal programs or other health care coverage systems?

☐ **3. Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine.**

- How can uniform standards of education, training, licensure and certification be applied to all CAM practioners?
- What training and eductaion should be required of all health care providers to assure

access to safe and effective CAM practices and interventions?
- Are performance standards or practice guidelines needed to ensure the public will have access to the full range of safe and effetive CAM practices and interventions?

☐ **4. Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public.**

- How can useful, reliable, and updated information about CAM practices and inteventions be made more accessible? How woul dyou like to receive su information?
- As a consumer, what kinds of information about CAM practices and interventions are most needed and important to you?
- As a health care provider, what kinds of information about CAM practices and interventions are most needed an important to you?

Please provide a written summary of your 3 minute oral statement (500 characters or less)

Was faxed on 5-8-01

Special Assistance Requirements:

☐ Sign Language Interpretion
☐ Wheelchair Access
☐

ok - not coming 5/9

Registration Form

May 14, 2001 -- 8:00 am -- 5:00 pm
May 15, 2001 -- 8:00 am -- 5:00 pm
May 16, 2001 -- 8:00 am -- 5:00 pm
Academy for Educational Development
1825 Connecticut Avenue, NW, Suite 800
Washington, DC

NO

Last/Family Name*	BRISBANE
First Name	FRANCIS
Middle Name	L.
Degree	PhD
Organization*	AMERICAN QIGONG ASSOCIATION (AQA)
Address	530 BUSH ST. #202
City	SAN FRANCISCO
State	CA
Zip	94108
Telephone*	(415) 788-2227 / ALTERNATE -(631) 444-3150
Fax	(415) 788-2242 / " -(631) 444-8908
Email Address	EASTWESTQI@aol.com / " - FRANCESB@SBW.HSC.SUNYSB.EDU

* Indicates Required Field

Anyone wishing to present oral comment must register by **May 04, 2001**

I wish to: provide oral comment on ○ datefromdatabase or ○ datefromdatabase

○ Observe (no oral statement)

NOTE: There is a 5 minute limit for all oral comments - 3 minutes for testimony and 2 minutes for questions

My oral comments will focus on:(check any that apply)

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Frances L. Cochran, Phd

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Please provide a written summary of your 3 minute oral statement (500 characters or less)

SEE ATTACHED pg. PLS.

Special Assistance Requirements:

☐ Sign Language Interpretion N/A

☐ Wheelchair Access

☐

TO: WHCCAMP

FROM: Frances L. Brisbane, Ph.D.

RE: 5/14-5/16/2001 Meeting – Oral Comment

I am a member of the American Qigong Association Board of Directors would like to provide information and data recently collected from the Fourth World Congress on Qigong and the 4th American Qigong Association Conference held in San Francisco, California on 5/4-5/7/2001.

This source of information and data was obtained from the "Qigong Policy Recommendations Forum". The Forum members were comprised of national organizations of professionals and experts that represent complementary and alternative health care. Also testifying on Qigong policy recommendations were Qigong Masters, health care practitioners, instructors, clients/patients and the general public.

The purpose of this Forum and testimonies was to establish and make recommendations for Qigong Policy, a part of complementary and alternative health care, that will be helpful for WHCCAMP and other policy making bodies.

The outcomes of this information and data is set forth in recommendations, existing and reliable models and applications of Qigong, and some solutions for Qigong in response to the four questions set forth by WHCCAMP.

The formal report will be presented at the WHCCAMP meeting.

Kingsbury, Doris (NCCAM)

From: CAHCACU@AOL.COM
Sent: Thursday, April 19, 2001 10:52 PM
To: Whccamp (NCCAM)
Subject: Comments for the Commission

no sent email 5/10/01

First Name: Doreen
Middle Initial: G
Last Name: Chen
Address: 217-15 Peck Ave Hollis Hills
Address2: 350 Central Park West
City: New York
State: NY
Zip: 11427
E-mail: CAHCACU@AOL.COM
Comment: Please allow me to present an master piece of work done in China in illustrating the scientific evidence both in clinical trail and laboratory research on the mechanism of the effect of acupuncture and the meridian system on May 14-16,2001
at Washington, DC.
I do not need to talk too much, this piece of work would speek for itself.
Please let me know what date and what time you will asign me to be there, because I have to arrange my plan ticket.
Thanks for your consideration.
Doreen Chen,Chair of CAC of AAOM,
AATCM, NACM, UANYSLA, President of EastWeast Integrated Care Ctr.

White House Commission on Complementary and Alternative Medicine Policy

Meetings

Registration Information

Washington, DC

Academy for Educational Development

Print This Page

Speaking? Y
Name: Yvette Benjamin P.A., M.P.H. No
Organiztion: Consultant
Address: 108 Pembrooke View Lane Giathesburg, MD 20877
Phone: 301-963-5822
Fax:
Email: ginger32147@aol.com
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Paul A. Berns M.D.
Organiztion: Institute for Molecular Medicine
Address: 15162 Triton Lane HUNTINGTON BEACH, AA 92649
Phone: 714-846-6360
Fax: 714-846-0398
Email: peers@westworld.com
Needs:
Registration Date:
Topics 1:2:3:4
Summary: Observe and interested in the above agenda....I am director of medical education for the INSTITUTE FOR MOLECULAR MEDICINE in Huntington Beach Ca. and chairman of the IRB for clinical trials which include integrative medicine...and conference director for Feb 23,2002 WOMEN'S HEALTH AND INTEGRATIVE MEDICINE..SEE WEBSITE...www.immed.org Thankyou

No

Speaking? Y
Name: Maria Bianchi MA
Organiztion: American Association of Naturopathic Physicians
Address: 8201 Greensboro Drive Suite 300 McLean, VA 22102
Phone: 703-610-0265
Fax: 703-610-9005
Email: mbianchi@naturopathic.org
Needs:
Registration Date:
Topics
Summary:

No

Speaking? Y
Name: E. Borchini
Organiztion: HRSA
Address: Bethesda, MD
Phone: 301-594-4464
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

No

Speaking? Y
Name: Dannion Brinkley
Organiztion: Compassion in Action
Address: PO Box 1919 Aiken, SC 29801
Phone: 803-643-3441
Fax: 803-648-7271
Email: dannion.mailexcel.com
Needs:
Registration Date:
Topics 2
Summary:

No

Speaking? N
Name: Briti (test2 , no oral)
Organiztion: Memberware
Address: , AA
Phone: 111
Fax:
Email:
Needs:
Registration Date: 05/03/2001 02:36 PM
Topics
Summary:

Speaking? Y
Name: Briti Briti (test2 , oral) MD
Organiztion: Memberware
Address: , MD
Phone: 111
Fax:
Email:
Needs:
Registration Date: 05/03/2001 02:37 PM
Topics
Summary: this is a test

Speaking? Y
Name: Candace Lee Campbell B.A. -48
Organiztion: American Preventive Medical Association
Address: Box 458 Great Falls, VA 22066
Phone: 703-759-0662
Fax: 703-759-6711
Email: candace@apma.net
Needs:
Registration Date:
Topics 2
Summary: I would like to tell the Commission about the Access to Medical Treatment Act, which would give Americans the right to use therapies that have not been approved by the FDA.

yes

Speaking? Y
Name: Diana L Chambers
Organiztion: Friends of Health
Address: 2014 Kalorama Rd. NW Washington, DC 20009
Phone: 202-483-3080
Fax: 202-483-3050
Email: diana@friendsofhealth.org
Needs:
Registration Date:
Topics 4
Summary: Access to CAM practices and interventions for the poor

No

Speaking? Y
Name: S Elizabeth Clay
Organiztion: US House of Representatives
Address: 2157 Rayburn House Office Building Washington, DC 20515
Phone: 202-225-5074
Fax: 202-226-1274
Email: beth.clay@mail.house.gov
Needs:
Registration Date:
Topics
Summary:

No

Speaking? Y
Name: Diane Davis Cole Master of Public Health 49
Organiztion: University of Virginia Cancer Center
Address: P. O. Box 800334 Charlottesville, VA 22908
Phone: 804-243-6015
Fax: 804-982-0918
Email: ddc2d@virginia.edu
Needs:
Registration Date:
Topics 4
Summary:

Yes

Speaking? Y
Name: Audrey Di Maria MA, ATR-BC
Organiztion: Sectretary of Art Therapy Credential Board
Address: 4200 Cathedral Ave., NW #901 Washington, DC 20016
Phone: 202.576.5141
Fax: 202.576.8804
Email: adimaria@msn.com
Needs:
Registration Date:
Topics 3
Summary: Summary: Report qualitfication standards of Art Therapists; report establishment of state liscensure across US

Yes

Speaking? Y
Name: Mark L Dreher PhD
Organiztion: Mead Johnson Nutritionals
Address: 2400 West Lloyd Expressway Evansville, IN 47721
Phone: 812-429-5539
Fax: 812-429-5054
Email: mark.dreher@bms.com
Needs:
Registration Date:
Topics
Summary:

No

Speaking? Y
Name: Richard Ira Goldberg MSW
Organiztion: Private Practice
Address: 4330 E_W Hwy. Ste. 306 Bethesda, MD 20814
Phone: 3016527792
Fax:
Email: goldberg@erols.com
Needs:
Registration Date: 05/04/2001 03:13 PM
Topics 1:2
Summary: This oral commentary concerns the use of Emotional Transformation Therapy: light and color combined with specialized interactive guidance. We shall identify the scientific research with respect to light stimulation, identfy obstacles to research and suggest remedies.

