Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Group A Registrants for Oral Comment (partial) (2 pages)	nd	b(6)

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

OA/Box Number: 43231

FOLDER TITLE:
WHCCAM Meeting Testimony, March 26, 2001 [1]

2011-0568-S
kc808

RESTRICTION CODES

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

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

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

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

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

FINAL

White House Commission on Complementary and Alternative Medicine Policy

Meetings

Meeting Registration Information

March 26, 2001
Washington, DC
Hyatt Regency Hotel on Capitol Hill

This report is a list of all Registrants for the meeting in alphabetical order. Those giving oral comment are denoted by a "Y" in the Talk column.

Meeting ID	Talk	Name (first, middle, last, degree)	Organization	Adc
013101113552	Y#8	JOHN DEAN ADLER MD	Wellness Triad Group	31 (
013101113552	Y#13	John Philip Adams Doctor of Chiropractic	John Adams, DC., PC	327
013101113552	N	Laura Lyn Aho	Reflexology Association of America	563
~~013101113552~~	~~N~~	~~Margaret v Ames PhD~~	~~IQ Solutions~~	~~115~~
013101113552	N	Margaret v. Ames PhD	IQ Solutions	115
013101113552	N	Gale Arden	DHHS, HCFA	750
013101113552	N	Catherine Ann Armetta	The George Washington University	, A
013101113552	N	Soaring Bear PhD	NIH/NLM	860
013101113552	N	William Mac Beckner BS	Intelimed	147
013101113552	N	William Mac Beckner BS	Complemenrtary Medicine Program	200
013101113552	N	Maria Bianchi MA in Education	American Association of Naturopathic Physicians	820
013101113552	N	Dort S. Bigg Juris Doctor	ACAOM	750
~~013101113552~~	~~N~~	~~Dort S. Bigg Juris Doctor~~	~~ACAOM~~	~~750~~
013101113552	X	Susan Bonfield Herschkowitz	representing self	174
013101113552	N	Fennen C Brian LAc, OBT, QME	Council of Acupuncture and Oriental Medicine	243
013101113552	Y#4	Diana L. Chambers	Friends of Health	201
~~013101113552~~	~~Y~~	~~Chi Chow Ph.D~~	~~New York Institute of Chinese Medicine~~	155
013101113552	N	W. Dennis Clark Ph.D.	Arizona State University	Dep

013101113552	N	Beth Clay	US House of Representatives	215
013101113552	N	Robert Draba Ph.D.	Retired	, A
013101113552	N	Dorothy A. Dupree MBA	Health Care Financing Administration	750
013101113552	N	Michael Joseph Dyer JD	AACOM	555
013101113552	Y	Shula S Edelkind BA	Progress in Medicine Foundation	216
013101113552	Y	Greg Englert	Highmark, Inc.	600
013101113552	Y #7	Donald M Epstein DC	Association for Network Care	444
013101113552	Y	Michele D. Forzley JD	Michele Forzley, Attorney at Law	312
013101113552	N	Nell Elizabeth Friar undergrad student	George Washington University	222
013101113552	N	Jeff Godell	Cancer Information Service	611
013101113552	Y	Victoria Mary Goldsten Doctor of Naturopathy, Bachelors of Nursing	Washington Institute of Natural Health	340
013101113552	N	Katherine J. Gorton	American Dietetic Association	112
013101113552	N	Karen Hagerty	Aspen Systems	, M
013101113552	N	Nancy Kristine Haller Guild Certified Feldenkrais Practitioner, BA	Feldenkrais Guild of North America	821
013101113552	N	Liangshu Han	Yat Chau (USA) INC.	One
013101113552	N	Jennifer D. Hannah	HRSA	560
013101113552	N	Jennifer Hannah	Health Resources and Services Administration	560
013101113552	N	Bonnie Sue Hillsberg M.Ed, M.H.A., D.C.	The CDM Group, Inc	533
013101113552	Y	Margaret M. Huddleston MTS, Harvard Divinity School	Center for Psychology & Social Change	205
013101113552	Y	Brenda Joyce Jasper M.Ed.	Association of Physician Assistant Programs	Uni
013101113552	N	Warren Jeter N.MD	Assn. For Integrative Health Care Practitioners	201
013101113552	N	Jerri Irene Johnson BS in Nursing	Minnesota Natural Health Coalition	176
013101113552	N	Alyssa Katz	Geogre Washington University	230
013101113552	N	Laurie Keene	THE BARBARA BRENNAN SCHOOL OF HEALING	PO
013101113552	N	Linda Kenney	PluraMed	11
013101113552	Y #9	Paula Kim	Pancreatic Cancer Action Network (PanCAN)	237
013101113552	Y #12	George Kurtz President	Feldenkrais Guild of North America	462
013101113552	Y #11	Scott Lamp CMT	American Massage Therapy Association	820
013101113552	N	Boyd J. Landry MPA	The Coalition for Natural Health	PM
013101113552	Y	Boyd J. Landry MPA	The Coalition for Natural Health	122

013101113552	N	William George Lang MPH	AACP	142
013101113552	N	Anne W. Lipe Ph.D., MT-BC	Certification Board for Music Therapists	506
013101113552	X	Ingrida Lusis	American Chiropractic Association	170
013101113552	X	Brian John McAulay D.C., Ph.D.	Sherman College of Straight Chiropractic	202
013101113552	Y#15	John David Melnychuk CCH, LCCH	California Health Freedom Coalition	655
013101113552	X	Diane Margaret Miller JD	National Health Freedom Coalition	139
013101113552	N	Kenneth Wayne Miller Ph.D.	American Association of Colleges of Pharmacy	142
013101113552	Y#5	Robert D. Miller	The First Church of Christ, Scientist	910
013101113552	N	Robert E. Miller ND	Trinity Consulting Services	247
~~013101113552~~	~~Y~~	~~David Edgar Molony Lisc Ac~~	~~American Association of Oriental Medicine~~	~~433~~
013101113552	Y#2	David Edgar Molony Dipl. Ac. & C.H., Lisc Ac.	AAOM	433
013101113552	N	Anne Heath Montgomery B.A., M.S.	General Accounting Office	441
013101113552	N	Jennifer Montgomery-Salguero PD	St Agnes Healthcare	700
013101113552	N	Leo Moody	HRSA, Bur. Primary Hlth Care	435
~~013101113552~~	~~N~~	~~Leo Moody~~	~~HRSA, Bur. Primary Hlth Care~~	~~435~~
013101113552	N	Avery Nelson	The Upledger Institute	112
013101113552	Y #14	Bruce Nordstrom Doctor of Chiropractic	American Chiropractic Association	170
013101113552	N	Jacqueline V. Offutt	Optimal Health Resources	160
~~013101113552~~	~~N~~	~~Njideka N. Olatunde ND, Ph.D.~~	~~Focus On Healing~~	~~Pos~~
013101113552	N	Njideka N. Olatunde ND, Ph.D.	Focus On Healing, Inc.	Pos
013101113552	N	Maressa Hecht Orzack Ph.D.	McLean Hospital	115
013101113552	N	SHERRY LEE PAE RN	THE BARBARA BRENNAN SCHOOL OF HEALING	PO
013101113552	N	Nehal Patel	George Washington University	, A
013101113552	Y#6	Kathleen Mary Quain CSW	Foundation For Health & The Environment	177
~~013101113552~~	~~Y~~	~~Kathleen Mary Quain CSW~~	~~Foundation for Health and The Environment~~	~~177~~
013101113552	N	Tina Marie Renneisen B.S. Candidate	George Washington University	210
013101113552	Y#10	Jennifer Roe BA	American Association of Naturopathic Physicians	820
~~013101113552~~	~~Y~~	~~Rustum Roy PhD~~	~~Pennsylvania State University~~	102
013101113552	(Y)	Robert D Scholten MSLIS	Beth Israel Deaconess Medical Center	330
013101113552	N	Peter V Scoles MD	National Board of Medical Examiners	375

