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Divider Title: Feigal

DAVID W. FEIGAL, JR., M.D., M.P.H.
Director
Center for Devices and Radiological Health

Dr. Feigal holds an M.D. degree from Stanford University and an M.P.H. from the University of California Berkeley. He did his internal medicine residency training at the University of California at Davis and a fellowship in clinical epidemiology at the University of California at San Francisco. He joined the UCSF School of Medicine faculty in 1984 with joint appointments in the Departments of Medicine and Epidemiology and Biostatistics. In 1989 he moved to the Department of Medicine at the University of California, San Diego.

He came to the Food and Drug Administration in 1992 to head the Division of Anti-Viral Drug Products. In 1996, he was also the Acting Director of the Anti-Infective Drug Division. From 1994 to 1997, he was the Director of the Office of Drug Evaluation IV. In the fall of 1997, he moved to the Center for Biologics Evaluation and Research as the Medical Deputy Director. In the spring of 1999, the Commissioner of the FDA appointed Dr. Feigal as the Director, Center for Devices and Radiological Health.

do we want to hear from the regulatory arm, the field investigation staff that may "visit" researchers/practitioners to hear of their approach to CAM interventions.

- ENFORCEMENT -

Overview of Center for Devices and Radiological Health

FDA's Center for Devices and Radiological Health is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products. There are thousands of types of medical devices, from heart pacemakers to contact lenses. Radiation-emitting products regulated by FDA include microwave ovens, video display terminals, and medical ultrasound and x-ray machines. The center accomplishes its mission by:

- reviewing requests to research or market medical devices
- collecting, analyzing, and acting on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products
- setting and enforcing good manufacturing practice regulations and performance standards for radiation-emitting electronic products and medical devices
- monitoring compliance and surveillance programs for medical devices and radiation-emitting electronic products
- providing technical and other nonfinancial assistance to small manufacturers of medical devices.

Office of Surveillance and Biometrics (OSB)

OSB develops and implements surveillance programs to assure that marketed products are safe and effective. It is the Center's source of expertise in the biometrics sciences and provides expert statistical consultation in the evaluation of premarket device applications. OSB administers a nationwide surveillance system to monitor and evaluate the safety and effectiveness of marketed devices by analyzing adverse-event reports. In collaboration with the other Center offices, OSB directs and monitors the analysis, resolution, and development of implementation strategies for postmarket issues through the Center's *ad hoc* process and postmarket safety notifications.

Office of Systems and Management (OSM)

OSM advises the Center Director on all management issues. It plans, develops, and implements cost effective Center management policies and programs concerning financial and human resource management, contract and grants management, ethics and program integrity, committee and conference management, occupational health and safety, and facilities. OSM develops and implements the Center's long-range, strategic, and operational plans; evaluates the effectiveness of Center programs; and designs administrative, scientific, and technical information systems to support Center programs. As the Center's electronic communications hub, OSM provides computer support services to the Center and web-based information to the public. Its library provides scientific information for Center staff, and the Freedom of Information (FOI) staff responds to public requests for information.

Center for Devices and Radiological Health

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Donald J. Sauer, Director
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For additional information, call:

1-888-INFO-FDA

or visit our website at:

www.fda.gov/cdrh

September 1999

#13
Feigal

Center for Devices and Radiological Health

Promoting and Protecting the Public Health

Center for Devices and Radiological Health
CDRH

U.S. Food and Drug Administration
9200 Corporate Boulevard, HFZ-1
Rockville, Maryland 20850

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The Center for Devices and Radiological Health (CDRH), part of the U.S. Food and Drug Administration (FDA), helps ensure that medical devices are safe and effective as authorized by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act and helps reduce unnecessary exposure to radiation from medical, occupational, and consumer products as authorized by the Radiation Control for Health and Safety Act of 1968.

Office of the Center Director (OCD)

OCD provides leadership and direction for all Center activities and is responsible for their evaluation and coordination. It provides advice and consultation on policy matters about medical device and radiological health activities to the Commissioner and other FDA officials, Congress, the Department of Health and Human Services, the Public Health Service, other government agencies, the scientific and academic community, and representatives of the regulated industry. It also supports the Equal Employment Opportunity (EEO) program and its management within the Center.

Office of Compliance (OC)

OC is the enforcement hub of CDRH with responsibility for directing and evaluating field inspections of manufactures of medical devices and radiological health products nationally and abroad. OC advises the Center Director and other FDA officials on legal, administrative, and regulatory programs and policies. It oversees the compliance and surveillance programs of the regulated industry and conducts field tests and inspections needed for regulatory purposes. OC also evaluates industry quality control and testing programs and advises the FDA field offices and CDRH regarding legal actions, case development, and contested case assistance. OC is responsible for the Establishment Registration, Medical Device Listing, Government-wide Quality Assurance, and Bioresearch Monitoring Programs. It trains Federal and State compliance personnel and advises manufacturers about the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Office of Device Evaluation (ODE)

ODE is the office responsible for review of marketing applications from the medical device industry. It plans, conducts, and coordinates Center actions regarding the approval, denial, and withdrawal of approval to market a medical device. ODE also reviews applications to conduct investigational clinical studies of unapproved medical devices under the Investigational Devices Exemptions. The data gathered in these clinical studies supports marketing applications.

ODE reviews four types of marketing applications: Premarket Notification (or a 510(k) application), Premarket Approval (PMA), Product Development Protocol (PDP), and Humanitarian Device Exemption (HDE). Most devices are cleared for marketing through the 510(k) process; PMA applies only to the highest risk and newly developed (class III) devices. ODE coordinates Center classification activities; reviews and initiates petitions for reclassification of devices; interacts with and provides support to the advisory panels which make recommendations on FDA actions regarding selected devices; and conducts continuing review, surveillance, and medical evaluation of device labeling and clinical experience.

Office of Health and Industry Programs (OHIP)

OHIP specializes in the areas of program-based communication, education, radiological health, mammography quality, and resolution of device user problems. Its audiences include the radiological health and device industry, health professionals, consumers, CDRH staff, and foreign governments.

In support of Center programs, OHIP provides expertise in communications technology and produces national and international teleconferences and educational videos; applies human factors theory to the design and labeling of devices to reduce use errors; conducts qualitative research studies for use in Center information programs for health professionals, consumers, and industry; operates a program to implement the Mammography Quality Standards Act of 1992 and provides technical expertise in applying health physics procedures and radiation protection principles; provides technical assistance to medical device manufacturers, coordinates international activities, and provides information to consumers; develops regulations for medical devices and radiological health activities; and provides educational programs for Center employees.

Office of Science and Technology (OST)

OST, the laboratory research hub of CDRH, supports FDA's regulatory decisions with laboratory research in the areas of standards, technical consultation, forensic analysis, and applied research. It leads the development and evaluation of standards used for regulatory assessments. OST supports other Center offices when specific expertise is required for solving problems or reviewing 510(k) or PMA applications. It identifies and analyzes failures of marketed devices. OST conducts research in the areas of life, physical, and engineering sciences as they relate to the health effects of radiation and medical device technologies, e.g., studying the effects of electrical fields around consumer products on cell development. OST's research assists the regulatory programs of CDRH and FDA in anticipating the impact of technology on the use, safety, and effectiveness of regulated products.

JOSEPH A. LEVITT
DIRECTOR, CENTER FOR FOOD SAFETY
AND APPLIED NUTRITION
U.S. FOOD AND DRUG ADMINISTRATION
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On February 1, 1998, Joseph A. Levitt was appointed Director, Center for Food Safety and Applied Nutrition (CFSAN). In this capacity, he provides executive leadership to the Center's development and implementation of programs and policies relative to the composition, quality, safety, and labeling of foods, food and color additives, dietary supplements and cosmetics. These products account for nearly 80% of the nation's food supply.

Since joining CFSAN, Mr. Levitt has revitalized FDA's food program through a combination of openness, creative management, and strict priority setting. Under Mr. Levitt's leadership, food safety has been the Center's top priority, with good agricultural practices, juice warning labels, increased inspections of both domestic and imported foods, and improved outbreak response, among FDA's major accomplishments. Mr. Levitt has also led development of the Dietary Supplement Strategic Plan, the Center's Affirmative International Agenda, and the Egg Safety Action Plan. During Mr. Levitt's earlier tenure in the Commissioner's Office, he played a central role in launching FDA's food labeling initiative.

Mr. Levitt began his FDA career in 1978 in the Office of the General Counsel. He later joined the FDA Commissioner's Office, progressing from Program Advisor to the Commissioner (1983), to Executive Assistant to the Commissioner (1984), to Director of Executive Operations (1987) and finally to Chief of Staff (1988). During 1989-90, Mr. Levitt functioned as the Agency's Acting Deputy Commissioner. He then continued as Chief of Staff until October 1991, when he joined FDA's Center for Devices and Radiological Health as the Deputy Director for Regulations and Policy.

Mr. Levitt has received numerous awards for his contributions and achievements. He received the FDA Award of Merit three times (1982, 1985, and 1987), the Commissioner's Special Citation five times (1985, 1989, 1992, 1993, and 1995) and the PHS Superior Service Award (1986). He also received the Department's Distinguished Service Award twice (1988 and 1996), the Secretary's Special Citation (1989), and the Secretary's Certificate of Appreciation and Award for Excellence in Public Service (1993). Mr. Levitt received the Presidential Meritorious Executive Rank Award twice - from President Bush (1991) and from President Clinton (1999).

Mr. Levitt's B.A. degree is from Cornell University in 1975 where he graduated *magna cum laude*. He graduated *cum laude* from Boston University in 1978, where he was a member of the law review. Mr. Levitt is a member of the Massachusetts Bar and the Phi Beta Kappa Society.

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 1998

Inside FDA: Center for Food Safety and Applied Nutrition

(Center for Food Safety and Applied Nutrition web site)

The Center for Food Safety and Applied Nutrition (CFSAN), regulates $240 billion worth of domestic food, $15 billion worth of imported foods, and $15 billion worth of cosmetics sold across state lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale.

CFSAN is one of six centers within FDA. With a work force of about 800, the center promotes and protects the public health and economic interest by ensuring that:

- Food is safe, nutritious and wholesome, and cosmetics are safe.
- Food and cosmetics are honestly, accurately and informatively labeled.

To achieve these goals, the center strives to be a leader in food safety, protect consumers from economic fraud, promote sound nutrition, and encourage innovation.

Recent center activities demonstrate the center's commitment. For example, in approving olestra as the first synthetic fat-based fat substitute, the center's scientific staff evaluated more than 150 studies on olestra's safety. Concerned about olestra's potential ability to reduce nutrient absorption in the body, the center approved olestra on the conditions that vitamins A, D, E, and K be added to olestra-containing foods and that a statement appear on such foods to inform consumers of possible nutrient losses and thus the reason for the addition of the fat-soluble vitamins. The center also requires the statement to warn consumers about the possible side effects of abdominal cramping and loose stools.

A Sampling of Highlights

Examples of other more recent center actions include:

- revamping food labels to make it easier for consumers to get nutrition information about the foods they eat
- approving certain health claims supported by scientific evidence showing a link between a food or nutrient and a disease or health condition. These health claims can be used in food labeling.
- requiring warning labels on iron-containing drugs and dietary supplements and individual-dose packaging for products with 30 milligrams or more of iron per unit to protect children from accidental iron poisoning, a leading cause of death in children under 6
- establishing new regulations based on modern food safety techniques to improve seafood safety

- issuing regulations calling for folic acid fortification of enriched grain products by 1998 to reduce the chances of certain birth defects in infants
- signing an agreement with the University of Maryland to form the Joint Institute for Food Safety and Applied Nutrition, paving the way for both organizations to pool specialized knowledge, equipment and facilities.

Behind the Scenes

Employees ranging from secretaries and other support staff to highly specialized professionals--such as chemists, microbiologists, toxicologists, food technologists, pathologists, pharmacologists, nutritionists, epidemiologists, mathematicians, and sanitarians--carry out the center's mission.

The center is divided into seven offices dealing with:

- cosmetics and colors
- food labeling
- plant and dairy foods and beverages
- premarket approval
- seafood
- special nutritionals, such as dietary supplements and infant formula
- special research skills and support.

Other center offices deal with consumers, industry and other outside groups; field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical foods' issues.

Most center staff members work out of the center's headquarters in Washington, D.C. The center also operates research facilities in Laurel, Md., and a fisheries research center in Dauphin Island, Ala., and helps staff the National Center for Food Safety and Technology in the Chicago area.

In Touch with Others

Much of the information evaluated by center personnel is gathered by FDA employees across the country. For example, FDA field investigators inspect food and cosmetic companies, examine food shipments from abroad, and collect samples. Laboratory scientists and technicians analyze samples. Compliance officers recommend legal action and follow through on enforcement issues.

Center personnel also work with other government agencies, such as the Centers for Disease Control and Prevention and state health departments, to resolve food safety concerns and economic fraud cases, for example.

The center is increasingly being called on to work with international organizations, such as the Codex Alimentarius Commission—an international food standard-setting organization of the Food and Agriculture Organization and World Health Organization—and foreign governments, to help establish internationally recognized safety standards, rules and regulations for imported foods.

In the past, most of the center's efforts dealt with U.S. products. But that's changing as a result of recent international treaties. Now, more and more food is traveling in international circles.

Future Considerations

Other areas that will increasingly draw the center's attention are:

- Foods derived from genetic engineering. The first of these on the market, the Flavr Savr tomato, can be shipped vine-ripened, thus improving texture and flavor. Future possibilities include insect-resistant apples, long-lasting raspberries, and potatoes that absorb less fat.
- New packaging materials. These include recycled products and those that prolong shelf life.
- The hazard analysis critical control point (HACCP) food safety system. HACCP is considered more effective than the current system because it focuses on preventing problems rather than reacting to them after they've occurred. FDA is considering whether to make HACCP mandatory for all of the food industry it regulates.
- Food adulteration for economic gain.
- The center is eyeing several proposals to see how to increase the pace of its review of new food additives without jeopardizing public safety.

Considering that almost 20 cents of every consumer dollar Americans spend goes to food and cosmetics, these and other concerns for the Center for Food Safety and Applied Nutrition eventually come to rest with American consumers. Center dealings that make news one day, such as the approval of olestra, usually make it to the marketplace another.

Computer users can keep up-to-date on CFSAN activities on the World Wide Web at http://www.cfsan.fda.gov/.

Center Director

The Center for Food Safety and Applied Nutrition is headed by Joseph A. Levitt, previously the deputy director of the FDA's Center for Devices and Radiological Health. Mr. Levitt began his career at the FDA in the Agency's general counsel's office. From 1983-1991, he held a series of positions in the Commissioner's office, progressing from program advisor to executive assistant to director of executive operations, and finally chief of staff. During 1990, he functioned as acting Deputy Commissioner.

While in the Commissioner's office, Levitt was instrumental in launching the nutrition labeling program and in speeding the availability of new drugs for desperately ill patients. At the Center for Radiological Health, he has had major responsibility for developing the Agency's mammography quality standards program and implementing the Safe Medical Devices Act of 1990.

Mr. Levitt is a magna cum laude graduate of Cornell University. He graduated cum laude with a J.D. from Boston University. He has received numerous awards including the Presidential Meritorious Executive Rank Award in 1992.