Yes

Speaking? Y
Name: Katherine Jane Gorton MS
Organiztion: American Dietetic Association
Address: 1120 Connecticut Avenue, NW, #480 Washington, DC 20036
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Fax: (202) 775-8284
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Needs:
Registration Date:
Topics
Summary:

50 left message

Yes

Speaking? Y
Name: Nancy Kristine Haller Guild Certified Feldenkrais Practitioner, LMP, BA
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Needs:
Registration Date:
Topics
Summary:

54 - 4:45

left message

Yes

Speaking? Y
Name: Nancy Kristine Haller Guild Certified Feldenkrais Practitioner, LMP, BA
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Phone: 253 852 7167
Fax: 253 850 8164
Email: nkhaller@aol.com
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Christina Herlihy PhD 55 left message
Organiztion: NCCAOM
Address: 11 Canal Center Plaza, Ste. 300 Alexandria, VA 22314
Phone: 703-548-9004 x 3250
Fax: 703-548-9079
Email: cherlihy@nccaom.org
Needs:
Registration Date:
Topics
Summary:

yes

Speaking? Y
Name: Libby Hogen Master of Science
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Phone: 202-872-1488
Fax: 202-872-9594
Email: lhogen@crnusa.org
Needs:
Registration Date:
Topics
Summary:

no

Speaking? Y
Name: Jeanie Kennedy
Organiztion: American Academy of Othopaedic Surgeons
Address: 6300 N. River Road Rosemont, IL 60018
Phone: 847/384-4308
Fax: 847/823-9769
Email: jkennedy@aaos.org
Needs:
Registration Date:
Topics
Summary:

no

Speaking? Y
Name: Su Liang Ku A.P., Professor
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Phone: 727-546-6565
Fax: 727-547-0703
Email: fitcm@gte.net
Needs:
Registration Date:
Topics 2
Summary: Will discuss thrid party reimbursement for CAM to include all types of health insurance inlcuding Medicare and Medicaid. Standardization of diagnostic and treatment procedures and coding. Assuring access to safe and effective CAM practices and treatment.

56 4:45 left msg on a/s w/ sec. yes

Speaking? Y
Name: Boyd J. Landry M.P.A.
Organiztion: The Coalition for Natural Health
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Phone: 202-216-9488
Fax: 800-598-4264
Email: boydlandry@naturalhealth.org
Needs:
Registration Date:
Topics 1:2:3:4
Summary:

no

Speaking? Y
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Phone: 212- 769-9028
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Needs:
Registration Date:
Topics
Summary:

no

Speaking? Y
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Needs:
Registration Date:
Topics 1
Summary:

no

Speaking? Y
Name: EKATERINI MALLIOU
Organiztion: OFFICE ON WOMEN'S HEALTH/OS/HHS
Address: 200 INDEPENDENCE AVE SW #730B WASH, DC 20201
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Email: EMALLIOU@OSOPHS.DHHS.GOV
Needs:
Registration Date:
Topics
Summary:

no

Speaking? Y
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Email: amccormick@nccaom.org
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Memberware (test - no oral)
Organiztion: Memberware
Address: , AA
Phone: 111
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Memberware (test -oral)
Organiztion: Memberware
Address: , AA
Phone: 111
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Leo Moody
Organiztion: HRSA, Bureau of Primary Health Care
Address: 4350 East-West Hwy. Bethesda, MD, MD 20814
Phone: 301-594-3726
Fax: 301-594-4987
Email: lmoody@hrsa.gov
Needs:
Registration Date:
Topics
Summary:

NO

58- 5:15

Speaking? Y
Name: Barbara E. Moquin PhD(cand),RN,MSN,CS-P
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Phone: (301)295-4041
Fax:
Email: tieda@aol.com
Needs:
Registration Date:
Topics
Summary:

Left message

YES

Speaking? Y
Name: Annette Oestreicher M.S., Biology
Organiztion: Oestreicher Medical Communications, Inc
Address: 300 East 54th Street, #9H New York, NY 10022
Phone: 212-758-7092
Fax: 212-371-6193
Email: Annetteoes@cs.com
Needs:
Registration Date:
Topics
Summary:

NO

Speaking? Y
Name: Craig (test) Powers (test)
Organiztion: self (test)
Address: 11111 street thecity, MD 22222
Phone: 301-111-2222
Fax:
Email:
Needs:
Registration Date:
Topics 1:4
Summary: This record was just put in for testing purposes, and will be deleted shortly.

Speaking? Y
Name: Craig (test) Powers (test)
Organiztion: self
Address: , AA
Phone: 301
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Craig (test2) Powers (test2)
Organiztion: self
Address: , AA
Phone: 301-266-3333
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Craig(test3) Powers(test3)
Organiztion: self
Address: , AA
Phone: 323
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Craig(test4) Powers(test4)
Organiztion: self
Address: , AA
Phone: 323
Fax:
Email:
Needs:
Registration Date:
Topics
Summary:

Speaking? Y
Name: Kathleen Quain CSW
Organiztion: Foundation for Health and the Environment
Address: 177 Prince St., 3rd floor New York, New York, NY 10012
Phone: 212.946.2172
Fax: 212.982.2850
Email: globalpeace4u@aol.com
Needs:
Registration Date:
Topics
Summary:

NO

Speaking? Y
Name: Rustum Roy
Organiztion: Pennsylvania State University
Address: 102 MRL University Park, PA 16802
Phone: 814-865-3421
Fax: 814-863-7040
Email: rroy@psu.edu
Needs:
Registration Date:
Topics 1
Summary: I will be sending a copy of my written comments on research issues to your office by May 7, 2001

NO

Speaking? Y
Name: Matt Ward Russell 59 - 5:15
Organiztion: National Integrative Medicine Council
Address: 5151 E. Broadway, Suite 1095 Tucson, AZ 85711
Phone: 520-571-1110
Fax: 520-571-1177
Email: mrussell@nimc.org
Needs:
Registration Date:
Topics
Summary:

yes

Speaking? Y #60 5:15
Name: Carolyn Jones Sabatini BA, MBA
Organiztion: Pharmavite Corp.
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Phone: (913) 338-2640
Fax: (913) 338-2815
Email: csabatini@pharmavite.net
Needs:
Registration Date:
Topics
Summary:

yes

Speaking? Y
Name: James S. Sensenig ND - 47 pdf mail out w/ letter.
Organiztion: AANP
Address: 2558 Whitney Avenue Hamden, CT 06518
Phone: 203-230-2200
Fax:
Email: jsensenig@aol.com
Needs:
Registration Date:
Topics 2
Summary: I will speak on the need for pluralism in American medicine. Give examples of reimbursement systems for naturopathic medicine that work, and give reccomendations to the commission for reimbursement of naturopathic services for inclusion of naturopathic physicians in federal programs.

yes

52

Speaking? Y
Name: Judy Simpson MT-BC
Organiztion: American Music Therapy Association
Address: 8455 Colesville Rd, Suite 1000 Silver Spring, MD 20910
Phone: 301-589-3300 x108
Fax: 301-589-5175
Email: Simpson@musictherapy.org
Needs:
Registration Date:
Topics 1:2
Summary: Music therapy has a 50 year history of contributing to the treatment of individuals with a variety of disabilities and illnesses in the U.S. However, the lack of understanding by the federal government regarding music therapy applications, along with limited funding for research, direct services, and reimbursement, seriously restricts access to services. We would appreciate the Commission's assistance in accessing research funding and third party reimbursement for music therapy interventions.

YES

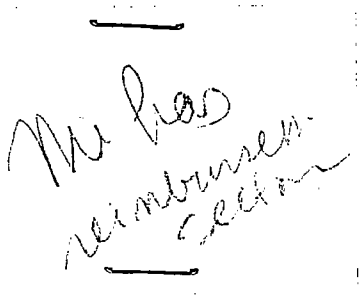
61 5:15

Speaking? Y
Name: Christina Lee Walker RN MA
Organiztion: The Schenk Human Energetic Instiutute
Address: 220 East 26th St. New York, NY 10010
Phone: 212-951-7107
Fax: 212-684-5692
Email: cwalkerrn@aol.com
Needs:
Registration Date:
Topics 1:2
Summary: will fax oral statement

Yes

Speaking? Y
Name: Sally M. Yamini DHM
Organiztion: Yamini Consulting
Address: 7010 Woodland Dr. Dallas, TX 75225
Phone: 214-692-0540
Fax: 214-987-0540
Email: smywolf@aol.com
Needs:
Registration Date:
Topics
Summary:

NO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Divider Title: Research Overview

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Divider Title: Eisenberg

Prepared 05/08/2001

David Eisenberg, M.D.
Center for Alternative Medicine Research

David M. Eisenberg, MD is the Director of the Center for Alternative Medicine Research and Education at Beth Israel Deaconess Medical Center and Associate Professor of Medicine at Harvard Medical School, Boston, and Massachusetts. He recently was named to head the new Harvard Medical School Division for Research and Education in Complementary and Integrative Medical Therapies.

Dr. Eisenberg's major research interests include the evaluation of complementary and alternative medical therapies in terms of their prevalence, safety, efficacy, cost-effectiveness and mechanisms of action.

Dr. Eisenberg is also the Director of two Harvard Medical School courses devoted to complementary and alternative medicine. One course is offered through the Department of Medicine and the other through the Department of Continuing Education.

From 1994-1998 he served as a member of the National Institutes of Health Alternative Medicine Program Advisory Council. He is currently a member of the FDA Subcommittee responsible for post market surveillance of dietary supplements. He has authored numerous scientific articles involving complementary and alternative medicine practice.

Harvard Medical School
Associate Professor of Medicine

David M. Eisenberg, M.D.
Director, Division for Research and Education in Complementary and Integrative Medical Therapies

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Testimony to The White House Commission On CAM Policy

David M. Eisenberg, M.D.
May 15, 2001

Enclosures

1) **Summary of Recommendations**

2) **Background Information with citations**

3) **Harvard Medical School Press Release**

Harvard Medical School
Associate Professor of Medicine

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Recommendations to The White House Commission on CAM Policy

1. Quality assurance of herbs and other dietary supplements is a prerequisite for credible research and is essential for public safety.

2. The Commission should argue for enhanced surveillance of adverse effects pertaining to herbs, vitamins and other dietary supplements. Examples of direct and indirect toxicity should be included in such a surveillance system. Ideally, the United States should participate in an international post-market surveillance of herb, vitamins and supplements, as these products are now sold on a global basis.

3. Improved standards for licensure and credentialing of CAM practitioners must be more consistent across states and across CAM disciplines in order to: a) conduct generalizable research; b) allow medical professionals to make appropriate referrals and treatment decisions; and c) provide relevant guidelines for the general public.

4. Issues of malpractice liability and ethical practice associated with CAM therapies and/or co-management of patients by conventional and CAM providers must be anticipated and studied.