013101113552	Y	Karen Scott	Progress in Medicine	585
013101113552	Y	Susan Silver	George Washington Center for Integrative Medicine	215
013101113552	N	Judy Simpson MT-BC	American Music Therapy Association	845
013101113552	Y	Colleen I Smethers CRNP	Progress in Medicine Foundation	102
013101113552	N	Andrew G Sparber RN, MS, CS	NIH	3 P
013101113552	Y	Judith (Judy) Springer Steele MTP (Master of Transpers Psych)	Nat'l Health Freedom Coalition	643
013101113552	N	Irene Elizabeth Stith-Coleman Ph.D.	Department of Health and Human Services	200
013101113552	N	TBA	The Upledger Institute	112
013101113552	Y	Test Craig t Test Powers	Self	338
013101113552	N	Judith Ann Valentine PhD	Self Employed Nutrition Educator	6 S
013101113552	Y	Christina Lee Walker RN MA	The Schenk Human Energetic Institute	220
013101113552	N	Christina Lee Walker MA	The Schenk Human Energetic Institute	220
013101113552	Y#3	Marcellus Andre Walker MD MD	africanamericanhealth.com	220
013101113552	N	Sarah Wegiel	Reflexology Association of America	148
013101113552	Y	Emily WhiteHorse DS,PA-C	Association of Physician Assistant Programs	310
013101113552	(Y)	Douglas Wood D.O,,PhD	AACOM	, A
013101113552	(Y)	Janet Wood RN	AACOM	, A
013101113552	N	Barbara Jane Woodhouse BSN	NCI Cancer Information Service Branch	921
013101113552	Y#1	Michael Zeng MD (China), DOM	International Institute of Chinese Medicine	488
013101113552	N	wendell conner allen nd	coalition for natural health	107
013101113552	Y	d dd d d	d	d (
013101113552	Y	d dd d d	dfgf fg fg fgdfasdfadf dsf sdf sdf sdf sdf	d (
013101113552	N	cristi morgan morotchie student	gwu	190
013101113552	Y	t t test t	t	t t
013101113552	Y	test t test	Test	333

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[001]

Attn: Craig Fox 301-571-5450

GROUP A: Registrants for oral comment who did NOT provide oral comment in Feb:

1. Y
John Philip Adams Doctor of Chiropractic
John Adams, DC., PC
(b)(6) Grand Junction, CO 81501
Healthydr@aol.com

4 Proper research into the safety and efficiency of mass vaccination has not been conducted. The medical profession is apparently not taking charge on this issue with the exception of a few courageous individuals. The CAM practitioner is the most likely force to mandate important safety precautions in the realm of mass vaccination. I will show my method of reaching the masses with this important message.

2. Y
Diana L. Chambers
Friends of Health
2014 Kalorama Road, NW, Suite #2 Washington, DC 20009
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202-483-3050
foh@friendsofhealth.org

I will focus on wellness provision for underserved populations

3. Y
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The First Church of Christ, Scientist
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202 857-0427
202 331-0587
millerr@csps.com

Public access to information about prayer as a whole system of self care is important. Prayer is a stand alone system that may include healing practitioners. Non-medical nursing assistance is available. Some may approach this system as complementary, while determining what is best for their needs. Assuring reliable authoritative information would be critical to any patient seeking the most appropriate means of advancing their health prospects.

4. Y

4. Bruce Nordstrom Doctor of Chiropractic
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703/243-2593
ilusis@amerchiro.org

5. Y
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703-610-9005
jroe@naturopathic.org

6. Y
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212-684-9652
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Testimony will be faxed.

7.
8.
9.
10.
11.
12.

GROUP B: Registrants for oral comment who also provided oral comment in Feb

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representing self
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My successful experiences using alternative medicine to cure chronic obstructive pulmonary

disease and other medical problems; my observations regarding alternative medicine of which the conventional medical community should be aware.

Y
Chi Chow Ph.D
New York Institute of Chinese Medicine
155 First St. Mineola, NY 11501
(516)739-1545(O), (~~631~~516-)385-7569(H)
(516)873-9622

1. Introduce myself background. 2. Introduce the standard training of acupuncture in US. (Didactic hour 1700; Clinic training hour 700) 3. Acup.program training included: Fundamental, Point L. Needle tech. West Bio-S. Practic issue.

Y
Shula S Edelkind BA
Progress in Medicine Foundation
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Our organization's mission is to support support medical research and physicians using non-mainstream research-based medicine. We have been focussed on support of Dr. Sinaiko, but plan to use our newsletter as both an educational and fund raising tool for outreach to doctors as well as supporting good research not of interest to the pharmaceutical company - particularly research on behavior and metabolism. But as long as doctors are ignorant or afraid, there is no access to such care.

Y
Michele D. Forzley JD
Michele Forzley, Attorney at Law
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301-565-1694
mforzley@tiac.net

I will address methods to harmonize education requirements across state lines to aid the development of more uniform credentialing requirements. I will also address the need for business skill training for health care professionals as one step necessary for delivery and integration of CAM to proceed.

Y
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202/966-8999
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Y
Margaret M. Huddleston MTS, Harvard Divinity School
Center for Psychology & Social Change
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617 547-6970
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As the author of the book, "Prepare for Surgery, Heal Faster", I've developed a 5-step protocol using mind-body techniques to prepare for surgery. I am the principal investigator of a randomized, controlled research study with 44 patients at a Tufts and Harvard Medical School teaching hospital. My program is offered at NYU Medical Center and Kaiser Permenante Santa Clara Medical Center.

Y
Brenda Joyce Jasper M.Ed.
Association of Physician Assistant Programs
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Provide educational info as well as standards and guidelines

Y
Brian John McAulay D.C., Ph.D.
Sherman College of Straight Chiropractic

SEE NEXT PG.

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864-599-7145
bmcaulay@sherman.edu

I will provide a brief synopsis of the eduational development of a doctor of chiropractic, including pre-chiropractic college prerequisites, chiropractic college curriculum, and post-graduate training. I will describe the focus and practice objective of graduates of Sherman College. I will describe for the Commission what contribution to health chiropractic care provides for those using the care.

Y
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Educational requirements in Oriental medicine are increassing to meet the responsibility of independent practice and the need for qualified and well trained practitioners who are well trained enough to provide effective treatment without falling back onto the more deleterious conventional modalities. I hope to be able to speak in the morning.

First, there has to be a comprehenisve evaluation of the persent educational system and its educational and certification criteria so to provide the public with access to credible standards of care in CAM, irrespective of Conventional or other medical education. While there might be flexibility in acceptance of present practitioners and overlap of fields, there should also be the development of viable standards for the future, developed with all fields at the table.

Y
Kathleen Mary Quain CSW
Foundation For Health & The Environment

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My statement will be forwarded to CAM within a week.

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1. NCCAM and NLM should initiate development of an informaton strategic plan 2. Information professionals at various NCCAM-supported research centers should be engaged to assist in creation of national databases in CAM 3. An authoritative national phytopharmacopeia should be developed by NCCAM or ODS. 4. The Healthfinder peer-review process for selecting web-based information should be made public so researchers can build off it.

Y
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Description and progress of our US Department of Education funded pilot project to train medical students in complementary and alternative medicine

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Importance of patients having a realistic informed consent

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Testimony will be faxed

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The Accreditation Commission for Acupuncture and Oriental Medicine will comment on the importance of national educational standards for the field of Oriental medicine and their implication for national policy.

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Public demand for reliable education relevant to CAM continues to rise. The avalanche of published information, good and bad, about CAM underscores people's need for education from disinterested sources about the complex relationships between the science and the practice of CAM. Educational strategies about CAM must be developed to fulfill this role. Specifically, curriculum development would meet the need for CAM or whole-person healing education at all levels of public interest.

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This statement looks at the efforts of the Council on Medical Education at the turn of the century to set educational mandates for medical education. The result? Natural health care in America disappeared. Cautions against making the same mistake now.