Additional background information on FDA's Center for Food Safety and Applied Nutrition

FDA Almanac: CFSAN or all of FDA

Home

Hypertext updated by ear/dms 2000-MAR-20

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White House Commission on Complementary and Alternative Medicine Policy

Joseph A. Levitt
Director, Center for Food Safety and Applied Nutrition

October 5, 2000

Topics to be Covered

- Why Develop a Dietary Supplement Strategic Plan?
- Public Outreach: What We Heard
- Summary of the Plan
- Next Steps: Where to From Here?

Why Develop This Plan?

Background

- DSHEA - 1994
- 25 Federal Register Notices -- 1994 - 1998
- Still, Much More To Do
- Road Map - One Year
- Collaborative Effort

"FDA is aware that Americans place great faith in dietary supplements to help maintain and improve their health and that the scientific evidence documenting the benefits of a number of supplements is increasing."

Jane E. Henney, M.D.
FDA Commissioner
Before the Committee on Government Reform
U.S. House of Representatives
March 25, 1999

"The challenge to FDA is to strike the right balance between preserving consumers' access to both products and information and assuring the safety and proper labeling of all of these products."

Jane E. Henney, M.D.
FDA Commissioner
Before the Committee on Government Reform
U.S. House of Representatives
March 25, 1999

"It is clear, with the benefit of hindsight, that we still have a way to go both in achieving full implementation of DSHEA and in developing a workable regulatory framework."

Jane E. Henney, M.D.
FDA Commissioner
Before the Committee on Government Reform
U.S. House of Representatives
March 25, 1999

Public Outreach: What We Heard

Stakeholder Outreach -- Public Meetings

- Washington, DC June 8, 1999
- Oakland, CA July 20, 1999
- Written Comments Also Received

What We Heard: Themes First Meeting (June)

Frequently Mentioned

- Safety First
- Adverse Event Reporting System
- GMP's
- Enforcement
- Enhance Science Base

What We Heard: Themes First Meeting (June)

Also Emphasized

- Claims/Substantiation
- Consumer Research Needed
- Botanicals
- Collaboration
- Resources/Leveraging

What We Heard: Themes Second Meeting (July)

What was Different?

Health Professional Focus

- Safety
- Validity of Labeling Claims
- Product Composition
- Public Education About Limitations

What We Heard: Themes Second Meeting (July)

What was Different?

Consumer Focus

- Parent of Victim
- Buyer Beware
- "Consumer Medwatch" for AER's
- Marketing to Elderly, Women, and Children

What We Heard: Themes Second Meeting (July)

What was the Same?

- Safety First
- Adverse Event Reporting
- Enforcement
- Enhance Science Base
- Claims/Substantiation

What We Heard: Themes Second Meeting (July)

What was the Same?

- GMP's
- Consumer Research Needed
- Botanicals
- Collaboration
- Resources/Leveraging

Internal Strategy Teams

- Safety
- Labeling
- Boundaries
- Enforcement
- Research

Strategy Insights

- Long-term Implementation Process
- Science Needs to Become More Central
- Will Require Resources
- But, Blueprint Development is Achievable

Overall Dietary Supplement Strategy Elements

- Safety
- Labeling
- Boundaries
- Enforcement
- Science-Base
- Outreach

Safety

- Adverse Event Reporting
- Good Manufacturing Practices
- New Dietary Ingredients

Labeling

- **Pearson v. Shalala**
- **Health Claims Petitions**
- **Substantiation**

Boundaries

- Structure/Function Claims
- Claims for Mitigation/Treatment of Disease
- Botanicals

Enforcement Activities

- Enforcement Strategy
- Capacity Building
- Federal Trade Commission Coordination

Science Base

- Enhance Internal Expertise
- Strengthen Research Efforts
- Oversight of Clinical Trials

Science-Base (Cont'd)

- Strengthen Research Efforts
  - Research Agenda
  - Research Capabilities
  - Dietary Supplement Ingredient Reviews
  - Leveraging

Outreach

- Advisory Committee
- Additional Stakeholder Outreach
- Communication

Next Steps: Where to From Here?

- 2000 Program Priorities: A/B Lists
- 2001 Budget Now Before Congress
- Develop Community Buy-in and Involvement

Contents of the Plan

Program Objectives

- Fully Implement DSHEA
- Consumer Confidence in Dietary Supplements
- Science-Based, Regulatory Approach
- Long-Term Effort

Why A Ten-Year Plan?

- Long Haul - Ongoing Issues
- Resources - Need Dedicated Staff
- DSHEA - Not a Low Maintenance Law

Program Goal

- **By the Year 2010, have a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products.**

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Leaders

Divider Title: _____

SPEAKER BIO

Floyd E. Leaders, Jr. Ph.D.
Chairman & CEO
Botanical Enterprises, Inc.,
Rockville, Maryland, USA.

Academic/Industry Experience:
University of Kansas Medical School: Faculty, - five years.
Department of Pharmacology
Pharmaceutical Industry: Twenty-four years as:
Head of Pharmacology, Director, Research Services and Director, Research and Development Laboratories for major pharmaceutical companies.
President/Co-founder of one of the first full service pharmaceutical CROs (contract research organizations).

The Leaders Group, Inc. (TLG):
Founded 1992 – CAM consultation. Became part of BEI in 1997.
Reactivated in 1999 to provide strategic consultation in areas of commercial interest to BEI.

Office of Alternative Medicine, NIH (1993-1995):
FDA liaison for OAM. Worked with FDA and sponsors to develop the first successful INDs for botanicals submitted in recent times.

Botanical Enterprises, Inc. (BEI):
Founded 1997 – Development and commercialization of botanical dietary supplements and FDA approved pharmaceuticals.

Personal:
Drake University: BS, Pharmacy.
State University of Iowa: MS, Pharmacology.
State University of Iowa: Ph.D., Pharmacology.
Over 100 presentations, publications and book chapters.
Co-Chair of a series of six cutting edge Botanical Workshops.
Frequent speaker on medicinal botanicals in the US and abroad.

Botanical Enterprises, Inc. [BEI-Botanicals]

Botanical Enterprises, Inc. (BEI) was founded to develop botanical therapies for re-introduction into US mainstream medicine. BEI defines botanicals products as multi-component mixtures derived from plant sources and excludes single chemical entities derived from plant sources. BEI focuses on botanical products with the potential for proprietary protection and a strong existing base of human data and other scientific support. Its primary, (long-term) objective is to develop botanical drugs (pharmaceuticals) with FDA approval. As a secondary (short-term) objective, it develops "companion products" for the dietary supplement market.

BEI is structured as a cutting edge "virtual" pharmaceutical development company that works with other companies through working agreements, partnerships and joint ventures to develop botanical pharmaceuticals through Phase II clinical trials. They are then out-licensed to pharmaceutical companies or co-developed through NDA approval.

BEI is a Delaware Corporation (since 1996) that has been working with botanicals since 1992. Its internal core competencies include selection of botanicals suitable for the US market, regulatory, development and marketing strategies for both pharmaceutical and dietary supplement commercialization and complex project management involving multiple corporate and social cultures. An overview of the company can be obtained by visiting the BEI web site at www.bei-botanicals.com.

ROBERT S. McCALEB

Curriculum Vitae

Robert McCaleb is President and founder of the Herb Research Foundation, an internationally recognized research and educational resource. Educated in Cellular Biology and Botany at the University of Texas and University of Colorado, he has studied beverage, aromatic and medicinal herbs since 1972 and is a PhD. candidate in Ethnobotany (Union Institute). . From 1976-1989, he was Director of Research at Celestial Seasonings, headed the Research Committee of the American Herbal Products Association (and the Herb Trade Association) and served on their Board of Directors. Mr. McCaleb founded the Herb Research Foundation as a nonprofit 501(c)(3) tax-exempt organization in 1983.

Mr. McCaleb has written numerous articles on botanicals for healthcare, and serves on the editorial boards of some of the field's leading journals. He has lectured on botanical medicine at Harvard and Columbia Medical Schools and at numerous symposia throughout the world. Mr. McCaleb has followed international herb research for over 20 years, with a focus on aromatic and medicinal plants, and has advised the US Congress and Administration and government officials of numerous other countries. Most recently, he served as a member of the Presidential Commission on Dietary Supplement Labels.

LECTURES, SYMPOSIA, WORKSHOPS

1st Annual Herb Technical Symposium: UC Santa Cruz, September 17, 1977. "Quality Indicators for Botanical Products."

2nd Annual Herb Symposium: UC Santa Cruz, Sept. 13-15, 1978. "Herbal Overview: The History of Herbs as Medicines."

3rd Annual Herb Symposium: UCSC. Aug. 24-26, 1979. The Herb Trade Association's Research Committee report detailed efforts to fund a limited literature search to present to FDA documenting the history and study of herbal teas and herbal medicine. Two workshop presentations covered New careers in the Herbal movement and Herbal Quality Assurance.

University of Colorado Medical School (Oct. 1979). "Herbal Overview: The History of Herbs as Medicines."

Sigma Xi Annual Awards Banquet, Colorado School of Mines (May 1980). "Herbal Overview: The History of Herbs as Medicines."

4th Annual Herb Symposium: UCSC. June 27-July 1, 1980. Informal talks on various subjects relating to the budding herb industry.

Herb Seminar, HTA. Trade Show, San Francisco, Oct. 31, 1980. "The Past, Present and Future of Herbal Medicine" including the legal dilemma which hinders all research and educational efforts on natural medicines.

Herb Seminar, San Antonio, Texas, Jan. 1981. "Commercial Production of Herbal Products" followed the production of Chamomile herb tea from the fields of Egypt to the highly mechanized factory in Colorado where the product is processed and packaged.

Herb Seminar, Anaheim, CA, May, 1981. "Commercial Production" slide show.

5th Annual Herb Symposium, San Diego, CA, Aug. 29-30 1981. "Herb Research in the 80s" concerned the lamentable lack of interest in the U.S. to fund or follow research

in Pharmacognosy, and the dispute between the medical/scientific community and holistic healers and herbalists.

National Nutritional Foods Association, New Orleans, LA, July 24, 1982. "Meeting the Growing Demand for Herbs." Also presented was a proposal for the Herb Research Foundation, to encourage and support herb research.

American Herbal Products Association, New Orleans, LA, July 23, 1982. HRF funding proposal accepted by AHPA, with the intent that HRF would be supported in part by the herb industry through AHPA.

Herb Research Foundation, Philadelphia College of Pharmacy and Science, Oct. 1-2, 1982. Organizational meeting of the HRF Professional Advisory Board.

Ginseng Research Institute, Philadelphia College of Pharmacy and Science, Oct. 1-2, 1982: Organizational meeting.

Herb Research Foundation Herb Seminar organizer, coordinator, speaker. July, 1983.

International Ginseng Symposium, State University of New York, Delhi, NY. June 1986: "Eleutherococcus senticosus, recent advances," "Ginseng research and ginseng press."

First National Herb Marketers and Growers Symposium, Purdue University Horticulture Dept., West Lafayette, IN. July 1986: Featured Speaker, "Celestial Seasonings: history and development."

Second National Herb Marketers and Growers Symposium, Indianapolis, IN.. July, 1987, "The Role of research in the Herb Industry."

Third Annual Herb Marketers and Growers Symposium, Louisville, KY. July, 1988, "Information Retrieval in Botanical Science."

Herbs '89, San Jose, CA. July, 1989, "World Botanicals Production."

Herbs '89, San Jose, CA. July, 1989, "The Q Word -- Assessing Quality in Botanicals."

Herbs '89, San Jose, CA. July, 1989, Banquet Master of Ceremonies.

Southwestern Health Organization, Dallas, TX. February 1990, "Recent Trends in Herb Research."

Sixth Annual Gaia Spring Herb Symposium, Ashland, MA. May 1990, "Recent Advances in Herb Research," and "Savings the Plants, Saving Ourselves."

National Nutritional Foods Association, Boston, July 1990, "Issues and Trends in the Herb World."

Natural Products Expo East, Philadelphia, PA, November 1990, "Herbal All-Stars: Herbalists Pick their Top Five."

Natural Products Expo West, Anaheim, CA, March 1991, "Herbs & the FDA: New Frontiers" and "Herbs to Enhance Peak Athletic Performance."

National Nutritional Foods Association, Las Vegas, NV, July 1991, "Herbs and Homeopathy."

Natural Products Expo East, Baltimore, MD, September 1991, "Congress, the FDA and your Business."

Herbs for Health Symposium, Washington, DC, September 1991, "Into the Mainstream: Rational Use and Regulation of Herbs for Health."

The Food and Drug Law Institute Conference on Dietary Supplements, Crystal City, VA, June 1992, "Safety Substantiation Efforts for Unique Ingredients, Including Herbs and Botanicals."

Health Options Expo '92, Denver, CO, October 1992, "A New World Vision of Herbs for Health."

Natural Products Expo West, Anaheim, CA, February 1993, "The Two Faces of Western Herbal Medicine."

Symposium on the Utilization of Medicinal Plants (by the World Health Organization and the Morris Arboretum) Philadelphia, PA, April 1993, "Trade in Medicinal Plants."

Rocky Mountain Drug Consultation Center, Denver, CO, October 1993, "Potential of Phytomedicines in Modern Medical Care."

Second International Reunion of Biological Medicine, Barcelona, Spain, December 1993: "Phytomedicines Face Social Obstacles Despite Promising Research."

Dietary Supplement Labeling Conference, presented by Council for Responsible Nutrition and National Nutritional Foods Association, Washington, DC, March 1994: "Industry Regulatory Concerns/The Herbal Perspective." Special challenges for herbal products under proposed FDA rules, especially documentation of safety and health benefits.

Restoring the American Community, presented by Social Venture Network, San Diego, CA, April 1994. Invited Participant: "Herbs for Health Care, Environmental Conservation and International Development."

Consultant to National Institutes Office of Alternative Medicine. Invited participant:
·Alternative Medicine Database Workshop, Washington, DC, May 3-4, 1994.
·The Role of Botanicals in American Health Care, Washington, DC, May 26-27, 1994.

Rocky Mountain Poison Center, Denver, CO, July 14, 1994. "Phytomedicines and Phytotoxins: An update on crude and semipurified plant-derived health care products."

National Natural Foods Association Convention, Las Vegas, NV, July, 1994. "Marketing Herbal Quality Professional Enrichment Program."

Herbfest '94, Norway, IA; August, 1994. "Medicinal Plants in Modern Health Care."

National Institutes of Health Office of Alternative Medicine, Washington, DC/ December, 1994. Speaker and panelist at the "Symposium on Botanicals: A Role in US Health Care?"

National Natural Foods Association Northwest Trade Show, Seattle, WA, February, 1995. "Natural Healthcare for the Twenty-First Century."

Natural Products Expo West, Anaheim, CA, March, 1995. Speaker and panelist.

Alternative Medicine Workshop on Botanicals, Washington, DC, March, 1995. " Medicinal Herbs: US and Canadian Perspectives, Cultural Use and Experience." Sponsored by DIA, NIH Office of Alternative Medicine and FDA.

Biodiversity and Human Health Conference, Washington DC, April, 1995. "Biodiversity and Traditional Health Systems." Sponsored by NIH Fogarty International Center, National Science Foundation, National Association of Physicians for the Environment, Smithsonian Institution, and Pan American Health Organization.

An International Training Program in New Crops: Aromatic and Medicinal Plants, West Lafayette, IN, June 28, 1995. "Regional and International Marketing of Medicinal Plants." Sponsored by Purdue University.

NutraCon '95, Las Vegas, NV, July 11-13, 1995. "New Research on the Health Protective Flavonoids in Fruits, Vegetables and Herbs for Use in Dietary Supplements." Sponsored by Global Business Research.