5. Federal agencies should be encouraged to increase fiscal resources for basic science, clinical research and health service research involving CAM therapies. Any one of these lines of inquiry, in the absence of the other two, will be insufficient to change medical management, policy and general perceptions pertaining to scientific evidence base regarding CAM therapies.

6. The research trajectory for CAM is unlike that of most conventional medical fields. Specifically, epidemiological and clinical investigations have preceded basic science (i.e., mechanistic) research in this area. It is imperative that mechanistic research be augmented and that plausible explanatory models be pursued if CAM/Integrative Medicine is to be satisfactorily incorporated into mainstream health care and biomedicine.

7. Additional controlled studies designed to document the presence or absence of clinical and financial cost offsets of CAM/integrative medical care must be

undertaken in order to inform reimbursement policies and procedures. Several options can be considered, including:

a) more targeted funding from federal agencies such as the NIH, CDC, etc., for health services research in this area;

b) additional funding for the Agency for Healthcare Research and Quality, arguably the federal agency with the most experience implementing health services research and the development of best practice guidelines;

c) incentives for HMOs, indemnity insurers, large corporations and large employer groups to sponsor CAM related health service research with or without matching federal funds; and

d) some combination of the above-mentioned public and private sector commitments.

8. Consider opportunities to fund a critical mass of academic health centers (i.e., medical institutions affiliated with universities and medical schools) with sufficient resources and infrastructure to perform CAM/integrative medicine:

- Research (basic, clinical and health services)
- Education/training of research and clinical experts
- Responsible delivery of integrative care services

These centers/institutes must also be informed by successful demonstration projects from the private sector as well as consumer demand and regulatory constraints. In this regard, the Consortium of Academic Health Centers for Integrative Medicine and the Federation of State Medical Boards as well as other relevant organizations should be consulted.

9. Encourage the NIH in its efforts to develop evidence-based, financially sustainable models of CAM/integrative care clinical delivery. Ideally, such integrative care models should participate in organized research and should utilize comparable data tracking of both clinical and financial outcomes. In this way, clinical and financial data can be accrued on a national basis and answer questions pertaining to CAM safety, efficacy, cost-effectiveness or the lack thereof.

10. CAM therapies shown to be effective must be made available to all individuals regardless of insurance status or ability to pay.

11. Detailed epidemiologic surveys of CAM patterns of use by minority populations must be made a priority. This information is essential to inform public policy and to protect particularly vulnerable populations.

12. Consider opportunities to create and sustain a national (or perhaps international) Society for CAM Research. Such an organization, if successfully organized, can help inform public policy in the years ahead. In addition, the non-US members of such a society can inform US policy through scientific research and clinical/financial experience elsewhere in the world.

13. The Commission should consider opportunities to increasingly engage the private sector, specifically HMOs, insurance carriers, pharmaceutical companies and Fortune 1000 employers, to secure resources to support basic, clinical and health service research involving the CAM therapies and models of integrative care. Sponsored research from these groups can and will likely exceed the resources available from Federal and State agencies. Consortia of this type can augment the research currently directed by NIH and other federal agencies and will, likely, be met with enthusiasm by investigators from universities, medical schools and other academic institutions.

14. One of the greatest impediments to CAM research is the current lack of faculty development in our medical and nursing schools, schools of pharmacy and allied health. In addition, the absence of exposure to CAM therapies and integrative care practices by the current allopathic healthcare workforce makes it difficult, if not impossible, to create suitable training environments for the next generation of CAM clinical and research scholars. Attention must therefore be placed on undergraduate, post-graduate and faculty development. Additional opportunities for "cross training" involving both CAM and conventional medical practitioners (and students) should be pursued.

David Eisenberg, MD
White House Commission
May 15, 2001

COMPLEMENTARY, ALTERNATIVE AND INTEGRATIVE MEDICAL THERAPIES EPIDEMIOLOGY AND OVERVIEW

I. Definitions and Terminology

"Complementary", "Alternative", and "Integrative" Medical Approaches

Alternative medical therapies encompass a broad spectrum of practices and beliefs (1). From an historical standpoint, they may be defined "... as practices that are not accepted as correct, proper, or appropriate or are not in conformity with the beliefs or standards of the dominant group of medical practitioners in a society" (2). From a functional standpoint, alternative (a.k.a. "complementary") therapies may be defined as interventions neither taught widely in medical schools nor generally available in hospitals (3). Ernst et al. contend that "complementary" medical techniques "[complement] mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine" (4). The terminology currently in use to describe these practices remains controversial. Many commonly used labels (e.g., "alternative," "unconventional," "unproven") are judgmental and may inhibit the collaborative inquiry and discourse necessary to distinguish useful from useless techniques (5). "Complementary and Alternative Medicine" (CAM) is the language currently used by the NIH and U.S. federal agencies to describe this field of inquiry.

"Integrative medicine" refers to ongoing efforts to combine the best of conventional and evidence-based complementary therapies while emphasizing the primacy of the patient-provider relationship and the importance of patient participation in health promotion, disease prevention and medical management. "It (integrative medicine) views patients as whole people with minds and spirits as well as bodies and includes these dimensions into diagnosis and treatment" (6). In the January 2001 *British Medical Journal* edition devoted entirely to Integrated Medicine, the Journal's editor, Richard Smith, wrote: "It mightn't be too pretentious (although it might) to say that such a growth (of integrative medicine) might restore the soul to medicine – the soul being that part of us that is the most important but the least easy to delineate" (7). Several recently published articles and editorials wrestle with the challenges of properly labeling and describing this field of inquiry (6, 8-13).

Dietary Supplements

The Dietary Supplement Health and Education Act defines dietary supplements as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, mineral, amino acid, herb or other botanical; or a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above; and intended for ingestion in the form of a capsule, powder, softgel, or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet.

II. Prevalence, Costs, and Patterns of Use of CAM Therapies in the United States

Findings from a 1997 follow-up national survey of complementary and alternative medicine (CAM) prevalence, costs, and patterns of use (14) include the following:

Between 1990 and 1997:

- The prevalence of CAM use increased by 25% from 33.8% in 1990 to 42.1% in 1997.
- The prevalence of herbal remedy use increased by 380%.
- The prevalence of high-dose vitamin use increased by 130%.
- The total number of visits to CAM providers increased by 47% from 427 million in 1990 to 629 million in 1997.
- The total visits to CAM providers (629 million) exceeded total visits to all primary care physicians (386 million) in 1997.
- In 1997, adults made an estimated 33 million office visits to professionals for advice regarding the use of herbs and high-dose vitamins.
- Estimated expenditures for CAM professional services increased by 45% exclusive of inflation and in 1997 were estimated at $21.2 billion dollars.
- Out-of-pocket expenditures for herbal products and high-dose vitamins in 1997 were estimated at $8 billion.
- Out-of-pocket expenditures for CAM professional services in 1997 were estimated at $12.2 billion. This exceeded the out-of-pocket expenditures for all U.S. hospitalizations.
- Total out-of-pocket expenditures relating to CAM therapies were conservatively estimated at $27.0 billion. This is comparable to the projected out-of-pocket expenditures for all U.S. physician services.
- An estimated 15 million adults in 1997 took prescription medications concurrently with herbal remedies and/or high-dose vitamins. These individuals are therefore at risk for potential adverse drug-herb or drug-supplement interactions.
- Current use of CAM services is likely to under-represent utilization patterns if insurance coverage for CAM therapies increases in the future.
- Despite the dramatic increases in the use and expenditures associated with CAM services, the extent to which patients disclose their use of CAM therapies to their physicians remains low. Fewer than 40% of CAM therapies used were disclosed to a physician in both 1990 and 1997.

The authors concluded that CAM use and expenditures increased substantially between 1990 and 1997, attributable primarily to an increase in the proportion of the population seeking CAM therapies, rather than increased visits per patient.

Other nationally representative surveys of CAM prevalence and patterns of use have provided additional useful information. These include a study by Astin (15) which concluded that "...the majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine, but largely because they find their health care alternatives to be more congruent with their own values, beliefs and philosophical orientation towards health

and life. Druss and Rosenheck's national survey (16) found that practitioner-based CAM therapies appear to serve more as a complement than an alternative to conventional medicine; and, individuals in the top quartile of numbers of physician visits were more than twice as likely as those in the bottom quarter to have used CAM therapies during the prior year. Two recent analyses of national survey data provide additional information regarding CAM patterns of use in adults over age 65 (17) and adults with anxiety or depression (18).

The above-mentioned surveys are all based on nationally representative random samples of adult Americans. In addition, there have been a number of convenience samples investigating CAM therapy use among individuals with a particular condition or disease. Examples include surveys involving CAM therapy use among individuals with: cancer (19-28), rheumatologic disorders (29-31), self-reported disability (32), HIV (33), inflammatory bowel disease (34) and rhinosinusitis (35), as well as surgical patients (36) and patients in an emergency department (37).

National surveys performed outside the United States suggest that CAM is popular throughout the industrialized world (38). The percentage of the population who used CAM therapies during the prior twelve months has been estimated to be 10% in Denmark (1987) (39), 33% in Finland (1982) (40), and 49% in Australia (1993) (41). Public opinion polls and consumers' association surveys suggest high prevalence rates throughout Europe and the United Kingdom (42-45). The percentage of the Canadian population who saw a CAM therapy practitioner during the previous twelve months has been estimated at 15% (1995) (46). The wide range of utilization rates can be explained, in part, by the disparity in definitions of CAM therapy and the selection of therapies assessed.

