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001. testimony	John Mastel (partial) (1 page)	nd	b(6)

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

OA/Box Number: 43231

FOLDER TITLE:
WHCCAM Town Hall Meeting Testimony, Minneapolis, Minnesota, March 16, 2001
[Folder 1] [2]

2011-0568-S
kc801

RESTRICTION CODES

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White House Commission, Testimony by Matthew Wood

Thank-you for the opportunity to speak before you today. I am a member of the Minnesota Natural Health Coalition and the American Herbalists Guild. I have been a practicing herbalist for twenty years, have seen thousands of clients and earn my income solely from my calling. I believe herbalism is one of the more difficult issues the Commission will face. Both safety and freedom issues are involved so I offer the following suggestions.

First, safety issues can be met by establishing an official herbal pharmacopoeia, like that for allopathy and homeopathy. Plants, genera and families with toxic compounds should be noted and controlled. A broad base of traditional non-toxic herbs (similar to those currently on the GRAS list of the FDA) can be established which will be in the public domain and available for professional and folk usage. Suspected side-effects and drug interactions should also be noted. Appropriate manufacturing methods for standardized extracts would be included, as well as simple standards for traditional preparations. Herbal products should be described in both scientific and traditional terms. For the latter, I would avoid terms implying specific uses such as diuretic, adaptogen, alterative, etc., in favor of a few wide, general categories based on obvious physical characteristics like bitter, astringent, stimulant, mucilage, etc. These are in fact scientifically valid.

Second, I believe there should be a two tier system of regulation for practitioners.

Tier 1. Medical and naturopathic physicians who desire licensure should be allowed it, but it should be based on their use of medical procedures, not alternative therapies – these should remain in the public domain.

Tier 2. CAM practitioners such as herbalists and homeopaths, who do not practice medical diagnosis or treatment, should be allowed to practice under guidelines similar to those we have developed here in Minnesota. However, if groups within these movements desire licensure in the future they should be allowed to have it, based on their education in and use of medical procedures. Thus there would be room for evolution within a profession. A third tier may have to be instituted for folk healers who do not keep records and practice completely without regulation. They should not be subjoined from practice but should be held responsible for injury.

Payment. Federal reimbursement of medical expenses should only extend to diagnosis and treatment of serious medical conditions. Competition for other services will improve care and control prices. The poor are protected by the protection of folk healers; this I know from working at an inner city herb store for eight years.

Most importantly, these guidelines should be established by people within the professions themselves, working in conjunction with the government, not by outside experts with no practical experience in the field.

STATEMENT FOR THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY, MARCH 16, 2001, MINNEAPOLIS, MN

Dear Commissioners,

Thank you for this opportunity to express the needs of 5000 Minnesota pharmacists, and more than 1000 physicians and nurses of HealthPartners, a non-profit HMO.

People, who are choosing to self medicate with herbal dietary supplements, are calling upon us for information in order to avoid adverse reactions and/or interactions with these products.
We are called upon because herbal dietary supplements lack appropriate labeling for self-medicating. The labels do not provide the information that would enable a person to avoid adverse reactions and/or interactions. In many cases, the information *itself* is not available.

Cases in point: ginkgo biloba, do the case reports of bleeding episodes imply a trend? Does ginkgo biloba really interact with warfarin? Kava, do the recent liver toxicity reports reflect a reaction that will be expected to show up in 0.01% of people using or in 10%? St.John's wort, the recently documented interactions between St.John's wort and pharmaceuticals makes us question our current sources for adverse reaction/interaction information, including traditional use and Germany.

The first article to systematically summarize the published literature on potential adverse reaction/ interactions was published last year.[1] The data suggests adverse reactions/interactions exist. We need to know which ones are relevant. We must be able to distinguish between significant adverse reaction/interactions and minor ones.

We need reliable data. Numerous authoritative references today have direct contradictions about adverse reactions/interactions. We do not have the data people need to safely self-medicate.

With no pre-marketing review for dietary supplements, we need a post-marketing program to increase the detection of adverse reactions/interactions.

We need a program that will:
1) Be publicized to healthcare providers, hospitals, pharmacies, clinics, and others.
2) Make it easy to report adverse reactions/interactions, such as a telephone hotline, one that involves no paperwork for the person reporting.[2]
3) Utilize a critical review process to distinguish between significant adverse reactions/interactions and minor ones.
4) Provide the information to manufacturers that will in turn provide the information to consumers via labeling.
5) Provide the information to healthcare providers so that they can: 1) assist their patients when labels state "seek advice from your doctor or pharmacist before using" and 2) eventually develop enough confidence in these products to recommend them.

The collection and distribution of adverse reaction/interaction information needs to be a priority so that people can safely reap the benefits of dietary supplements.

Sincerely,

Jodi A.Chaffin RPh
Herbal Resource Pharmacist for HealthPartners,
Chair of the Herbal Committee of MN Pharmacists Association.

[1] Ernst, E. Possible interactions between synthetic and herbal medicinal products. Part 1: a systematic review of the indirect evidence. Perfusion, 2000; Vol. 13 pp. 4-15.
[2] Vitillo, J. Adverse Drug Reaction Surveillance: Practical Methods for Developing a Successful Monitoring Program. Medscape Pharmacists, 2000.

Rick Kingston PharmD
University of Minnesota, College of Pharmacy
PROSAR International Poison Center

Statement to the Presidents Commission on Complementary and Alternative Medicine Policy

Dear members of the Commission. As a University of Minnesota professor in the College of Pharmacy serving as course director for one of the only CAM courses in the Academic Health Center that specifically focuses on the clinical application of herbal and other dietary supplements, I personally believe in the incredible potential of CAM practices as they pertain to improving and maintaining the health of Americans. Unfortunately, my views are not shared by many of my colleagues. CAM certainly includes a variety of approaches and practices, but often times the most visible link with patients and their healthcare provider regards patient use of commercially available Dietary Supplements, more broadly defined as Nutraceuticals. Although these substances are regulated by the FDA through DSHEA, Pharmacists and other mainstream medical practitioners continually cite inadequate regulation as a barrier to full acceptance.

In a study to assess the attitudes of pharmacists regarding dietary supplements, Mitzi Welna, a Colleague of mine in the College of Pharmacy randomly sampled practitioners throughout the State. Almost ninety six percent (95.9%) of the 533 survey respondents indicated that they felt "government oversight/regulation of herbal/natural products" is only "somewhat" or "less than adequate". It's apparent that GMP's which are in large part supported by Industry are on the way. What will remain an issue with many is how we can monitor both for the successful implementation of these GMPs as well as the overall patient experience regarding safety including interactions with pharmaceuticals and, adverse incidents.

Along with many of my colleagues and others interested in the safe and efficacious use of these valuable healthcare related products, I believe there are a few specific things that can be done to address this area.

1) The Commission needs to embrace strategies that encourage and support the development of product stewardship programs that address these concerns on the part of product manufacturers and/or their professional trade associations. Effective post market surveillance cannot be accomplished solely by regulatory bodies. It will only be accomplished with effective partnerships with responsible manufacturers. As regards dietary supplements the partnership is even more important as consumer routinely turns to the manufacturer as the product expert. Thus the manufacturer is in the best position to monitor the patient experience and share necessary information that they learn with regulators, the patient, and the practitioners that recommend/advise on product use. Changes in DSHEA which could require manufacturers to report adverse effects involving their products may be one way to move the process forward. Another option would be for the Commission to encourage conscientious manufacturers to implement voluntary systems of their own that collect, analyze and report information related to the patient experience.

2) The Commission should also support the development of multidisciplinary education programs that teach clinical application of dietary supplements in a broader sense across the multiple healthcare disciplines that typically recommend or advise on their use.

3) The Commission should also support the development of recognized certification programs by professional bodies that assess the competency of those professionals that request the public trust when recommending or advising on the use of these products for a variety of medical or health related needs.

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[001]
15

DIETARY SUPPLEMENTS – PANEL
JOHN MASTEL – RETAILER 33 YEARS
(b)(6)
ST. PAUL, MN 55105
(b)(6)

The AMA, FDA, and pharmaceutical companies seem to be involved in a silent conspiracy to prevent the average consumer from getting proper access to nutritional supplements and information regarding supplements' role in bettering our health. Though it may not be a full-fledged conspiracy, the results are certainly the same.

One example is the B vitamin, folic acid; until 1974, regulations for a non-prescription supplement only allowed one fourth of the daily adult requirement. Studies on folic acid showed a decrease in instances of spina bifida with increased consumption of folic acid. Folic acid has also been shown to help lower homocysteine levels. Excess levels of homocysteine have been implicated in heart, stroke and other diseases. However, we cannot make claims for folic acid's benefits as a supplement. Meanwhile, the food industry is now fortifying foods, for example white flour, with folic acid to prevent health problems. Similarly, scientific studies on food-source vitamin C show many health benefits yet we cannot claim these same benefits for vitamin C *supplements.* Also the critical mineral, iodine, is required in table salt but a large number of people no longer use it.

The AMA and the dairy industry are telling people to get their vitamin D from fortified milk rather than supplements. Regardless of the fact that a large percent of the population are lactose intolerant or have milk allergies.

Guidelines and laws seem to be made more to please the legal regulators and large industries than to benefit the average citizen. In fact the FDA, through their Federal Register, tried to make the law that any vitamin supplementation beyond the Recommended Daily Allowance could be dispensed only by prescription.

Medical doctors in the United States seldom recognize nutritional problems but our health system depends on them for it.

A research and regulatory body needs to be established to provide adequate and *unbiased* information on dietary supplements. The German Commision E Monograph is a fine example of what needs to be done in this country to create standards and guidelines for dietary supplements.

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

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

Oral Testimony of the Consumer Healthcare Products Association to the White House Commission on Complementary and Alternative Medicine Policy

Minnesota Town Hall Meeting
Hubert H. Humphrey Institute
301 19th Avenue South
Minneapolis, MN
on
March 16, 2001

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

The Consumer Healthcare Products Association is a 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research, and advertising sectors of the self care industry.

We have been intimately involved in the regulatory development of the industry, commenting and facilitating dialogue and activities relating to safety, labeling, quality and other matters affecting the production and distribution of dietary supplements. Just last week our Association adopted eight voluntary programs on dietary supplements relating to manufacturing, labeling, and formulation of safe and high quality products, adding to our programs already in place on St. John's wort, ephedra, and use of dietary supplements during pregnancy.

My remarks address two aspects of the questions that were set forth in the announcement of this meeting: (a.) health professional and consumer access to safe and effective dietary supplements[1]; and (b.) educational issues relating to complementary and alternative medical practitioner use of dietary supplements.[2]

First, on safe, effective, high quality dietary supplements, our call is to the White House Commission as well as health professionals to support the Congressional

[1] WHCCAMP Registration Form Question 2.a.: How can access to safe and effective CAM practices and interventions be improved?

[2] WHCCAMP Registration Form Question 3: Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine.

appropriations process soon to be initiated by the Center for Food Safety and Applied Nutrition (CFSAN). Consumers, health professionals and industry need an FDA that is adequately funded to appropriately and reasonably implement the spirit and intent of the Dietary Supplement Health Education Act, or DSHEA. Along these lines, let me share the following points:

- FDA and the Federal Trade Commission have the tools they need to adequately regulate dietary supplements[3] [4].
- FDA has put in place the strategic management tools to justify allocations of increased funding[5], including the development of its long range plan and annual priorities through extensive stakeholder input, as well as use of a year-end report card process to define the extent it met its priorities that year.
- This Spring, FDA will provide Congress with two important fiscal reports – one pertaining to the how much it spent on dietary supplement regulation in 2000; another pertaining to the funding needed to implement its long-range strategic plan. This is the start of the appropriations process.