National Natural Foods Association 58th Annual Convention and Trade Show, July 14-17, 1995, Las Vegas, NV. Invited Panelist, "Current Issues of Safety, Claims and Regulations on Herbs in the United States."

Herbs '95, July 27-30, 1995, Chicago, IL. "Developing Quality Assurance Procedures for the Small to Medium Size Herbal Processor and Manufacturer." "Reflections on the Botanical Herb Industry: Problems and Future Promise." Sponsored by the International Herb Association (10th annual conference).

Council for Responsible Nutrition Annual Conference, September 18-20, 1995, Squaw Valley, CA. Invited panelist, "Broadening the Mix of Products in the Changing Marketplace: Vitamins, Minerals, Herbs, and Phytochemicals."

Harvard Medical School Department of Continuing Education, March 27-29, 1996. Boston, MA. "Clinical and Experimental Evidence for Botanicals in Health Care."

Columbia University, College of Physicians & Surgeons Botanical Medicine in Modern Clinical Practice Conference, May 10-17, 1996, New York. "Herbal Product Sources, Resources and Assessment."

Utah Natural Health Week, Salt Lake City, UT, June, 1996. "Using and Understanding Herbal Remedies: the latest research on medicinal plants." Sponsored by Utah Natural Products Alliance and the University of Utah Red Butte Garden & Arboretum.

American Herbalists Guild, Boulder, CO, June, 1996. "Herb Research & Quality Control Issues."

University of Colorado Museum, Boulder, CO, July, 1996. "Medicinal Plants in Modern Health Care." Presented at the opening of a year-long exhibit entitled "The Healing Power of Plants."

Education Design, Boulder, CO, August, 1996. "Botanicals in the Pharmacy". Continuing Education for Pharmacists workshop.

Wilderness Medical Society, Alberta, Canada, August, 1996. "Medicinal Plants: The Importance of Biodiversity to Alternative and Traditional Therapies," and "How to Use Medicinal Plants in Your Clinical Practice."

Herbfest '96, Norway, IA; August, 1996. "Stop the Aging Process with Antioxidant Herbs" and "Scientific Evidence for Herbs in Prevention and Treatment."

Indena Workshop: From Acts to Action when Dealing with Botanicals. Milan, Italy, September 9, 1996. Chairman and presenter.

Creating the Natural Formulary, Washington, DC, October 9-11, 1996. "Maximizing the Effect of the Four Modalities of Medicinal Herb Use."

Harvard Medical School Department of Continuing Education, Boston, MA, March 9-12, 1997. "Clinical and Experimental Evidence for Botanicals in Health Care."

Herbs and Modern Health Care Symposium, Boulder, CO, March 15, 1997. Sponsored by the University of Colorado Museum. "Botanicals in the Pharmacy."

International Symposium on Kava and Other Medicinal Plants of the South Pacific, May 14-17, 1997, Kona, HI. presenter: "The Safety of *Piper methysticum*," and panelist, "Kava, The Regulation."

Medicines from the Earth: Exploring Nature's Pharmacy, Black Mountain, NC, May 31-June 2, 1997. Guest presenter and moderator: Childhood Immunity: Conventional Immunizations vs. Botanicals and Naturopathy; Herbal Regulatory Update; Medical Models for the Use of Vitex, St. John's wort, and Ginkgo.

Quality Herbal Products: A Marketing and Regulatory Workshop, Boulder, CO, June 6, 1997. Guest presenter: "Commission on Dietary Supplement Labels: Regulatory Update on Dietary Supplements."

An International Training Program in New Crops: Aromatic and Medicinal Plants, West Lafayette, IN, June 28, 1997. Guest presenter: "Marketing and Herbal Product Development." Sponsored by Purdue University.

National Nutritional Foods Association (NNfA), MarketPlace '97, Las Vegas, NV. Panelist, "Labeling, Claims & the FDA," and "Answering Questions on Standardized Extracts."

Wilderness Medical Society, Sun Valley, ID, August, 1997. Guest presenter: "How to Use Medicinal Plants in Your Clinical Practice."

Denver Botanic Gardens, Denver, CO, September 13, 1997. "Medicinal Plants in Modern Health Care." Presented at the opening of "The Healing Power of Plants"exhibit.

Cost Saving Strategies & Advances in Hormone Intervention Therapy: Long Term Treatment & Prevention, Boston, MA, September 22-23, 1997. Guest Presenter: "Phytotherapy for Menopause."

Natural Products EXPO, Baltimore, MD, September 18-21, 1997. Guest presenter at *Natural Foods Merchandiser* luncheon: "Regulatory Update and Good Research Protocols for Botanicals."

Columbia University, College of Physicians & Surgeons Botanical Medicine in Modern Clinical Practice Conference, New York, October 13-17, 1997. Guest presenter: "Botanical Products: Quality, Sources, Resources and Assessment;" and "Botanical Shop, Sampling Botanical Products."

Kaiser Northern California, Vallejo, CA, October 25-26, 1997. Guest presenter: "Botanicals in Natural Healthcare: Clinical Evidence, Information Resources, and Product Sources and Assessment."

Exploding Botanical Medicines Market, San Francisco, CA, October 27-29, 1997. Guest presenter: "Leading Botanicals for Clinical Use."

Harvard Medical School Department of Continuing Education, Boston, MA, March 1-4, 1998. "Clinical and Experimental Evidence for Botanicals in Health Care."

Barnett International: Dietary Supplements: Strategies to Comply with Emerging Regulations and Promote Product Sales, Washington, DC, March 5-6, 1998. Presenter: "The Role of Dietary Supplements in Healthcare: Four Modalities of Medicinal Herb Use."

Natural Products EXPO West, Anaheim, CA, March 13-15, 1998. Guest presenter at media luncheon: "Mood Enhancing Herbs."

American Herbal Products Association, Anaheim, CA, March 12, 1998. Update on the Report of the Commission on Dietary Supplement Labels.

American Herbal Products Association: St. John's Wort Symposium, Anaheim, CA, March 16-17, 1998. Invited panel moderator.

American Premium Tea Institute, Denver, CO, April 17, 1998. Guest presenter: "Herbal Tea."

Columbia University, College of Physicians & Surgeons Botanical Medicine in Modern Clinical Practice Conference, New York, May 26-29, 1998. Guest presenter: "Botanical Products: Quality, Sources, Resources and Assessment;" and "Botanical Shop: Sampling Botanical Products."

American Psychiatric Association Annual Meeting, Toronto, Canada, May 30-June 4, 1998. guest presenter,: "Herbal Medicine: Ancient Roots to Modern Use."

Seventh National Kaiser Permanente Internal Medicine Conference, Kona, HI, July 18-25, 1998. guest presenter: "Botanical Medicines for Modern Healthcare," "Herbal Products: Information Resources and Assessment," and "Leading Botanicals for Clinical Use."

Natural Products EXPO East, September 11-13, 1998, Baltimore, MD. Guest presenter: "Regulatory Issues."

American College of Nutrition Annual Meeting, Albuquerque, NM, October 2-4, 1998. guest presenter: "Botanicals *vs.* Conventional Treatment for Menopause and BPH."

Harvard Medical School Department of Continuing Education, Boston, MA, February 28-March 3, 1999. "Clinical and Experimental Evidence for Botanicals in Health Care."

National Nutritional Foods Association (NNfA), conference "Third Party Literature for Dietary Supplements and Functional Foods: Opportunities Overlooked." March 22, 1999. Panelist, "Herbs, Traditional Medical Literature and the Effect on Dietary Supplement Third Party Literature Standards."

Columbia University, College of Physicians & Surgeons Botanical Medicine in Modern Clinical Practice Conference, New York, May 24-27, 1999. Guest presenter: "Botanical Products: Quality, Sources, Resources and Assessment;" and "Botanical Shop, Sampling Botanical Products."

An International Training Program in New Crops: Aromatic and Medicinal Plants, West Lafayette, IN, June 14-25, 1999. Guest faculty: "History and Use of Herbs in Modern and Traditional Health Care Systems and Scientific Evidence Supporting Herbs for Health;" "The Botanicals Marketplace;" "Marketing and Product Development;" "Resources for Herb Information." Sponsored by Purdue University and University of Illinois.

National Nutritional Foods Association (NNfA), MarketPlace '99, Las Vegas, NV. invited panelist.

NutraCon '99, Las Vegas, NV, July 12-13, 1999. Keynote Speaker: "The Premier Investment for the Next Millennium." Sponsored by Global Business Research.
Thirteenth Annual Wilderness and Travel Medicine. Big Sky Resort, MT. August 4-8, 1999. guest presenter: "The Herbal Travel Kit," and "Clinical and Experimental Evidence for Botanicals in Health Care."
Vitam Cottage. Lakewood, CO. February 22, 2000. "Informed Herb Use for the New Millenium."
Harvard Medical School Department of Continuing Education, Boston, MA, March 12-15, 2000. "Botanical Medicine: Information Resources."
National Summit on Africa, Washington DC, February 16-20, 2000. "Teaming Large U.S. Agribusiness with African Small Farmers: A Win-Win Situation."
Natural Products EXPO West, Anaheim, CA, March 23-26, 2000. "Genetic Engineering and the Natural Products Industry: Where Do We Stand?"
Columbia University, College of Physicians & Surgeons Botanical Medicine in Modern Clinical Practice Conference, New York, May 22-26, 2000. Guest presenter: "Scientific Literature & Botanical Products;" and "Botanical Shop: Herbal Teas, etc.; Displays & Sampling."
An International Training Program in New Crops: Aromatic and Medicinal Plants, West Lafayette, IN, June 19-30, 2000. Guest faculty: "History and Use of Herbs in Modern and Traditional Health Care Systems and Scientific Evidence Supporting Herbs for Health;" "The Botanicals Marketplace;" "Marketing and Product Development;" "Future of Herbs and Medicinal Plants in the US and Europe and American Healthcare;" Sponsored by Purdue University and University of Illinois.
National Nutritional Foods Association (NnfA): MarketPlace 2000, Las Vegas, NV. Invited panelist: "To The Root of It: A Complete Herbal Workshop."

LEGAL and REGULATORY

Consultant, 1988-present, on herb safety and regulatory matters.
Celestial Seasonings, 1976-89, primary contact with food and drug law attorneys.
Herb Safety Review, 1989-present, developed an industry-wide program for food additives safety affirmation. TO date, HRF has completed over 35 Herb Safety Reviews for various sponsors.
Food and Drug Law Institute, July 1992 presentation "Food Ingredient Safety Evaluation."
FTC meeting, September, 1993, FTC policy on dietary supplement labeling issues.
Congressional meetings, 1993, with Rep. Skaggs, and Senators Brown and Mitchell, and Health Aides for Rep. Waxman and Senator Hatch, regarding dietary supplement legislation.
Congressional Hearings, oral and/or written testimony regarding FDA's Regulation of Dietary Supplements for:
· House Energy and Commerce Subcommittee on Health and the Environment (Waxman), July, 1993.
· Senate Labor and Human Resources Committee (Kennedy), October, 1993 .
· House Subcommittee on Human Resources and Intergovernmental Relations (Towns), August, 1993.
Congressional Office of Technology Assessment's Advisory Panel on Dietary Supplements, 1993-94. Invited Panelist.
Texas Department of Health, April 1995, presenter at a Public Hearing on proposed rules which would restrict the sale, distribution or possession of certain foods and drugs which contain ephedrine.
Office of Dietary Supplements, September 30, 1996. Strategic planning with ODS, Office of Disease Prevention, and National Institutes of Health to define realm of

activities of the new ODS in relation to the scientific understanding of the role of dietary supplements in life span health.

Commission on Dietary Supplement Labels, 1995-97. Presidential appointment. The Commission conducted hearings, took testimony, received evidence, and secured information to make its recommendations on the regulation and legislation related to label claims for dietary supplements.

Food and Drug Administration Working Group on Consumer Research, Winter 1998. The Working Group will meet to gather information and discuss consumer issues regarding dietary supplements, and what research should be done to improve consumer information and knowledge.

US House Reform Committee, March 25, 1999. written and oral testimony on FDA's activity in the regulation of dietary supplements.

NON-PRINT MEDIA PARTICIPATION

Guest, *CNN's Sonia Live.* Alternative Medicine, March, 1993.
Guest interview, *CBS Evening News.* Herbs, Vitamins & Amino Acids, May, 1993.
Guest, *America's Talking, Alive and Wellness*, July, 1993.
Guest interview, *Here's To Your Health Radio*, January, 1994.
Media Interviews: Newsweek, New York Times, Science News, National Geographic Newswire, Prevention, Self, Asian Wall Street Journal, Consumer Reports, Esquire, Ladies' Home Journal, Outside, First for Women, Bicycling, LA Times Syndicate, New York Post, and numerous other magazines, newspapers, all major TV networks, and radio stations countrywide.
Guest interview, *Here's To Your Health Radio*, June 1995, March 1996, May 1996.
Guest interview, *Of Mind and Medicine Radio*, July 1995.
Guest interview, *Pathway to Wholeness Radio*, January 1996.
Guest participant, *The Diane Rhem Show,* WAMU National Public Radio, April, 1996.
Guest interview, *Newsweek on Air Radio*, April 27, 1996.
Guest interview, *Discovery Channel Online Live with Derek McGinty*, July, 1996.
Guest interview, *Gary Null Radio Show*, December, 1996.
Guest interview, *Crossroads Radio*, WCBR, December 1996.
Guest interview, *Bull Session*, CNBC TV, March, 1997.
Guest interview, *NBC Dateline*, April, 1997.
Guest interview, *Here's To Your Health Radio*, June, July, August, 1997.
Guest interview, *Herbs and Health Radio*, August, 1997.
Press Briefing, Natural Products EXPO, Baltimore, MD, September 19, 1997
Herbal Health Seminar, New York, September 30, 1997. Sponsor: Warner Lambert.
Seventh on 6th, New York, November 6, 1997. Media seminar sponsor: Warner Lambert.
Guest interview, *Here's To Your Health Radio*, January, 1998
Guest interview, *A Word on Health*, Danielle Linn syndicated radio, March 14, 1998
Guest interview, *Here's To Your Health Radio*, February, 1999
Guest interview, *KGNU Radio*, February 2000
Guest interview, *KWAB Radio*, March 20,2000
Media Interview, *OneBody.com*, July 2000.

PUBLICATIONS

"Food Ingredient Safety Evaluation" *Food and Drug Law Journal*, 1992, Vol. 47, No. 6.
Senegal Fruit Concentrate Project. Final Report for USDA/USAID funded project in Senegal. June 30, 1992.
Alternative Medicine: Expanding Medical Horizons. A Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States."

Prepared under the auspices of the Workshop on Alternative Medicine, Chantilly, VA, 9/14-16, 1992. (Contributing Author, "Herbal Medicine," pp.183-206.)

Herbs as Specialty Exports. Final Report for Uganda project funded by USDA/USAID. July, 1994.

Agroindustrial Markets Workshop Report. Final report for USDA/USAID funded project in Lusaka, Zambia, September 5-15, 1994.

"Food Ingredient Safety Evaluation" *Spices, Herbs and Edible Fungi*, edited by George Charalambous. (Developments in Food Science: 34) 1994 Elsevier Science B.V.

Herbs and Medicinal Plants in Mali. Final report for USDA/USAID funded project in Mali. In cooperation with Ronco Consulting Corp and OHVN. November 1997.