III. Top Herbal Products, Vitamins and Non-Herbal Dietary Supplements Sold in the U.S.

U.S. Vitamins and Minerals Sales

	$Millions
Multivitamins	839
Vitamin E	373
Calcium	340
Vitamin C	230
Vitamin B-complex	90
Vitamin B	82
Iron	57
Vitamins A & D	34
Zinc	28
Potassium	14

(*Drug Store News*, May 2000)

U.S. Herbal Products Sales

	$Millions		$Millions
Gingko biloba	147	Valerian	10
St. John's wort	104	Evening primrose	9
Ginseng	84	Grape seed	8
Garlic	77	Milk thistle	8
Echinacea	72	Bilberry	6
Saw palmetto	45	Black cohosh	6
Kava kava	18	Pycnogenol	5
Soy	18	Ginger	2

(*Drug Store News*, May 2000)

Non-Herbal Dietary Supplement Sales

	$Millions
Glucosamine / chondroitin	288
CoQ-10	41
Melatonin	31
Amino acids	21
Fish oil / omega fatty acid	14
DHEA	11
Acidophilus	11
Lecithin	10
Gelatin	8
Glucose	7
Shark cartilage	6

(*Drug Store News*, May 2000)

Top Herbs, U.S. vs. Europe

	United States[†]	Europe[‡]
1	Gingko biloba	Gingko biloba
2	St. John's wort	St. John's wort
3	Ginseng	Horse chestnut
4	Garlic	Yeast
5	Echinacea	Hawthorn
6	Saw palmetto	Myrtle
7	Kava kava	Saw palmetto
8	Soy	Stinging nettle
9	Valerian	Ivy
10	Evening primrose	Mistletoe

[†] *Drug Store News*, May 2000

[‡] *German Commission E*, 1998

IV. Educational Programs in the United States

A recent survey of courses involving CAM at U.S. medical schools was published in the 1998 *JAMA* theme issue devoted to medical education (47). This article, by M. Wetzel et al, included the following results: 64% of the U.S. medical schools reported offering courses on CAM. Of the 123 courses reported, 68% were stand alone electives and 31% were part of required courses. Common topics included chiropractic, acupuncture, homeopathy, herbal therapies and mind-body techniques. The American Association of Medical Colleges has established a Special Interest Group devoted to CAM, and this topic continues to be discussed at the AAMC's annual meetings.

The Department of Medicine at the University of Arizona College of Medicine is currently the only school with an "integrative medicine" clinical fellowship training program (48). In 1999, the NIH awarded its first (T-32) Research Fellowship Training Grant in CAM to Harvard Medical School. Additional NIH-funded CAM Fellowship training programs are to be anticipated.

For the past seven years Harvard Medical School has offered a Department of Medicine elective entitled, "Alternative Medicine: Implications for Clinical Practice and Research." The principal objective of this course has been to provide physicians in training with sufficient knowledge and management skills to responsibly advise patients who use or request CAM therapies. A series of four cases and relevant bibliographies used in this course can be obtained from Harvard Medical School. Continuing education courses devoted to CAM are increasingly popular. For the past several years, Columbia University has offered a one-week intensive course on the topic of herbal therapies. This year, the NIH awarded educational grants intended to incorporate CAM information into the medical, dental, nursing and allied health professional school curriculums, residency training programs, and into continuing education courses.

V. Research Issues

Prior to 1994, relatively little was known about the relative safety, efficacy, cost-effectiveness and mechanism of action of individual alternative therapies. Increasingly, however, the peer-reviewed medical literature has included consensus conferences, systematic reviews, case studies and randomized trials involving CAM therapies. In November 1998, the *JAMA* and AMA specialty journals published more than eighty articles devoted to CAM. Additional studies have subsequently been published in leading medical journals. Noteworthy examples of recently published reviews and original trials include:

Examples of Articles/Consensus Reports Suggesting Efficacy

1) Chiropractic for Acute Low Back Pain (49, 50)
2) Mind/Body Techniques for Pain, Insomnia (51)
3) Acupuncture for Nausea and Dental Pain (52)
4) Psychosocial Support Groups for Cancer (53)
5) Homeopathy as Distinct from Placebo (54)
6) St. John's wort for the Treatment of Depression (55)
7) St. John's wort vs. Imipramine vs. Placebo (56)
8) Gingko for the Treatment of Alzheimer's Type Dementia (57, 58)
9) Chinese Herbs for the Treatment of Irritable Bowel Syndrome (59)
10) Saw Palmetto for the Treatment of Benign Prostatic Hyperplasia (60)
11) Garlic for Hypercholesterolemia (61-63)
12) Glucosamine and Chondroitin for Osteoarthritis (64, 65)
13) Kava Kava for Anxiety (66)
14) Homeopathy for Vertigo (67)
15) Homeopathy for Allergic Rhinitis (68)
16) Osteopathic Manipulation for Low Back Pain (69)
17) Moxibustion for Breech Presentation (70)
18) Acupuncture for Recurrent Headaches (71)
19) Acupuncture for Post-operative Nausea (72)
20) Acupuncture for Fibromyalgia (73)
21) Distant Healing (74)
22) Intercessory Prayer (75)

Examples of Articles/Studies Suggesting Lack of Efficacy

1) Acupuncture for Peripheral Neuropathy (76)
2) Hydroxycitric Acid for Obesity (77)
3) Chiropractic vs. Physical Therapy vs. Education for Low Back Pain (78)
4) Acupuncture for Tinnitus (79)

Over the past year, the medical literature has included several reports of clinically significant adverse events caused by the direct or indirect toxicity of herbal products. These include:

Examples of Articles Describing Significant Drug-Herb Interactions and/or Toxicity

1) Case Studies Involving the Most Commonly Used Medicinal Plants (80)
2) Adverse Reactions Between St. John's wort and Prescription Drugs (81)
3) Open-label Study Showing St. John's wort Decreases Indinavir Concentrations (82)
4) Association of a Chinese Herb (*Aristolochia fangchi*) with Renal Failure and Urothelial Carcinoma (83)
5) Letter to *Lancet* Editor regarding St. John's wort Induced Heart Transplant Rejections (84)
6) Summary of Ephedra's toxicity (85)

In 1992, the National Institutes of Health established the Office of Alternative Medicine. In November of 1998, Congress established the National Center for Complementary and Alternative Medicine (NCCAM). The Congressional mandate establishing the NCCAM stated that the Center's purpose is to "facilitate the evaluation of alternative medical treatment modalities" to determine their effectiveness. The mandate also provides for a public information clearinghouse and a research training program. The NCCAM does not serve as a referral agency for various alternative medical treatments or individual practitioners. The NCCAM facilitates and conducts research. The Center is located on the NIH campus in Bethesda, Maryland. The NIH National Center for Complementary and Alternative Medicine (NCCAM) conducts and supports basic and applied research and training and disseminates information on complementary and alternative medicine to practitioners and the public. Currently, the NIH supports more than 200 studies involving complementary and alternative medicine therapies. (Additional information on NCCAM can be found at: **http://www.nccam.nih.gov**.

The NIH has also established the Office of Dietary Supplements (ODS). The scientific goals of the ODS include:

Goal 1: Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.
Goal 2: Evaluate the role of dietary supplements in physical and mental health and in performance.
Goal 3: Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
Goal 4: Improve scientific methodology as related to the study of dietary supplements.
Goal 5: Inform and educate scientists, health care providers and the public about the benefits and risks of dietary supplements.

(Additional information on the ODS can be found at **http://odp.od.nih.gov/ods/about/about.html**)

VI. Future Considerations

1. Description of Current Environment

In spite of the creation of the NIH National Center for Complementary and Alternative Medicine, the current status quo may be described as follows:

- There is an enormous popular demand and increasing interest on the part of employers and third party payors.
- CAM treatments including herbal products and other dietary supplements lack standardization and include both relatively safe and toxic interventions.
- The training, licensing, and credentialing of CAM providers, including practitioners who dispense herbs and other dietary supplements is highly inconsistent.
- Malpractice liability issues remain unclear. Note: This past year the Federation of State Medical Boards established a committee to develop explicit policy in this area.
- Toxicity issues pertaining to individual herbs, vitamins and supplements remain inadequately studied and are not readily available.
- Accepted professional guidelines whereby medical doctors advise patients regarding the use or avoidance of individual CAM therapies are absent.
- Explicit criteria by hospital Pharmacy and Therapeutics Committees, medical organizations and regulatory authorities regarding the recommended use or avoidance of individual herbs and dietary supplements do not yet exist.
- Formal evidence-based policies to advise patients about the use or discontinuation of herbs and supplements prior to surgery do not exist. (The American Society of Anesthesiologists has published information pamphlets for patients and for physicians (86); however, no formal guidelines exist due to lack of authoritative data.)
- There is a paucity of research aimed at documenting the cost-effectiveness (or lack thereof) of individual CAM therapies or integrative care approaches to the management of common diseases.
- Until now, there has been relatively little basic science (i.e., mechanistic) investigation involving individual CAM therapies.
- Until now, there has been no sustainable financial model for the successful delivery of CAM therapies.

2. Advising the Patient Who Seeks Alternative Medical Care

The *Annals of Internal Medicine* article entitled "Advising Patients Who Seek Alternative Medical Therapies" (87) provides a strategy whereby conventionally trained physicians discuss the use or avoidance of CAM therapy with their patients. This strategy highlights the need for a formal discussion of patients' preferences and expectations, the maintenance of symptom diaries, a list of questions to be asked of the CAM provider, the need for follow-up visits to monitor for potentially harmful situations, and the importance of shared decision making. It is hoped that more detailed strategies for patients with specific illnesses (e.g., cancer, musculoskeletal pain, coronary artery disease, neurologic deficits) will be published and incorporated into routine, best patient practices. Explicit professional recommendations regarding the use or avoidance of commonly used herbs and supplements are urgently needed.

3. Unaddressed Policy Issues

A selected list of relevant policy issues includes the following:

- Distinction between CAM and Integrative Medicine.
- Labeling and standardization of herbal products and other dietary supplements.
- Liability and malpractice concerning referrals to CAM providers and recommended use of herbs and dietary supplements. (See also item 4 below.)
- Specific referral guidelines unique to each of the CAM professions.
- A review of educational requirements for licensed CAM providers (including education requirements by those recommending herbs and supplements).
- Suggested educational requirements for allopathic physicians with regard to CAM practices including a working knowledge of safety and efficacy data pertaining to herbs and supplements.
- Heterogeneous reimbursement patterns which now include paid benefits and/or a range of reduced fee-for-service products and CAM "carve-outs." (Note: This will likely involve proposed coverage for selected herbs, vitamins and supplements.)
- The need for coordination with the Federation of State Medical Boards and other licensing organizations.
- The role of the newly established Presidential Commission on CAM Policy. The Commission will address issues of: (1) training and education, (2) coordination of research, (3) provision of useful information; and, (4) guidance for appropriate access to and delivery of CAM services. Increasing consumer demand for enhanced regulatory authority over herbs, vitamins and other dietary supplements (88).
- The addition of CAM specific examination questions to possible future medical licensure exams and subspecialty board examinations.
- The role of the newly established Consortium of Academic Health Centers for Integrated Medicine.