N
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Comments: I registered my organization earlier today with a "TBA" representative. This registration is the completion of that email. Feel free to contact me with any questions. Thank You

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White House Commission on Complementary and Alternative Medicine Policy

Hyatt Regency Hotel on Capitol Hill
400 New Jersey Avenue, N.W.
Washington, DC 20001

March 26-27, 2001

AGENDA

DAY ONE: MONDAY, MARCH 26, 2001

CAM Information Development And Dissemination

7:30 a.m. Registration opens

8:00 a.m. Opening Remarks and Introductions

- Stephen C. Groft, Pharm.D.
  Executive Director, White House Commission on Complementary and Alternative Medicine Policy

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

8:15 a.m. CAM Information on the Internet: Government, Academia, and Public

- Irene Liu, M.P.H., C.H.E.S.
  National Center for Complementary and Alternative Medicine, NIH

- Sheldon Kotzin
  National Library of Medicine, NIH

Speaker Guidelines:(NCCAM & NLM):
As government agencies, what are your responsibilities to provide CAM information to the public; what sources are available and how are they selected; what process is used to determine accuracy of the information; what are the barriers people have to accessing CAM information and how can they be overcome; what types of information is being requested; what types of people and organizations are requesting CAM information; what are your future plans for providing CAM related information; what suggestions do you have for the Commission; etc.

cautionary
1. enforce existing regs; adequate resources
2. FDA enforcement & labeling
CDC
3. repeal/amend DSHEA scientific evidence
4. mixture of burden of proof of safety

- Dale Ogar
  University of California Berkeley Wellness Letter

Speaker Guidelines:
As a large academic institution, what is UC Berkeley doing to provide CAM information to the public and university community; what sources are used for the information and how are they selected; what process is used to determine accuracy of the information; what are the barriers people have to accessing CAM information and how can they be overcome; what types of information is being requested; what types of people and organizations are requesting CAM information; what are your future plans for

Chowka – How to determine needs of the public?

"Wheel for Health & Well-being"

ODPHP

NLM: educate public librarians; use public libraries as resources

Public Library Assoc (Consumer Health libraries) list

How are we training kids / parents to navigate internet information – looking at the future, the 3 R's maybe now should include "I" "critical thinking"

Voluntary organization w/ stated policies

Consortium of websites > disclosure of COI

> unbiased

providing CAM related information; what recommendations should the Commission consider in their report to the President and Congress, etc.

- Burton Goldberg
  AlternativeMedicine.com
- Peter Chowka
  Natural Health Line
- Andrew Weil, M.D.
  Ask Dr. Weil

Speaker Guidelines (Goldberg, Chowka, Weil):
As private internet sites, how do you assure that the information you provide is accurate; what types of information is being requested; what types of people and organizations are requesting CAM information; what are your future plans for providing CAM related information; what recommendations should the Commission consider in their report to the President and Congress, etc.

9:15 – 9:55 a.m. ◆ Discussion (40 minutes)

9:55 – 10:10 a.m. 15-MINUTE BREAK

10:10 a.m. CAM in the Media: Newspapers, Magazines, Television, and Radio

Session Guidelines (all speakers):
How much CAM-related information are you providing and why; what topics are covered and how are they selected; how is accuracy of the information is determined; whom do you rely on for expert advice; how does corporate sponsorship influence the information provided; what would help provide more accurate, balanced, and useful information; who is your target audience; do you target information to people of different educational and literacy levels and people of different cultural, ethnic, and racial groups; what changes do you see over the next several years in your programming; what recommendations should the Commission consider in their report to the President and Congress, etc.

- Craig Stoltz, M.A.
  Washington Post
- Sara Altshul
  Prevention Magazine
- Christine Gorman, M.A.
  Time Magazine
- Susan Schiller
  CBS Evening News
- Joe Neel
  National Public Radio
- Elmer Huerta, M.D., M.P.H.
  Prevención

11:10 – 11:50 a.m. ◆ Discussion (40 minutes)

11:50 – 12:55 p.m. LUNCH BREAK

1:00 p.m. Evaluation of CAM Information

- Harrison "Lee" Raine, M.S.
  Pew Internet and American Life Project

- Susan Detwiler, M.B.A.
  The Detwiler Group

Speaker Guidelines (Pew and Detwiler):
What is your assessment of the current state of CAM information on the internet; how accurate is the information; how accessible is the information; what are some good and bad examples of CAM information on the internet; what can be done to promote quality and broaden the scope of information; what is the future of CAM information on the internet; what recommendations should the Commission consider in their report to the President and Congress, etc.

- V. Srini Srinivasan, Ph.D.
  U.S. Pharmacopeia

- Lucinda Maine, Ph.D.
  American Pharmaceutical Association

Speaker Guidelines (USP and APhA):
What is the current state of information on nutritional and dietary supplements; how is this information developed; how accurate is the information; how accessible is the information; what are some good and bad examples of nutritional and dietary supplement information; what can be done to promote accuracy in the information; what is the future of nutritional and dietary supplements information; what recommendations should the Commission consider in their report to the President and Congress, etc.

- David Schardt, M.S.
  Center for Science in the Public Interest

- Christopher Hendel, M.S.
  Consumer Reports

Speaker Guidelines (CSPI and CR):
What is the current state of information on CAM in the media; how accurate is the information; how accessible is the information; what are some good and bad examples of CAM information in the media; what can be done to promote accuracy and quality of the information; what is the future of CAM information in the media; how do you evaluate what CAM information consumers want; what recommendations should the Commission consider in their report to the President and Congress, etc.

2:00 – 2:40 p.m. ◆ Discussion

2:40 – 2:50 p.m. **15-MINUTE BREAK**

2:50 p.m. CAM Marketing and Advertising

◆ Michelle Rusk, J.D.
Federal Trade Commission

Speaker Guidelines:
What is the role of the FTC in the advertising and marketing of CAM information and products; what has FTC done to assure that the advertising and marketing of CAM information and products is accurate; how do they decide what claims to investigate; what is the process; what barriers do they have in their oversight responsibilities; what recommendations or issues should the Commission consider in their report to the President and Congress, etc.

◆ Christine Lewis, Ph.D., R.D.
U.S. Food and Drug Administration

Speaker Guidelines:
What is the role of the FDA in the labeling of CAM information and products; what has FDA done to assure that the labeling of CAM information and products is accurate; how do they decide what claims to investigate; what is the process; what barriers do they have in their oversight responsibilities; what recommendations or issues should the Commission consider in their report to the President and Congress, etc.

◆ Sarah E. Taylor, J.D., R.D., M.P.H.
Covington & Burling

Speaker Guidelines:
How do corporations assure that their marketing and advertising is accurate; what responsibility do they have in providing information to the consumer; what barriers do they encounter in promoting their products; are there any aspects of current law that may need changing to help assure corporate responsibility and/or public safety; what recommendations should the Commission consider in their report to the President and Congress, etc.

◆R. William Soller, Ph.D.
Consumer Healthcare Products Association

Speaker Guidelines:
What are the issues for consumers on the marketing and advertising of CAM information and products; is the information provided to consumers accurate, adequate, and useful; what are the barriers to consumers getting the information they need; what responsibility do companies have in providing information to the consumer; are current regulations adequate to assure consumer access and assure consumer safety; what recommendations should the Commission consider in their report to the President and Congress, etc.

◆ Mark Land
Boiron Homeopathic Products

Speaker Guidelines:
How do companies such as Boiron develop and provide information about their products to the public; how do they assure that their marketing and advertising is accurate; what responsibility do they have in providing information to the consumer; are there any liability issues; what barriers do they encounter in promoting their products; are there any aspects of current law that may need changing to help assure corporate responsibility and/or public safety; what recommendations should the Commission consider in their report to the President and Congress, etc.

3:40 – 4:20 ◆ Discussion (40 minutes)

4:20 – 5:20 p.m. Commission Workgroups

Breakout Room Workgroup #1 - CAM Information (Internet and Media)
Facilitator: Veronica Gutierrez

Plenary Room Workgroup #2 – CAM Marketing and Advertising
Facilitator: George DeVries

5:30 – 6:10 p.m. Commission Discussion (20 minutes for reporting out; 20 minutes for discussion)

6:15 p.m. **ADJOURNED**

DAY TWO: TUESDAY, MARCH 27, 2001

CAM In Self-Care And Wellness

7:30 a.m. Registration Opens

8:15 a.m. Welcome and Introductory Remarks

8:20 a.m. Overview of CAM in Wellness and Self-Care

- John Astin, Ph.D., M.A.
  University of Maryland, Complementary Medicine Program

Speaker Guidelines:
What are the links between wellness, self-care, and CAM; what are the similarities and differences in approaches to health, healing, and enhancing quality of life; what are areas of overlap and gaps; what is the historical perspective; what data and references are available; what are some opportunities for collaboration in preventive medicine; what are the emerging issues in self-care; what will wellness, self care, and CAM look like in the future; etc.