Our message is, the White House Commission should report to the new Administration the clear need to push for the level of appropriations necessary for CFSAN to fairly and reasonably implement DSHEA, thereby allowing FDA to use its existing substantial enforcement tools to regulate dietary supplements, in order to ensure safe, effective, high-quality dietary supplements for consumer and health professional use[6].

Further to this point, the Commission has an opportunity to support FDA in achieving its priority "A" list in its 2001 Annual Priorities[7] (Attachment A), including especially the publication of Good Manufacturing Practices, the finalization of which is necessary before FDA can have an effective field presence through an enforcement program. Additionally, FDA proposes to develop a master research plan for dietary supplements, and the White House Commission should recommend that this be developed with full stakeholder input, including that from CAM practitioners.

Other "A" priorities should be evaluated by the Commission as possible areas for additional recommendations. A member of the Commission should be tasked with this activity, and I have appended a copy of FDA's long-range strategic plan and 2001 annual priorities for this purpose (Attachment B).

---

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

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

[5] Levitt, J.: Formal address to the CHPA Annual Meeting, *Nutritionals 2001*, Anaheim, CA, 1/31/01.

[6] Soller, R. W.: Will FDA Get the Funds to Effectively Regulate Dietary Supplements? *JANA* March, 2001.

[7] See Attachment B: Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments [65 *Federal Register* 39415-39416 (6/26/2000)].

Second, with respect to the educational aspects of CAM practitioners and dietary supplements, we recommend a strategic perspective on the use of collaborative educational partnerships between the National Institutes of Health (i.e., National Center for Complementary and Alternative Medicine and Office of Dietary Supplements) and professional groups. For example, we are aware that the University of Minnesota and the American Nutraceutical Association are developing a collaborative approach to certifying licensed healthcare practitioners in dietary supplement use. Such certification brings quality to the informational aspects of product use, and special funding vehicles should be developed to encourage such upgrading of the knowledge base of health professionals.

Thank you.

Attachments A FY 2001 CFSAN Program Priorities: www.cfsan.fda.gov.
B Center for Food Safety and Applied Nutrition: Dietary Supplement Plan: Ten-Year Strategy, www.cfsan.fda.gov.

WS/jq:DietSup:WhitehouseCommissions/Minn Mtg Mar 2001 Testimony

A

FY 2001 CFSAN Program Priorities

Center for Food Safety and Applied Nutrition
Food and Drug Administration

January 2001

Excerpts from FY 2001 CFSAN Program Priorities
Pertaining to Dietary Supplements Only
Reproduced by CHPA 3/15/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JAN 9 2001

Dear Colleague, FDA Foods Community:

I am pleased to share with you the FY 2001 program priorities for FDA's Center for Food Safety and Applied Nutrition (CFSAN). This is the third consecutive year we have developed a program priorities document, incorporating input we received from many stakeholders. This workplan builds on the success we have had with the last two plans (see most recent "Report Card" dated December 5, 2000 on our website, www.cfsan.fda.gov). There are three points I would like to highlight:

1. The paramount theme for the FY 2001 workplan is program continuity. We will continue to place our highest emphasis on food safety, food additives, dietary supplements, and food biotechnology. This includes completing those goals from last year's plan that were not fully completed by the end of fiscal year 2000 (see Appendix B in the December 5, 2000 "Report Card").

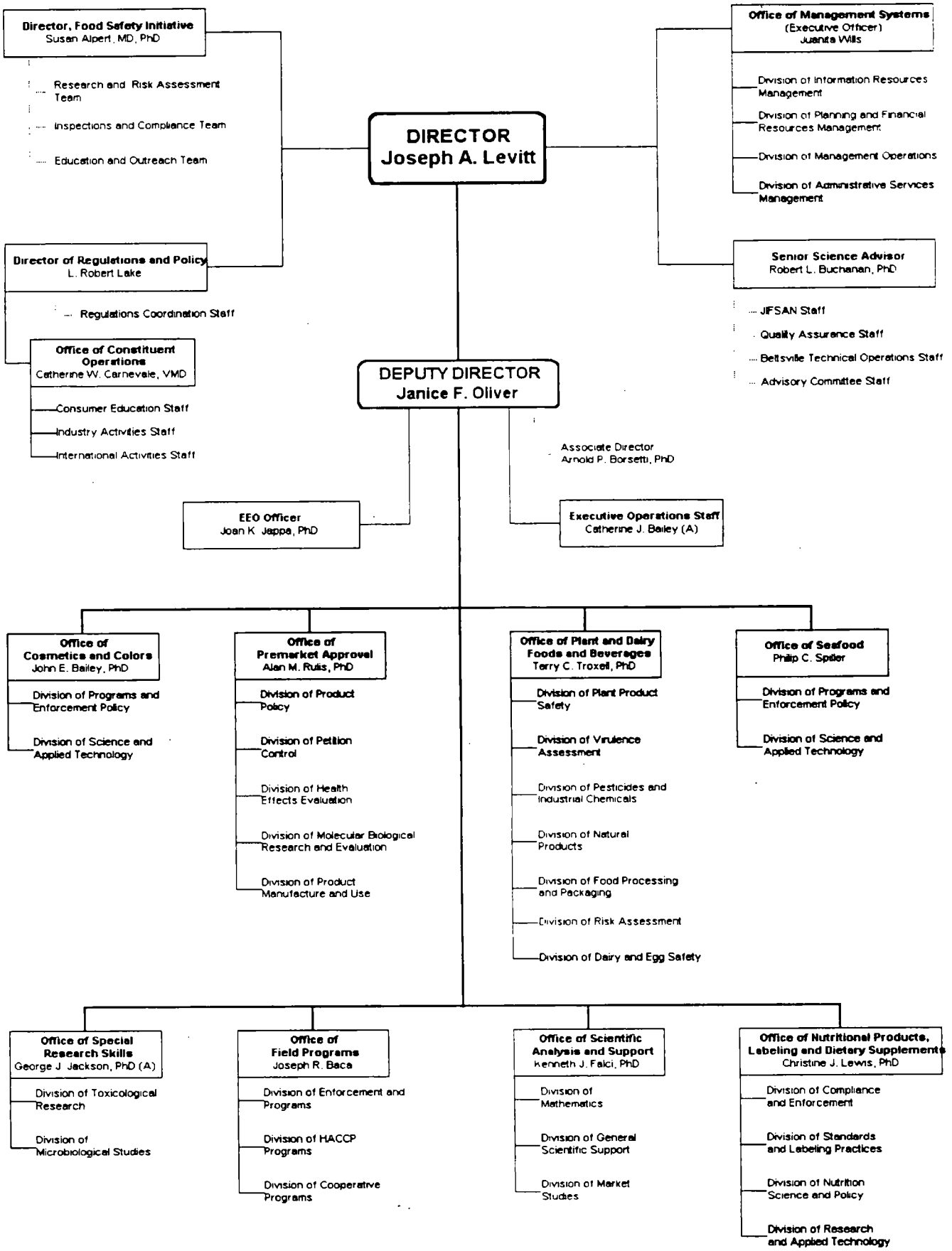
2. You will see a substantial list of goals in the cross-cutting program section regarding our move to College Park. As you may know, CFSAN personnel and laboratories in the downtown D.C. area have the good fortune to be moving to a new facility in College Park, Maryland, starting in the fall of 2001. We have included this new section in the 2001 workplan to highlight that preparing for the move, in and of itself, is going to be a major effort this year, and needs to be factored into our overall productivity planning.

3. As in previous years, we will again provide a mid-year "progress report" later this spring. This will also provide an opportunity to make any needed adjustments in the workplan (additions or deletions) for the balance of the fiscal year.

In keeping with the format of the last two annual priorities documents, the workplan contains two lists of activities in most major sections -- the "A" List and the "B" List. In total, there are over 120 discrete "A" list activities. (This is an increase from 83 "A" List goals in 1999 and 108 "A" List goals in 2000.) Our goal will be to fully complete at least 90% of the "A" List activities by the end of the fiscal year, September 30, 2001. I frequently describe these as the "boulders" we will strive to move up and over the mountain top. Activities on the "B" Lists are those we plan to make progress on during the year, but may not complete. A new feature of the FY 2001 workplan is "B" list items with an asterisk. These are the highest priority "B" List activities, most of which are two-year projects that we are positioning to be on the "A" List next year.

The Center has responsibility for many important ongoing activities that are not identified in the workplan. For example, the Center's base programs in data collection, research and enforcement

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION



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Part II: Major Program Areas

Strategy 2.3
****
Dietary
Supplements

"A-List" Goals:

1. **Regulations/Guidance**

   (a) Publish dietary supplement GMP proposed rule and conduct outreach program.

   (b) Complete health claim evaluations for three diet/disease relationships begun in FY 2000: antioxidants and cancer; vitamin B and vascular disease; and vitamin E and heart disease.

   (c) Continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

2. **Enforcement/Outreach**

   (a) Continue to identify highest priority safety issues and initiate appropriate enforcement actions against unsafe, adulterated, or misbranded dietary supplement products and ingredients.

   (b) Establish a system for making adverse event reports (AERs) promptly available to manufacturers that includes the timely redaction of confidential information.

   (c) Establish strategy for dietary supplements that contain ephedrine alkaloids based on March 2000 release of AER's and related material and August 2000 public meeting/public comments.

   (d) Complete Dietary Supplement Labeling Guide.

3. **Research/Science Base**

   (a) Work with National Academy of Sciences' (NAS) Institute of Medicine (IOM) to review dietary supplement safety.

   (b) Develop mechanisms to expedite dietary supplement adverse event investigations and enhance timely clinical assessment of dietary supplement adverse event reports.

Strategy 2.3
****
Dietary Supplements
Contd.

"B" List

Regulations/Guidance (contd.)

(d) Develop final rule on 'per day' labeling for dietary supplements.

(e) Collaborate across Agency to complete guidance document on structure/function final rule. (CDER Lead)

(f) Collaborate across Agency to publish proposal for labeling dietary supplements for women who are or may become pregnant. (CDER Lead)

2. **Enforcement/Outreach**

(a) Continue to review the 30-day postmarket notifications for structure/function claims in a timely manner.

(b) Clarify policy and enforcement strategy for the definition of "represented as a conventional food" (e.g., beverages).

(c) Develop dietary supplement consumer information document on topic of product category boundaries.

(d) Enhance and improve the dietary supplement website and create a "list serve" for dietary supplement topics.

(e) Prepare regulatory guidebook for industry.

3. **Research/Science Base**

(a) In conjunction with NAS/IOM, investigate criteria and options for evaluating emerging science relative to dietary supplements.

(b) Develop analytical methods for conjugated linoleic acids (CLA).

(c) Implement a 'Dietary Supplement Analytical Methods Working Group' for safety issues.