4. Credentialing and Malpractice Liability Concerns

With regard to the delivery of CAM therapies, the oversight of educational requirements, credentialing, malpractice insurance and scope of practice vary from state to state (87, 89). A tabular summary of state licensing patterns for chiropractic, acupuncture, massage therapy, homeopathy and naturopathy is available elsewhere (87, 90).

David Studdert, JD, PhD and Troy Brennan, MD, JD of the Harvard Law School and Harvard School of Public Health, working as co-investigators with Drs. Eisenberg, Kaptchuk and others, examined malpractice insurance claims data from both the conventional (MD) and CAM (i.e., chiropractic, acupuncture, massage) communities (90). Their findings, published in the *Journal of the American Medical Association,* 1998 included the observation that claims against licensed CAM practitioners occurred less frequently and typically involved injury that was less severe than claims against physicians during the same period. This article also described specific

situations in which referral by a medical doctor to a licensed CAM practitioner will or will not likely be construed as negligent. The texts by Michael Cohen (91, 92) also highlight many CAM related legal concerns. Malpractice liability with regard to the recommended use of herbal products and dietary supplements will, no doubt, become an increasingly complicated aspect of medical care.

5. Education and Training

The following opportunities for improved training should be considered:

- The standardized medical school curricula pertaining to CAM theory, practice, safety and efficacy.
- The development of residency training opportunities as concerns: (a) appropriate and responsible discussion and referral; (b) the possibility of clerkships by MDs in the offices of CAM practitioners; and (c) the possibility of clerkships by licensed CAM students-in-training (e.g., acupuncturists, chiropractors) in allopathic hospitals and clinics.
- Improved continuing medical education courses for physicians, nurses and allied health professionals.
- Faculty development for selected faculty who wish to supervise the above mentioned training programs.
- The possibility of specific fellowship training grants for primary care and subspecialty physicians. The notion here is to train "resident experts" (e.g., oncologists, rheumatologists, general internists, pharmacists) who, in addition to their conventional expertise and responsibilities, are knowledgeable about the state of the science pertaining to CAM treatments and integrative medical approaches for specific patient populations. Such individuals would fill an important educational role for medical students and housestaff who will require mentoring in this complicated area. These issues are currently being discussed by the American Association of Medical Colleges Special Interest Group in CAM.
- The Macy Foundation recently held a national conference devoted to the future of CAM education (93).

6. Attitudes Within the Medical Profession

There is a need to address the challenge posed in a 1998 editorial by Drs. Angell and Kassirer, editors of the *New England Journal of Medicine*, who wrote, "There cannot be two kinds of medicine – conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work" (11). At the same time, there is a parallel need to acknowledge the importance of sociological, cultural and pragmatic factors as they relate to investigation of CAM (and conventional) therapies. This sentiment, articulated by David Grimes in an editorial in *JAMA*, reframes this same challenge. Grimes, writing about the use of medical technology wrote, "Doing everything for everyone is neither tenable nor desirable. What is done should be inspired by compassion and guided by science and not merely reflect what the market will bear" (94).

7. Exploring Health Service Models for the Delivery of Complementary and Alternative Medical Therapies

Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby complementary and alternative therapies are made available to members/subscribers/employees. The spectrum of existing models, all relatively new, is broad and includes:

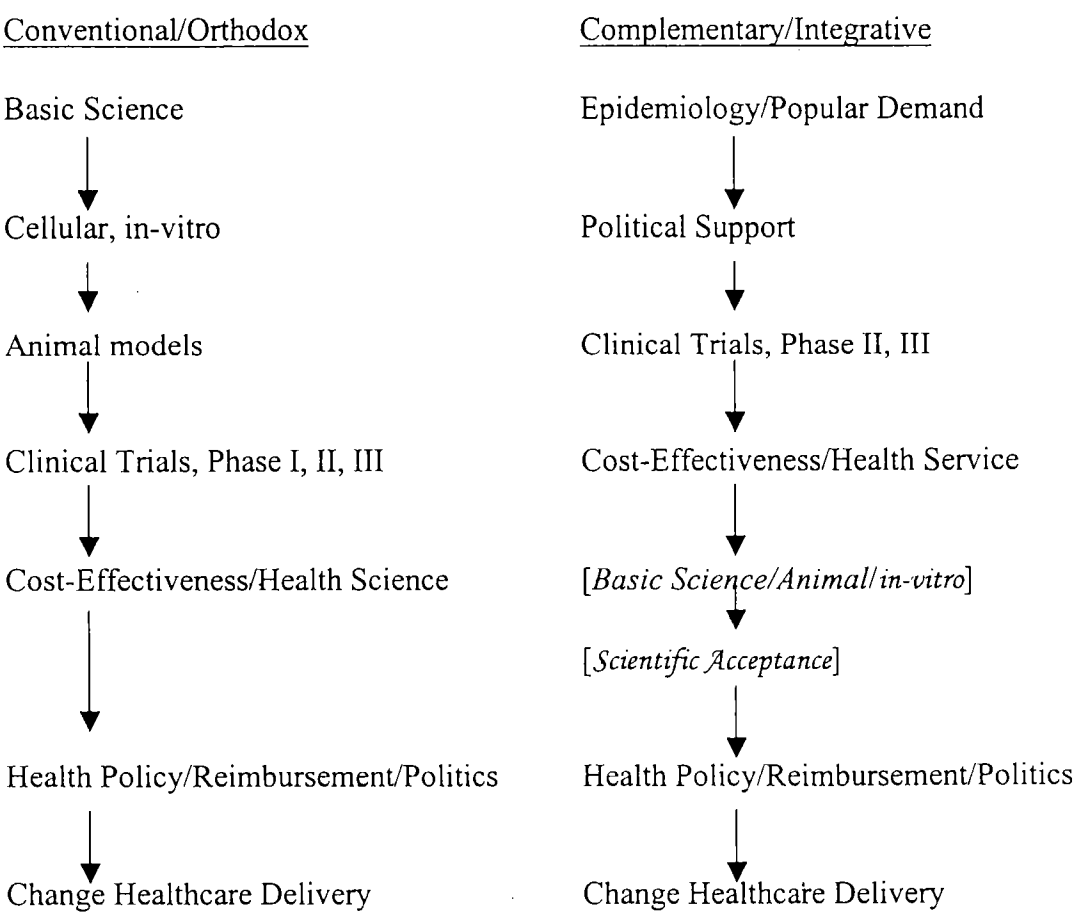
- The establishment of networks of "credentialed" complementary and alternative therapy practitioners.
- Reduced "fee-for-service" models whereby members/subscribers/employees receive a discount on routine CAM services provided by "credentialed" networks of identified practitioners in a given geographic area. (Note: This model does not typically include reimbursement for or liability assurance regarding the delivery of CAM services.)
- Covered benefits, which include a predetermined maximum of complementary and alternative therapy services for selected medical conditions (usually with a required referral from an MD).
- Covered CAM benefits without a required referral from an MD.
- "Integrated" medical services which typically include both conventional and complementary/alternative services, usually in an outpatient (ambulatory) setting. Reimbursement options vary as do referral requirements.
- "Integrated" consultation services, i.e., the provision of complementary and alternative therapies for inpatients in hospitals.
- Specialized integrative care teams consisting of conventional and complementary care providers who share a single clinical focus (i.e., the treatment of musculoskeletal pain, cancer, cardiovascular disease, women's health issues, etc.).
- The incorporation of complementary and alternative (a.k.a. "integrative") services as part of an individual medical practice, a group medical practice, a managed care organization, a PPO, an insurance product, a community hospital, or university affiliated teaching hospital.

Unlike hospitalizations and physician services, complementary and alternative therapies are only infrequently included in insurance benefits. The percentage of CAM users who paid entirely out-of-pocket for these services did not change significantly between 1990 (64%) and 1997 (58.3%) (14). Even when alternative therapies are covered, they tend to have high deductibles and co-payments and tend to be subject to stringent limits on the number of visits or total dollar coverage. Because the demand for health care (and presumably alternative therapies) is sensitive to how much patients must pay out-of-pocket, current use is likely to under represent utilization patterns if (and when) insurance coverage for alternative therapies increases in the future (14). Trends involving insurance coverage for CAM therapies have recently been reviewed by Pelletier et al. (95, 96). Clearly, more and more third party payors (and employers) are considering the inclusion of CAM therapies within their benefits programs.

Regrettably, there is a paucity of rigorous prospective studies that could provide conclusive evidence of differences in costs and outcomes between complementary and orthodox medicine (97).

VII. The Role of Scientific Inquiry and Discovery Involving Complementary, Alternative and Integrative Medicine

1) How CAM/Integrative Medicine Research has followed a different trajectory



2) "Breakthrough ideas" are more likely to occur as a result of collaborative projects involving investigators from disparate disciplines (e.g., neuroscience, acupuncture and experimental radiology; dietary intervention, mental health and molecular biology, etc.), working as teams to explore focused questions of common interest relating to complementary and integrative approaches to patient care.

Examples of CAM-Related Topics Requiring Multi-disciplinary Research Teams

- Neuro-imaging of CAM, mind-body techniques and placebo responders
- Mechanisms of CAM treatment for pain management
- CAM therapies as immuno-modulators
- CAM/lifestyle (e.g., diet, stress management) effects on gene regulation

- Mechanisms of herb/supplement effects, interactions
- Developing sustainable financial models of Integrative Care delivery
- Identifying objective correlates of and plausible explanatory models for energy-related healing phenomena (e.g., magnets, homeopathy, non-touch therapies).

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$10 Million Gift Supports Division for Research and Education In Complementary and Integrative Medical Therapies

BOSTON—April 30, 2001—Harvard Medical School received a $10 million gift from the Bernard Osher Foundation of San Francisco to support its recently established Division for Research and Education in Complementary an Integrative Medical Therapies. The gift will also establish the Harvard Medical School–Osher Institute for Research and Education in Complementary and Integrative Medical Therapies.