8:35 a.m. Integrative Approaches to Wellness: Children, Families, and Community

- Adrian Sandler, M.D.
  American Academy of Pediatrics

Speaker Guidelines:
What is the role of CAM in pediatric and family health care; how can the medical community utilize CAM to enhance the health and wellness of children and families; what are some obstacles or opportunities to including CAM in the care of families and children; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

- Marc Micozzi, M.D., Ph.D.
  College of Physicians, Philadelphia

Speaker Guidelines:
How can families and communities utilize CAM to teach wellness and promote healthy behaviors; how can CAM practices such as relaxation and stress management enhance

family relationships and social interactions; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

◆ David Larson, M.D., M.S.P.H.
National Institute for Healthcare Research

Speaker Guidelines:
What is the relationship between spirituality and health and between spirituality and CAM; what are some barriers and opportunities to incorporating spirituality in healing; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

9:15 – 9:55 a.m. ◆ Discussion (40 minutes)

9:55 - 10:10 a.m. **15-MINUTE BREAK**

10:10 a.m. Integrative Approaches to Wellness: Nutrition

◆ Walter Willett, M.D., Dr.P.H.
Harvard School of Public Health

Speaker Guidelines:
What is the current state of nutrition in the U.S.; what are the trends in nutrition and wellness; to what extent is nutrition part of CAM; what are the areas of overlap between CAM and nutrition; what are some current or emerging issues in the field of nutrition in CAM; and wellness; etc.

◆ ~~Kate Gordon~~ Cyndi Reeser
American Dietetic Association

Speaker Guidelines:
What is the American Dietetic Association's policy on CAM and nutrition; what are the issues for ADA's members regarding CAM; how can CAM be integrated into dietary practices to enhance wellness; what obstacles and opportunities are dieticians facing in integrating CAM into their work; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

◆ Michio Kushi
Kushi Institute

Speaker Guidelines:
What are some alternative approaches to using nutrition to enhance wellness; what are the barriers and opportunities to implementing alternative approaches; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

◆ Jeffrey Bland, Ph.D.
Metagenics

Speaker Guidelines:
What is the role of nutritional and dietary supplements in wellness; what are the issues regarding the use of vitamins and supplements for wellness and self-care; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

◆ Mark Hyman, M.D.
Canyon Ranch

Speaker Guidelines:

What is the role of nutritional and dietary supplements in wellness; what are the issues regarding the use of vitamins and supplements for wellness and self-care; what recommendations should the Commission consider in preparing its report to the President and Congress; etc.

11:00 -- 11:40 a.m. ◆ Discussion (40 minutes)

11:45 - 1:00 p.m. LUNCH BREAK

1:00 p.m. Integrative Approaches to Wellness: Self-Care

Underserved and Minority Communities:
◆ Frances Brisbane, Ph.D.
School of Social Welfare, SUNY

Speaker Guidelines:
How are underserved and minority communities using self-care; what are some examples of programs that provide CAM to underserved and minority populations to promote and enhance wellness; what are some of the difficulties (institutional, economic, conceptual, etc.) encountered; what recommendations the Commission should consider in preparing its report to Congress; etc.

Workplace:
◆ Cathy Moxley, M.A.
Marriott Wellness Program

Speaker Guidelines:
What is being done to promote wellness and self-care in the workplace with CAM; what are some examples of successful programs; why are these programs initiated and are they successful; what are the future trends for wellness activities in the workplace; what recommendations the Commission should consider in preparing its report to Congress; etc.

Elderly:
◆ Karen Prestwood, M.D.
Claude Pepper Older Americans Independence Center
University of Connecticut Health Center

Speaker Guidelines:
What are the issues for the elderly in CAM and self-care; what can the medical community do to promote wellness among the elderly; what are some successful models; what are the obstacles and opportunities; what recommendations the Commission should consider in preparing its report to Congress; etc.

End of Life:
◆ Christina Puchhalski, M.D.
George Washington University School of Medicine

Speaker Guidelines:
How can the concepts of CAM and wellness be used at the end of life; how is self-care used among terminally ill patients and their families; what recommendations should the Commission consider in preparing its report to Congress; etc.

1:40 – 2:20 p.m. ◆ Discussion (40 minutes)

2:20 – 2:35 p.m. 15-MINUTE BREAK

2:35 p.m. Public Testimony (Open Session –as pre-registered)

1. Michael Zeng, MD (China), DOM: President, International Institute of Chinese Medicine
2. David Edgar Molony, Dipl Ac & CH, Lisc Ac: American Association of Oriental Medicine
3. Marcellus Andre Walker, MD :africanamericanhealth.com
4. Diana L. Chambers: Friends of Health
5. Robert D. Miller: The First Church of Christ, Scientist
6. Kathleen Mary Quain, CSW: Foundation For Health & The Environment
7. Donald M. Epstein, DC : President, Association For Network Care

Panel Discussion (15 minutes)

8. Paula Kim: Chairman of the Board and CEO, Pancreatic Cancer Action Network (PanCAN)
9. Jennifer Roe, BA: American Association of Naturopathic Physicians
10. Scott Lamp, CMT: American Massage Therapy Association
11. George A. Kurtz: President, Feldenkrais Guild of North America
12. John Philip Adams, DC, FC
13. Bruce Nordstrom, DC:American Chiropractic Association
14. John D. Melnychuk, CCH, LCCH: California Health Freedom Coalition

Panel Discussion (15 minutes)

3:45 -- 4:50 p.m. Workgroup Discussion

Breakout Room — Workgroup #1 - CAM in Self-Care and Wellness: Nutrition
Facilitator: Joseph Fizzorno

Plenary Room — Workgroup #2 - CAM in Self-Care and Wellness: Special Populations
Facilitator: David Bresler

5:10
~~5:00~~ – 6:00 p.m. Discussion (20 minutes reporting out; 20 minutes discussion)

6:15 p.m. **MEETING ADJOURNED**

Panel A

1.) Funding for public librarians to become core community resources for internet and CAM – community programs, etc
2) Support for networking between consumer health professionals & public librarians
3) Training of public librarians to increase their comfort & skills at guiding users
4) Community programs to allow roundtables, etc community docs, pharms, others thru library system

Website consortium with voluntary code of ethics and accountability

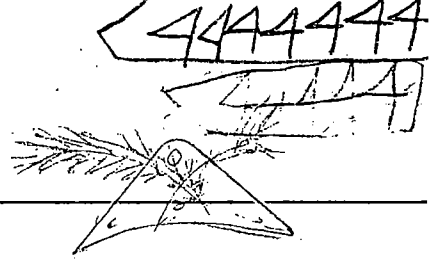
incorporating more skills training in critical thinking for children & their parents

Panel B

Public education of quality websites
Support of consortium w/ public edu campaign
- non restrictive ~~rules to~~ educational grants to neutral sites to ensure regular updating of info
Special Libraries Associations
→ except to specify use for updating

3rd party verification - NSF, of certificates
FDA, USP

Resources MUST BE ADEQUATE



Workgroup 1: Internet & Media

1. Don Wauer
2. Veronica Gutierrez
3. Buford Rolen — Gilda Scott
4. Conchita Paz
5. Joe Pizzorno
6. David Brooks
7. Effie Chew

Workgroup 2 - Marketing & Advertising

1. George DeVries
2. George Bernier
3. Charlotte Kerr

Plenary

4. Xiaoming Tian
5. Lunnie Kasen
6. Tieraona Low Dog
7. Joe Fins

Cost of implementation of FDA plan

Liaison & Communicating w/ others

- other fed agencies
- manufacturers - other researchers

Review Soller testimony DSHEA gap

If you think going to church will make you a Christian, go sit on your garage and you'll become a car.

Missing ~~Charlotte~~ ~~Wayne~~

March 27 - Wellness & Self-Care

Research - diagnostic testing

necessity is the cause of trying anything

John Astin: wellness & self-care includes
optimizing health (not preventing or treating disease

Recommendations

difficult to quantify

Medical research - efficacy of CAM for prevention
How to document that CAM optimizes good health & life
- energy, creativity, vitality

Marcoyz

Health & Wellness Program incentives from States? to employers

? CDC survey of ~~EE~~ koopckick info line

O. Lawson

Quality & Quantity of Life

Spirituality Training in Conventional Meds
Model curriculum based on multiple spirituality bases (different religion)

Jrl of Academic Medicine - special issues on CAM (AAMC)

Ecumenical medicine -> common denominator

At-risk & impact of stress reductions - CDC Survey

BOIRON®

White House Commission on Complementary and Alternative Medicine Policy

Complementary and Alternative Medicine in Self-Care and Wellness and Information Development and Dissemination

Monday, March 26, 2001
Washington, D.C.