B

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2000

Dietary Supplement Strategy

(Ten Year Plan)

Letter | Outline | The Plan

Letter from the Director

Dear Colleague, FDA's Food Community:

This document sets forth the Center for Food Safety and Applied Nutrition's (CFSAN's) overall dietary supplement strategy. In January, 1999, CFSAN issued its 1999 workplan. In that workplan, the Center announced that in calendar year 1999, it would "in conjunction with other involved Agency units, and providing an opportunity for stakeholder input, develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994." I am pleased to report that this document sets forth that strategy. There are five points I would like to highlight:

1. FDA held public meetings on June 8, 1999 in Washington, D.C. (East Coast) and on July 20, 1999, in Oakland, California (West Coast) to solicit comments on the development of its overall dietary supplement strategy. In addition, throughout the 1999 calendar year, FDA held several other public meetings on other dietary supplement issues that are part of this strategy (e.g., structure/function claims and current good manufacturing practices). All of these public meetings built upon themes that emerged from a broader stakeholder meeting sponsored by CFSAN in June, 1998.

2. Shortly after the June 8, 1999, public meeting, FDA developed five internal dietary supplement strategy teams to consider the ongoing stakeholder input, and to discuss the dietary supplement activities. The team members were drawn from several Agency units. The teams were organized as follows: Safety, Labeling, Boundaries, Enforcement, and Research. Except for the addition of a section on Outreach, and the broadening of the Research category to Science Base, these categories formed the organizational structure of this strategy.

3. This strategy is built on the "twin pillars" of law and science. Therefore, the strategy establishes a clear program goal to accomplish, by the year 2010, having 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.

4. As with other new legislative mandates, there needs to be a long-term implementation process

to accomplish all of the dietary supplement activities the Agency and/or its stakeholders identified. Therefore, the Agency developed a strategy that sets forth a ten-year implementation plan. This strategy can be accelerated or decelerated, depending on resource availability and safety concerns. FDA will continue to seek additional resources for initiatives identified in this plan through the established budget process. The items in this strategy are not listed in priority order. Instead, FDA will develop, on an annual basis, specific items that are to be accomplished that year within the level of available resources.

5. FDA recognizes that the success of this strategy will not only depend on adequate funding levels, but also on FDA's new and continued partnerships with other governmental agencies, academia, health professionals, industry, and consumers. FDA will continue its outreach to stakeholders to enhance two-way dialogue, establish stronger working relationships, leverage resources, and communicate dietary supplement information.

I am pleased that I had the opportunity to personally chair the June 8 and July 20 public meetings. If you had the opportunity to attend either meeting, I'm sure that you'll agree that one theme prevails, and that is we all want to do what's best for the American consumer. I truly believe that this strategy reflects that goal. With the consumer's interest at the forefront, I look forward to working with you during its implementation.

Sincerely yours,

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

Outline

Overall Ten-Year Goal

I. Safety
   - A. Adverse Event Reporting
   - B. Good Manufacturing Practices
   - C. Health Hazard Evaluation
   - D. Dietary Supplement Safety Database
   - E. New Dietary Ingredients
   - F. Voluntary Submissions
   - G. Internet Surveillance

II. Labeling
   - A. Pearson v. Shalala
   - B. Health Claim Petitions
   - C. Database
   - D. Substantiation
   - E. Authoritative Statements
   - F. Consumer and Marketplace Labeling Surveys
   - G. Publications
   - H. Small Business Exemption

III. Boundaries
- A. Structure/Function Claims
- B. Dietary Supplement vs. Drug
- C. Dietary Supplement vs. Conventional Food
- D. Botanicals
- E. Dietary Supplement Exclusions
- F. Dual Status
- G. Combination Products
- H. Dietary Supplement vs. Cosmetic

IV. Enforcement Activities
- A. Enforcement Strategy
- B. Capacity Building
- C. Federal Trade Commission Coordination

V. Science-Base
- A. Strengthen Science-Base
- B. Strengthen Research Efforts
- C. Regulatory Oversight of Human Studies
- D. Adverse Event Report Monitoring System
- E. Claims
- F. Inter-agency Clearinghouse

VI. Outreach
- A. Advisory Committee
- B. Additional Stakeholder Outreach
- C. Communication

Ten Year Plan

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.

I. SAFETY

A. Adverse Event Reporting.

1. **Systems Enhancement.** Improve adverse event report monitoring system capability by enhancing the data systems and integrating them into the Agency-wide adverse event report monitoring system program.

2. **Timely Release of Reports.** Eliminate freedom of information act backlog and make reports available promptly to manufacturers on an ongoing basis.

3. **Clinical Evaluation and Follow-Up.** Institute an efficient system for the monitoring, clinical evaluation, and timely regulatory follow-up of significant adverse event reports.

4. **Outreach.** Educate consumers and health care professionals on how to use the adverse event reporting system.

B. **Good Manufacturing Practices.** Publish regulations on good manufacturing practices. Once the regulations are issued, establish an outreach program to small business manufacturers and an ongoing inspection program.

C. **Health Hazard Evaluations.** Enhance mechanisms for evaluating health hazards of dietary supplement ingredients and contaminants.

D. **Dietary Supplement Safety Database.** Explore development of a database to help anticipate health hazards.

E. **New Dietary Ingredients.**

1. **Notifications.** Continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

2. **Guidance.** Develop guidance for safety substantiation for premarket (75-day) notifications for new dietary ingredients.

3. **Database.** Incorporate the premarket (75-day) notifications in the comprehensive database created for claims notifications (see strategy item in II. C.).

F. **Voluntary Submissions.** Explore mechanisms for encouraging voluntary submissions of confidential premarket safety data to FDA (e.g., similar to procedural mechanisms for food additive master files).

G. **Internet Surveillance.** Implement an Internet surveillance program to monitor whether products are marketed for safe uses.

II. LABELING

A. **Pearson v. Shalala.** Implement court decision as outlined in December 1, 1999, strategy notice.

B. **Health Claim Petitions.** Meet statutory obligations by responding to health claim petitions within statutory timeframes.

C. **Database.** Complete and activate database for 30-day label claim notifications and courtesy letters.

D. **Substantiation.** Identify criteria for substantiation of structure/function and related claims and identify conditions for sharing substantiation documents.

E. **Authoritative Statements.** Publish final rule on the applicability to dietary supplements of the FDA Modernization Act provisions on nutrient content/health claim notifications based on authoritative statements.

F. **Consumer and Marketplace Labeling Surveys.** Perform surveys and track data of consumer purchases and marketing trends to support sound labeling policies.

G. **Publications.** Resolve issues on use of third-party publications.

H. **Small Business Exemption.** Resolve small business exemption issues for dietary ingredient claims.

III. BOUNDARIES

A. **Structure/Function Claims.**

1. **Final Rule.** Publish a final rule on structure/function claims.

2. **Small Business Regulatory Enforcement and Flexibility Act (SBREFA) Guidance.** Following publication of final rule, issue SBREFA guidance.

3. **Claims Review.** Review 30-day postmarket notifications for supplement claims.

B. **Dietary Supplement vs. Drug.**

1. **Definitions.** Clarify the boundaries between dietary supplements and drugs by defining key terms and phrases (e.g., "dietary substance" and "intended to supplement the diet").

2. **Claims.** Clarify when a disease-related statement is an appropriate health claim for a dietary supplement, and when a disease claim is necessarily a drug claim.

C. **Dietary Supplement vs. Conventional Food.**

1. **Definitions.** Clarify boundaries between dietary supplements and foods by defining key terms and phrases (e.g., "intended for ingestion" and "represented for use as a conventional food") and clarifying the forms of dietary supplements.

2. **Stakeholder Discussions.** Coordinate and review stakeholder discussions addressing structure/function claims issues on conventional foods that may impact dietary supplement boundary issues (e.g., nutritive value).

D. **Botanicals.** Develop a regulatory framework for botanicals used in traditional/alternative medicine (including how they relate to over-the-counter drugs).

E. **Dietary Supplement Exclusions.** Clarify statutory provisions that exclude selling a

product as a dietary supplement if the substance was first approved as a new drug under a New Drug Application or studied as an Investigational New Drug.

F. **Dual Status.** Clarify the regulation of dual status products (i.e., one substance intended for use as a supplement and a drug).

G. **Combination Products.** Clarify regulation of combination products (i.e., a supplement and a drug combined in a single dose, unit, or package).

H. **Dietary Supplement vs. Cosmetic.** Develop criteria for defining boundaries between products intended for cosmetic effect from dietary supplements.

IV. ENFORCEMENT ACTIVITIES

In cooperation with the Office of Regulatory Affairs, and assisted, where appropriate, by other agency components:

A. **Enforcement Strategy.**

1. **Safety Issues.** Identify the highest priority safety issues and take appropriate action against unsafe products.

2. **Boundary Issues.** Take appropriate action on products excluded from being marketed as dietary supplements.

3. **Labeling and Consumer Fraud.** Take appropriate action on inaccurate and misleading labeling and consumer fraud, including trade complaints.

4. **Routine Compliance.** Maintain routine compliance activities, incorporating enforcement of final rules.

5. **Surveillance and Monitoring.** Conduct marketplace surveillance and monitoring activities.

6. **Partnerships.** Establish partnerships with federal, state and local agencies to enhance enforcement efforts by sharing data, heightening communication, and utilizing resources.

B. **Capacity Building.** Make necessary internal enhancements to effectively fulfill enforcement obligations.

1. **Agency's Compliance Procedures.** Develop standard operating procedures for improving the compliance review process.

2. **Case Tracking System.** Contract for and activate computerized dietary supplement case tracking system.

3. **Training.** Provide in-house training to field and headquarters staff to ensure

consistency with current FDA regulatory procedures and practices.

4. **CFSAN/CDER Coordination.** Evaluate, and streamline, to the extent possible, current mechanisms for resolution of cross-center compliance issues.

5. **Laboratory Capacity.** Enhance analytical lab support for regulatory decisions.

C. **Federal Trade Commission (FTC) Coordination.** Enhance coordination with FTC on enforcement cases.

V. SCIENCE-BASE

In collaboration with stakeholders (e.g., academia, health professionals, other organizations, and industry), enhance research/science capabilities, including:

A. **Strengthen Science-Base.** Ensure a sound science-based program for all dietary supplement review and develop a core of well-trained, multidisciplinary scientists in support of supplement review and research.

B. **Strengthen Research Efforts.**

1. **Research Agenda.** With the assistance of a nationally recognized organization, develop a broad research agenda and needs assessment framework to implement priority-based research for dietary supplement issues.

2. **Research Capabilities.**

a. **Inventory and Peer-Review Process.** Identify the Agency's scientific research capabilities relative to dietary supplements, and develop a mechanism for ensuring dietary supplement research is mission-relevant, of high scientific quality, and consistent with regulatory priorities.

b. **Intramural/Extramural Research.** Determine what research can or should be done by FDA (in-house) and what research should be done by extramural sources.

c. **Laboratory Based Research.** Conduct priority- based methods development and safety research for dietary supplement ingredients and contaminants.

3. **Dietary Supplement Ingredient Reviews.** Identify mechanisms for obtaining state-of-the-art science reviews on dietary ingredients in the marketplace, giving highest priority to those with potential health risks.

4. **Leveraging.** Identify leveraging opportunities with universities, JIFSAN, and other government agencies.

5. **Consumer Research.** Conduct research on consumer understanding of label

information, and compare consumer understanding of labeling of conventional foods and dietary supplements for support of regulatory decisions.

6. **Marketplace Research.**

   a. **Economics and Marketplace Research.** Perform necessary economics and marketplace research for support of regulatory decisions.

   b. **Market Analysis.** Explore innovative mechanisms to determine the nature and scope of the dietary supplement market.