The missions of both the division and new institute are to facilitate interdisciplinary and interinstitutional faculty collaboration to evaluate rigorously complementary and integrative medical treatments. The division will concentrate on assessing the safety, efficacy, cost-effectiveness, and mechanisms of action of these approaches. Appropriate educational activities and policies pertaining to the clinical delivery of complementary medical therapies will also be developed.

"This extraordinary gift from the Osher Foundation will allow us to take a leadership role in building a scientific understanding of the opportunities and risks encountered by patients seeking complementary and alternative therapies," said Harvard Medical School Dean Joseph B. Martin. "We need to evaluate scientifically the effectiveness of these techniques—to assess the current status of our knowledge and determine what we need to do to advance that knowledge."

Complementary therapies are health care practices that mainstream, conventional medicine has not routinely made available, like acupuncture, herbal therapies, chiropractic, relaxation techniques, and therapeutic massage. In 1997, Americans made an estimated 600 million office visits to practitioners of complementary medicine and spent roughly $30 billion out of pocket on complementary care. The budget of the National Institutes of Health for research in this area has roughly doubled every two years since 1993.

Integrative medicine refers to ongoing efforts to combine the best of conventional and evidence-based complementary therapies while emphasizing the primacy of the patient–provider relationship and the importance of patient participation in health promotion, disease prevention, and medical management.

The existing division and new institute will be directed by David Eisenberg, Harvard Medical School associate professor of medicine at Beth Israel Deaconess Medical Center, where he directs the hospital's Center for Alternative Medicine Research and Education.

"Bernard Osher, through his extraordinary generosity, has made this line of inquiry permanent. My hope is that when five or 10 universities have sustainable infrastructure for research, education, and responsible patient care in this area we will forget the terms "alternative" and "complementary" altogether and simply provide the best available medicine, based on the best available information," said Eisenberg, who studied complementary and alternative medicine in the People's Republic of China in 1979 as the first U.S. medical exchange student to that country.

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The Osher gift, which is being augmented by a $2 million contribution from Harvard Medical School, will endow several positions and programs, including the creation of the Bernard Osher Chair in Complementary and Integrative Medical Therapies, hiring of basic science and clinical research directors for the division, establishment of pilot study grants for Harvard faculty and fellows, and creation of educational programs and electronic databases.

The new Harvard programs are indicative of ongoing efforts by many medical schools and academic health centers to evaluate complementary therapies, to distinguish useful from useless treatments, to discover mechanisms of action for these treatments, and to foster a rational, evidence-based introduction of complementary and integrative medical care into mainstream medical education and practice.

The Bernard Osher Foundation was founded in 1977 by Maine businessman Bernard Osher, who later relocated to San Francisco. Its mission is to improve the quality of life for residents of the San Francisco Bay Area and the state of Maine. In addition to the establishment of the Harvard Medical School–Osher Institute, the Osher Foundation previously established the Osher Center for Integrative Medicine at the University of California, San Francisco.

"Bernard Osher deserves our admiration and our gratitude," said Daniel Federman, Harvard Medical School senior dean for alumni relations and clinical teaching who with Eisenberg helped to launch the new division at the Medical School. "The first, for recognizing that an emphasis on research and evaluation is the best way to integrate complementary medicine into the care available to all; and the second, for deciding that Harvard Medical School deserves to join UCSF in accomplishing the Osher vision."

Harvard Medical School has more than 5,000 full time faculty working in eight academic departments based at the School's Boston quadrangle or in one of 47 academic departments at 18 affiliated teaching hospitals and research institutes. Those HMS affiliated institutions include:

Beth Israel Deaconess Medical Center
Brigham and Women's Hospital
Cambridge Hospital
Center for Blood Research
Children's Hospital
Dana-Farber Cancer Institute
Harvard Pilgrim Health Care
Harvard Vanguard Medical Associates
Joslin Diabetes Center
Judge Baker Children's Center
McLean Hospital

Massachusetts Eye and Ear Infirmary
Massachusetts General Hospital
Massachusetts Mental Health Center
Mount Auburn Hospital
Schepens Eye Research Institute
Spaulding Rehabilitation Hospital
Veterans Administration Medical Center (Brockton/West Roxbury)

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Divider Title: Foundation Support

Questions for the Panel on Foundation Support:

Does your foundation support CAM research and/or research training? If so, how does your foundation determine what (CAM) research or research training it will fund?

What types of research are you currently funding or are considering funding? Does your foundation support health services research related to CAM?

What role can foundations play in stimulating CAM research, e.g., seed money, research grants, publication of research results, research training support, conferences?

What are the obstacles and possible solutions to accomplishing your foundation's goals in this area regarding CAM?

Do you work collaboratively with other foundations to stimulate CAM research and research training? What do you think might be done to enhance collaboration among foundations active in this area? What do you think might be done to increase collaboration with foundations that are not active in this area?

How can CAM research coordination be enhanced between the Federal government and the not-for-profit sector?

Do you consider areas of interest to the public in your decision making on funding priorities?

What policy recommendations can your foundation offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

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Duffy

Divider Title: _____

M. Bridget Duffy, MD

Dr. Duffy is Medical Director, Medtronic, Inc., Minneapolis, Minnesota. She is responsible for the development and implementation of integrative patient care programs: programs that foster the convergence of information, technology and a humanistic delivery of that care. In this capacity she is involved in patient-centered care initiatives that look beyond the company's traditional product-centered focus. This approach recognizes that there are critical factors – in addition to technological interventions – that impact patient outcomes as well as the effectiveness of the implanted devices. Central to this approach is designing programs that address the chronic nature of cardiovascular and neurologic disease, thereby ensuring earlier and more appropriate management of the disease. As Medical Director of the Medtronic Foundation, she oversees programs that support the development of these new models of care. To date, grantees for work in Integrative Medicine include Harvard, Stanford, Duke, Scripps, Allina, Beth Israel NY, and St. Barnabas Healthcare System.

In addition to this patient-centered initiative, Dr. Duffy is responsible for developing relationships with health care leaders worldwide. Through Medtronic's Alliance Program, Dr. Duffy conducts executive education and leadership forums that connect these leaders to other health care professionals. These leaders also develop critical relationships with Medtronic, further enhancing the company's position in the worldwide health care market.

Prior to joining Medtronic, Dr. Duffy established, and was medical director for one of the first "Hospitalist" services in the country – an inpatient care service designed to improve the clinical, economic and quality of life outcomes of hospitalized patients. She also was instrumental in the development of community-based health care programs in Central America and the British West Indies, and helped develop a migrant children's health program in Colorado.

Dr. Duffy attended medical school at the University of Minnesota, and completed her residency in Internal Medicine at Abbott Northwestern Hospital in Minneapolis, Minnesota. She was an attending physician at Abbott Northwestern Hospital and in this role served as an educator and mentor to medical students and residents. She also served in a volunteer capacity at NIP (Neighborhood Involvement Program) and the Excelsior Teen Clinic. Dr. Duffy is a member of the American College of Physicians.

Dr. Duffy's passion for patient-centered initiatives is inherent in her professional goals. This includes being meaningfully involved in the creation of health care environments that treat the "whole patient," and understanding the role of the physician and the application of medical technology in this new, innovative model of care.

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY RESEARCH CHALLENGES

SUBJECT: Not-for Profit Support for CAM Research
PRESENTER: M. Bridget Duffy, MD, Medical Director, Medtronic, Inc.

1) Does your foundation support CAM research and/or research training?

ANSWER: The Medtronic Foundation supports research efforts that seek to identify clinical care models that will improve the lives of people living with chronic cardiac or neurologic conditions. We do not support the study of specific CAM modalities.

2) What type of research are you currently funding or are considering funding?

ANSWER: We have identified several of the top cardiovascular and neurological centers of excellence in the country who have the executive and physician leadership in place to build integrative models of care for these specific patient populations. We are interested in developing new standards of care, or clinical algorithms for these patients.

3) What does your foundation hope to accomplish through support in this area?

ANSWER: We hope to transform the way care is delivered to individuals with chronic disease. We recognize that pharma and technology alone do not restore individuals to "full life," and the mission and culture at Medtronic supports programs that "restore people to full life."

4) How does your foundation determine who you will support?

ANSWER: Institutional and program criteria for funding under Medtronic Foundation's Health Center Leadership Grant program include: nationally recognized thought leaders driving the initiative, support at the executive level within the institution, strategies in place for system-wide adoption of successful integrative care models, nationally recognized clinical and research centers of excellence in cardiovascular and neurologic care, interdisciplinary integrative care team, integrative programs and services that care for the "whole person", mechanisms in place to measure and disseminate best practices.

5) What are the obstacles and possible solutions to accomplishing your foundation's goals in this area?

ANSWER: The greatest obstacle is **not the absence of data**, rather it is the "perception" that we are supporting the use of alternative therapies, when in fact we are seeking to restore "healing" to healthcare. What we believe is at the center of healing, is relationship. The current system does not value the healing and needed relationship

that benefits a patient with chronic disease. According to our informal survey, physicians, followed by administrators are the greatest obstacle to the adoption of integrative care models. Nurses are clearly the champions and possess most of the knowledge and expertise in this area. A solution would be to create experiential leadership and training opportunities for physicians and administrators.

6) Do you work collaboratively with other foundations to stimulate CAM research and training? How might collaboration among foundations be enhanced?

ANSWER: To date, we have not worked collaboratively in this area, however we see great opportunity for this to occur. To do this effectively, a clearinghouse should exist to pair or match institutional initiatives with foundations that share a similar mission or vision. Clearly, philanthropic collaboration will help to accelerate this field.

7) How can CAM research coordination be enhanced between the Federal government and the not-for-profit sector?

ANSWER: Philanthropy is poised to rapidly support the development and implementation of successful integrative patient care models. Federal government should play a **proactive** role in assessing needed policy and reimbursement changes.

8) Do you consider areas of interest to the public in your decision making on funding priorities?

ANSWER: The Medtronic Foundation supports numerous national patient advocacy and support groups. We are very interested in supporting their initiatives in advancing access and reimbursement of needed care and of new models of care.