Presented by
Mark Land
Boiron USA

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Table of Contents

Introduction

Mark Land currently holds the position of Technical Manager at Boiron USA's headquarters in Newtown Square, PA. In this capacity Mark is responsible for Boiron USA distribution operations and regulatory compliance. Mark has 20 years experience at Boiron and participates in the elaboration and implementation of the strategy of Boiron USA as a member of the Management Team.

We would like to thank this commission, commissioners and organizers for the opportunity to address you. We have followed with interest your work and look forward to contributing to the goals of the commission.

Company Profile

The Company

Boiron was founded in 1932 in Lyon, France. It is now a leading firm specializing in the manufacture, marketing and distribution of homeopathic medicines worldwide.

The Mission Statement

To give every physician and healthcare professional the world over the opportunity to learn about homeopathic medicines and use them in daily practice.

Facts About Boiron

- Boiron USA operates facilities in the United States near Philadelphia (Newtown Square) and Los Angeles (Simi Valley).
- Other subsidiaries in Canada, the Caribbean, Belgium, Italy, and Spain.
- 2,500 employees worldwide.
- Products sold in 61 countries.

Boiron USA

- Established in 1983
- CEO: Thierry Boiron
- Organized into three divisions:
  1. Marketing, Sales and Distribution, servicing independent pharmacies, natural-product stores, food, drug and mass market stores.
  2. Boiron Institute, providing educational services to healthcare professionals.
  3. Boiron Research Foundation, working with major research centers, such as UCLA and University of Washington.

Boiron: How To Reach Us
Boiron Information Center: 1-800-BOIRON-1
www.boiron.com
E-mail: info@boiron.com

Brief History of Homeopathy in the United States

Homeopathy was developed more than 200 years ago by Samuel Hahnemann (1755-1843), a German physician. Homeopathy then developed through Europe and has been practiced in the United States for over 175 years. As early as 1834, many states established homeopathic medical societies, and by 1844 homeopathic trade associations and journals emerged in the United States. The first pharmacopeia (unofficial) was published in 1841. The first official pharmacopeia has been continuously published since 1897. There are currently numerous homeopathic medical boards, medical state societies, professional societies, and medical journals in the United States. It is estimated that $230 million worth of homeopathic medicines are currently sold in the United States each year and that 10 million Americans use homeopathic medicines.

Legal and Regulatory Aspects of Homeopathic Medicines

Key Points

Homeopathy is unique within the category of CAM in that manufacturers are required to comply with strict drug labeling and manufacturing regulations:

Homeopathic products are officially classified as drugs in the United States.

Homeopathic manufacturing is required to comply with GMP (Good Manufacturing Practices).

Applicable Legal Framework

Homeopathic Medicines are Stringently Regulated by FDA

Prior to the passage of the Federal Food, Drug, and Cosmetic Act, ("FDCA") in 1938[1/], key homeopathic medicines were characterized as "drugs." Congress codified this characterization in 1938, when, in passing the FDCA, it defined the term "drug" to include "articles recognized in the official United States Pharmacopoeia, *official Homeopathic Pharmacopoeia*, or official National Formulary, or any supplement to any of them."[2/] This is the definition in effect today.

In 1988 in cooperation with the homeopathic industry, FDA issued a compliance policy guide ("CPG") that set forth the agency's regulatory approach toward homeopathic medicines.[3/] A CPG constitutes a formal "advisory opinion"[4/] that the agency, and the regulated community, is obligated to follow unless or until it is amended or revoked.

The homeopathic CPG states that "[t]he FDCA recognizes as official the drugs and standards in the Homeopathic Pharmacopoeia of the United States and its supplements." Under the CPG, homeopathic medicines are subject to a broad array of

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1/ Pub L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392 (1994)).
2/ 21 U.S.C. § 321(g).
3/ FDA Compliance Policy Guide, Sec. 400.400, (formerly CPG 7132.15).
4/ 21 C.F.R. § 10.85(d)(3).

quality control standards, much like other drugs, including significant labeling requirements, manufacturing protocols, purity benchmarks and other FDA restrictions on drug adulteration. Moreover, homeopathic manufacturers must follow stringent "good manufacturing practices" and are subject to routine FDA inspections. The homeopathic CPG also requires drug manufacturers to register with the FDA and "list" their drug products with the agency pursuant to the Drug Listing Act. Homeopathic medicines are also subject to the same type of extensive labeling and promotional restrictions generally applicable to other drug products marketed in the United States. In addition, homeopathic drug manufacturers are subject to standards imposed by the Homeopathic Pharmacopoeia of the United States (HPUS), an "official compendium" recognized by Congress under the FDCA.

It is also important to note that the Health Care Financing Administration ("HCFA"), the agency that administers the federal Medicare program, treats homeopathic medicines as "covered" items and services for which reimbursement may be made. *See* 42 U.S.C. § 1395x(t)(1); Medicare Carrier's Manual (HCFA Pub. 14-3) § 2049.1.

The classification of homeopathic products as "drugs" brings with it numerous rights and responsibilities. Homeopathic products are required to bear "adequate directions for use" as well as indications. They are required to make claims with respect to those conditions that the product may help. All claims must be consistent with the literature.

Safety of Homeopathic Medicines

Homeopathic medicines have an overall excellent safety profile owing to their lack of toxicity. They are well suited for the treatment of self-limiting conditions amenable to diagnosis by consumers, and because of their lack of toxicity, they are not contraindicated in patients taking other medications.

The majority of these medicines sold in the United States are OTC.

Research in Homeopathy

More than 100 clinical trials have yielded positive results, including research centering on effectiveness in allergy, asthma, acute diarrhea, and withdrawal from minor tranquilizers.

Because there have been many publications on the efficacy of homeopathic treatments, it has been possible to conduct synthesis studies, or meta-analyses, on these different trials.

The three meta-analyses which have already been carried out have demonstrated homeopathic medicines' efficacy over placebo.

The most recent, published in the September 1997 issue of the Lancet[5/], is based on 186 clinical trials. The authors K. Linde and W. Jonas concluded that: "the findings of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo."

[5/] Linde, K., Clausius, N., Ramirez, G., Melchart, D., Eitel, F., Hedges, L.V., Jonas, W.B. THE LANCET 1997; 350: 834-843.

Market Size Evaluation

Worldwide Pharmaceutical Sales	$211 billion
Worldwide Homeopathic Pharmaceutical Sales	$1.5 billion
Total U.S. Pharmaceutical Sales	$88 billion
U.S. Sales of Homeopathic Medicines	$230 million

Distribution of Homeopathic Medicines at Retail in the U.S.

Channel	% Stocking
Health Food Stores	95%
Chain Pharmacies	70%
Independent Pharmacies	30%

Consumer Use of Homeopathic Medicines in the U.S.

Eisenberg[6/]	1990	0.7% of those interviewed
Eisenberg[7/]	1997	3.4% of those interviewed

[6/] Eisenberg, D.M., Kessler, R.C., Foster, C., Norlock, F.E., Calkins, D.R., & Delbanco, T.L.. Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use, The New England Journal of Medicine, 1993; 328: 246-252.

[7/] Eisenberg, D.M., Davis, R.B., Ettner, S.L., et al. Trends in Alternative Medicine Use in the United States, Journal of the American Medical Association, 1998; 260(18): 1569-1575.

Advertising and Marketing Information of Homeopathic Medicines

Categories of Information: Product Labeling
Promotional Literature
Continuing Education Programs
Drug Information Center
Internet
Public Relations

Development of Information

At Boiron, we feel strongly that it is our responsibility as manufacturers and marketers to provide accurate and reliable information regarding the use and administration of our products. Since homeopathic products are drugs within the meaning of the Food Drug and Cosmetic Act, the guidelines for labeling content are quite clear.

As a 200 year old medical discipline, homeopathy is rich in reported treatment and research (homeopathic provings). This information is compiled in texts known as materia medicas. It is these documents that are the first step in the development of label indications for homeopathic drugs.

Thus the claims for homeopathic drugs are generally supported by a long history of safe documented use and clinical experience.

Proposed new homeopathic drugs undergo a rigorous review by the Homeopathic Pharmacopeia of the United States prior to marketing.

Internally Boiron exercises a careful review of label content and format by medical, pharmaceutical and legal experts prior to distribution.