"Trade in Medicinal Plants" *Medicinal Plants: Their Role in Health and Biodiversity. Proceedings of the 1993 Symposium on the Utilization of Medicinal Plants* (sponsored by the World Health Organization and the Morris Arboretum). Tomlinson, R. and Akerele, O., eds. Philadelphia: University of Pennsylvania Press, 1998.

"Medicinal Plants for Healing the Planet: Biodiversity and Environmental Health Care." *Biodiversity and Human Health: Proceedings of the 1995 Conference on Biodiversity and Human Health* (sponsored by NIH Fogarty International Center, National Science Foundation, National Association of Physicians for the Environment, Smithsonian Institution, and Pan American Health Organization). Grifo, F. and Rosenthal, J., eds. Washington: Island Press, March 1997.

Intensification of Mint Production. Final Report for USDA/USAID funded project in Assilah, Morocco, in cooperation with Fintrac and Moroccan Association for the Development of Aromatic and Medicinal Plants. April, 1998.

"Types of Botanical Products Used in the US." *Botanical Medicine: Efficacy, Quality Assurance and Regulation*. Proceedings from the 1994 Office of Alternative Medicine / FDA "Symposium on Botanicals: A Role in US Health Care?" Eskinazi, Daniel (ed). 1999. Larchmont, NY: Mary Ann Liebert, Inc. Publishers.

The Encyclopedia of Popular Herbs: Your Complete Guide to the Leading Medicinal Plants. McCaleb, Robert S., Leigh, Evelyn and Morien, Krista. February, 2000. Prima Health, Rocklin, CA.

ARTICLES

"Are Herbs Safe?" *Health Foods Retailing*, March 1980
"Herbal Safety," *Herb News*, May 1981
"Herb Blurbs," *Herb News*, May 1981
"Hibiscus," *Herb News*, July 1981
"Rob's Research Reviews," Regular column, *Herb News*, July 1981 to present
"Media Watch," regular column, *Herb News*, July 1981 to present
"Poison Pen Award," *Herb News*, July 1981
"Herb Of The Month," Regular Column in *Whistle Stop*, June 1980 to 1984
"Herbs As Medicine; Therapeutic Potential vs. Economic Reality," *Health Foods Business*, October 1984
"Herbal Teas," presented to Ministry of Revenue, Canada, October 1984
"World Botanicals Production," *Herbs '89 Proceedings*
"The Q Word -- Assessing Quality in Botanicals," *Herbs '89 Proceedings*
"Botanical Resources Threatened," *Herb Market Review*, Spring 1990
"Natural Help for Memory Loss," *Longevity*, August 1990
"Valerian: Nature's Potent Sleep Aid," *Better Nutrition*, August 1990
"Astragalus: Immunity Enhancer," *Better Nutrition*, October 1990
"Herbal Wellness," *Delicious!*, October 1990
"Ginseng for Vigor," *Better Nutrition*, November 1990
"Cayenne Pepper: One Hot Medicinal Plant," *Better Nutrition*, December 1990

"Legal Issues Heat Up for Herbs," The American Herb Association, Vol. 8:1, 1991
"Milk Thistle for Liver Protection," *Better Nutrition,* January 1991
"Ginkgo: A Living Fossil and Modern Medicine," *Better Nutrition,* February 1991
"Ginseng: An Age-Old Panacea," *Better Nutrition,* March 1991
"The Herbally Aware Traveler," *Delicious!,* March 1991
"Herb: Just Another 4-Letter Word For Drug," *Longevity,* April 1991
"Astragalus: Keeping the Body Balanced," *Better Nutrition,* April 1991
"Herbs and the Environment," *Delicious!,* April 1991
"Labeling Law Challenges Herb Industry," *Herb Market Review,* Spring 1991
"Chinese Herbalism Gains Credibility," *Natural Foods Merchandiser,* June 1991
"The Soothing Effects of Chamomile," *Better Nutrition,* May 1991
"Bilberry: Health from Head to Toe," *Better Nutrition,* June 1991
"Goldenseal: Native American Treasure," *Better Nutrition,* July 1991
"Ginseng: Energy Enhancer," *The Energy Times,* July/August 1991
"Blessed Thistle: Nature's Antiseptic," *Better Nutrition,* August 1991
"Echinacea for the Immune System," *Better Nutrition,* September 1991
"Hawthorn for Heart Health," *Better Nutrition,* October 1991
"Garlic for Sound Circulation," *Better Nutrition,* November 1991
"Red Clover: Herbal Healer," *Better Nutrition,* December 1991
"Ginseng: Energy Booster," *Better Nutrition,* January 1992
"Garlic: Fantastic Health Aid," *Better Nutrition,* February 1992
"Antibiotic Properties of Echinacea," *Better Nutrition,* March 1992
"Ginkgo biloba: Ancient Healer," *Better Nutrition,* April 1992
"Cayenne: Hot Healer," *Better Nutrition,* May 1992
"Milk Thistle: Herbal Detoxifier," *Better Nutrition,* June 1992
"Bilberry for Circulation," *Better Nutrition,* July 1992
"Garlic: Herbal Antibiotic," *Better Nutrition,* August 1992
"Platinum Performance from Goldenseal," *Better Nutrition,* September 1992
"Chamomile: Calming Herb," *Better Nutrition,* October 1992
"Bitters: Nature's Tonic," *Better Nutrition,* November 1992
"Ayurveda: Ancient Healing Art," *Better Nutrition,* December 1992
"Heart Herb: Garlic," *Better Nutrition,* January 1993
"Circulation Herb: Ginkgo," *Better Nutrition,* February 1993
"Milk Thistle: Herbal Detoxifier," *Better Nutrition,* March 1993
"Echinacea: Immune Stimulant," *Better Nutrition,* April 1993
"Astragalus for Immunity," *Better Nutrition,* May 1993
"Bilberry for Circulatory Health," *Better Nutrition,* June 1993
"Ginseng: Mental Booster," *Better Nutrition,* July 1993
"Garlic: Infection Fighter," *Better Nutrition,* August 1993
"Chamomile, the World's Most Soothing Herb," *Better Nutrition,* September 1993
"Cayenne: A Spicy Remedy," *Better Nutrition,* October 1993
"Goldenseal - Medicinal Herb," *Better Nutrition,* November 1993
"Ayurvedic Medicine - A Balanced Approach," *Better Nutrition,* December 1993
"Boosting Immunity," *The Energy Times*, Vol. 2, No. 4
"What Form of Herbs Are for You?" *The Energy Times*, Vol. 3, No. 1
"The Healthful Pleasures of an Herb Garden," *The Energy Times*, Vol. 3, No. 2
"Traditional Chinese Medicine," *The Energy Times,* Vol. 3, No. 3
"Echinacea: Popular, Potent Herbal Extract," *Better Nutrition,* January 1994
"A Cup of Relief," *The Energy Times,* Vol. 4, No. 1
"Herbs for Long-Term Mental and Physical Stimulation," *Better Nutrition,* Feb1994
"Time Tested Benefits of Garlic," *Better Nutrition,* March 1994
"Herbal Lullabies to Gently Rock You to Sleep," *Better Nutrition,* April 1994
"How Much Do You Know About Ginkgo Biloba?" *Better Nutrition,* May 1994
"The Feminine Side of Herbal Therapies," *Better Nutrition,* June 1994

"Herbs in Your Medicine Chest," *The Energy Times,* May/June 1994
"Ayurvedic Medicine," *Better Nutrition,* July 1994
"Preserving Herbs at Home," *Energy Times*, July/August 1994
"Herbs to Halt Hypertension," *Better Nutrition,* August 1994
"Unearthing the Health Care of Goldenseal," *Better Nutrition*, September 1994
"Herbal Medicine Cabinet," *Energy Times*, September/October 1994
"When Hot is Healthy! The Pepper as a Medicinal Plant." *Energy Times*, Jan/Feb 1995
"Pros & Cons of Herbal Weight Loss Products," *Delicious!*, January 1995
"The World's Tastiest Medicine," *Delicious!*, February 1995
"Natural Medicines and Modern Health Care," *Delicious!,* March 1995
"Herbs Can Heal the Planet," *Delicious!,* April 1995
"Ginkgo: Nature's Circulation Booster," *Delicious!,* May 1995
" Upset Stomach? Try Ginger," *Delicious!*, June 1995
"High-Performance Herbs," *Delicious!*, July 1995
"Wild Remedies," *Energy Times*, July/August 1995
"10 Best Herbs to Keep You Healthy," *Delicious!*, August 1995
"Chasteberry: A Tonic for Menstrual Problems," *Delicious!*, September 1995
"Calming Herbs," *Energy Times*, September/October 1995
"Medicinal Mushrooms," *Delicious!*, October 1995
"Feeling Anxious? Take Valerian," *Delicious!*, November 1995
"Tea Time," *Energy Times*, November/December 1995
"Two Immune-Enhancing Herbs," *Delicious!*, December 1995
"The Fruits of Healing," *Delicious!*, February 1996
"Alternative and Complementary Medicine, Preventive Medicine, and Natural Healthcare," *Alternative Therapies*, March 1996
"Stay Mentally Alert with Ginkgo," *Delicious!*, May 1996
"Pain Relievers from Nature," *Delicious!*, June 1996
"Teas for Good Health," *Delicious!*, October 1996
"Neem: Ancient Herb From India," *Delicious!*, December 1996
"Herbs: With Caution," *Natural Health*, February 1997
"Protecting Endangered Herbs," *Delicious!*, May 1997
"Safety Requirements Are More Strict For Supplements Than For Pharmaceuticals," Opinion piece for *Herbs for Health*, May/June 1999.
"Echinacea: Nature's Way to Boost the Immune System," *Government West*, January/February 2000.

PROFESSIONAL ASSOCIATIONS

Alternative Medicine Foundation, Herbal Advisory Board, 1999-
American Herbal Products Assn., Trustee; Scientific Director, 1983-1989
American Society for Pharmacognosy, member
Columbia Univ.Rosenthal Ctr. for Alt/Comp Medicine, Advisory Group
Complete Wellness Education, Inc., Educational Board
Ethnopharmacology Society, member
Ginseng Research Institute, Advisory Board, 1980-1986
Herb Research Foundation, President and Founder
Herb Trade Association, Trustee; Scientific Committee Chair, 1979-1982
Natural Products EXPO, Planning Committee
North American Ginseng Association, Advisory Board
Society for Economic Botany, member
United Plant Savers, Advisory Board

Co-Publisher, *HerbalGram*
Technical Editor, *HerbalGram*, 1987-present

Co-Editor, *HerbalGram*, 1983-1987
Advisory Board, *Alternative Therapies in Health and Medicine Journal*
Editorial Board, *Delicious! Magazine*
Editorial Board, *Herbs for Health Magazine*
Editorial Advisory Board, *Natural Foods Merchandiser*
Editorial Advisory Board, *Natural Health Magazine*
Editorial Advisory Board, *Tea Trade Magazine*

EDUCATION

INSTITUTION	FIELD OF STUDY	YEAR
University of Texas, Austin	Biology	1968/70
University of Colorado, Boulder	Molecular/Cellular Biology and Botany	1976/79
Union Graduate School	PhD Program, Ethnobotany	1987
Union Graduate School	PhD Candidate, Ethnobotany	1990-
Institute of Food Technologists	Micro Analytical Entomology	Oct. 1976
DIALOG Information Services	Computer Bibliographic Retrieval	June 1982
	Medline Database Searching	May 1983
	Excerpta Medica Database Searching	May 1983
	Biosciences Database Searching	May 1983
Alec Mackenzie Center for Management Development	Time Management	Jan. 1983
	Developing A Professional Team	April 1983
Front Range Community College	Project Management	May 1983
Mountain States Employers Council	Communications Tools for Maximizing Performance	June 1983
Kraft Inc.	Presentation Skills	1986
	Management Development Seminar	1987
Union Institute	East-West Intercultural Dimensions	1988
Technical Assistance Center	Grant Writing	1990
Union Institute	Philanthropy Seminar	1992

INDEPENDENT STUDY

Laboratory analysis of botanicals, Pharmacology, Pharmacognosy, Toxicology, Food Technology, Computer Programming, Physiological Chemistry, Biochemistry, Lab Management, Research & Development, Technical Writing, Folk Medicine.

EMPLOYMENT HISTORY

1983-Present	Herb Research Foundation	Founder, President
1976-1989	Celestial Seasonings	Research Director

INTERNATIONAL DEVELOPMENT PROJECTS

1976-1989: Served as Research Director for Celestial Seasonings, Inc. Established and managed their analytical lab for quality assurance. Initiated and implemented international research programs on quality improvement in the countries of origin. Projects included the following:

Switzerland, Germany / April, 1980: Met with major European herb brokers, dealers and manufacturers. This was an important introduction to the commodities market in herbs and spices, largely controlled by European companies.

Egypt / April, 1980: Research mission to study cultivation and production of chamomile, spearmint and peppermint, and to assess and solve quality problems.

Sudan / May , 1980: Studied post-harvest cleaning of crude hibiscus calyces, and socioeconomic limitations to Sudanese herb production. Predicted loss of international market share due to persistent quality problems.

China / November, 1985: Studied hibiscus production in Southern China (Fujian Province), began collecting herbarium specimens of different cultivars. Worked to improve quality of rosehips, *Eleutherococcus*, lemon grass and other herbs.

Thailand / December, 1985: Preliminary research on improving Thai hibiscus, then inferior in major flavor attributes and with potentially serious contaminants. Also investigated lemon grass, ginger, galanga, bergamot, lime leaf and other herbs and spices.

Mexico / April, 1986: Researched production problems with lemon grass, raising its quality to match that of their major competitors. Began research on improving hibiscus in Mexico. Investigated production of cinnamon, "star tilia" (*Ternstroemia* spp.), licorice mint (*Agastache*) and others.

Thailand / October, 1986: Initiated cooperative project between the Royal Agricultural Project, three universities and Celestial Seasonings to explore the possible role of hibiscus and other herbs to replace opium poppy production in northern Thailand.

Philippines / November, 1987: Investigated the potential for herb production in the Philippines. Political instability at this time prevented an otherwise promising development project.

Singapore / November, 1987: Researched Singapore as a centralized collection and shipping center for Asian herbs. Singapore has overtaken Hong Kong as Asia's major shipping port. Herb production in this tiny country is unlikely because of prices and the premium on arable land. However, proximity to Malaysia could provide opportunities in the future for both countries.

Thailand / November, 1987: Evaluated research in progress and completed work on seed trials of 94 cultivars of *Hibiscus sabdariffa* in Northern Thailand. Conducted economic analysis of the costs of each step of hibiscus production and shipping, collected data on different methods of processing, drying and their quality impacts. Initiated trials of alternative drying technology for use in wet years.

China / November, 1987: Explored intensive cultivation of *Hibiscus sabdariffa* in China, contrasting it with methods used elsewhere. Also researched the growth, production and export of lemon grass, rosehips and other herbs.

Dominican Republic / May, 1987: Initiated test production of *Hibiscus sabdariffa* in the Dominican Republic in an area which produces primarily cotton; also in the *Malvaceae*. Hibiscus has not been produced in the Dominican Republic, but should grow well there. Seeds from Asia and Africa were planted on land belonging to the world's largest aloe farm. The purpose was to determine if a country so close to the U.S. could produce quality herbs at a competitive price.

Thailand / December, 1988: Collected and evaluated samples from drying tests and cultivar trials; studied regional differences in production and quality management from field to shipping.

China / December, 1988: Market study of all aspects of herb production, processing, transport, warehousing, quality control, marketing and shipping. Explored several botanicals with high market potential in the U.S. and Europe which are currently underutilized.