9) What policy recommendations can your foundation offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

ANSWER: Support of unique educational initiatives that seek to restore healing to healthcare is as important, if not more than proving which alternative therapy works or doesn't work. Both of these must be studied, but to date, the focus has been on the use and efficacy of the modality alone vs. the context in which it is delivered. The Commission can play a significant role in improving healthcare in this country by refocusing or broadening its mission to include these issues as they look at the adoption of CAM in this country.

5 recommendations not included
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Divider Title: Miller

Doriane C. Miller, M.D.

Dr. Miller joined the Robert Wood Johnson Foundation staff as program vice president in July 1997. She brings to the Foundation 15 years' experience as a community-based primary care provider who has worked with under-served, minority populations with special issues in mental health and substance abuse. She most recently served as medical director of the Maxine Hall Health Center of the San Francisco Department of Health, while also serving as assistant clinical professor of medicine in the Department of Medicine at San Francisco General Hospital, University of California, San Francisco.

As a 1993 winner of an RWJF Community Health Leadership Award, she directed the Grandparents Who Care Support Group, which she co-founded in 1989. The Program provides psychological help and community resources to relatives who are raising children because the child's parents are mentally ill, incarcerated or have substance abuse problems.

At the Foundation, she heads the Clinical Care Management Team of the Health Care Group. She is responsible for coordinating strategies and funding in the area of clinical care management and quality improvement. Dr. Miller continues her professional practice by volunteering at the Chandler Clinic in New Brunswick a half day per week.

TESTIMONY TO

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

RESEARCH CHALLENGES

BY

DORIANE C. MILLER, M.D.

PROGRAM VICE-PRESIDENT

THE ROBERT WOOD JOHNSON FOUNDATION

P.O. BOX 2316

PRINCETON, NJ 08543

Thank you Chairman and members of the committee for inviting me to testify today on the subject of not for profit support of Complementary and Alternative Medicine (CAM) research. My name is Doriane Miller. I am a vice-president at The Robert Wood Johnson Foundation. I am a physician and general internist by training, with a background in the care of underserved populations, particularly with co-existing substance abuse, mental health issues and HIV. In my previous positions at the San Francisco Department of Public Health and the University of California, San Francisco, I

served as medical director of a community public health center that provided both traditional and CAM services to a poor, inner city population. My work at The Robert Wood Johnson Foundation is in the areas of clinical care management, community health, health and behavior and care of the underserved.

The Robert Wood Johnson Foundation, established as a national philanthropy in 1972, is dedicated to the improvement of the health and health care of the people of the United States. We fund programs that fall into three major goal areas: 1) increasing access to health care services, 2) providing care and support for people with chronic health conditions and 3) reducing the harm from substance abuse. From an asset base of approximately $8 billion, we will fund $400 million in grants this calendar year.

The committee has asked this panel representing the health philanthropic sector to comment on current support of CAM research and to address the following issues:

- How our foundation decides to fund CAM
- The role foundations could play in stimulating the field of CAM
- Some of the obstacles in funding of CAM research
- The barriers to translating CAM research into practice
- The role public-private funding partnerships can play in CAM research
- The role the public should have in the decision making process about funding CAM research
- Policy recommendations to the committee regarding CAM research.

In preparation for my testimony today, I reviewed The Robert Wood Johnson Foundation's grantmaking in the area of CAM for the committee. You will find a summary of those grants attached. However, for the purposes of our discussion today, I think that it will be more helpful to you if I shared our grantmaking approach at The Robert Wood Johnson Foundation. A description of our grantmaking approach will answer some of the questions posed to this panel by the committee.

In my opening comments I mentioned the major funding areas of The Robert Wood Johnson Foundation: improving access to care; improving the care of the chronically ill and reducing the harm caused by substance abuse. Within these broad goals narrower focus areas help the foundation staff direct their programmatic development and grantmaking and helps grant applicants to understand our strategic priorities. I am direct program development and grantmaking in the Clinical Care Management area and I assist in the areas of Health and Behavior, Community Health and Care of the Underserved. Within each of these areas, staff link program development and grantmaking to measurable strategic objectives. We base our program development and funding decisions on a specific project's ability to contribute to achieving these strategic objectives. The Robert Wood Johnson Foundation funds projects that use the tools of research and policy analysis, demonstration, education and training, communications and evaluations to achieve our strategic objectives.

The goal of Clinical Care Management is to narrow the gap between what is known and what is practiced in health delivery systems today for people with chronic medical

conditions. We attempt to effect change in three strategic areas: 1) changing purchaser behavior to support the delivery of evidence-based medicine, 2) improving delivery system capacity to provide evidence-based medicine and 3) engaging people both as consumers and as patients to become more involved in evidence-based medical care. The projects funded to date are cross-cutting and disease-specific. Examples of such projects include a project in Edina, MN, that has developed a protocol for depression screening at an adult day center; a project in Lafayette, CO that is working to improving the use of community resources to support chronic illness self-management within a low-income Spanish speaking population; and a project at the Medical University of South Carolina that is testing the benefits of group visits in low income people with type 2 diabetes. The agenda for the Clinical Care Management team is a translational one, that is, translating research in best practices into health delivery settings with a focus on the strategic elements I described earlier.

How does this translational agenda affect our view of funding CAM research? If there were sufficient evidence that a particular CAM approach to treatment could positively affect the outcome of treatment of a condition we are targeting, we would consider funding CAM as a part of a total program or system of care. CAM is not an area of strategic funding for The Robert Wood Johnson Foundation, nor are we considering making it a funding priority for the foundation. To the extent that current and future CAM research and implementation could help to make improvements in our strategic funding areas, we would consider funding on a case by case basis.

In 'Crossing the Quality Chasm', the Institute of Medicine promotes a consumer/patient-centric model of care. I think that the public as consumers of health care and as patients should have a voice in establishing an agenda for research in this area. The creation of the Federal Office of Alternative Medicine is an example of such interest.

The Robert Wood Johnson Foundation has tremendous experience in the area of convening, training and demonstrations in the health field. If we chose to become more active in the area of CAM, we would draw upon those experiences to help stimulate more activity and interest in CAM. We would also welcome public and private funding partners in this endeavor.

Thank you for your time today. I look forward to your questions and comments.

Appendix : Sample of CAM Grants from The Robert Wood Johnson Foundation
White House Commission on Complementary and Alternative Medicine Policy
Doriane C. Miller, M.D.
5/14-5/15/01

National Forum on Uterine Fibroids and African-American Women
Grantee: The Wholistic Health and Healing Association, Roseville, CA
Summary: Funding provided support for a national conference to explore the combination of allopathic diagnostic and evaluative techniques and holistic modalities in the treatment of uterine fibroids.
1/1/2000-4/30/2000 Amount: $49,989

Preparation of an Updated Book on Surviving Cancer
Grantee: National Coalition for Cancer Survivorship
Summary: Funding provided support for the author to write a revised edition of the book, 'Hanging in There: Living Well on Borrowed Time,' by Natalie Davis Spingarn, a 25 year cancer survivor, cancer activist and medical journalist. The book addressed both traditional and nontraditional approaches to cancer treatment and support including stress reduction activities
1/1/98-12/31/98 Amount: $14,500

National Program: Strengthening the Patient-Provider Relationship in a Changing Health Care Environment
Grantee: University of California, San Francisco
Summary: Funding supported an investigation of patients and physicians' concerns regarding discussions about complementary and alternative medicine, leading to the development of guidelines on how physicians should discuss CAM and how health care systems can facilitate discussions between physicians and patients regarding CAM.
5/1/2000-4/30/01 Amount: $305,624

Assessing the Workforce of Physicians and Non-Physicians Providing Clinical Services
Grantee: Medical College of Wisconsin
Summary: Funding supported the acquisition and analysis of data for both physician and non-physician clinicians looking at workforce supply and scope of work. Non-physician clinicians included provides of CAM services such as chiropractors, naturopaths and acupuncturists.
2/1/97-7/31/98 Amount: $200,000

Appendix : Sample of CAM Grants from The Robert Wood Johnson Foundation
White House Commission on Complementary and Alternative Medicine Policy
Doriane C. Miller, M.D.
5/14-5/15/01

National Program: Research Development Program to Improve Patient Functional Status
Grantee: University of North Carolina at Chapel Hill School of Medicine
Summary of Project: Assessment of spinal manipulation as an effective therapy in the management of low back pain
4/1/84-3/31/86 Amount: $72,432

Focus Group Sessions for Latino Consumers and Providers on Primary and Preventive Care Access Issues
Grantee: Lake, Snell and Perry Associates
Summary: Qualitative research project addressed issues of primary care and preventive services for Latinos including attitudes and beliefs and practices regarding traditional and CAM services including the use of curanderos and botanicas.
11/15/2000-2/14/01 Amount: $128, 900

Partnerships in Healing Conference
Grantee: Grace Counseling Center, Madison, NJ
Summary: Funding was provided for a conference that presented a paradigm for integrating spirituality and health and how this approach can be integrated into cancer treatment.
10/1/98-10/31/98 Amount: $10,000

Establishment of Breast Cancer Survivors Camp
Grantee: Breast Cancer Recovery Foundation, Inc. of Madison, WI
Summary: Funding provided start up support for the creation of a breast cancer survivors' camp. The purpose of the camp is to help women who have developed breast cancer to learn mind-body healing approaches that have been demonstrated to increase ten-year survival rates for breast cancer.
11/1/97-10/31/98 Amount: $49,965

Planning for a Study of the Effects of a Stress Reduction Program on Health Care Utilization, Costs and Patient and Provider Satisfaction
Grantee: University of Massachusetts Medical Center, Worcester, MA
Summary: Funding provided support for the development of a multiyear controlled, randomized, prospective study of the economic and clinical impacts of a meditation and relaxation program called Mindfulness-Based Stress Reduction.
2/1/98-10/31/98 Amount: $49,660

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Braun

Divider Title: _____

The Susan G. Komen
Breast Cancer Foundation
National Headquarters

Susan Braun
President and CEO
Susan G. Komen Breast Cancer Foundation

Susan Braun, president and chief executive officer, joined the Susan G. Komen Breast Cancer Foundation in July 1996. She works together with the Foundation staff and Board of Directors to fulfill the organization's mission: to eradicate breast cancer as a life-threatening disease by advancing research, education, screening and treatment. Her commitment to this mission is fueled by her professional background and her personal losses to breast cancer. Among her present appointments and responsibilities, Ms. Braun serves on leadership committees for several organizations, including: the National Action Plan on Breast Cancer, American Society of Clinical Oncology (international and health services research), American Society for Breast Disease (ASBD), World Society of Breast Health, Editorial Board of the Breast Journal, and Americorps NCCC.