C. **Regulatory Oversight of Human Studies.**

1. **Oversight Mechanism.** Clarify when an Investigational New Drug filing is necessary for a substance marketed as a dietary supplement and determine whether a separate mechanism needs to be developed for clinical studies on supplements.

2. **Science-Based Standards.** Develop science-based standards for conducting human studies of dietary supplements using human subjects.

D. **Adverse Event Report Monitoring System.** Conduct research to support enhancing and improving the quality and reporting rate of the adverse event report monitoring system and consider how the adverse event report monitoring system can be used for trend identification of adverse events.

E. **Claims.** Evaluate systems used in other organizations (e.g., health care reimbursement) to distinguish "valid substantiation" for claims (structure/function) from "invalid substantiation" for such claims.

F. **Inter-agency Clearinghouse.** Explore the establishment of an inter-agency dietary supplement research clearinghouse and develop an integrated list of information to be included.

VI. OUTREACH

Enhance outreach efforts to stakeholders to assure effective communication, including:

A. **Advisory Committee.** Establish a standing group to provide a routine public forum to obtain and integrate stakeholder input related to various dietary supplement issues. The group will be comprised of members having expertise relevant to the review of dietary supplement issues (e.g., subcommittee of the Food Advisory Committee).

B. **Additional Stakeholder Outreach.**

1. **Public Forums.** Sponsor and participate in public forums for enhancing dialogue with stakeholders.

2. **Partnerships.** Establish a stronger working relationship with organizations interested in promoting two-way communication and cooperation.

C. **Communication.**

1. **Mechanisms.** Develop mechanisms to communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. **Website.** Expand use of FDA website to communicate dietary supplement information to the general public and health care professionals, and guidance to the industry.

   b. **Information Kits.** Develop information kits for FDA field staff.

2. **Information Dissemination.** Communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. **Safety Data.**

   b. **Enforcement Policies and Procedures.**

This document was issued in January 2000.
For more recent information on Dietary Supplements
See http://www.cfsan.fda.gov/~dms/supplmnt.html

Hypertext updated by cjm/dms/kwg 2000-NOV-16

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To : White House Commission on Complementary and Alternative Medicine March 16, 2001

My name is Margery Wells. I am here representing the American Association of Oriental Medicine, (AAOM), the largest and oldest national association of oriental medicine professionals. I am licensed by the Minnesota Board of Medical Practice and a Diplomate of Traditional Oriental Medicine by the National Certification Commission of Acupuncture and Oriental Medicine. I have been practicing and integrating medicine since 1982.

In our paper, "Integrative Medicine: Merging Traditional Oriental and Western Medical Practices", Dr Gonzalez-Campoy, M.D., Ph.D. and I define oriental medicine , compare it to western medical practices, and address the potential for creating collaborative research and clinical work.

Traditional Oriental Medicine (TOM) is a system much different than Western Medical (WM) practice, with its own views of pathogenesis, its own methods of diagnosis, and its own methods of treatment. There are numerous modalities of treatment within this system as a whole, which in general, are meant to be used together to provide the best possible benefit to the patient.

Just as individuals have the right to responsibly choose how they care for themselves and the right to choose their health care practitioners, people also have the right to expect that the licensed acupuncturist they select is fully trained in TOM. Nationally, graduates from colleges of TOM, have on average, between 2700 and 3300 classroom and clinical hours over a two to three year period. These hours are over and above the health science prerequisites of a two to four year undergraduate degree. Then the focus of training is on pathogenesis, methods of diagnosis , and methods of treatment in TOM, which includes acupuncture, herbal pharmacopoeia, nutritional therapies, and various exercise recommendations. The health care consumer has the right to know if a practitioner has abbreviated or partial system training of anything less than the above mentioned educational hours. And since there are new immigrants who wish to practice acupuncture, people also have the right to expect that their licensed practitioners speak fluent and articulate English, and that they are capable of communicating with patients and their physicians. It is the recommendation of the AAOM and myself that only those with full TOM training be allowed to advertise and practice the treatment modalities of TOM.

Also, utilizing any of the TOM modalities without proper TOM diagnosis training, as in a "cookbook" approach has resulted in a great deal of variability in the type and quality of care among current practitioners. For the future development of our profession, for the benefit of our patients, and for the opportunities to collaborate on research projects with the WM community, which ultimately benefits all, I respectfully submit these recommendations.

March 12, 2001

To: White House Commission on Alternative and Complementary Medicine

The Minnesota Homeopathic Association was founded as a state-wide professional organization for homeopathic practitioners with the following mission:

to promote homeopathy as a safe and effective health care choice for Minnesotans;
to protect the public interest by upholding high standards of care by its member practitioners;
to serve and support the community of Minnesota's professional homeopaths.

We would like to share with you our dedication to the idea that health care consumers should have access to the modalities they feel are most appropriate to their individual needs. While government should protect citizens from harm, we believe it is also the government's important role to protect the citizen's right to individual choice and autonomy as regards the way in which they decide to protect and enhance their own health and well-being.

We enthusiastically support the Minnesota Model as it has supported maximum access by health care consumers to the many modalities and types of healers available while at the same time protecting the individual through a Health Department consumer hot-line for complaints and the enforcement of 24 paragraphs of practitioner prohibited conduct.

We believe that the Minnesota Model was carefully crafted after much thought and deliberation as well as the legislative give-and-take of all interested parties. We want you to know that the Minnesota Complementary and Alternative Health Care Freedom of Access Act has the full support and confidence of our professional organization. In sum, the Minnesota Model provides the opportunity for the citizens of Minnesota to maintain their health and well-being across a broad spectrum of choices while at the same time protecting Minnesota health care consumers from harm.

Best regards,

Valerie Ohanian, R.S. Hom., C.C. Hom.
President

Written Statement: Education of CAM Providers Panel Discussion

Jackson Petersburg, CenterPoint Co-Director
Formerly Northern Lights School of Massage Therapy and the Minnesota Center for Shiatsu Study

"The Evolution of Massage Therapy Education in the United States"

Let me begin by saying what a privilege it is for me to be participating in a process that I am convinced will impact on the very nature of the health care delivery system in this country. I would especially like to thank Mary Jo Kreitzer and the Center for Spirituality and Healing for organizing this event and allowing me the time to share my thoughts concerning the education of complementary and alternative health care providers.

I originally intended to start by giving a brief history of my own profession, citing some of the major factors that may have influenced how massage therapists were and are educated in this country. Unfortunately, that took up all of my allotted time. I will instead give you a very condensed version of the salient points of this history. In a nutshell, war, drugs, sex and a defining moment in time.

After WWII, the development of analgesic drugs started to replace manual methods of pain control. There also seemed to be a proliferation of massage parlor activity, which slowly eroded the reputation of legitimate therapists. This tainted reputation lasted well into the end of the twentieth century and heavily influenced the development of municipal massage parlor ordinances, that are still in effect in many cities and towns across the country that do not have some form of statewide regulation that supersedes municipal jurisdiction. In fact, the city of Minneapolis still has such an antiquated ordinance. If it were strictly enforced, most self-employed massage therapists would be required to work in a five square block, red

light section of downtown. To my knowledge, we are the only emerging health care profession regulated by municipal law.

In addition to drugs and sex, the other primary factor that influenced massage therapy education after WWII, was the conscious decision by massage therapy organizations not to align themselves too closely with the conventional medical model. In hindsight, this proved to be a defining moment for the profession. I think that it severely slowed down the development of educational standards for the profession, while at the same time, allowing the profession to develop in a much more organic way. It moved out of the medical model of the first half of the century, to the experiential model of the 1970's. This model was tremendous for fostering experimentation, and disastrous for establishing well defined professional boundaries and a strict ethical code of conduct. Eventually, this dichotomy created dissonance in the souls of the new wave of massage therapy educators. The most balanced of these educators managed to create a system that established boundaries and ethics, while at the same time, retaining this experimental energy and heart.

In my experience, I don't think that this history is decidedly different than many of the other complementary and alternative health care professions. In my opinion, the development of educational standards goes hand in hand with the development of other nationally recognized standards or benchmarks, that assist the consuming public in defining a professional. My professional association, the American Massage Therapy Association (AMTA), and more specifically, the AMTA Council of Schools, planted the seeds to create the National Certification Board for Therapeutic Massage & Bodywork (NCBTMB) and the Commission on Massage

Therapy Accreditation (COMTA). COMTA was then and still is primarily comprised of professionals in the field who volunteer their time and energy to create a realistic, programmatically-based, accreditation model. These oversight agencies may not be perfect, but their mission is driven by people currently working in the field. This is critical!

Finally, what national trends do I see in massage therapy education that may also apply to other CAM professions? The first trend that is especially evident across the country is that cutting edge education will never be contained by either state or municipal laws. This is evidenced by the fact that training institutions across the country are developing degree granting programs (AA, BS, MS, Ph.D.), that far exceed the requirements of existing laws. Another trend that is closely related to this is that freestanding training programs are establishing some form of articulation agreement with colleges and universities to streamline this process and also allow them to participate in research that otherwise would too complicated and costly for them to do on their own. A third trend is the rapid growth of programs across the country being developed by trade and technical schools who are scrambling to create curriculum and find qualified faculty to teach their program.

In conclusion, there will always be individuals and institutions that are pushing the envelope in educational standards and experimentation and there will always be individuals and groups that will resist these changes. The key is to not become complacent. Or as my father used to say, "If you can keep your head in all this confusion, then you don't understand the situation." Thank you.

Professional Biography

Jackson Petersburg founded and directed Northern Lights School of Massage Therapy from 1985-2000. This year, Northern Lights School combined with the Minnesota Center for Shiatsu Study to become CenterPoint. CenterPoint offers training programs in both massage therapy and Shiatsu therapy, Advanced Certification programs and a public clinic. Jackson received his training in massage therapy from the Boulder School of Massage Therapy. He has a Bachelors Degree in Recreation Education, from the State University of New York, College at Cortland. Jackson has served on the National Board of the American Massage Therapy Association (AMTA), the Executive Committee of the AMTA Council of Schools and as President of the Minnesota Chapter of the AMTA. He has been in private practice since 1979, focusing primarily on soft tissue injuries and conditions. Jackson has presented workshops throughout the U.S. for the past fifteen years.

White House Commission
On Complementary and Alternative Medicine Policy
Hubert H. Humphrey Institute, Cowles Auditorium
Minneapolis, Minnesota
March 16, 2001

Education of CAM Providers Panel

Barbara York

President, MTMN—Minnesota Touch Movement Network

Board Member, MN Natural Health Legal Reform Project

Chair, IMA Network of Minnesota

Jin Shin Jyutsu® Practitioner

Massage Practitioner

Member NCBTMB

Member UMC

I believe that the best practitioners of complementary and alternative medicine are those who realize that this work is best met with experience, personal study and the time to know their client. Because of the variety of practices, I do not believe that uniform standards can be applied in this field. It has been said that you cannot put your foot into the same river twice. By the same token, every session with a client is a new experience for both parties no matter how exacting the technique may be.

Though I personally chose to pursue a thousand hour accreditation course and passed the national certification exam for massage therapists, I still believe the best lessons come in hands-on experience, whether as an apprentice or a seasoned practitioner of 18 to 30 years. Essentially learning is never finished, regardless of certificates and testings. The true lesson is with the client. Without respect for that, any education is worthless.