Senegal / May, 1992: Researched hibiscus and mangoes for a project sponsored by USAID and the OICD office of USDA. Evaluated the feasibility of establishing a fruit concentrate factory in Dakar, using dried hibiscus concentrate as a potential off-season product.

Uganda / November, 1993: Performed field research on high capital yield herb cash crops. Sponsored by USAID.

Zambia / September, 1994: Agroindustrial Markets Workshop: Co-Facilitator. Sponsored by USAID.

African-American Institute/USAID Africa Bureau, Washington, DC, December, 1994. "Trade and Investment Opportunities in Natural Products from Southern Africa."

India / March, 1995: International Conference on Horticultural Development. Presenter on "Product, Technology and Market Opportunities in Medicinal Herbs." Sponsored by USAID and ICICI (Industrial Credit and Investment Corporation of India Limited).

India / March, 1995: Horticultural Development Conference. Speaker on "The Botanicals Marketplace." Sponsored by Agricultural & Processed Food Products Export Development Authority (APEDA).

USAID Agricultural Marketing and Private Sector Collaborators Workshop, April, 1995: Forum participant for review and planning for AID/Washington private sector development activities in sub-Saharan Africa.

Mali / 1995-1996: Assessed opportunities for botanicals agribusinesses. In-depth exploration of marketing opportunities. Established test herb crop in May, 1995. Crop evaluation, training in harvest methods and production of value added products. Successful negotiations for purchase of 1996 crop by large tea manufacturer. Oversaw harvesting of 11 tons of herb crop (for export and local distribution), and completion of project which provided income and training for more than 1,000 people from 280 participating subsistence farmers in the Niger River Valley. Sponsored by USAID, with Ronco Consulting (USAID contractor).

South Africa / November 1996: Assessed opportunities for botanicals agribusinesses for USAID-sponsored projects. In cooperation with The Rural Foundation, HRF will work with disadvantaged farmers on projects which will provide income from herbal cash crops as well as better access to low cost botanical health care. The challenge is threefold: to help protect wild plant populations by cultivating over-collected species, to foster regional production of traditional herbal remedies, and to develop cash crops for low-income farmers. Sponsored by USDA/USAID Africa Bureau.

Manila, Philippines / June 1997: BIO-Search '97 Southeast Asian Regional Conference and Exhibition on Natural and Herbal Products. Produced by Center for International Trade Expositions and Missions. Guest presenter: "Botanicals in Healthcare," and facilitator of workshops on herbal product development and marketing.

Ontario, Canada / October 6, 1997: Nonprescription Drug Manufacturers of Canada Board of Directors meeting. Guest presenter: "Emerging Opportunities for Botanicals in Healthcare."

Mendoza, Argentina / November 10-15, 1997: II World Congress on Medicinal and Aromatic Plants for Human Welfare. Organized by the International Council for Medicinal and Aromatic Plants, International Society for Horticultural Sciences, and the Sociedad Argentina para la Investigación de Productos Aromáticos. Guest presenter: "Registration of herbal preparations as drugs," and "Technical and Legal Aspects of the Regulation of phytomedicines."

Mali, Africa / November 25, 1997: Botanical Agribusiness in Mali: Focus on Hibiscus. Key presenter at day-long workshop for businesses. Sponsored by USAID.

Sao Paulo, Brazil / March 23-24, 1998: III Herbal Medicinal Products Conference. Sponsored by the Association of Pharmaceutical Industry in the State of Sao Paulo. Guest presenter: "Scientific Evidence for the Safety and Efficacy of Medicinal Botanicals."

Assilah, Morocco / April 21-14, 1998: Moroccan Association for the Development of Aromatic and Medicinal Plants. Sponsored by USAID's Moroccan Agribusiness and Promotion Project and Agribusiness Marketing Investment (AMI). Guest Presenter: "Intensification of Mint Production."

Accra, Ghana / April 27-30, 1998. Consultant on conversion of the former Ghanaian pharmaceutical manufacturing plant into a herbal and natural products development and production and center.

South Africa / May 3-8, 1998. Assessed opportunities for botanicals agribusinesses and for improving local agricultural research and business development networks. TheUSAID-sponsored pilot projects in several areas of South Africa are in cooperation with the Agriculture Research Council of the Republic of South Africa. The botanical pilot projects partner traditionally disadvantaged rural economies with resources necessary to contribute to the economic growth of their communities. If successful, the projects will be implemented in other sub-Saharan countries.

Baltimore, MD / September 8-14, 1998. International Agribusiness Symposium co-sponsored by Herb Research Foundation and USDA/USAID. Guest presenter: "Herbs 101," and "International Botanical Marketplace."

Delhi, India / October 27-November 8, 1998. Consultant with large organic tea grower and natural products manufacturer on product line development.

Cairo, Egypt / November 11-17, 1998. Consultant with USAID contractor RONCO on development of botanical businesses in Egypt for entrance into the international marketplace.

South Africa and Madagascar/ April 8-27, 1999. Continued work on business development networks for this USAID-sponsored pilot projects in several areas of South

Africa are in cooperation with the Agriculture Research Council of the Republic of South Africa. Assessed potential for various agribusiness pilot projects in Madagascar. The botanical pilot projects partner traditionally disadvantaged rural economies with resources necessary to contribute to the economic growth of their communities.

South Africa / April 4-6, 2000. Host for Agribusiness in Sustainable Natural African Plant Products (A-SNAPP) Roundtable. Gathering of 150 producers of African natural products and related organizations to network and learn about the opportunities and constraints of the global natural products marketplace. This was the first of several planned events during A-SNAPP's 3 year program, a USAID funded and HRF managed program to facilitate business linkages between African producers and both regional and international buyers of natural products including herbs, spices and aromatic plants. Presenter: "North American natural products and botanicals marketplace" and "International Trade and Regulation of Plant Based Products." Panelist: "An A-SNAPP approach to natural plant product commercialization: Africa – a potential supplier of natural plant products."

ROBERT S. MCCALEB

Background

Rob McCaleb is founder and president of the Herb Research Foundation in Boulder, CO, an internationally recognized research and education organization dedicated to providing facts on the health benefits of herbs. The Herb Research Foundation has over 250,000 scientific studies and references on file covering thousands if herbs used in foods, dietary supplements, medicines and cosmetics. HRF, under Rob's direction tracks the scientific study of these plants throughout the world, providing the latest research information to scientists, doctors, the media and public. Its goal is to support and encourage herb research and education, and to promote responsible and informed herb use.

Rob has over 20 years' experience in botanical research and business. He was Research Director for Celestial Seasonings (America's largest herbal tea company) for 13 years and served on the Board of Directors of the American Herbal Products Association and Herb Trade Association. He was one of five scientists appointed by President Clinton to the Commission on Dietary Supplement Labels.

He has also served as an advisor to U.S. Congress, the Office of Technology Assessment, the Office of Dietary Supplements, the Office of Alternative Medicine and other federal and state agencies. He has educated hundreds of doctors and pharmacists through Harvard and Columbia Medical Schools' programs and other Continuing Medical Education programs.

Mr. McCaleb lectures and writes widely on medicinal plants. He is co-author of *The Encyclopedia of Popular Herbs* and serves on the editorial boards of a number of popular and scientific publications, including *HerbalGram, Herbs for Health, Natural Health, Journal of Alternative and Complementary Medicine* and others. Educated in Cellular Biology and Botany at the University of Texas and University of Colorado, he is currently a PhD candidate in ethnobotany at Union Institute. His international work has involved development of herbs as cash crops and medicinal resources throughout Africa and Asia since 1980, including projects for U.S. Agency for International Development and the U.S. Department of Agriculture.

Key focus and strengths

Scientific research and validation of benefit claims and safety for herbs; substantial writing experience, both commercial and informational; product formulation experience in both flavor and functionality; regulatory expertise in food and drug law; agroeconomics of commercial herb production; quality assurance programs and testing methodology. Excellent presentation skills and materials.

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Research Funding Policy

Testimony of Robert S. McCaleb
President, Herb Research Foundation
October 5, 2000

The Herb Research Foundation, founded in 1983 is a nonprofit research and educational organization focusing on herbs used for food, supplements, conventional and folk medicines. We are primarily a specialty library of current journal literature on the safety and efficacy of herbs. HRF is not a grant-making foundation and does not fund original research. Over the past 17 years, we have assembled one of the nation's best collections of scientific, cultural and historic information about the use of herbs for health care. HRF uses this resource to help educate the public, doctors, pharmacists, other health care providers, government agencies and the international community, as well as the media, about the rational, safe, appropriate and effective use of herbs in health care.

I have worked with the herb industry for over 25 years, including 13 years as Research Director of the nation's largest herbal tea company, Celestial Seasonings. I was appointed and served on the Commission on Dietary Supplement Labels (CDSL), which discussed many of the issues you are grappling with today.

The United States has produced very little research on alternative and complementary medicine in recent decades. Drug research and approval costs have skyrocketed to an average of $350 million per drug, and natural products, because they are not patentable, are not viable candidates for this level of research funding. In the past 40 years, the US has failed to approve a single new drug from nature without special patent or orphan drug protection. All the best researched and most widely used herbal medicines have lengthy histories of use or extensive published information, excluding them from patent protection and hence new drug status. As these natural remedies fell into disuse, medical and pharmaceutical education dropped them from the curricula. Natural product experts were no longer a part of the hierarchy of grant-making organizations and government agencies. We successfully shut down all but a minimal level of natural product research in the US.

American natural product research in the last half of the 20th century has focused primarily on finding and identifying single chemical compounds in plants in the hope that they could become patentable synthetic or purified monosubstance drugs. The majority of research and the best of that research during this time has been done in Europe and Asia. Many of the 250,000 scientific articles in the Herb Research Foundation archives are from European and Asian researchers.

What can we do to return natural products research to a place of prominence in the USA?

The question has been answered in part by the Dietary Supplement Health and Education Act of 1994, DSHEA. This law has created more private research incentives than any other factor in recent decades. Since its enactment, research sponsored by American companies has increased dramatically. Government and academic research has increased as well. The incentive here, as in Europe, has been the ability to make health benefit claims based on quality research, and the marketing power of having clinical studies on a company's own products, not using "borrowed science" in the form of other companies' research. Clearly, though, not every one of the hundreds of products based on one herb needs igts own clinical research. We simply do not have enough money or researchers to have independent clinical trials on each of the thousands of herbal products on the market.

It has been suggested that we let the companies that fund major herbal drug research have limited exclusivity for their claims. But is it fair for any company to buy an exclusive claim for a plant whose benefits have been known for centuries?

Shortly after the passage of DSHEA, the FDA seemed intent on treating dietary supplements as "new drugs," even though tens of thousands or even millions of Americans were already using these products. Acupuncture needles were initially treated as "new" medical devices. Changes in these policies have already eased the cost of research and created opportunities for advances in high quality CAM research in the US.

The CDSL recommended strongly that the FDA establish a natural products over-the-counter (OTC) drug review panel to review herbal products as OTC drugs. If the threshold of research needed to satisfy that panel were reasonable, or at least no higher than that threshold applied to the majority of currently approved OTC drugs, there would be a very strong incentive for private and public funding of research into natural product medicines. The same may be true of other CAM therapies. If approval policies allow for a realistic and economically viable path to approval, research will be forthcoming.

In terms of government-sponsored and academic research on CAM therapies and agents used in those therapies, we need to make a strong and effective effort to include on the review boards for research funding, experts in these fields.

We believe that the US has entered a new era, in which medicine can become truly integrated, in which we can use the best of natural products, alternative, complementary and conventional therapies to offer greater treatment options for Americans and their physicians. We believe that this can be accomplished by cooperation between government, academia and industry. We believe that this can be accomplished in an atmosphere of rigorous and open-minded scientific and medical investigation, and that the results can have a major and lasting effect on public health and quality of life.

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY
Testimony for Meeting on Obstacles and Barriers to CAM Research, October 5-6, 2000

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INTRODUCTION:

Until 25 years ago, chiropractic research was vastly underdeveloped and appeared to some as an oxymoron. In 1975, a conference at the NINDS/NIH concluded that "There are little scientific data or significance to evaluate this [chiropractic's] clinical approach to health and to the treatment of disease."[1] From that time onward, both clinical and basic research have advanced to the point at which [i] over 40 randomized clinical trials comparing spinal manipulation with other treatments in the management of back pain have been published in the scientific literature,[2,3] [ii] meta-analysis and systematic reviews attesting to the support of spinal manipulation in the management of back pain[4,5] have also appeared, and [iii] multisidciplinary panels representing the governments of the United States,[6] Canada,[7] Great Britain,[8] Sweden,[9] Denmark,[10] Australia,[11] and New Zealand[12] have expressed similar recognition of the robust evidence base in support of spinal manipulation for managing low back conditions.

BARRIERS:

The efforts to launch and develop a National Center for Complementary and Alternative Medicine within the framework of the NIH are indeed admirable, taking the Center from a humble $2M annual budget in 1991 to one that approaches $70M today. This has taken place despite the comments of highly visible and influential individuals within the medical community to discredit alternative medicine in virtually any shape or form, a topic that I shall return to momentarily. Following are what I believe to be the most significant barriers to research efforts in alternative medicine, the barriers having either remained in place or only recently having been removed.

1. Collaborative arrangements:

Dating from the first RFA in March 1993, the Office of Alternative Medicne required that researchers in alternative medicine collaborate with people from an orthodox medical background, described as "individuals familiar with conventional research methodologies."[13] The implication was that researchers in alternative medicine, having fewer resources and shorter bibliographies than their allopathic counterparts to begin with, were somehow less qualified to pursue research questions of any kind. With the lack of exposure to either the theory or practice of alternative medicine modalities, potential allopathic medical collaborators had to overcome both gaps in knowledge and professional prejudices in order to become allied with alternative medical researchers, clearly delaying their efforts to launch research programs fundable from a federal point of view.

Furthermore, directing grant funding and their associated indirect costs toward allopathic medical centers rather than specific institutions in alternative medicine served to delay the building of the research infrastructure specifically within alternative medicine. NCCAM's establishment of specific research centers [including the chiropractic center at Palmer University] and its recent provision of RO1 programs [in which individual researchers in CAM may step forward as the PI on a fundable grant application] are major steps in overcoming this obstacle.

2. Domestic institutions:

A number of major milestones of research that have significantly lowered barriers to both the practice and research of chiropratic have been accomplished abroad. The low-back studies of Meade [Great Britain],[14,15] the cervicogenic and tension headache studies of Nilsson [Denmark],[16,17] the first randomized clinical trial addressing colic--possibly a nonmusculoskeletal condition in infants--[Denmark],[18] and numerous asthma

case reports[19] and a pilot for a randomized clinical trial from Australia[20] to lay the foundation for future clinical trials directed at this condition are but a few outstanding examples. Thus the requirement of many past federal programs restricting grants to *domestic institutions only* represents a major impediment to the accomplishments and potential of research in alternative medicine–which recognizes no national boundaries and which has clearly benefited from the additional resources available beyond American borders.

3. Composition and proceedings of institutional review boards:

Undoubtedly institutional review boards are an indispensable component of insuring patient safety and knowledgability in a clinical trial.[21] From this writers' firsthand experience, however, there have been instances in which a proposed randomized clinical trial within a major medical center have been rejected out of hand from what was probably the harboring of anti-chiropractic sentiments by the head of the IRB, who among other transgressions referred to this treatment alternative as "chiropracty." While implementing panels to monitor the behavior of IRBs may appear excessive, the issue does bear further scrutiny in the event that viable and safe alternatives in the patients' interest fall victim to prejudice within an IRB.