The Susan G. Komen Breast Cancer Foundation was established in 1982 by Nancy Brinker to honor the memory of her sister, Susan G. Komen, who died of breast cancer at the age of 36. From its inception through the end of fiscal year 1998, the Foundation has raised more than $214 million for breast cancer research, education, screening and treatment programs. The Foundation has more than 35,000 volunteers working through a network of U.S. and international Affiliates and Komen Race for the Cure® events to eradicate breast cancer as a life-threatening disease by advancing research, education, screening and treatment. The Foundation runs one of the most innovative, responsive grant programs in breast cancer today, having awarded more than $45 million in research grants since its inception. In addition to funding research, the Foundation and its Affiliates fund non-duplicative, community-based breast health education and breast cancer screening and treatment projects for the medically underserved.

Prior to joining the Komen Foundation, Ms. Braun served in various positions within the Oncology/Immunology Division at Bristol-Myers Squibb in Princeton, New Jersey. Prior to joining Bristol-Myers Squibb, Ms. Braun was an executive with the health care consulting firm Pracon Incorporated and the Center for Economic Studies in Medicine.

Ms. Braun received a bachelor's degree in English and sociology from George Mason University and a master's degree in health sciences from the University of Maryland. She also completed the graduate program in international marketing at the University of Muenster in Muenster, Germany.

Overview of remarks by Susan Braun, President and CEO of the Susan G. Komen Breast Cancer Foundation.

The Susan G. Komen Breast Cancer Foundation was founded in 1982 by Nancy Brinker after her sister Susan Komen died from breast cancer at the age of 36. Our mission is to eradicate breast cancer as a life threatening disease by advancing research, education, screening and treatment. The Komen Foundation Grant Program is regarded as the most innovative and responsive grant program in breast cancer today. As a pioneer in the funding of groundbreaking breast cancer research, the Komen Foundation is often the only source of funding for cutting-edge research, much of which has led to landmark discoveries in our quest to find a cure and eventually prevent breast cancer. Since its inception, the Komen Foundation has awarded more than $68 million for breast cancer research projects.

Patient empowerment through access to information; the dramatic change in the physician/patient relationship; and increasing pressure for flexibility and funding from public and private institutions are radically altering our research and treatment landscape. Complementary medicine research is an important component of our research portfolio. In 2000, the Komen Foundation instituted a separate study section for complementary and alternative medicine. Prior to that time, we had never excluded this area of research, but in 2000 we began to actively foster it.

Through a grassroots network of 115 Affiliates across the country, we disseminate information on CAM to diminish myth and rumor and encourage participation in clinical trails that seek to legitimize CAM products. The challenge of CAM is that we are researching substances already in current use, but where there's been some anecdotal history of effectiveness. The Komen Foundation aims to support the use of CAM products that are safe and effective, and to combat potential market forces regulating procedures that encourage CAM entrance in the market without sufficient testing.

Not all non-traditional therapies have the potential for dramatic change. But because we have yet to find a cure for cancer, the Komen Foundation is not willing to rule out any reasonable, safe therapy that could be a breakthrough in the prevention, control or cure of cancer or in the quality of life for cancer patients.

Research on Black Cohash - Cedar Sinai + Columbia
Larry Dossey lecture series
funded by S.B.K.
F. Kronenberg
funded by ?

Funders' Consortium

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Samueli

Divider Title: _____

Susan Samueli

~~**Ronald Chez, M.D.**~~

Samueli Institute for Information Biology

#24

RONALD A. CHEZ, MD

Abstract of CV

Present Position:

1989- *University of South Florida College of Medicine*
Professor of Obstetrics and Gynecology
Director Ambulatory Services
University of South Florida College of Public Health
Professor of Community and Family Health

Training:

1950-1953 AB	Johns Hopkins University
1953-1957 MD	Cornell University Medical College
1958-1964 Resident	UCLA, Obstetrics and Gynecology
1964-1966 Fellowship	Harvard Medical School, Biophysics

Previous Appointments:

1966-1971 *University of Pittsburgh School of Medicine*
Professor, Obstetrics and Gynecology
Associate Dean of Academic Affairs

1971-1977 *National Institutes of Health*
National Institute of Child Health and Human Development (NICHD):
Chief, Pregnancy Research Intramural Branch
Clinical Director
Georgetown University School of Medicine
Clinical Professor of Obstetrics and Gynecology
George Washington University School of Medicine
Professor of Obstetrics and Gynecology
Howard University School of Medicine
Clinical Professor of Obstetrics and Gynecology
Professor of Obstetrics and Gynecology [1977-1978]

1978-1982 *Pennsylvania State University School of Medicine*
Professor & Chair, Obstetrics and Gynecology

1986-1989 *New Jersey Medical School*
Clinical Professor of Obstetrics and Gynecology [1983-1986]
Professor & Vice Chair, Obstetrics and Gynecology

Certifications:

American Board of Obstetrics and Gynecology
Maternal-Fetal Medicine Subspecialty

Bibliography:

Author or co-author of over 500 basic science research, clinical research and continuing education articles and audiovisual learning aids.

The Samueli Institute

Supporting Research on Information Biology

The Samueli Institute is a non-profit medical research organization supporting the scientific investigation of information biology and its application in health and disease.

Information Biology

As used by the Institute, the term "information biology" refers to the interaction of biological systems with non-molecular (i.e. informational) signals. It is especially interested in how biological systems interact with signals separated or demodulated from their molecular and electromagnetic carriers.

The Institute focuses on several types of non-molecular signals. Examples are:

- ultra low dose hormetic and homeopathic exposures,
- non-ionizing and non-thermal electromagnetic and magnetic signals,
- so called "biofield" or "subtle energy" signals that emanate off the body,
- digitally produced signals, both computer generated and electronically imprinted and,
- the family of signals that accompany consciousness, such as mental intention, the transfer of meaning (semiotics), the placebo effect, and aspects of spirituality.

In addition, the Institute supports the development of biologically and technologically based systems for the detection and measurement of these signals such as biosensors.

A Network of Investigators

The Samueli Institute conducts its research through a network of laboratory programs around the world with a planned faculty and staff of over 200 individuals. Institute programs are guided by a Board of Directors, a Scientific Advisory Council and a Vision and Planning Group for the creative and rigorous scientific exploration of Institute topics.

Science and Discoveries

The Samueli Institute's scientific programs are organized into four research areas.

1) physical chemistry that investigates the nature of informational signals on molecular structure and function with methods such as nuclear magnetic resonance, infra-red and Raman spectroscopy and High Performance Liquid Chromatography coupled with ICP mass spectroscopy;
2) cellular biology that investigates cellular function and dynamics with techniques such as gene microarray and functional genomics methods, RT-PCR, ion and protein flux monitoring and examines the effects of informational therapies in animal models;
3) neuroscience that explores brain function using technology such as functional MRI, multi-channel EEG/EKG, and SPECT scanning;
4) clinical investigation and epidemiology that explore the effects of informational therapy and detection methods on health promotion, quality of life, symptom reduction, and healing processes in the treatment and prevention of disease.

The current foci of scientific investigation are to determine whether stable water complexes exist in homeopathic and informational preparations, to identify informational signals that alter cell function and gene regulation, to map the effects of informational signals on neurological function, and to determine if informational signals can reduce symptoms, improve health and quality of life and alter the course of disease.

Applications

Potential applications from Samueli Institute research include the development of biosensors in which biological systems are used to detect subtle environmental signals; digital pharmacology in which specific treatments are produced and delivered by computer; a method for creating conditioned healing spaces that enhance recovery; and, electromagnetic treatments that alter the progression of cancer, degenerative brain disease and atherosclerosis.

Education and Creativity

Meetings, conferences and educational programs sponsored by the Samueli Institute will probe the fundamental nature of reality. Topics of interest are the direction and boundaries of causation, the relationship between discovery and creation, the biophysics of multi-dimensional space, mechanisms of homeopathic action, the meanings and mechanisms underlying placebo effects, and the intersection of science and spirituality.

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Divider Title: Evaluating Research Literature

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Questions for the Panel on Approaches to Evaluating Research Literature:

Donald Lindberg:

What criteria are used when deciding to include a peer-reviewed journal or other information sources in the NLM database? How are CAM journals and other sources identified?

What recommendations can you offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

Douglas Kamerow:

What criteria are used by the agency when deciding on topics for evidence-based practice reports?

How does AHRQ assess the quality of the research it includes in its systematic reviews/meta-analyses?

Has AHRQ supported and published evidence-based assessments of CAM practices and products? If so, what evidence-based assessments in CAM have you conducted?

How does AHRQ collaborate with other agencies; e.g., NIH, CDC? Please comment on AHRQ's collaboration on evidence-based reviews of dietary supplements with the NIH Office of Dietary Supplements.

Does AHRQ conduct research evaluating health services (health services research)? If so, is CAM part of the research portfolio? What aspects of CAM have been investigated? If not, are there plans to include CAM in the future?

Please comment on national data, such as MEPS data, and the agency's future plans on the use of such data to examine CAM utilization.

Does AHRQ conduct any research studies, and if so, are any studies related to CAM?

What is the role, if any, of public input in the selection and dissemination of research information on CAM?

What recommendations can you offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

Brian Berman:

Does the Cochrane Collaboration for Evidence-based Medicine include in its database information on CAM practices and products? What criteria are used in your selection process with regard to CAM topics? How does the Cochrane Collaboration assess the quality of the research it includes in its systematic reviews/meta-analyses?

Does the Cochrane Collaboration consider public input when selecting and disseminating research information on CAM?

What policy recommendations can you offer regarding the evaluation of research literature in CAM for the Commission's consideration as it develops its report to the President and Congress?

Additional questions for Brian Berman:

Please give us your views and recommendations on the training of CAM practitioners to become research investigators, and any recommendations you may have on this issue.

Please comment on the difficulties of integrating CAM research into conventional academic institutions, and any recommendations you may have on this issue.