As a Jin Shin Jyutsu® practitioner, I participate in an ancient art that was passed down from generation to generation by word of mouth. Jin Shin Jyutsu is a Japanese phrase which means the "art of the Creator through compassionate man". The study of Jin Shin Jyutsu is a way to expand awareness and understanding. The practice is considered a demonstration of the art. The responsibility for usage of knowledge received, is within each practitioner. I believe each person in this room is equally wonderful at Jin Shin Jyutsu, the only difference between us is in awareness. The Art of Jin Shin Jyutsu is a simple and powerful tool, equally available to all.

In similar fashion, I have a book called Primitive Remedies which was collected by John Wesley the founder of the Methodist church. It was a record of

parishioners remedies which he collected and shared as he traveled his church circuit. He did not present himself as a trained healer. Many of these remedies are practical and based on principles recognized by contemporary healers.

I would like to quote from the introduction to Primitive Remedies— "Wesley's concern was for the common people and it was his purpose to give them 'a plain and easy way of curing most diseases'; 'to set down cheap, safe, and easy medicines; easy to be known, easy to be procured, and easy to be applied by plain, unlettered men.'

The field of Complementary and Alternative Medicine remains this simple. It is safe, it is accessible to the consumer. It is uncomplicated, despite the sometimes confusing emphasis on technique. The Minnesota Complementary and Alternative Health Care Freedom of Access Act of 2000 provides a legal environment in which practitioners of alternative health can practice regardless of their education and training as long as they practice within reasonable conduct guidelines.

I encourage the commission to consider this simple, profound approach of honoring both the consumer and the practitioner.

Respectfully,
Barbara York

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Further Points:

• Safe and easy remedies become packaged and sold as privately held techniques.

One of the simple and common ideas of John Wesley's, is recommended in his "Plain Easy Rules" "(9) The flesh brush is a most useful exercise, especially to strengthen any part that is weak." [1], which now in our time is rediscovered and trademarked as a technique called "Vital Chi Skin-Brushing System™" which is being sold by a Bruce Berkowsky, N.M.D. [2]

• Even children are capable of providing CAM.

The founder of shiatsu, Tokujir Namikoshi, who recently died at the age of 94, developed his approach starting at seven years of age massaging his own mother

who suffered from rheumatoid arthritis. [6]

•Educational standards can become an obstruction for the consumer to find their appropriate provider.

Jin Shin Jyutsu® is considered modality training. Many CAM providers take specialized, extensive and expensive training in fields such as; Ortho-Bionomy™, the Rosen Method of Bodywork and Movement™, Reflexology, and NeuroMuscular Therapy. [5] Dawn Nelson, though a nurse, found her most profound connection and effectiveness with patients was in simple holding. [3] Many providers have created simple ways of being with people. They have found that the CAM client is a very subjective healing relationship. It is not based on outcome but support and understanding of the patients belief system. Though many long time providers are also teachers, they would not qualify for many regulation requirements. [4]

•Lack of harm in CAM providers.

With the number of practitioners, modalities and contact hours incidents of harm would be headlines. Yet professional liability insurance providers know that the true issues of concerns are standard "trip and fall" hazards. One company allows membership with full benefits based upon experience. [7]

•Delayed care concerns

John Wesley [1] recommended "In uncommon or persistent cases, he advised 'every man without delay to apply to a Physician that fears God.' " Many consumers come to CAM providers **after** they have exhausted traditional medicine or while they **wait** to see their primary care provider or specialist who may not be able to see them for weeks.

RESOURCES:

1—Primitive Remedies, John Wesley, Woodbridge Press Publishing Company, Santa Barbara, California, 1973.

2—Massage & Bodywork, Associated Bodywork & Massage Professionals, Inc., Evergreen, CO, Vol.#XV, Issue #5, October/November 2000, pg.13-20.

3—Compassionate Touch, Dawn Nelson. Station Hill Press, Inc., Barrytown, NY, 1984

4—Healers On Healing, Richard Carlson and Benjamin Shield, Jeremy P. Tharcher, Inc., Los Angeles, CA, 1989.

5— The Encyclopedia Of Bodywork, Elaine Stillerman, Facts On File, Inc., NY, NY, 1996.

6— Massage Magazine, Massage Magazine Inc.,Spokane, WA, Issue 90, March/April, 2001, pg. 31

7—The IMA—International Massage Association, P.O. Drawer 421, Warrenton, VA 20188-0421• (540) 351-0800 • Info@IMAGroup.com • www.imagroup.com/

MTMN—Minnesota Touch Movement Network

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www.geocities.com/mtmn4u/

The Minnesota Touch-Movement Network is a professional, state-wide, non-profit, inclusive organization of complimentary and alternative health care providers; including massage therapists, touch therapists, somatic educators, energy therapists, body workers and healing artists. The MTMN was founded in 1981.

The purpose of the MTMN is to support and protect the practice of massage and touch movement therapy.

The MTMN is a grassroots organization. The focus of networking, or exchange of information is vital to its existence. The MTMN places members' ethics above the amount or style of training. Because the MTMN is a statewide organization, it has more flexibility than groups which are national in scope to adapt to the individual needs of its membership.

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Mary Burmeister, President, Jin Shin Jyutsu, Inc.

David Burmeister, Director, Jin Shin Jyutsu, Inc.

OUR MISSION STATEMENT

Through the dynamic Art of Jin Shin Jyutsu (Physio-Philosophy), our mission IS to create a safe environment for reawakening the true SELF. Being the testimony of this simple, profound Art of Living, made known to us by Mary Burmeister and Jiro Murai, we educate, harmonize and inspire ourselves and others through integrity, compassion, trust and freedom to BE...NOW KNOW MYSELF.

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INTRODUCING JIN SHIN JYUTSU®
PHYSIO-PHILOSOPHY

JIN SHIN JYUTSU literally translated is:

JYUTSU - Art
SHIN - Creator
JIN - Man of Knowing and Compassion

(Art of the Creator through man of knowing and compassion)

JIN SHIN JYUTSU is the art of releasing tensions which are the causes for various symptoms in the body. Our bodies contain several energy pathways that feed life into all of our cells. When one or more of these paths become blocked, this damming effect may lead to discomfort or even pain. This blockage or stagnation will not only disrupt the local area but will continue and eventually disharmonize the complete path or paths of the energy flow.

Through JIN SHIN JYUTSU our awareness is awakened to the simple fact that we are endowed with the ability to harmonize and balance ourselves (in rhythm with the universe) physically, mentally and spiritually.

JIN SHIN JYUTSU is an art as opposed to a technique because a technique is a mechanical application, whereas an art is a skillful creation. This beautiful, simple Art is our inheritance. According to ancient written records, which remain in the Archives of the Imperial Palace in Japan, JIN SHIN JYUTSU was widely known before the birth of Gautama (Buddha, India), before the birth of Moses (recorded in the Bible), and before the Kojiki (Record of Ancient Things - Japan, A.D. 712). JIN SHIN JYUTSU is an innate part of man's wisdom - simplifying the complexities of existence - and is truly an ART OF LIVING.

JIN SHIN JYUTSU was rediscovered by Master Jiro Murai early in this century. His student, Mary Burmeister, brought the Art from Japan to America in the 1950's. Classes in JIN SHIN JYUTSU are currently offered by Mary's associate instructors, Muriel Carlton, Philomena Dooley, Wayne Hackett, Susan Brooks (on sabbatical), Lynne Pflueger, Waltraud Riegger-Krause, Matthias Roth Jed Schwartz, Ian Kraut, and Birgitta Meinhardt.

Jin Shin Jyutsu® physio-philosophy is an ancient art of harmonizing the life energy in the body. Born of innate wisdom and passed down from generation to generation by word of mouth, the Art had fallen into relative obscurity when it was dramatically revived in the early 1900's by Master Jiro Murai in Japan.

After clearing himself of life-threatening illness, Master Murai devoted the rest of his life to the research and development of Jin Shin Jyutsu, gathering insight from a range of experiences and resources, including the Kojiki (Record of Ancient Things). The resulting knowledge of Jin Shin Jyutsu was then given to Mary Burmeister, who brought it to the United States in the 1950's.

Mary Burmeister began teaching the Art to others in the early 1960's, and today there are thousands of students throughout the United States and around the world.

Jin Shin Jyutsu brings balance to the body's energies, which promotes optimal health and well-being, and facilitates our own profound healing capacity. It is a valuable complement to conventional healing methods, inducing relaxation and reducing the effects of stress.

Jin Shin Jyutsu employs twenty-six "safety energy locks" along energy pathways that feed life into our bodies. When one or more of the paths becomes blocked, the resulting stagnation can disrupt the local area and eventually disharmonize the complete path of energy flow. Holding these energy locks in combination can bring balance to mind, body, and spirit.

Learning Jin Shin Jyutsu engages one in self study, self help. Through the process of "now know myself" we recognize the wisdom of the body, and we learn to interpret the messages provided and utilize them to restore balance.

Jin Shin Jyutsu can be applied as self-help and also by a trained practitioner. A Jin Shin Jyutsu session generally lasts about an hour. It does not involve massage, manipulation of muscles, or use of drugs or substances. It is a gentle art, practiced by placing the fingertips (over clothing) on designated safety energy locks, to harmonize and restore the energy flow. This facilitates the reduction of tension and stress which accumulate through normal daily living.

For those of us addressing existing stress or health disharmonies, or for those simply wishing to participate actively in maintaining health, harmony and well-being, the Art of Jin Shin Jyutsu is a simple and powerful tool, available to all!

Mary Burmeister,
by Melissa Higgins
Article published in the March/April 1988 issue of Yoga Journal
(Slightly revised to reflect today's teaching staff)

The tiny, energetic woman placed one of my hands in hers, grasping my forefinger firmly but not tightly. Her eyes sparkled as she looked into mine and said, "See? Isn't that simple?" Miraculously, the tension of months of work disappeared. It was Jin Shin Jyutsu in action, she explained.

Categorizing Jin Shin Jyutsu can be as difficult as pigeonholing its one-woman leading force, Mary Burmeister. More than a style of bodywork, it's a philosophy of life taught by a master who lives her philosophy.

Burmeister describes Jin Shin Jyutsu (which means "art of the Creator through compassionate man" in Japanese) as a "physio-philosophy" that is used by everyone unconsciously, doesn't "do" anything, yet encompasses everything. "I call it the art of life, the art of life itself. It is the whole cosmos and cannot be categorized," Burmeister explains.

The purpose of Jin Shin Jyutsu is to release the tensions that cause various physical symptoms. The body, Burmeister teaches, contains energy pathways that feed life into all cells. When one or more of these paths become blocked, the damming effect can lead to discomfort or pain. Jin Shin Jyutsu, like acupuncture and acupressure, reharmonizes and balances the energy flows.

Recently I participated in Burmeister's five-day Jin Shin Jyutsu course to learn more about this little-known "art" from the Orient. Although she has a large and loyal following, Burmeister keeps a low public profile and, until now, has never allowed an interview.

Based on ancient knowledge of the body and creation, Jin Shin Jyutsu was passed down orally from one generation to the next and had virtually disappeared in Japan when it was rediscovered in the early 1900s by Jiro Murai, a Japanese philosopher. As a young man, Murai contracted what was diagnosed as a terminal illness. He asked his family to take him to the mountains and leave him in solitude for seven days.