4. Composition of study sections:

For many of the same reasons as in the previous section, there must be an equitable number of individuals within each study section of a grant proposal who are familiar with and sensitive to the conduct of the therapeutic regimens to be tested. Common sense dictates that as eloquent and sympathetic a presentation of the therapies to be studied be made to the study section as a whole. This writer recalls with dismay an egregious violation of this principle in the first round of alternative medicine applications reviewed by the OAM in 1993, in which only a single member among the eight 17-member study sections drafted by the NIH was a chiropractor, who was unfortunately undistinguished as a researcher and lacked the necessary background to provide constructive critiques of grant proposals in this field. Adding insult to this injury was the fact that the OAM had been provided with the names of over 15 highly qualified and accomplished chiropractic researchers. Completing this sorry state of affairs was the fact that these sections were charged with reviewing over 400 applications, *nearly half of which pertained to chiropractic*. Providing properly balanced and enlightened study sections reviewing grant applications is clearly an absolute requisite for reducing significant barriers to the conduct of CAM research.

5. Publication bias and quotas:

Examples can be introduced of editorial bias and quotas which have prevented the most robust of chiropractic research from reaching necessary audiences. A headache study by Boline,[22] for instance, rated the highest in quality by two independently conducted systematic literature reviews,[23,24] was denied publication at The New England Journal of Medicine, Headache, and Cephalalgia before finally appearing in the Journal of Manipulative and Physiological Therapeutics two years later. Examples exist in which editorial comments to the principal authors of studies have clearly indicated that obtaining *negative* results for spinal manipulation was the criterion for acceptability for publication.[25,26] Thus it is with dismay that this writer finds two inferior and widely-publicized studies in chiropractic which *did* get published in the New England Journal of Medicine,[27,28] extensive rebuttals of which have been published elsehwere.[29-32] Statements by two previous editors of the New England Journal of Medicine offer little encouragement, as they have been patently biased with little qualificaton in their negative assessments of alternative medicine.[33,34]

Publication quotas likewise impede the dissemination, and therefore the incentive, to perform CAM research. The American Journal of Public Health, for example, allows the publication of but one chiropractic study per year based upon current membership. While subsidization of publication costs through membership is entirely appropriate, restricting access of information from a modality which has been experienced by 37% of the American population at some point in their lifetime[35] appears arbitrary and Draconian.

6. Distortion of research results in the press and in the journals:

The crippling effects of bias and editorial policy of certain medical journals just discussed has ramifications in what is actually stated in papers and subsequently in the lay press. One study published in the New England Journal of Medicine, for instance, stated a conclusion that was far beyond anything supported by the data. Specifically, the study discouraged the routine referral of patients to chiropractic: "Given the limited benefits and high costs, it seems unwise to refer patients with low back pain for chiropractic or McKenzie therapy."[27] As egregiously out-of-bounds as a statement such as this is for a scientific journal, the lay press [to which the NEJM reportedly controls half of what health news we hear of] only made matters worse. Such scare headlines as "Study Targets Worth of Chiropractic,"[35] and "Chiropractic Care Blasted in Two Studies"[37] only poisoned the atmosphere, inhibiting further research efforts and inducing third party payors to deny reimbursements for chiropractic services in which the outcomes have yet to be definitively disproved. News releases such as these need to be actively discouraged, and the public needs to be further enlightened as to the research and potential of multiple modes of alternative therapy--not just chiropractic.

7. Mainstream vs alternative status of chiropractic:

Primarily due to the aforementioned research accomplishments regarding spinal manipulation and low-back pain,[2-7,14,15] chiropractic intervention has often been regarded as "mainstream" rather than alternative in the management of low-back pain--[8-12] and possibly at least some types of headache as well.[16,17,22-24] However, in the treatment of asthma,[19,20,28,32] scoliosis,[38,39] otitis media,[40-42] infantile colic,[18,43] enuresis,[44] repetitive stress disorders,[45-48] dysmenorrhea[49-51] and premenstrual syndrome,[52-54] chronic pelvic pain,[55] GI dysfunctions,[56-58] and attention deficit disorder/hyperactivity,[59] chiropractic must be regarded as an alternative therapeutic approach. As a hybrid, therefore, chirorpactic should therefore be regarded as having important attributes of alternative medicine. Accordingly, it should therefore not be dismissed as only a mainstream specialty ineligible for funding from sources that are supporting research in alternative medicine.

8. The origins of mainstream medicine:

As suggested in the preamble to the 5-year Strategic Plan of NCCAM, "As CAM practices once considered unorthodox...are proven safe and effective by rigorous scientific investigation, they become part of mainstream healthcare." This is certainly the way one hopes to transform good research into practice and clearly represents the mission of both NCCAM and our Foundation. However, since only 15% of medical procedures have been reported to be supported by any documentation[60] and only 1% is considered to be scientifically sound,[61] it is presumptuous to assume that what is currently accepted in standard medical procedures is intrinsically robust from a scientific point of view. Have large-scale clinical trials supported the use, for instance, of every variation of catheter used in angioplasty, for instance? One need only consult the Merck Index of 100 years ago to realize that the following treatments--now woefully inadequate, outdated, and even dangerous--were unflinchingly accepted into the mainstream as *de rigeur*[62] within at least some of our lifetimes:

1. Formaldehyde for the common cold,
2. Aresenic or ammonia for baldness,
3. Opium and morphine for typhoid fever,
4. Blood-letting and chloroform for streptococccal infections; and
5. Strychnine, ice and lemon juice for diphtheria.

Thus, it is my belief that the idealism expressed regarding the origins of mainstream practices [in medicine or elsewhere] has to be tempered with realism. It is simply unreasonable to expect that every procedure and variation in healthcare delivery will be supported by a randomized clinical trial.

9. Intervention paradigms:

Perhaps most flagrantly illustrated by both studies published in the New England Journal of Medicine,[27,28] chiropractic must never be confused with merely high-velocity thrusting of the spine. Such is to reduce it to a one-dimensional specialty of cracking joints. Indeed, low-force contact procedures that have been incorrectly classified as placebos [shams][28] have actually been shown to produce major improvements in both lung functional tests and patient symptoms with regard to asthma.[63]

According to the preamble of the charter for the Council of Chiropractic Education, chiropractors are fully trained as a portal of entry primary care health service capable of complete diagnosis. The Council of Chiropractic Education has accrediting status with the U.S. Department of Eeucation [since 1974] and the Council on Postsecondary Accreditation [since 1976]. Among the therapeutic regimens for which chiropractors are licensed to administer are the use of hot and cold packs, electrical stimulation, soft tissue procedures [including trigger point therapy], and nutritional counseling.[64]

Building upon preliminary studies appearing just this year,[65,66] more attention needs to be paid to *long-term outcomes* and *supportive care*. These attributes may differ somewhat from allopathic medicine's historical approach to disease management. The point is to emphasize the effects of interventions over the long term, which have the potential of forestalling or preventing far more invasive and expensive procedures which are substantially riskier for the patient. In terms of overall cost control and offering the possibility of reducing both the costs and morbidity of medication error-related deaths,[67,68] the implications of earlier intervention by alternative medical procedures are enormous.

10. The role of the RCT:

There is no doubt that the RCT remains an important piece of the mosaic of evidence that needs to be assembled to substantiate a clinical procedure. However, it is certainly not the only piece and in many instances in my experience has been overrated:

1. In a highly publicized randomized clinical trial regarding the use of chiropractic in managing asthma,[28] both the use of a highly invasive sham procedure [an inappropriate placebo] and the possibility of small sample sizes obscuring possible effects by a Type II error have led to misleading conclusions, let alone interpretation by the lay press.[36,37]

2. Another highly visible clinical trial comparing three interventions in the management of acute low-back pain[27] suffered from poor design[30] and inappropriate statistical procedures[31] Worse, it implied that a single intervention represented chiropractic care such that its clinical relevance was highly questionable. Indeed, the Royal College of General Practitioners in a very recent systematic review of the literature designed to update the CSAG Guidelines of the United Kingdom[8] has concluded that this trial neither adds nor detracts from the evidence base regarding appropriatge interventions for low-back pain.[69]

3. A meta-analysis has shown that contrasting interpretations can be obtained, depending upon which of 25 scales used to distinguish between high- and low-quality trials is actually employed.[70]

4. A review of clinical trials comparing two antifungal agents has indicated that the apparent advantages of one of the instruments could have been obtained by manipulations of the design of most of the trials, in which the competing agent was inappropriately administered.[71]

5. The weight of evidence produced by clinical trials may be overcalculated due to the fact that the clinical trials are overrepresented as duplicate, "sausage" publications by the same authors.[72-75]

6. Methdological scores attached to clinical trials create a misleading profile of high- and low-quality studies if they place too much emphasis upon sham procedures which we already know will seriously compromise controlled studies involving physical methods such as spinal manipulation if they are not true placebos. In other instances, the mere utterance of such terms as "blinded" or "randomized" in the title of the paper cited may be sufficient to glean points in the rating of clinical trials--even though such terms are never defined or qualified. The proper remedy in this instance would be to *demote* the trial ratings if such terms are inappropriately used.[70]

The point to realize here is that RCTs are subject to misinterpretation and outright abuse. Their generalization from a fastidious, defined laboratory setting is problematical. It is sometimes forgotten that the source of randomized clinical trials remains the *sound, well-documented observations in the clinical setting*. This has led no less an epidemiologist than David Sackett to conclude that there are essentially two pillars of sound clinical evidence, only one of which is experimentally derived from the RCT:[76]

"External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision."

In light of these many arguments, I would maintain that the WHCCAMP should place far greater emphasis upon cohort studies and case series in its research goals rather than assume categorically that they provide inferior guidance to clinical decision-making than RCTs. It should be quite clear from this discussion that a well-crafted cohort or case series is far more informative than a flawed or corrupted RCT.

SOLUTIONS:

In light of the foregoing discussion, I would recommend that the WHCCAMP pursue the following:

1. Encourage all qualified researchers in alternative medicine to apply for federal and private grant support, taking into account refusals of attempted publication in peer-reviewed medical journals.

2. Encourage researchers from around the world rather than only from American soil to apply for such support;

3. Institute an appeals process if a research team believes that an Institutional Review Board has turned down a research proposal unfairly;

4. Ensure that all study sections include a sufficient number of individuals who are both familiar with and sensitive to the therapeutic regimens described within the proposal under review;

5. Frame and encourage legislation which encourages better communication of both researchers and practioners of alternative medicine with the media, limiting the contacts with those journals found to harbor unjustifiable biases against alternative medical procedures.

6. Ensure that chiropractic is recognized as both a mainstream and an alternative intervention, depending upon the condition for which therapy is indicated. Accordingly, ensure that chiropractic is excluded from neither category in terms of grant eligibility and collaboration.

7. Encourage research directed at long-term outcomes and supportive care, areas which have commonly been neglected in allopathic medical care and which offer the possibility of low-cost, preventive health management.

8. Ensure that chiropractic is not limited to referral-only specialty care limited to the back, based upon current accreditation, licensure, and research. In this regard, it is to be appreciated as a direct portal of entry for patient care--appreciating the ability of chiropractors to diagnose and apply treatments that are broader in scope than merely high-velocity thrusts.

9. Appreciate the limitations of randomized clinical trials, admitting well-designed and well-executed cohort and case studies into the evidence base supporting a given intervention.

10. Frame and encourage legislation which does not permit third party payors to restrict reimbursements beyond the scope of practice currently stipulated by licensure laws within the states.

11. Coordinate activities with NCCAM and avoid duplication of efforts whereever possible.

12. Encourage private sources to invest in all types of alternative and mainstream medical research with adequate oversight. This would have the twofold benefit of offsetting the phramaceutical industry's virtual monopolizing the private support of medical research, as well as offering a variety of measures to reduce the chances of having research quality compromised.

REFERENCES:

[1]Goldstein M [ed]: Monograph No. 15. The research status of spinal manipulation, U.S. Department of Health, Education, and Welfare, Washington, DC, February 3-4, 1975.

[2]Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter LM. Spinal manipulation for low-back pain: A updated systematic review of randomized clinical trials. Spine 21(24): 2860-2871.

[3]van Tulder M, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain: A systematic review of randomized controlled trials of the most common interventions. Spine 1997; 22(18): 2128-2156.

[4]Anderson R, Meeker WC, Wirick BE, Mootz RD, Kirk DH, Adams A. A meta-analysis of clinical trials of spinal manipulation. Journal of Manipulative and Physiological Therapeutics 1992; 15(3): 181-194.

[5]Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low-back pain. Annals of Internal Medicine 1992; 117(9): 590-598.

[6]Bigos S, Bowyer O, Braen G, et al. Acute low back pain in adults. Clinical practice guideline No. 14. AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. December 1994.

[7]Manga P, Angus D, Papadopoulos C, Swan W. The effectiveness and cost-effectiveness of chiropractic management of low-back pain. Ottawa, Ontario, CANADA: Pran Manga & Associates, Inc., University of Ottawa, 1993, pp 65-70.

[8]Rosen M. Back pain. Report of a Clinical Standards Advisory Group Committee on back pain. May 1994, London: HMSO.

[9]Commission on Alternative Medicine, Social Departementete, Legitimization for Vissa Kiropraktorer, Stockholm, SOU [English Summary] 1987; 12: 13-16.

[10]Danish Institute for Health Technology Assessment: Low-back pain, frequency, management, and prevention from an HTA perspective. Danish Health Technology Assessment 1999; 1(1).

[11]Thompson CJ. Second Report, Medicare Benefits Review Committee, Canberra, AUSTRALIA: Commonwealth Government Printer, June 1986, Chapter 10 [Chiropractic].

[12]Hasselberg PD. Chiropractic in New Zealand, Report of A Commission of Inquiry. Wellington, NEW ZEALAND: Government Printer, 1979.

[13]NIH Guide, March 26, 1993; 22(12).

[14]Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Low back pain of mechanical origin: Randomised comparison of chiropractic and hospital outpatient treatment. British Medical Journal 1990; 300: 1431-1437.

[15]Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Randomised comparison of chiropractic and hospital outpatient management for low back pain: Results from extended follow-up. British Medical Journal 1995; 311: 349-351.

[16]Nilsson N, Christensen HW, Hartvigsen J. The effect of spinal manipulation in the treatment of cervicogenic headache. Journal of Manipulative and Physiological Therapeutics 1997; 20(5): 326-330.

[17]Bove G, Nilsson N. Spinal manipulation in the treatment of episodic tension-type headache. Journal of the American Medical Association 1998; 280(18): 1576-1579.

[18]Wiberg JMM, Nordsteen J, Nilsson N. The short-term effect of spinal manipulation in the treatment of infantile colic: A randomized controlled trial with a blinded observer. Journal of Manipulative and Physiological Therapeutics 1999; 22(8): 517-522.

[19]Jamison JR, McEwen AP, Thomas SJ. Chiropractic adjustment in the management of visceral conditions: a critical appraisal. Journal of Manipulative and Physiological Therapeutics 1992; 15(3): 171-180.

[20]Hayek R, Ali S, Brice C. Asthma and chiropractic: An Australian trial [single blind cross over study]. Proceedings of the 1998 International Conference on Spinal Manipulation, Vancouver, British Columbia, July 16-19, 1998, pp. 72-74.

[21]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Institutional Review Boards. Washington, DC: U.S. Government Printing Office, 1978.