Dissemination of Information

Product Labeling:

Labels for homeopathic medicines are required to bear adequate directions for use, indications for use and warnings. At Boiron, labels are developed and reviewed by medical, legal, marketing and technical experts.

Label information development relies heavily on the Code of Federal Regulations parts 200, 210, 330, advice issued by FDA and interpretation of the current literature.

Promotional Literature:

Promotional Literature is designed to visually acquaint the retailer, healthcare professional and consumer with the product benefits. We are not making claims in advertising and/or promotional materials other than what we state on labels.

Continuing Education Programs:

Pharmacy – Boiron Institute is an approved ACPE (American Council on Pharmaceutical Education) provider and continuing education articles are developed and written within the guidelines of the ACPE.

Medical – Professional texts and programs are written to further the knowledge of practitioners in the use of homeopathic medicines. Some are delivered in partnership with CME providers.

Drug Information Center:

Drug information personnel are instructed to provide information to consumers that are consistent with product labeling. Diagnosis and/or establishment of treatment regimens are strictly prohibited. Healthcare professionals are available to respond to inquiries from practitioners. Responses to practitioners are limited to information found in the literature.

Internet Websites:

Today the internet is one of the most productive information dissemination mediums. We recognized this by creating our own website where we provide information to consumers as well as to healthcare professionals on many topics relevant to Homeopathy and Boiron more specifically.

Public Relations:

Boiron seeks to supply accurate information consistent with product labeling and a fair and balanced interpretation of clinical results.

Barriers to Further Development of Homeopathy in the United States

Environment:

Today it is necessary to recognize that existing within the scientific medical community is a certain bias against so called CAM and more specifically as far as we are concerned, Homeopathy. The bias extends to teaching establishments like universities and also to some publishers (consumers or healthcare professionals).

We have observed a bias within the publishing community regarding homeopathy. Specifically publishers have refused to accept advertising for homeopathic products and medical journals have been reluctant to publish research articles related to homeopathic medicines.

We would like to see a more positive and constructive attitude that would allow for the proper dissemination of information. Specifically, we would welcome a more open minded approach to the benefits of homeopathic medicine in medical schools.

Research:

While the 200 year history of homeopathy is rich in clinical information, we believe the public could benefit from even greater insight into their clinical application and mechanisms of action. We would like to see more funds allocated towards this research in order to contribute to a better healthcare system; more compassionate, more economical and more effective.

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THE LANCET

Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials

Klaus Linde Nicola Clausius Gilbert Ramirez Dieter Melchart
Florian Eitel Larry V Hedges Wayne B Jonas

Reprinted from THE LANCET Saturday 20 September 1997
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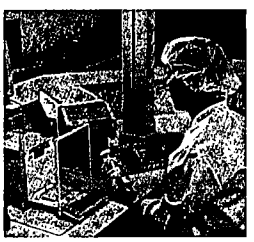
BOIRON Homeopathic Medicines: experience and reliability

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHPA
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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

Comments Before the White House Commission on Complementary and Alternative Medicine Policy on Information Development and Dissemination

Meeting in Washington, DC
March 26, 2001

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology
Consumer Healthcare Products Association

Mr. Chairman. Members of the Panel. Good afternoon.

I am Dr. Bill Soller, Senior Vice President and Director of Science & Technology of the Consumer Healthcare Products Association (CHPA), the 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research and advertising sectors of the self-care industry.

CHPA has commented on numerous aspects of the evolving regulatory framework for dietary supplements, including aspects relating to claims, advertising, promotion, adverse experience reporting, Good Manufacturing Practices (GMPs), analytical methods, among other areas of interest to our members.

I addressed the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP; hereafter, the Commission) at its March 16, 2001, Minnesota Town meeting, where I commented on the need for the Commission to support actively the appropriate funding of the Food and Drug Administration (FDA) to implement its long-range plan for dietary supplements.

I repeat this plea today, noting that last week at a hearing of the House Committee on Government Reform Mr. Joe Levitt, director of the FDA Center for Food Safety and Applied Nutrition (CFSAN), indicated CFSAN seeks appropriations of $6 million per year, starting with $3 million, scaling up in the second year to about $4.5 million, and reaching full funding in year three.

If Complementary and Alternative Medical (CAM) practitioners are concerned with quality and labeling issues affecting dietary supplements, then fiscal support to develop reasonable standardization that appropriately implement the statutory provisions of the

Dietary Supplement Health and Education Act (DSHEA) is vital to their interests, as well as those of consumers, patients, and, indeed, the industry.

I thank you for your invitation to me to return to the Commission to address the following questions pertaining to CAM information, specifically:

- Are current regulations adequate to assure consumer access and assure consumer safety?
- What are the barriers to consumers getting the information they need?
- What is the company responsibility in providing information to the consumer?
- Is the information provided to consumers accurate, adequate and useful?
- What recommendations the Commission should consider in their report to the President and Congress?

The answers to these questions should be set against the backdrop of Congress' intent in enacting DSHEA. Specifically, Congress wanted to facilitate providing consumers with products; information and education that would help promote health, and prevent disease through maintenance of healthy aspects of the structure and function of their bodies. In fact, Congress notes in the "findings" section of the Act, that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Clearly, adequate truthful information transfer is vital to meeting the intent of DSHEA.

In addition, while my answers to these questions are made primarily from a dietary supplement standpoint, the general points that I make are applicable across other CAM product categories.

Are current regulations adequate to assure consumer access and assure consumer safety?

Yes, in relation to dietary supplements, both the FDA and the Federal Trade Commission (FTC) are on record stating they have the tools and the intention to regulate such products. For example:

- On March 25, 1999, by Food and Drug Administration Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform stated: "FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA."

- Similarly, Ms. Jodie Bernstein, Director of the FTC Bureau of Consumer Protection, has given the Bureau's commitment to effective regulation of dietary supplements: "... FTC must and will continue to maintain an enforcement presence here, giving priority to cases that present serious safety considerations or prey on the very sick and especially vulnerable consumer." [1]

[1] Bernstein, J.: the FTC and Dietary Supplements. FDLI Conference on Substantiating Claims for Dietary Supplement Advertising and Labeling, Washington, D.C., November 13, 1997.

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) work together under a long-standing agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements [2]: FDA has the primary responsibility for claims on the product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale; FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

The Food and Drug Administration [3] [4] has the power to:

- Stop any company from selling a dietary supplement that is toxic or unsanitary [see Food Drug and Cosmetic (FDC) Act, Section 402(a)];
- Stop the sale of a dietary supplement that has false or unsubstantiated claims [see FDC Act, Section 403(r)(6)];
- Take action against dietary supplements that pose "a significant unreasonable risk of illness or injury" [see FDC Act, Section 402(f)];
- Stop any company making a claim that a product cures or treats a disease [see FDC Act, Section 201(g)];
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance (see FDC Act, Section 413);
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [see FDC Act, Section 402(g)].

The Federal Trade Commission [4] has the power to:

- Enforce laws outlawing "unfair or deceptive acts or practices" [5] and false advertisements to ensure consumers get accurate information about dietary supplements, so they can make informed decisions about these products [see Federal Trade Commission (FTC) Act, Sections 5 and 12];
- Challenge and stop advertising that is not adequately substantiated (see FTC's Deception Policy Statement and Advertising Substantiation Policy Statement);
- Investigate complaints or questionable trade practices; FTC can investigate either informally or formally, where it has strong compulsory investigative authority, including the power to require a respondent to produce documents, give testimony, or answer written questions [see FTC Act, Sections 6(a and b) and 9];

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[2] Federal Trade Commission, Bureau of Consumer Protection: Dietary Supplements: An Advertising Guide for Industry. 1998. (see www.ftc.gov)

[3] Taken from comments by Scott Bass, Esq. before Representative Dan Burton, Chairman of the House of Representatives Committee on Government Oversight, Oversight Hearing on the Dietary Supplement and Health Education Act of 1994, March 25, 1999.

[4] Soller, R. W.: Regulation in the Herb Market: The Myth of the Unregulated Industry. *Herbalgram* Feb.-Mar., 2000.

[5] An unfair trade practice is one that: causes or is likely to cause substantial injury to consumers; is not reasonably avoidable by consumers themselves; and not outweighed by countervailing benefits to consumers or competition (see FTC's Deception Policy Statement and Advertising Substantiation Policy Statement at www.ftc.gov).