In a feverish state, Murai imagined sages in spiritual meditation using hand mudras, which he applied to himself as he went in and out of consciousness. By the seventh day he was completely healed, and he vowed to spend the rest of his life studying the connection between his amazing recovery and the mudras he had used.

Searching for answers, Murai studied the Bible (which he translated himself) and ancient Chinese, Greek, and Indian texts. But it was the Kojiki, the Japanese "Record of Ancient Things," that opened the door for him.

"He unraveled the mystery of a plain, old story, the Kojiki, which describes creation in allegories," says Burmeister. "He read into the words."

From his study of the Kojiki and his 50 years of personal experimentation, Murai concluded that Jin Shin Jyutsu was more than a philosophy of the body.

"Murai studied the Chinese acupressure points, then took them a step further by experimenting on himself and fasting. He compared what he experienced to the ancient acupuncture writings and compared them to what he felt. His experiences were much deeper than what he found in the writings. There is an awareness in Jin Shin Jyutsu that is deeper than technique," Burmeister says.

Theories of the body and philosophies of creation were far from Burmeister's mind when she met Murai in the late 1940s. A first-generation Japanese-American born in Seattle, she went to Japan to learn Japanese, not to study Jin Shin Jyutsu. "A young lady came to me and asked me to tutor her in English," Burmeister recalls. "It was through this casual meeting that some months later I met Jiro Murai at her home. The first words he said to me were, 'How would you like to study with me to take a gift from Japan to America?' I had no idea what he was talking about, but I went to hear him speak and knew I would stay to listen. I studied with him in Japan for five years, then in America through correspondence for seven more years."

It was 17 years, however, before Burmeister started sharing Jin Shin Jyutsu with others. "I just felt I had to know something before I could say I knew it. Then I realized you can't say you ever really know an art like this. One day I found myself timidly putting my hand out to a neighbor with a back problem and saying, 'Maybe I can help you.' After five years of working with her, I moved, and she then went back to her chiropractor, who called me soon after and requested that we meet. The chiropractor became my first student.

"After two years of sharing with the chiropractor, I started to translate and write down what I had learned from Jiro Murai. I'd stay up late at night after taking care of the children, writing and making

drawings. The chiropractor said she had a few colleagues with whom she'd like me to share Jin Shin Jyutsu. Our group grew to about six students, including a psychologist, a physician, and another chiropractor. That's how it began."

Burmeister explains that our revitalizing energy, which flows up the back and down the front of the body, can become blocked in 26 "safety energy locks," or what she terms "specialists," located throughout the body and in the organs themselves.

"As we abuse our bodies in our daily routines, mentally, emotionally, digestively, or physically, our safety energy locking system becomes activated," says Burmeister. "This is simply to let us know we are abusing our bodies."

A flow can be unblocked through a sequence of steps, or through a "quickie" step as simple as grasping a finger. The revitalizing energy then flows through the hands, or what Burmeister calls the "jumper cables," and can penetrate through clothing, even a brace or a cast.

"Light pressure goes through the skin and into the bone. If pain is present, it's because there is blockage and the pain is coming from the person, not the pressure. We don't have to dig into the very marrow of the bone. All we have to do is take away the dams."

Burmeister says that in Jin Shin Jyutsu there is no diagnosing, healing, or curing. "Some of you can go out today and look at the book and try this out. But you're not doing it, it's the light and the 'specialist' that are doing it. And the person you're working on says, 'Hey, my headache's gone.' But it's not you who's done it, it's the 'specialist' on step one, step two, step three, that's cleaning the debris for that particular complaint. We cannot do wrong because we are not doing anything. We are only jumper cables."

"Not doing anything" while at the same time doing something is one of several paradoxes in Jin Shin Jyutsu. Despite its esoteric principles, however, Burmeister maintains that Jin Shin Jyutsu is an inborn art that anyone can learn without much training.

"Plato said, 'Learning is remembering.' There's nothing we have to learn. We're always utilizing part of Jin Shin Jyutsu naturally, but as soon as we come into the world, it's 'gotta get,' 'gotta go,' 'gotta get your education,' and the skill lies dormant."

A student with a sprained ankle tells Burmeister that after her accident she has developed a habit of holding her wrist "That's helping the sprained ankle," Burmeister replies. "We carry a baby a certain way, and that's helping the little one without our knowing why. When a baby sucks its thumb, we tell it, 'No, no, that's wrong,' but the baby is telling us about its needs. It's in need of real energy, or its digestion needs help. Sucking the thumb helps the baby's nervous and muscular systems. As adults, we can hold the thumb and get the same result."

Burmeister says that Jin Shin Jyutsu not only aids the body, but changes the attitudes that underlie the physical symptoms. "Jin Shin Jyutsu helps everything from head to toe and toe to head. There are 27 trillion cells in the body, and if we smile, all 27 trillion cells smile with us. This is how we help ourselves in health.

"A five-year-old girl came in for a session with her parents. At the first session she was unhappy, all frowns. After the third session, she smiled at her mother and said, 'I love life.' Isn't that dynamic?"

During the five days of class, Burmeister shared other success stories. A woman in a wheelchair whose hands were stiff with arthritis was unable to enjoy her favorite hobby, knitting. A friend who was familiar with Jin Shin Jyutsu told her about holding the fingers. A few days later, after using Jin Shin Jyutsu on herself every night, the woman was knitting again.

A teenager working in a fast-food restaurant burned his arm in a vat of hot oil. His mother, a student of Burmeister's, placed her hands gently on his calves, the location specified in Jin Shin Jyutsu for helping skin ailments. The next morning, not only had all signs of the burn disappeared, but his complexion had cleared up as well.

Amazing as these stories are, I wondered how any kind of body therapy that didn't include direct and deep manipulation of the spine or muscles could be so effective. Although I felt tension disappear when Burmeister held my finger, I was not completely convinced.

Then I experienced a full Jin Shin Jyutsu treatment firsthand. In a class practice session, Burmeister took one look at me and said, "You're a 'doer.' You're always out in the world trying to get things done, rather than relaxing and letting things be."

From observing my body - the bend of my toes, my hands held over my stomach, my left shoulder higher than the right - Burmeister seemed to know almost everything about me. Yet she insists there is nothing unusual in what she does.

"When someone comes in for a session, I know the way they eat, I know what their needs are. And they say, 'Gee, you're psychic.' I'm not psychic. There's nothing mysterious about it. I'm just reading what the body is telling me."

At Burmeister's direction, one student placed her fingers under the back of my neck and another held my big toe and ankle. Two students on either side of my body each put a hand under my back. Then one of these students grasped my inner thigh at the knee, and the other put his free hand on top of my calf. Over the next 20 minutes I felt the tension in my back muscles melt away. Gurgles rose up from the depths of my torso. Toes and fingers twitched and moved. My breathing became deeper and more even. In general, I felt a sense of calmness, balance, and well-being. Even the puffiness in my cheeks disappeared.

Other students experienced their own small successes. Obviously something was working, but would the results last?

"The physical, mental, and emotional may be cleaned up for now," Burmeister says, "but if we go out and dirty it up again, we need to clean up the dirt, dust, and grime again. That's all it is. You'll just come in for more housecleaning, or you'll do it yourself."

Although dedicated to her work, Burmeister is hesitant to promote Jin Shin Jyutsu as a business. She does no advertising for her courses or private practice in Arizona, yet her classes fill quickly with students from around the world, and new clients have to wait up to one year for treatment. Watching and talking with Burmeister, I soon understood why: By living the simplicity, calmness, patience, and self-containment that lie at the heart of Jin Shin Jyutsu, she has become its best promoter.

"In Jin Shin Jyutsu there are no teachers or masters, they are all the same. I always say, 'Be the example.' We don't have to preach to other people. When people see me and say, 'You're so calm and relaxed. How do you do it, are you on pills or something?' then I can tell them about the hands. The jumper cables are the light. I've been studying for 30 years, and I know nothing.

"I don't see a future. I'm just in the now. Whatever direction it is, so it is. Whatever direction comes up, that's what I am. We're having this interview because David [her son and business manager] said it's time to get out a little bit more. I never butt into God's plans, I just go along with what is. Life is not a struggle, life is enjoying the now. It's simple."

Resources: Jin Shin Jyutsu, Inc.

JIN SHIN JYUTSU IS.

by David Burmeister and Michou Landon

Article from Massage and Bodywork Quarterly; Fall 1992 - slightly revised to reflect our current teaching staff and accommodate this home page.

Jin Shin Jyutsu is an ancient Japanese Art of harmonizing life energy within the body. Said to predate Buddha and Moses, it was rediscovered in the early 1900's by Master Jiro Murai, who, after recovery from "terminal" illness, devoted himself to the revival of the Art for future generations. He believed that the capacity to use this Art is born to all of us, like our hands, the tools with which it is applied.

Literally defined, Jin Shin Jyutsu is the Art of the Creator expressed through knowing and compassionate man.

It is a physio-philosophy that involves the application of the hands for gently balancing the flow of life energy in the body; more generally, it is the awakening to awareness of complete harmony within the self and the universe.

There are two important distinctions between Jin Shin Jyutsu and many other massage and oriental healing modalities to which it is often compared.

First, Jin Shin Jyutsu is an art, as opposed to a technique; a technique is a mechanical application, whereas an art is a skillful creation.

Second, Jin Shin Jyutsu is not a physical manipulation of tissue and uses only minimal pressure. The hands are used as "jumper cables," contacting 26 "safety energy locks" to redirect, or unblock the flow of energy along its pathways.

A practitioner of Jin Shin Jyutsu is not the "do-er", s/he simply assists in the flow of an infinite supply of universal energy. This process does not affect the practitioner's personal supply of energy.

In a typical Jin Shin Jyutsu session, which lasts about one hour, the receiver remains clothed and lies face-up on a cushioned surface. After "listening" to the energy pulses in the wrists, a practitioner employs a harmonizing sequence, or "flow," appropriate for unblocking particular pathways and restoring the energy to the energy rhythm of the universe.

A "flow" is a series of hand placement combinations (using the "safety energy locks") that stimulates circulation of energy along a given pathway. There are many such pathways in the body, each with a distinct function or essence.

To a certain extent, the experience of Jin Shin Jyutsu is unique to each person for each session.

However, the most common effect is that of deep relaxation. Who among us doesn't welcome any opportunity to let go of stress, which so often interferes with optimum health?

Mary Burmeister, a close student of Master Murai, brought the gift of Jin Shin Jyutsu to America upon returning from Japan in the 1950's. Over the years, demand for Jin Shin Jyutsu has grown steadily, primarily by word of mouth. Mary began teaching in the early 1960's, and, although she does not currently present the basic workshops herself, she continues to see clients in her office in Scottsdale, Arizona.

Now, the five-day seminars are offered by Mary's ten associate-instructors, Muriel Carlton, Philomena Dooley, Wayne Hackett, Susan Brooks (on sabbatical), Lynne Pflueger, Waltraud Riegger-

Krause, Matthias Roth Jed Schwartz, Ian Kraut, and Birgitta Meinhardt. These workshops are held throughout America, as well as in Canada, Europe and South America. There are currently well over 5,000 students of Jin Shin Jyutsu worldwide.