[22]Boline P, Kassak K, Bronfort G, Nelson C, Anderson AV. Spinal manipulation vs. amitriptyline for the treatment of chronic tension-type headaches: A randomized clinical trial. Journal of Manipulative and Physiological Therapeutics 1995; 18(3): 148-154.

[23]Hurwitz EL, Aker PD, Adams AH, Meeker WC, Shekelle PG. Manipulation and mobilization of the cervical spine: A systematic review of the literature. Spine 21(15): 1746-1760.

[24]Kjellman GV, Skagren EI, Oberg BE. A critical analysis of randomised clinical trials on neck pain and treatment efficacy: A review of the literature. Scandavian Journal of Rehabilitative Medicine 1999; 31: 139-152.

[25]Brennan P. Personal communication, 1992.

[26]Nilsson N. Publication bias in the medical journals: An n of 1 study. Presentation at the 2000 International Conference on Spinal Manipulation, Bloomington, MN, September 24, 2000.

[27]Cherkin DC, Deyo RA, Battie M, Street J, Barlow W. Comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. New England Journal of Medicine 1998; 339(14): 1021-1029.

[28]Balon J, Aker PD, Crowther ER, Danielson C, Cox PG, O'Shaugnessy D, Walker C, Goldsmith CH, Duku E, Sears MR. A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. New England Journal of Medicine 1998; 339(15): 1013-1020.

[29]Rosner AL. Response to the Cherkin article in The New England Journal of Medicine. Dynamic Chiropractic November 2, 1998; 16(23).

[30]Chapman-Smith D. Back pain, science, politics and money. The Chiropractic Report November 1998; 12(6).

[31]Freeman MD. A critical evaluation of the methodology of a low-back pain clinical trial. Journal of Manipulative and Physiological Therapeutics 2000; 23(5): 363-364.

[32]Blum CL. Chiropractic and sacro-occiptal technique in asthma treatment. Chiropractic Technique 1999; 11(4): 174-180.

[33]Bunk S. Is integrative medicine in the future? Debate between Andrew Weil, M.D. and Arnold Relman, M.D. The Scientist 1999; 13(10): 1,10-11.

[34]Angell M, Kassirer, JP. Alternative medicine - The risks of untested and unregulated remedies. New England Journal of Medicine 1998; 339(12): 839-841.

[35]www.Intersurvey.com, July 2000.

[36]Haney DC. Associated Press, October 8, 1998.

[37]Des Moines Register, October 8, 1998, p. 1.

[38]Plaugher, G, Cremata EE, Phillips, R. A retrospective consecutive case analysis of pretreatment and comparative static radiological parameters following chiropractic adjustments. Journal of Manipulative and Physiological Therapeutics 1990; 13(9): 498-506.

[39]Tarola GA. Manipulation for the control of back pain and curve progression in patients with skeletally mature idiopathic scoliosis: two case studies. Journal of Manipulative and Physiological Therapeutics 994; 17(4): 253-257.

[40]Froehle RM. Ear infection: A retrospective study examining improvement from chiropractic care and analyzing for influencing factors. Journal of Manipulative and Physiological Therapeutics 1996; 19(3): 169-177.

[41]Fallon J. The role of chiropractic adjustment in the care and treatment of 332 children with otitis media. Journal of Clinical Chiropractic Pediatrics 1997; 2(2): 167-183.

[42]Degenhardt BF, Kuchera ML. Efficacy of osteopathic evaluation and manipulative treatment in reducing the morbidity of otitis media in children. Journal of the American Osteopathic Association 1994; 94(8): 673.

[43]Klougart N, Nilsson N, Jacobsen J. Infantile colic treated by chiropractors: a prospective study of 316 cases. Journal of Manipulative and Physiological Therapeutics 1989; 12(4): 281-288.

[44]Reed WR, Beavers S, Reddy SK, Kern G. Chiropractic management of primary nocturnal enuresis. Journal of Manipulative and Physiological Therapeutics 1994; 17(9): 596-600.

[45]Sucher B. Palpatory diagnosis and manipulative management of carpal tunnel syndrome. Journal of the American Ostoepathic Association 1994; 94(8): 647-663.

[46]Strait BW, Kuchera ML. Osteopathic manipulation for patients with confirmed mild, modest and moderate carpal tunnel syndrome. Journal of the American Osteopathic Association 1994; 94(8): 673.

[47]Davis PT, Hulbert JR, Kassak KM, Meyer JJ. Comparative efficacy of conservative medical and chiropractic treatments for carpal tunnel syndrome: A randomized clinical trial. Journal of Manipulative and Physiological Therapeutics 1998; 21(5): 317-326.

[48]Bersten G, McCarthy K. Conservative chiropractic approaches to carpal tunnel syndrome. Topics in Clinical Chiropractic 1999; 6(4): 62-72.

[49]Liebl NA, Butler LM. A chiropractic approach to the treatment of dysmenorrhea. Journal of Manipulative and Physiological Therapeutics 1990; 13(3): 101-106.

[50]Boesler D, Warner M, Alpers A, Finnerty EP, Kilmore MA. Efficacy of high-velocity low-amplitude manipulative technique in subjects with low back pain during menstrual cramping. Journal of the American Osteopathic Association 1993; 93(2): 203-214.

[51]Kokjohn K, Schmid DM, Triano JJ, Brennan PC. The effect of spinal manipulation on pain and prostaglandin levels in women with primary dysmenorrhea. Journal of Manipulative and Physiological Therapeutics 1992; 15(5): 279-285.

[52]Stude DE. The management of symptoms associated with premenstrual syndrome. Journal of Manipulative and Physiological Therapeutics 1991; 14(3): 209-216.

[53]Walsh MJ, Chandraraj S, Polus BI. The efficacy of chiropractic therapy on premenstrual syndrome: a case series study. Chiropractic Journal of Australia 1994; 24(4): 122-126.

[54]Walsh MJ, Polus BI. A randomized, placebo-controlled clinical trial on the efficacy of chiropractic therapy on premenstrual syndrome. Journal of Manipulative and Physiological Therapeutics 1999; 22(9): 582-585.

[55]Hawk C, Long C, Azad A. Chiropractic care for women with chronic pelvic pain: A prospective single group intervention study. Journal of Manipulative and Physiological Therapeutics 1997; 20(2): 73-79.

[56]Falk JW. Bowel and bladder dysfunction secondary to lumbar dysfunctional syndrome. Chiropractic Technique 1990; 2(2): 45-48.

[57]Wagner T, Owen J, Malone E, Mann K. Irritable bowel syndrome and spinal manipulation: a case report. Chiropractic Technique 7(4): 139-140, 1995.

[58]Pikalov A, Kharin VV. Use of spinal manipulative therapy in the treatmentof duodenal ulcer: A pilot study. Journal of Manipulative and Physiological Therapeutics 1994; 17(5): 310-313.

[59]Giesen JM, Center DB, Leach RA. An evaluation of chiropractic manipulation as a treatment of hyperactivity in children. Journal of Manipulative and Physiological Therapeutics 1989; 12(5): 353-363.

[60]Smith R. Where is the wisdom: The poverty of medical evidence. British Medical Journal 1991; 303: 798-799.

[61]Rachlis N, Kuschner C. Second opinion: What's wrong with Canada's health care system and how to fix it. Toronto: Collins, 1989.

[62]Merck's 1899 Manual, or the Materia Medica. New York, NY: Merck & Co., 1899.

[63]Field T, Henteleff T, Hernandez-Reif M, Martinez E, Mavunda K, Kuhn C, Schanberg S. Children with asthma have improved pulmonary functions after massage therapy. Journal of Pediatrics 1998; 132(5): 854-858.

[64]Haldeman S, Chapman-Smith D, Peterson, DM Jr. Guidelines for chiropractic quality assurance and practice parameters. Proceedings of a consensus conference commissioned by the Congress of Chiropractic State Associations, held at the Mercy Conference Center, Burlingame, CA, January 25-30, 1992. Gaithersburg, MD: Aspen, 1993.

[65]Rupert RL. A survey of practice patterns and the health promotion and prevention attitudes of U.S. chiropractors: Maintenance care: Part I. Journal of Manipulative and Physiological Therapeutics 2000; 23(1): 1-9

[66]Rupert RL, Manello D, Sandefur R. Maintenance care: Health promotion services administered to U.S. chiropractic patients age 65 and older: Part II. Journal of Manipulative and Physiological Therapeutics 2000; 23(1): 10-19.

[67]Lazarou J, Pomeranz B, Corep P. Incidence of adverse drug reactions in hospitalized patients. Journal of the American Medical Association 1998; 279(15): 1200-1205.

[68]Johnson JA, Bootman JL. Drug-related morbidity and mortality: A cost-of-illness model. Archives of Internal Medicine 1995; 155: 1949-1956.

[69]Royal College of General Practitioners, unpublished update of CSAG Guidelines [reference 8], 1999.

[70]Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. Journal of the American Medical Association 1999; 282(11): 1054-1060.

[71]Johansen HK, Gotzsche PC. Problems in the design and reporting of trials of antifungal agents encountered during meta-analysis. Journal of the American Medical Association 1999; 282(18): 1752-1759.

[72]Rennie D. Fair conduct and fair reporting of clinical trials. Journal of the American Medical Association 1999; 282(18): 1766-1768.

[73]Gotzsche PC. Multiple publication of reports of drug trials. European Journal of Clinical Pharmacology 1989; 36: 429-432.

[74]Huston P, Moher D. Redudancy, disaggregation, and the integrity of medical research. Lancet 1996; 347: 1024-1026.

[75]Tramer MR, Reynolds DJM, Moore RA, McQuay HJ. Impact of covert duplicate publication on meta-analysis: A case study. British Medical Journal 1997; 315: 635-640.

[76]Sackett DL. Editorial: Evidence-based medicine. Spine 1998; 23(10): 1085-1086.

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Dr. James Winn is the Executive Vice President of the Federation of State Medical Boards of the United States, Inc., a national organization whose membership includes medical licensing and disciplinary boards in the United States, District of Columbia, Guam, Puerto Rico and the Virgin Islands. Since 1989, Dr. Winn has worked diligently as the Federation's leader and primary spokesperson representing the Federation to the leadership of other organizations on the state, national and international levels. Under his direction, the Federation has prospered rapidly and has had significant recognition as the premier organization concerned with medical licensure and discipline.

Dr. Winn is a Charter Fellow of the American Academy of Family Physicians and a former Diplomate of the American Board of Family Practice. He received his medical degree from the University of Texas Medical Branch at Galveston in 1967 and immediately served a one-year internship at Breckenridge Hospital in Austin. He completed additional postgraduate training at the University of Texas Medical Branch at Galveston. Since completing his medical training, Dr. Winn has been actively involved with countless organizations and committees concerned with the promotion of quality medical care and protection of the public. He is a former member of the Texas State Board of Medical Examiners and was the Chairman of the Board's Committee on Reciprocity, as well as a member of the Board's Legislative Committee and Foreign Medical Graduates Committee. He is a former member of the State Quality Assurance Executive Committee of the Texas Medical Foundation, a former member of numerous committees of the Texas Medical Association (TMA) and currently serves as a consultant for TMA's Council on Medical Education. Additionally, he served as President of the Texas Academy of Family Physicians and is currently a member of the Board of Directors of the Tarrant County Medical Society located in Fort Worth. On the national level, Dr. Winn is a former member of the National Board of Medical Examiners and currently sits on the Executive Committee of the National Practitioner Data Bank, as well as the Composite Committee and the Budget Committee of the United States Medical Licensing Examination. He is also a member of the National Advisory Committee for a grant on "Pain Management and State Regulatory Policy" awarded by the Robert Wood Johnson Foundation to the University of Wisconsin Comprehensive Cancer Center's Pain and Policy Studies Group.

Dr. Winn's involvement in international affairs is especially noteworthy. Under his direction, the Federation has been the catalyst for organizing an International Association of Medical Licensing Authorities for the purpose of facilitating the ongoing exchange of medical regulatory information, promoting high standards for physician licensure, registration and practice, and supporting licensing authorities in protecting the public interest in the field of health care. With his support on the Interim Governance Committee, the Federation will act as the initial Secretariat for the Association. Additionally, Dr. Winn frequently participates as an invited speaker at conferences abroad or of a global nature to ensure the Federation's international recognition as a leader in providing support for medical licensure and discipline around the world.

Special Committee on Questionable and Deceptive Health Care Practices

Note: Originally, this report was produced by the Special Committee on Health Care Fraud. At the Federation's 1999 House of Delegates meeting, the committee was renamed the Special Committee on Questionable and Deceptive Health Care Practices.

The Federation of State Medical Boards' governing body accepted this Report as policy in April 1997.

Section I: Preamble

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

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

The committee recognized that the primary responsibility of state medical boards is to protect the public from the incompetent, unprofessional, improper and unlawful practice of medicine and, further, that the authority for state medical boards to regulate medical practice is determined by each state's medical practice act. In its capacity as a resource for research, policy development, education and information, the Federation has developed a model medical practice act *(A Guide to the Essentials of a Modern Medical Practice Act)* to assist state medical boards in developing legislative language necessary to effect regulation of medical practice.

Accordingly, the committee's initial recommendations included a proposal to revise pertinent sections of *A Guide to the Essentials of a Modern Medical Practice Act* in order to strengthen the ability of state medical boards to regulate fraudulent behavior. These recommendations were adopted by the Federation's House of Delegates during its April 1996 meeting and have been incorporated in the policy document. The revisions expand the responsibilities of the medical board to include protection against the fraudulent and/or deceptive practice of medicine and render the unlicensed practice of medicine a felonious offense.

The following objectives were identified by the committee.

- To develop recommendations to assist state medical boards in identifying, evaluating, investigating and prosecuting cases involving questionable health care practices.
- To develop strategies to monitor legislative initiatives supporting increased access to unconventional and unproven treatments and assist state medical boards in responding to such initiatives in the interest of public health, safety and welfare.
- To solicit support for the Federation's efforts to control health care fraud from medical professional organizations, governmental agencies and other interested organizations.
- To develop and implement educational opportunities for state medical board members, executive directors and investigative staff on effective regulation of questionable health care practices.

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

Section II: Definitions

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

- advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in the jurisdiction;
- offering or undertaking to prescribe, order, give or administer any drug or medicine for the use of any other person;
- offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;
- offering or undertaking to perform any surgical operation upon any person; and
- using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., MD, DO or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction.

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

Section III: Identification

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

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

delay of appropriate diagnoses and/or treatments.

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

- Encourage consumer/patient reporting by increasing awareness among the public through distribution of educational materials and utilizing media sources.
- Encourage and expand reporting from licensees and other health care professionals by increasing awareness of reporting requirements through newsletters, announcements, alerts, advisory opinions and collaboration with state and local medical professional organizations and societies.
- Expand liaison efforts with regulatory agencies (federal, state and local), including the Federal Trade Commission, other state licensing authorities, state attorneys general, district attorneys and public health departments.
- Improve reporting from third party payers and peer review organizations (PROs).
- Periodically monitor health care promotional materials, including random review of newspapers, periodicals and other advertising mediums.