- Following its own investigation, negotiate a consent order or proceed through an FTC adjudication resulting in a cease and desist order, which can be quite broad in its scope (see FTC Act, Section 5);
- Seek civil penalties for violations of cease and desist orders (see FTC Act Section 5).

Given that both FDA and FTC have the tools they need to ensure dietary supplements are safe, effective, high quality and properly labeled and promoted, it is important for the Commission to consider support of the general position that both agencies should be adequately funded to ensure that DSHEA is appropriately implemented, consistent with Congress' intent in passing the statute.

What are the barriers to consumers getting the information they need?

The following is a categorical listing of barriers and facilitators to CAM information transfer to consumers:

Barriers	Facilitators
Rogue manufacturers making unsubstantiated claims	Legitimate manufacturers making evidence-based claims
Lack of research incentives	NIH-sponsored research
Lack of a defined label warning policy within CFSAN[6]	CFSAN's grant to IOM/NAS to develop a scientific approach to DS
Too many information sources; no clear/central information authority	Health professional groups defining their roles as information multipliers
Educationally-unprepared consumers, patients, and conventional healthcare practitioners	Evidence-based CAM providers and consumer interest in visiting CAM providers
Limited base of current science	Evolving science base for CAM products
Limited standardization of CAM practitioner guidelines	WHCCAMP recommendations to the President and Congress on licensing and continuing CAM education models

What is the company responsibility in providing information to the consumer?

By law, companies must ensure that their labeling[7] and advertising is both truthful and not misleading,[8] and we believe claims made by CAM practitioners about CAM products, especially dietary supplements, should be held to the same standard.

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[6] On several occasions, CHPA has commented to FDA's Center for Food Safety and Applied Nutrition that the Center needs to articulate a clear labeling policy on when to warn. FDA has a long standing policy that has been used for consumer products, including OTC medicines and foods, which is that warnings (or decisions about product availability) should be "scientifically documented, clinically significant, and important to the safe and effective use of the product by the consumer." The importance of such a policy openly acknowledged by the Center cannot be underestimated, as it focuses public health decisions on the first hurdle, scientific documentation, as the basis for decision making. See also: [47 *Federal Register* 1982: 54754]; [53 *Federal Register* 1988: 46213]; and Soller, R.W.: When to Warn. *Regulatory Affairs Focus* Vol 2 Issue 10 Oct 97.

[7] Food, Drug Cosmetic Act; Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417).

Is the information provided to consumers accurate, adequate and useful?

Given that consumer- and patient-related labeling, advertising, and promotion must be by law both truthful and not misleading, the question is better re-framed in two parts:

- Is enforcement adequate to ensure the information provided to consumers is accurate, adequate and useful?
- Since both FDA and FTC acknowledge they have the statutory tools needed to implement the labeling and promotional provisions of the Food Drug Cosmetic Act and Federal Trade Commission Act, do FDA and FTC have the fiscal resources needed for adequately fulfilling their statute-derived enforcement functions, consistent with existing law?

Furthermore, CAM practitioners may distribute CAM-related products, including dietary supplements. It is therefore important that they be cognizant of the regulations and policies promulgated by FDA and FTC. For example, FDA has issued regulations pertaining to nutritional labeling, structure/function claims and health claims, to name two areas of specific interest.

FTC has re-issued a compilation of its policies, tailored for dietary supplement manufacturers (i.e., *"Dietary Supplements: An Advertising Guide for Industry"*). FTC notes in this policy guide, for example, that supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. Therefore FTC appropriately cautions that all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.

FTC's D/S Advertising Guide has been supported by our Association. Our members, many of whom have also marketed medicinal products under the policies set forth in the guidance, recognize the value of this guide in helping to inform companies of FTC policies. CHPA has broadly distributed copies of the Guide to its members and held workshops with FTC officials to review it and respond to questions.

Companies complying with the law implementing regulations provide consumers with accurate and useful information on dietary supplements. Enforcement by FDA and FTC is intended to create a sufficiently broad environment of truthful and non-misleading information on consumer and professional products. Consequently, the issues are

[8] The FTC's truth-in-advertising law can be boiled down to two common-sense propositions: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.[5] A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

whether FDA and FTC have sufficient resources to fulfill their enforcement duties in this area, and whether CAM practitioners are sufficiently aware of their responsibilities in the context of promoting, for example, dietary supplements.

What recommendations the Commission should consider in their report to the President and Congress?

1. The Commission should provide a strong recommendation to the Administration to support for adequate funding for CFSAN to implement its long-range plan to regulate dietary supplements, consistent with DSHEA.

   Funding of reasonable, appropriately-targeted regulatory activities by CFSAN would help address a significant barrier to consumers getting accurate, adequate and useful information – i.e., address the practices of rogue manufacturers who ignore the statutory and regulatory framework of DSHEA.

2. The Commission should consider encouraging FTC to develop industry and practitioner guides in the CAM product arena as was developed for dietary supplements.

   Such guides are helpful to define the standard expected of industry, allowing well-intentioned manufacturers and practitioners to optimize their understanding of the ground rules.

3. The Commission should support a consistent standard for advertising and promotion of all CAM products, as explained in part herein for dietary supplements.

WS/jq:DIETSUP/WhiteHouseCommissions/March Testimony 2001 WHCCAMP Draft #2

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Testimony of Sarah E. Taylor, Esq.
Covington & Burling
Washington, D.C.

Before the

White House Commission on
Complementary and Alternative Medicine (CAM) Policy
March 26, 2001

Testimony of Sarah E. Taylor, Esq.*
Covington & Burling
Washington, D.C.

Before the

White House Commission on
Complementary and Alternative Medicine (CAM) Policy
March 26, 2001

Panel #4: Advertising and Marketing of CAM Products

Good Afternoon. It is a privilege for me to address the White House Commission on Complementary and Alternative Medicine Policy. Thank you for this opportunity to discuss the key issues which I believe must be considered for our policies on the advertising and marketing of CAM products to serve the public interest as we confront the continuing advances in biomedical science and communications technology which challenge our current regulatory philosophy.

My views are shaped largely by my experience as an attorney in private practice, specializing in food and drug law, advertising law, and First Amendment law for the past 12 years. A substantial part of my law practice is devoted to advising product manufacturers and marketers on the legal requirements governing the dissemination of health information and claims for CAM products through labels, labeling, advertising, internet, and other marketing materials. Most of my practice in this area concerns food and dietary supplement products, including herbal and botanical products, for which health-related claims are a central marketing focus. I advise companies on the kinds of scientific evidence required to substantiate product claims, and on formulating claims to ensure they accurately reflect the nature and weight of the substantiating evidence on which the manufacturer relies. In addition, I advise companies on setting research priorities to help fill gaps in the scientific evidence in order to solidify the scientific basis for potential product claims. In addition, I represent companies in responding to investigations and enforcement actions brought by federal and state regulatory bodies, including by presenting the substantiating evidence supporting specific claims.

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* Sarah E. Taylor, J.D., R.D., M.P.H. is Of Counsel with the law firm of Covington & Burling, Washington, D.C., and specializes in food and drug, advertising, First Amendment and trade association law. Ms. Taylor's recent publications include Promoting Functional Foods and Nutraceuticals on the Internet, 54 Food and Drug Law Journal 423 (1999).

EXPANDING ENFORCEMENT OF ANTIDECEPTION AND SUBSTANTIATION LAW

While I have worked with a wide range of companies and types of marketing programs - - from small startup companies marketing a single product - - to multifaceted national marketing programs sponsored by industry groups - - it goes without saying that my experience has been with those companies who have taken the responsible step of seeking legal advice to ensure that their marketing activities conform with legal requirements. Such companies quickly learn that the requirements of current law are rigorous and impose on companies a heavy responsibility for ensuring compliance.

Much can be said about the complexities of the legal requirements imposed under the Federal Food Drug and Cosmetic Act (FD&C Act), Federal Trade Commission Act (FTC Act), and the overlapping consumer protection statutes in the 50 states. It is important, however, that in examining these complexities we not lose sight of the bottom line: current law requires all CAM products to be safe under the conditions of use, and all claims must be accurate and fully substantiated based on scientific evidence providing a reasonable basis for the specific claims made. This "tell the truth" standard is the minimum standard required by current law, and it applies uniformly to advertising and marketing materials for CAM products.