Jin Shin Jyutsu, Inc., offers practitioner certification to students who complete the training; this certification does not constitute a license, however, such as that required for massage therapists. Jin Shin Jyutsu training is based upon two text books, which are only issued to workshop students and are not available to the general public. However, in addition to the text books, three self-help books are available to everyone. There is even a self-help book designed for children. For more information about these materials consult various sections of this web site: http://www.jinshinjyutsu.com/

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Dear Students and Friends of Jin Shin Jyutsu,

Thanks to your love and enthusiasm, the Blessings of the Art of Jin Shin Jyutsu continue to ripple out into ever-widening circles, reaching growing numbers of people around the world. It is inspiring to see so many of you continue to grow in your awareness and to hear your beautiful stories about the special ways Jin Shin Jyutsu has touched the lives of your friends and families.

In order to grow together as a strong community, we feel it will be helpful to clarify certain practical matters which, until now, may have seemed vague. What follows are several questions that we have consistently heard over the years. We feel that a discussion of these will be helpful to students and practitioners alike.

PRACTICING THE ART OF JIN SHIN JYUTSU:

1. Q: When am I able to practice Jin Shin Jyutsu on a professional basis and refer to myself as a Jin Shin Jyutsu practitioner?

A: First of all, we encourage you to use your jumper cables from the beginning. However, since such a volume of material is covered in the seminar, and no test is given to measure one's understanding, we feel that a certain amount of time and experience is essential to assimilate the teachings. For this reason, we encourage new students not to hurry through the process of completing three classes. A time period of about 18 months is as fast as we recommend for proper integration of understanding the Art.

Upon completing the five-day seminar three times, each student receives a certificate, which we regard as the practitioner level certificate. At this point, a student has usually gained a basic understanding with which to embark upon a lifelong study and practice of the Art of Jin Shin Jyutsu.

2. Q: Is a Jin Shin Jyutsu certificate the same as a license?

A: No. The certificate issued by Jin Shin Jyutsu, Inc. does not constitute a license like those required by state or municipal governments for massage therapists. We suggest that a practitioner consult the laws concerning bodywork* in his or her own community to determine whether (and if so, what) licensing is necessary. Some locations do not require any license.

*Although we do not label Jin Shin Jyutsu as "bodywork", it is generally laws pertaining to "bodywork" that govern the practice of Jin Shin Jyutsu.

3. Q: What should I charge for a Jin Shin Jyutsu session?

A: Fees charged for a Jin Shin Jyutsu session tend to vary according to the location and experience of the practitioner. (For instance, Mary Burmeister herself charges $80 while her associates at the Scottsdale office charge $55 per session.) Factors such as local cost of living, overhead expenses for

an office, and the extra expense of house calls will all influence a practitioner's fee.

(Also, we have found that Jin Shin Jyutsu practiced at luxury resorts and health spas is often priced much higher than fees of a private practitioner.)

Keeping all of this in mind, we encourage practitioners to keep prices affordable, because modest pricing (and even a sliding scale) makes Jin Shin Jyutsu available to all.

4. Q: What terminology is appropriate to use as a practitioner and as a self-help instructor?

A: Mary Burmeister and Jin Shin Jyutsu, Inc. tend not to use terms, concepts, and practices which are closely associated with the medical profession such as "therapy", "diagnosis", etc. We do not make claims to "cure" or to supplant appropriate medical care. Indeed, the use of such terms or the making of such claims could be illegal in certain circumstances. However, we believe Jin Shin Jyutsu profoundly supports the healing process of body, mind and spirit, and is a valuable complement to conventional healing methods.

5. Q: Can I use the name Jin Shin Jyutsu and its Kanji (Japanese characters) on my business card?

A: The name Jin Shin Jyutsu, the Kanji and finger logos are valuable assets of Jin Shin Jyutsu, Inc. and serve to identify and distinguish the Art brought to us by Master Jiro Murai and Mary Burmeister from other forms of "bodywork" which are practiced by people who neither understand nor share our values and teachings. Jin Shin Jyutsu, Inc. registered these marks with the government so they would truly identify the gift given to us. It is our policy to license and encourage practitioners trained by Jin Shin Jyutsu, Inc. to use the marks. In that respect, the certificate issued by Jin Shin Jyutsu, Inc. to persons who have completed the five day seminar three times serves as a license to use the name Jin Shin Jyutsu, the Kanji and finger logos, always identified with the trademark symbol ®, in connection with the practice of the Art of Jin Shin Jyutsu as given to us by Master Jiro Murai and Mary Burmeister. We encourage qualified practitioners to use the marks on stationery, business cards, promotional fliers, etc., together with the trademark symbol. Of course, Jin Shin Jyutsu, Inc. reserves the right to revoke a person's right to use any of the registered trademarks if the marks are not being used in a manner consistent with the Blessings of the Art of Jin Shin Jyutsu or for other reasons which are in the best interest of Jin Shin Jyutsu, Inc.

6. Q: How may I inform people about Jin Shin Jyutsu?

A: Jin Shin Jyutsu, Inc. is making available an information brochure for use in introducing Jin Shin Jyutsu to others. Further, we happily permit publication of articles in your community, provided that we are given the opportunity to review them in advance for accuracy.

7. Q: Who is authorized to teach Jin Shin Jyutsu?

A: Currently Jin Shin Jyutsu, Inc. has ten instructors - three senior and seven more recent instructors authorized to present the materials in Text I & II. The senior instructors are: Muriel Carlton, Philomena Dooley and Wayne Hackett. The more recent instructors are: Susan Brooks (who is presently on sabbatical), Lynne Pflueger, Waltraud Riegger-Krause, Matthias Roth, and Jed Schwartz, Ian Kraut and Birgitta Meinhardt. The above mentioned are the only instructors (of text materials), other than Mary Burmeister, recognized by Jin Shin Jyutsu, Inc.

PRESENTING SELF-HELP CLASSES

1. Q: At what point can I present a self-help class?

A: We believe a self-help class should be taught only by people who have completed the five day seminar at least three times. Upon completion of the basic training, Parts I & II three times, a practitioner level certificate will be issued. This qualifies you to attend the "Instructor Training in Self-Help" (IT IS) seminar. The IT IS seminar helps prepare interested students to conduct self-help classes using Mary Burmeister's self-help books. A certificate of attendance is issued upon completion of the IT IS training. Please note that the IT IS certificate does not give one the right to use the name Jin Shin Jyutsu, the Kanji or the finger logos other than in connection with self-help classes and your private practice. Our authorized instructors for this new class are Sara Harper, Janet Oliver, Phyllis Singer, Iole Lebensztajn, and Birgitta Meinhardt.

2. Q: Are there any other considerations I should know about before presenting self-help Jin Shin Jyutsu to others?

A: Please use our name and trademark properly when producing brochures or fliers about your class. We do ask that you clearly refer to yourself as a self-help instructor (preferably including the words "self-help" in the title). Please contact David Burmeister in Scottsdale, should you have any questions.

We have found it very helpful when you present a self-help class to communicate to students that, while this instruction is intended to assist them in helping themselves (and perhaps friends and family), it is not intended to prepare them to share Jin Shin Jyutsu with others in a professional capacity (such as practitioner or instructor). Making the latest seminar calendar brochure available can help students differentiate between the levels of training.

We deeply thank you for your loving participation in sharing the Art of Jin Shin Jyutsu. We know that our community will continue to flourish with your collective support and dedication.

In Unconditional Cosmic Love,

Mary Burmeister
President, Jin Shin Jyutsu, Inc.

David Burmeister
Director, Jin Shin Jyutsu, Inc.

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WHITE HOUSE COMMISSION on CAM
TOWN HALL MEETING

MINNEAPOLIS, MINNESOTA, March 16, 2001

Submitted by: Rose Haywood, L.Ac., Dipl.Ac. (NCCAOM)
Academic Dean, Minnesota College of Acupuncture and Oriental Medicine
of Northwestern Health Sciences University.

The Importance of Quality Education in Oriental Medicine

Introduction
Patients have the right to safe and effective health care.
The key to safe and effective healthcare is education.
Professional education of Oriental medicine practitioners is rigorous, comprehensive, and accredited, and exemplifies quality education in CAM.

Definition of terms:
Oriental medicine is a comprehensive system of healthcare, which may include acupuncture, herbs and oriental bodywork.

The theories underlying traditional oriental medicine, including physiology, pathology, diagnosis and treatment strategy and methods, rest on an understanding of natural phenomena that has evolved over two thousand years. These theories are quite different from those of western biomedicine, but entirely logical and pragmatic when considered from within the whole paradigm.

The treatment modalities of OM should be used within the complete framework of OM, or efficacy is compromised. For example, acupuncture is not merely the insertion of needles into so-called "trigger" points (painful spots). The choice of acupuncture points is guided by a complete Oriental medicine diagnosis, which can be performed correctly only by a thoroughly trained practitioner. The choice of a Chinese herbal formula for a particular patient depends on the ability to make a competent traditional diagnosis, a thorough knowledge of the many traditional characteristics of over three hundred herbs in common use, as well as the traditional rules of combination, an in-depth knowledge of the traditional herbal formulae and how to adapt them to the requirements of the individual patient, and contra-indications for their use. It is impossible to practice Chinese herbal medicine safely and effectively outside of the framework of the complete system of oriental medicine.

Regulatory organizations
Standards of competency for the practice of OM are regulated by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) The NCCAOM administers written and practical board examinations in acupuncture, herbology and bodywork, requiring documentation of thorough professional education via apprenticeship or formal education. Formal education consists of graduation from an accredited school.

The Accreditation Commission for Acupuncture and Oriental Medicine is a specialized accrediting agency recognized by the US Dept of Education and the Council on Higher Education Accreditation. ACAOM was established in 1982 to set up and assess compliance with educational standards for acupuncture and OM programs in the U.S.
In order to receive and maintain accreditation, schools must constantly assess and improve their programs.

The Masters of Acupuncture and the Master's of Oriental Medicine accredited by ACAOM

The accredited Master's level acupuncture curriculum is 3 academic years (minimum 1725 hours) with 705 hours in Oriental medical theory diagnosis and treatment techniques and 660 hours of clinical training.

The accredited Master's degree in Oriental medicine (i.e. including herbology) is four academic years (2175 hours) with 705 hours in Oriental medical theory diagnosis and treatment techniques, 450 hours in Oriental herbal studies, 660 hours of clinical training.

These are minimum guidelines. In reality, most programs are considerably longer.
Our college's program is typical, at 2800 hours for OM and 2350 for Acupuncture.

Why should the training program be this long?

The simple answer is: to ensure safe and effective practice.
Graduates of ACAOM-accredited institutions receive a thorough training in the OM theory, diagnosis and treatment, clinical practice and sufficient hours in biomedical clinical sciences to enable them to recognize serious conditions and conditions that require referral to a western physician. The program lengths are those deemed necessary to produce graduates who can practice safely and effectively.

The problems that we face

Oriental medicine is an extremely safe system when practiced by properly trained individuals. Unfortunately, the treatment modalities of oriental medicine are being taken out of the larger theoretical and philosophical context and practiced by other professionals with minimal training.
Acupuncture is known to be a highly effective treatment modality. It is therefore being adopted as a tool by other types of provider. Without the knowledge of the complex theoretical background of the medicine, however, and without the rigorous and comprehensive training necessary to gain this knowledge, what is being practiced becomes a mere mechanical procedure, which bears little resemblance to acupuncture as practiced by professional practitioners who understand the whole system.