Section IV: Evaluation and Investigation

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

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

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

- Has an adequate patient assessment been conducted, including history and physical examination, laboratory studies, x-rays and other evaluative measures, to determine that the patient has the condition for which the treatment is being prescribed?
- Is the methodology promoted for diagnosis as reliable as other available methods of diagnosis?
- Is the risk/benefit ratio greater or less than that for other treatments for the same condition?
- Is it based upon competent and reliable scientific evidence, including properly conducted clinical trials, and/or is it supported by a scientific rationale?
- Is there logical and reasonable expectation that the treatment offered will result in a favorable patient outcome?
- Is the practitioner excessively compensated for the service provided?
- Are the practitioner's promotional claims supported by competent and reliable scientific evidence?
- Is the benefit achieved greater than that which can be expected by placebo alone?
- Has the patient's informed consent been adequately documented in the medical record?

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

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

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

- Federation of State Medical Boards Library Services, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039; (817) 868-4000; Fax (817) 868-4099;
- National Council Against Health Fraud (NCAHF), PO Box 1276, Loma Linda, California 92354; Fax (909) 824-4848;
- Consumer Health Information Research Institute (CHIRI), 300 East Pink Hill Road, Independence, Missouri 64057; (816) 228-4595; Fax (816) 228-4995;
- Food and Drug Administration, Office of Health Affairs; 5600 Fishers Lane, HFY-1, Rockville, Maryland 20857; (301) 443-6143;
- Federal Trade Commission, Division of Service Industry Practices, Washington, DC 20580; (202) 326-3291; Fax (202) 326-3392; and
- Office of Alternative Medicine, National Institutes of Health, 6120 Executive Boulevard, EPS, Suite 450, Rockville, Maryland 20892; (301) 402-2466; Fax (301) 402-4741.

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

- Reader's Guide to Alternative Health Methods, Zwicky, John F., PhD; Hafner, Arthur W., PhD; Barrett, Stephen, MD; and Jarvis, William T., MD. American Medical Association 1993.
- Alternative Medicine: What Works, Fugh-Berman, Adriane, MD. Odonian Press, 1996.
- The Vitamin Pushers: How the "Health Food" Industry is Selling America A Bill of Goods, Stephen Barrett, MD, and Victor Herbert, MD, JD, 1994. NY: Prometheus Press.
- The Health Robbers: A Close Look at Quackery in America, edited by Stephen Barrett, MD, and William T. Jarvis, PhD. Foreword by Ann Landers, 1993. NY: Prometheus Press.
- HealthSmarts, John H. Renner, MD. 1990, Health Facts Publishing, 300 E. Pink Hill Road, Independence, Missouri 64057-3220.
- The Honest Herbal, 3rd Edition, Varro E. Tyler, PhD. 1993, Pharmaceutical Products Press, Division of The Haworth Press, Inc., 10 Alice St., Binghampton, NY 13904-1580.
- Examining Holistic Medicine, edited by Douglas Stalker, PhD, and Clark Glymour, PhD. 1985, Prometheus Press, NY.

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

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

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

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

- Gather evidence to include (1) promotional and other materials used to produce patient consent, (2) drug samples or medical devices together with manufacturer's package inserts and specifications, (3) proponent literature describing the practice in question together with medical/scientific justification and (4) competent and reliable scientific evidence on the efficacy/safety of the practice.
- Conduct a thorough review of the Medical Practice Act to determine all applicable breaches to be included in the board's complaint.

Section V:Disciplinary Action/Disposition

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

It is necessary to employ procedures to effectively present cases in the disciplinary process. The committee identified elements that are commonly utilized by respondents in cases involving questionable health care practices, specifically the use of testimonials and anecdotal evidence. Proponents of questionable health care practices likely hold strong views and convictions regarding the therapeutic approach and may have a large cadre of devotees, willing to testify on the respondent's behalf.

In order to successfully prosecute such cases, it is imperative that state attorneys be familiar with medical practice and terminology and be able to apply and argue case law and rules of evidence in terms of generally accepted scientific standards so that unreliable evidence may be excluded and not used by respondents in defense of prosecution. Following a determination by the state medical board to prosecute a complaint, the committee suggests the following elements be utilized in the disposition of cases involving questionable health care practices.

- Conduct thorough prehearing discovery to obtain additional information and the names and qualifications of defense expert witnesses.
- Conduct careful research of defense experts and their writings.
- Request a prehearing conference or evidentiary hearing to suppress unreliable evidence and exclude testimony of unqualified proponents testifying on behalf of the respondent as unreliable and inadmissible. Review Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) and relevant state law to establish legal precedent on admissibility of disputed scientific evidence.
- Strategize trial presentation to not only prove the board's case, but to disprove the proponent of the practice in question.
- Utilize expert witnesses who can not only establish the board's case but also who can provide credible rebuttal of the evidence in support of the practice in question.

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

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

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

- Federal Trade Commission (deceptive/fraudulent health care promotions/claims);
- State Attorney General (consumer complaints/protection and deceptive/fraudulent health care promotions/claims);
- State Insurance Board/Commission (billing practices);
- Health Care Financing Administration (Medicare claims);
- U.S. Postal Service (mail fraud);
- U.S. Customs Service (import of unapproved/illicit drugs/devices);
- Food and Drug Administration (unapproved drugs/devices); and
- District Attorney (unlicensed practice of medicine and related criminal offenses).

Section VI: Legislative Strategies

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

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

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

- The unlicensed practice of medicine should be deemed a felonious offense.
- State medical boards should be granted authority to use injunctive powers to order physicians and others engaged in questionable health care practices to immediately cease such practice pending hearing.
- State medical boards should be granted authority to monitor physicians engaged in questionable health care practices, including, but not limited to, requirements that physicians: (1) file treatment plans with the board, (2) report patient outcomes and (3) file periodic reports regarding the efficacy of treatment.

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

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

- Request assistance from the Legislative Services Department of the Federation of State Medical Boards in analyzing and developing strategies in opposition to such state legislative measures.
- Identify individuals within the state willing to educate state legislators and legislative staff on the potential effects of such legislative initiatives.
- Assist legislators in soliciting written comments from the Food and Drug Administration and the Federal Trade Commission on the potential consumer health and economic effects of such legislative initiatives (requests are honored only if submitted by legislator).

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

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

Section VI: Education

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

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

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

- Present educational information at meetings of state and local medical professional societies and associations and other organized physician educational forums.
- Include educational information in board newsletters and other communications with licensees.
- Utilize media sources, public service announcements, consumer advocacy groups and other means to disseminate information to the public.

Section VII: Collaboration

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

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

The committee suggests the following forums for collaboration.

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

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

Section VIII: Conclusion

It has been estimated that up to $100 billion is lost to health care fraud in the United States annually.[1] Medical interventions that do not conform to prevailing scientific standards are becoming increasingly popular. It is estimated that in 1990, Americans made 425 million visits to providers of "unconventional" medicine, exceeding the number of visits to all U.S. primary care physicians, at a cost of approximately $13.7 billion.[2] It may be recognized that some alternative therapies may be beneficial and therefore warrant further investigation and possible integration into mainstream medical practice. However, because of the lack of reliable scientific evidence and clinical validation, safety has not been established for most of these modalities.

Questionable health care practices can pose significant risks to the public safety, either by causing direct patient harm, or indirectly by being needlessly expensive, delaying a more effective treatment or from being administered in an incompetent manner. This proliferation of questionable health care practices and promotions will continue if left unchecked and unregulated. State medical boards are charged with protecting the public from the unprofessional, improper, incompetent, unlawful, fraudulent and deceptive practice of medicine[1] and, therefore, state medical boards must assure that physicians practice responsible medicine.

Section IX: References

1. Stern, 1994.

2. Eisenberg et al, 1993.

3. *A Guide to the Essentials of a Modern Medical Practice Act*, Section I.

The Regulation of Complementary and Alternative Medicine

James R. Winn, MD
Executive Vice President
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Medical Regulation in the U.S.

- Responsibility of states and territories
- 50 states & District of Columbia
  - Puerto Rico, U.S. Virgin Islands, Guam
  - 69 state medical boards
    - allopathic, osteopathic, composite
  - Legislated authority (Medical Practice Act)
- <u>Primary responsibility</u>
  - All states have the common purpose of protecting the public from unqualified and unfit physicians.

Physician Responsibility

- To know the Medical Practice Act
  - Rules and regulations
  - Policies and guidelines
  - Medical board communications
- To comply with recognized professional ethical and practice standards
- To maintain professional behavior and conduct
- To report breaches of professional conduct standards to appropriate authority(s)

CAM – What are the Concerns?

- Proliferation of complementary and alternative medical practices has caused concern for public safety
  - Some lack scientific research and clinical validation
  - Some are fraudulent and/or deceptive medical practices
- Federal and state legislative initiatives
  - Restrict medical board authority to provide oversight of licensees

Concerns About Adverse Impact on Patients

- Potential levels of harm:
  - Economic harm which results in monetary loss but presents no health hazard
  - Indirect harm which results in a delay of appropriate treatment
  - Direct harm which results in adverse patient outcome

FSMB Efforts

- Report of the Special Committee on Questionable and Deceptive Health Care Practices (1997)
  - OBJECTIVE: To provide guidance to medical boards in evaluating, investigating and prosecuting cases involving questionable or deceptive health care practices
- Report recommends that prevailing standard of care used in evaluating health care practices be consistent, whether such treatment is regarded as "conventional" or "unconventional"

Elements Utilized in Evaluation of Health Care Practices

- Adequate patient assessment
- Reliable diagnosis methodology
- Favorable risk/benefit ratio compared to other treatments
- Support of scientific evidence
- Expectation of a favorable patient outcome
- Expectation of greater benefit than placebo alone
- Documentation of informed consent

FSMB Model Guidelines on the Use of CAM

- FSMB developing guidelines to assist state medical boards in educating and regulating physicians who use CAM in their practices
  - Practicing in an integrated environment
  - Co-managing patients with licensed non-physician alternative providers
- OBJECTIVE: To provide guidance to medical boards and licensees in utilizing CAM in a manner consistent with safe and responsible medicine

Office-Based Research Issues

- Physicians must fulfill their ethical responsibilities when engaging in the clinical investigation of new therapies and procedures
  - "A physician may participate in clinical investigation only to the extent that those activities are a part of a systematic program competently designed, under accepted standards of scientific research, to produce data which are scientifically valid and significant."[1]

[1]AMA Policy E-2.07: Clinical Investigation

Office-Based Research Issues (continued)

- "In conducting a clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation."[2]

[2]AMA Policy E-2.07: Clinical Investigation

State Board Policies

- Four (4) medical boards have adopted CAM policies
  - Illinois
  - Kentucky
  - Nevada
  - Texas
- Assist boards and physicians in determining whether specific medical practices constitute a violation of a state's Medical Practice Act
- Assist boards and physicians in determining boundaries for use of medical experimentation or research

Another Medical Board's Efforts

- TN Board of Medical Examiners
  - Adopted position statement on chelation therapy (July 2000)
    - May not be used for conditions other than heavy metal poisoning, as approved by FDA
    - May be used as part of an approved, carefully controlled clinical investigation – must follow protocol satisfactory to the Board and conducted in an academic institution

Need for Research, Information and Collaboration

- Promote and support scientific research to determine efficacy of CAM therapies
- Information-sharing and education
- Collaboration
  - Medical profession
  - Medical education institutions
  - Governmental agencies
  - Private sector

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State medical boards are moving to include alternative and complementary medicine in mainstream guidelines

Once-unorthodox practices such as acupuncture, chiropractic, homeopathy and herbs now are the treatments of choice for many Americans health consumers, and as a result, 12 state medical boards have issued guidelines and regulations covering this complementary, or alternative, medicine (CAM). As well, model guidelines are being drawn up by the Federation of State Medical Boards (FSMB) to help licensed physicians across the country integrate alternative procedures into their practices while upholding accepted medical standards.

Times have changed since 1996, when the federation decided to examine CAM by appointing a group ultimately named the Special Committee on Questionable and Deceptive Health Care Practices, says Dale Austin, Chief Operating Officer of the FSMD. The ensuing report criticized "the proliferation of unconventional and unproven medical practices and promotions...some of which may be questionable and thereby pose a risk to public health, safety and welfare."

By contrast, the guidelines now under consideration recognize the increased interest in alternative therapies. "We understand that times have changed, and we want to move progressively with the times," says Austin. A draft of the FSMB guidelines is scheduled for a vote by the federation's House of Delegates in 2001.

Even before the national guidelines are released, individual states have begun the regulation process. In 1998, complaints filed against five Kentucky doctors led the state medical licensure board to create the country's first policy on complementary care. Alternative therapies listed under the Kentucky policy include acupuncture, homeopathy, chiropractic, acupuncture, aromatherapy, biofeedback, botanical/herbal remedies, hypnosis, mind/body medicine, nutrition, traditional Chinese medicine, and reflexology.

While granting that innovative practices could benefit patients, the 1998 policy aimed "to protect people weakened by illness from the dangers attendant to unsound heath practices" and specified three categories of treatments: validated (conventional and generally accepted), invalidated (no empirical evidence of health benefit and implausible), and nonvalidated (may have basis in scientific theory but are unproved or experimental).

Physicians and providers should never accede to invalidated treatments, the Kentucky

board said. But physicians "may incorporate nonvalidated treatments if research results are very promising, the physician believes that a particular patient may benefit, the risk of harm is very low, and if the physician adheres to conventions that govern the doctrine of informed consent for nonvalidated treatment."

While the Kentucky policy opened communication between the two schools of thought, a definite change of tone is apparent just two years later in the regulations for non-conventional methods of medical treatment adopted by the Nevada Board of Medical Examiners last month. The new rules allow the state's 3,000 medical doctors to practice what the board calls "integrative medicine," so long as a conventional method of treatment beneficial to the patient is not abandoned, the alternative treatment plan is well documented and there is informed consent.

Today, at FSMB conventions, "everyone is talking about alternative medicine," says Larry Lessly, executive director of Nevada's state board. "A lot of doctors around the country are learning how to collaborate and interact with nonconventional practitioners. All our regulations do is say to doctors, if you are so inclined and if it's going to help your patient, go ahead and do it-just do it safely."

The change in attitude by the medical establishment is widely credited to the work of David Eisenberg, director of the Center for Alternative Medicine Research and Education at Boston's Beth Israel Deaconess Medical Center. Eisenberg, recently appointed head of Harvard Medical School's Division for Research and Education in Complementary and Integrative Medical Therapies, spearheaded two well-known national surveys, one in 1990 and a follow-up in 1997, on the use by Americans of 16 alternative methods. The surveys, supported in part by the National Institutes of Health, included such practices as relaxation techniques, herbal medicine, acupuncture, homeopathy and folk remedies. The Eisenberg report revealed a 25% increase in the use of alternative medicine by U.S. medical consumers between 1990 and 1997. During that period, the total number of visits to alternative practitioners increased 47%, and the 1997 total (629 million visits) surpassed total visits in that year to all conventional primary care physicians in the U.S. (386 million visits). At the same time, expenditures for alternative practitioners increased by 45% to an estimated 1997 total of $27 billion dollars in out-of-pocket expenses.
In light of these observations, the Eisenberg report authors suggested "a more proactive posture" in regards to the need for more clinical and basic scientific research, relevant educational curricula, and credentialing and referral guidelines. The report also advocated improved quality of dietary supplements and surveillance of drug-herb and drug-supplement interactions after the substances go to market.

Not surprisingly, alternative practitioners applaud the new developments. "In years past, we had an adversarial relationship with medical doctors," says New York chiropractor Charles Franchino. "But this has changed because Americans were dissatisfied with the care they had been getting for chronic problems, such as back pain, and pain in general.

It's great because the person who benefits from the incorporation of alternative medicine with traditional medicine is the patient."

* Joanna Kyd

The Federation of State Medical Boards has a web site at [http://www.fsmb.org/]