To ensure claims comply with current antideception and substantiation standards, substantial resources and technical sophistication can be required. Smaller companies, in particular, may lack the knowledge and resources necessary to ensure full compliance before entering the market. As a result, claims may be misstated or lack appropriate substantiation. It is important to recognize that the presence of unsubstantiated or inaccurate claims in the market is symptomatic of weakness in our system for enforcing current law, and not in the standards applied to the claims themselves. The CAM product market is dynamic and is populated by many new entrants and smaller companies. Accordingly, it seems important to carefully consider ways in which the enforcement of existing antideception and substantiation requirements could be expanded, and positive incentives for compliance enhanced.

Among the most sophisticated and effective "watchdogs" against deceptive claims are competitors in the marketplace. Competitors within the same product market frequently have substantial knowledge concerning the scientific evidence available to support claims. It is not uncommon for competitors to report violations to federal agencies to encourage enforcement action. Responsible companies striving to conform with legal requirements are frustrated when competitors expand their market share through marketing programs based on unfounded claims. Expanding our vision on enforcement and compliance policy to more fully engage the industry in self-regulatory activity could substantially enhance consumer protection.

DEFINING STRATEGIES FOR CONSUMER PROTECTION IN CONFORMANCE WITH "FREE SPEECH" PROTECTIONS MANDATED BY THE FIRST AMENDMENT

1. The First Amendment Mandate

While the government has broad authority to adopt regulations to protect public health and safety, its power to restrict "free speech" to advance its objectives, including by regulating the content of product labeling, advertising, internet, and other forms of commercial speech, is confined by the First Amendment.

Stated succinctly, while claims that are false or propose an unlawful transaction can be banned outright, the government otherwise cannot regulate the content of commercial speech unless it can establish from evidence that the restriction would directly alleviate a genuine harm, and the restriction is reasonably tailored to address the harm and does not overlook obvious, less burdensome alternatives.

The First Amendment presumption favoring the free flow of commercial speech encompasses health-related claims, as recognized in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). Health claims are constitutionally protected even when the scientific validity of the potential benefit identified has not been fully established. It is sufficient that the claim be stated to communicate accurately the weight of scientific evidence that, in fact, supports the claim.

This reflects a basic constitutional principle of our democracy which protects the freedom of citizens to have access to information to make their own choices, including in matters concerning their health. This founding principle harmonizes with the philosophy embraced in the disciplines of complementary and alternative medicine and consumer "self-care."

The First Amendment principles protecting commercial speech are helpful in distinguishing regulations that provide legitimate consumer protection from those that cross into the zone of unconstitutional paternalism. The Supreme Court addressed this line drawing issue directly in Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976). The Court made clear that the alternative to paternalism

> assume[s] that . . . information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. . . . But the choice among . . . alternative approaches is not ours to make or the [government's]. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. . . .

Id. at 770.

2. First Amendment Tensions in Current Regulatory Scheme

Under the FD&C Act, the regulatory requirements concerning CAM products are dictated by the classification of the product as a "food," "dietary supplement," "drug," "cosmetic," or "medical device" under the respective statutory definitions. In determining what classification applies, FDA looks to the health information disseminated by the manufacturer to determine the "intended use" of the product. For example, under current FDA policy, a dietary supplement product promoted using the advertising claim, "helps lower cholesterol levels," would be classified as a "drug," subject to NDA requirements. The same dietary supplement product advertised instead with the claim, "helps maintain normal cholesterol levels," would be classified as a "food." This dramatic change in regulatory treatment under the FD&C Act could depend on nothing more than the change of wording from "helps lower" to "helps maintain normal" cholesterol levels. For a dietary supplement product, "drug" status usually presents an impossible barrier to market entry.

Under current policy, the "helps lower cholesterol" claim would be construed as a "disease prevention" claim - - implying that the product is intended for use in the prevention of disease - - and thus qualifying as a "drug" under section 201(g)(1)(B) of the FD&C Act. In contrast, the "helps maintain normal cholesterol" claim would be construed as a "structure function" claim which is permitted under section 201(g)(1)(C) and 403(r)(6) of the act, provided the claim accurately reflects the substantiating scientific evidence.

The policies which have developed around the FD&C Act "drug" definition are difficult to fully justify on public health or antideception grounds, and have become the most significant obstacle to manufacturers attempting to include health information about CAM products in their marketing materials. This is because satisfying the antideception and substantiation requirements of the FTC Act is not sufficient to avoid an enforcement action by the FDA on the ground the claim renders the product an unapproved new drug. Beyond the FTC Act requirements, to avoid FDA enforcement, the manufacturer must be careful to avoid any use of a term that may imply a connection to a disease or health related condition - - even if the claim is true -- because to do so potentially subjects one's food or dietary supplement product to the same kind of premarket approval requirements that apply to prescription drugs. While as a technical matter, FDA approval of health claims on a case-by-case basis is an alternative to NDA approval, the "significant scientific agreement" standard limiting health claim approval was found to violate the First Amendment in Pearson, and the approved claims written by government regulators typically have limited marketing value. Such claims seem premised on the idea that formulating claims in the most scientifically precise manner will best educate consumers and prevent deception. This concept is at odds with the communication principles which drive successful marketing programs.

The severe chilling effect the "drug" definition has on the content of advertising, internet, and other promotional matter may be best appreciated by considering basic marketing principles. Fundamentally, for a marketing program to be successful, it must be effective in motivating consumers to purchase the product being promoted. This means that the content of a promotional message must be compelling to real consumers in the target population groups.

The power of a message to motivate consumer behavior relates to the degree to which the message resonates with the already established motivations of the consumer. This means that, to design an effective promotional campaign, a marketer must not only know the product benefits, but must attempt to understand the mindset of the relevant consumer population groups so that the benefits can be communicated effectively. The health messages that are most motivating to one group of consumers, may be different than those for another group - - even for the same product benefit. These differences typically reflect the distinctive health and lifestyle concerns inherent to each group, and may require market segmentation based on age, gender, or other demographic characteristics. In all cases, to be effective, marketers must have the flexibility to respond to shifting market dynamics, and to frame and reframe claims to keep them fresh and meaningful to real consumers.

On the other hand, the responsibility of manufacturers to ensure product safety merits emphasis here. CAM products typically are marketed directly to consumers as over-the-counter products. Accordingly, product safety must be established under the promoted conditions of use. Products, which by virtue of formulation or design cannot be established as safe are prohibited and cannot be lawfully marketed.

In some cases, potential safety concerns can be resolved appropriately through the disclosure of information concerning potential health risks and warning statements. This approach may apply where a CAM product is inherently safe, but may be used for health conditions that may be confused with more serious conditions requiring medical treatment. Safety issues of this kind are routinely considered as labeling is formulated for over-the-counter drug products being switched from prescription status. As a general matter, the disclosure of the pertinent health risk information and appropriate warnings are effective where such information equips the consumer to distinguish the symptoms of the more serious disease condition and obtain timely medical treatment.

The marketing of unsafe products is prohibited on several grounds including under the FD&C Act and under federal and state consumer protection laws. Notably, although proving compliance with statutory safety standards can be helpful to a manufacturer defending against a products liability action, it is well established that such compliance does not insulate a company from products liability. Companies thus remain responsible for the safety of their products, and may be held liable for harms caused by a product, even when it fully complies with statutory safety standards.

While marketing materials may be required to contain information and warnings that are necessary for safe product use, regulations which attempt to regulate product safety indirectly by restricting promotional claims raise significant constitutional concerns. The First Amendment requires that a direct connection be established between the harm the government is seeking to avert, and the restriction on commercial speech it would impose. Such a direct connection might exist when the government establishes that consumer deception is averted, for example, by banning false claims or requiring potentially misleading claims to be qualified with clarifying information. On the other hand, it would be difficult to establish the requisite connection where the speech restriction is not established to directly alleviate the harm at issue.

3. Considerations for Further Policy Development

In view of the challenges presented by the advertising and marketing of CAM products using health information and claims, future policy development is merited in the following areas:

- Expand incentives for industry self-regulation and enforcement of existing antideception and substantiation requirements for promotional claims.

- Eliminate policies restricting the dissemination of accurate, substantiated health information and claims in conformance with First Amendment requirements.

- Ensure that restrictions on the content of promotional messages can be established to directly alleviate a genuine harm to consumers, such as to prevent deceptive claims, or disclose information necessary for safe product use.

Thank you for this opportunity to present these views on the advertising and marketing of CAM products. I am pleased to respond to any questions you may have.