The results of this co-optation of oriental medicine are, first, that efficacy and patient safety are compromised. (Please refer to the appended: Safety Record of Acupuncture)
Chinese herbal medicine, indeed, herbal medicine in general, is being practiced by a variety of practitioners with minimal training. The potential consequences of practicing herbal medicine without proper training are serious.
One of the subtler but no less destructive outcomes of this type of low-level practice of oriental medicine, is the deception of the general public, who are generally unaware of the differences in the level of education between professional oriental medicine practitioners and those who have taken short courses. The patient who visits a minimally-trained practitioner may, at the worst, be harmed, at best, helped somewhat, but very frequently, does not see results from the treatment, and then blames the medicine rather than the practitioner. This harms our profession.

Our desires as a profession

We wish to work in harmony with biomedical providers, in a professional atmosphere of mutual respect, where the skills of each type of practitioner can be best utilized.
We wish to have our medicine respected as a comprehensive system, not misunderstood, devalued, co-opted by other providers who do not recognize the necessity for rigorous educational standards in oriental medicine.
Practitioners in the few states that require referral from an M.D wish to have the freedom to practice without the requirement of referral.
In fact, three states' medical boards have recommended dropping the referral requirement.

Recommendations

1. Public education: The public needs better information on educational standards for the practice of acupuncture and herbology, in order to make better informed choices of practitioner.
2. Access: members of the public should be able to consult an OM practitioner of their choice without a referral.
3. The practice of OM is safe and effective and much cheaper than western biomedicine. It should be reimbursed by insurance providers.
4. The educational standards for the practice of acupuncture and Chinese herbal medicine as set up by ACAOM should be the standards adopted for the practice of Oriental medicine by all providers. Educational programs in acupuncture and chinese herbology offered by medical schools, naturopathic colleges and colleges of chiropractic should be held to ACAOM standards.

Acupuncture and Oriental Medicine Alliance

Legislative Update

May 5, 2000

Jurisdictions With Acupuncture Laws

Alaska	Arizona	Arkansas
California (own exam)	Colorado	Connecticut
District of Columbia	Florida	Georgia New 2000
Hawaii	Idaho	Illinois
Indiana	Iowa	Louisiana (no exam)
Maine	Maryland	Massachusetts
Minnesota	Missouri	Montana
Nevada (own exam)	New Hampshire	New Jersey
New Mexico	New York	North Carolina
Ohio New 2000	Oregon	Pennsylvania
Rhode Island	South Carolina	Tennessee New 2000
Texas	Utah	Vermont
Virginia	Washington	West Virginia
	Wisconsin	

States That Allow Practice Through a Ruling by the Board of Medical Examiners

Kansas Michigan

States in Which There is No Legislation or Rule

Alabama*	Delaware	Kentucky*
Mississippi	Nebraska* This passed bill on Gov's desk	North Dakota
Oklahoma*	South Dakota	Wyoming*

*A statute has been introduced

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For a current list, see our web page at *www.AcupunctureAlliance.org*

NATIONAL ACUPUNCTURE FOUNDATION

EDUCATION AND RESEARCH IN ACUPUNCTURE, ORIENTAL HERBS, AND OTHER ASPECTS OF ORIENTAL MEDICINE
P.O. BOX 2271 GIG HARBOR, WA 98335-4271 PHONE (253)851-6538 FAX (253)851-6883

January 1, 2000

Safety Record of Acupuncture

Due to the growing demand for acupuncture services, regulators throughout the United States are faced with setting standards to protect the public. One of the first questions which surfaces in discussing legislation is the risk of harm involved in acupuncture.

The evidence shows that, when performed by trained individuals, acupuncture is an extremely safe procedure and has a remarkably low record of accidents.

In 1983 - 84, recognizing that it was essential to set standards of competence, the acupuncture profession in the United States established the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). One of the primary reasons for setting national standards was - and is - to protect the public from unqualified practitioners.

Potential harm to the public falls into two primary categories, the risk of accidental injury to internal organs and complications due to improper sterilization and clean needle technique, including the possible spread of infectious disease.

The attached chart, *Safety Record of Acupuncture,* reflects reports in the medical literature in English since 1958 from the United States, West Germany, England, Israel, Ireland, Australia, Japan, China, Spain, Belgium and Switzerland. Three additional articles in foreign languages cited in the English literature are also included, one each from Belgium, West Germany and Japan.

The chart shows a remarkable safety record for acupuncture throughout the world. This is particularly true considering that in three of the countries listed, China, Korea and Japan, acupuncture is a frequent form of health care for hundreds of thousands of people.

Regarding the risk of injury to internal organs, the first risk, acupuncturists are trained in exact needle placement, angle and insertion depth. This results in an extremely low risk of injury when acupuncture is performed by a competent individual. This is demonstrated by the following:

- In China and Japan, both of which have excellent training programs for acupuncturists and thousands of treatments annually, only ten injuries to internal organs have been reported since 1972.
- No injuries have been reported from Korea.
- In the United States, only ten incidents of injury have been reported since 1965.

- Of the ten cases in the United States, one was noted as a "one-in-a-million" complication, another as a bizarre set of circumstances involving self-inflicted injury by an untrained individual.
- Of the reports from the United States, only one specified that the treatment had been performed by a licensed or certified acupuncturist and that individual was licensed without examination or standards of competency.
- In the reports from the other Western countries, in most of which only M.D.s may practice acupuncture, it was unclear who had performed the treatment.
- In the fourteen years that the NCCAOM has certified over 9000 individuals in acupuncture, NCCAOM has never had reason to take action against a Diplomate due to negligent or harmful treatment to a patient.

Additionally, in the cases in which there was damage to internal organs, in most cases, except the two unusual cases noted above, the patient recovered and the damage was minimal. In fact, in the cases of retained or broken needle, the needle had been in place up to 35 years without complications.

From the outset, the acupuncture profession in the United States recognized the second risk of harm to the public, the risk inherent in the use of unsterile needles and lack of clean needle technique. Thus, one of the first tasks of the profession was to establish standards for clean needle technique (CNT). Therefore, in concert with the Center for Disease Control in Atlanta, Georgia, the profession developed the Clean Needle Technique Manual, published by the National Acupuncture Foundation. The CNT Manual serves as the basis for questions on the NCCAOM written examination as well as for the national CNT Course offered by the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM). Passage of the CNT Course is required for NCCAOM certification and for licensure in most states.

The chart demonstrates that complications due to improper clean needle technique occur in countries, states or professions which have not set standards of clean needle technique for acupuncture practice. Additionally, of the seven complications due to improper clean needle technique in the United States, only three were due to treatment by acupuncturists. One individual was not licensed or certified, one was licensed without exam and the status and background of the third was not mentioned. No such incident to date has been reported involving a nationally certified acupuncturist who has met national CNT requirements.

In the entire literature search, only four fatalities were reported. Three of these involved patients with significant health problems which the authors stated contributed to the death. The fourth involved self-treatment for a heart condition.

The second chart, *Safety Record of Certified, Licensed or Registered Acupuncturists,* reemphasizes the safety of acupuncture when performed by trained individuals. This chart shows the responses received from a survey of twenty state licensing boards regarding injuries due to acupuncture which had been reported to them. Of the 20 states surveyed, only two states reported any injuries due to acupuncture. Again, this is a remarkable record. Several of the states have permitted practice for over ten years and have over one hundred licensed acupuncturists

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The evidence clearly shows that acupuncture is extremely safe when performed by well-trained individuals who have met solid standards of practice. Thus, the only significant danger to the public lies in lack of standards and in performance of acupuncture by improperly or poorly trained individuals. For this reason, regulations establishing standards of competence are essential to protect the public.

NATIONAL ACUPUNCTURE FOUNDATION
January 1, 2000

SAFETY RECORD OF ACUPUNCTURE

Complication	Author/Year	Practitioner	Note
Complications Due To Injury to Internal Organs -			
Pneumothorax	Schneider & Salzberg Annals of Emergency Medicine 13: 8 (1984)	M.D.	- full recovery - acupuncture licensure (New York) - standards for M.D.s
	Bodner et al Annals of Allergy 51: 401 (1983)	1 non-M.D. 1 not specified	- full recovery in both cases - no set standards (Israel)
	Valenta & Hengesh Lancet 2: 322 (1980)	not specified	- full recovery - acupuncture licensure (California) - no standards for other health professionals
	Goldberg Medical Journal of Australia 1: 941 (1973)	not specified	- full recovery without treatment - no set standards (Australia)
	Stack British Medical Journal 1: 96 (1975)	not specified	- full recovery without treatment - no set standards (England)
	Ritter & Tarala British Medical Journal 2: 602 (1978)	3 cases non-M.D.	- full recovery in all three cases, one without treatment - no set standards (England)
	Mazel et al New England Journal of Medicine 302: 1365 (1980)	not specified	- recovery after hospitalization - acupuncture licensure (New York) - standards for M.D.s
	Corbett & Sinclair New England Journal of Medicine 290: 167 (1974)	not specified	- complete recovery after treatment - no set standards (California 1974) - no standards for other health professionals
	Waldman New England Journal of Medicine 290: 633 (1974)	not specified	- complete recovery after treatment - no set standards (Florida 1974)
	Lewis-Driver Medical Journal of Australia 2: 296 (1973)	non-M.D.	- complete recovery - no set standards (Australia)
	Smith & Rauscher Journal of the American Medical Association 229: 1286 (1974)	not specified	- fatal; pneumothorax resolved but patient reserves minimal due to severe pulmonary emphysema and patient died - said was "one-in-a-million" complication - no set standards (Arizona)
	Kuiper Journal of the American Medical Association 229: 1422 (1974)	not specified	- full recovery - no set standards (California 1974)

NATIONAL ACUPUNCTURE FOUNDATION
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SAFETY RECORD OF ACUPUNCTURE

Complication	Author/Year	Practitioner	Note
Cardiac Tamponade	Nieda & Kuribayashi Japanese Journal of Thorasic Surgery 26: 881 (1973)	not specified	- surgery; uneventful post operative recovery - retained needle (Japan)
Compartment Syndrome	Smith et al Western Journal of Medicine 144: 478 (1986)	physician trained in acupuncture	- full recovery - no standards for physicians (Oregon) - noted necessity to weigh possibility of intercompartmental hemorrhage on patients receiving anticoagulation therapy vs. benefits of acupuncture
Renal Complications	Keller Journal of the American Medical Association 222: 1559 (1972)	not specified	- asymptomatic for 35 years, removed without problem - retained needle (China)
	Drake Journal of the American Medical Association 229: 1285 (1974)	not specified	- asymptomatic for "many years"; removed without difficulty - retained needle (China)
	Shiff Medical Times 93: 630 (1965)	non-M.D. self-inflicted	- fatal; authors noted bizarre circumstances of self-inflicted injury - no set standards (Florida 1965)
Spinal Cord Root Injuries	Toyohiko et al Surgical Neurology 23: 255 (1985)	3 cases not specified	- full recovery in 2/3 cases post-op; one case not operated - numb fingers only - authors note rarity of spinal cord injury by acupuncture (Japan)
	Kataoka & Sakata Geka 20: 578 (1958)	unknown	- unknown
	Kondo et al Surgical Neurology 11:155 (1979)	not specified	- minor sensory impairment after surgery - retained needle (Japan)
	Shiraishi & Gota Neurology 29: 1188 (1979)	acupuncturist (unknown if licensed)	- minor sensory impairment after surgery - retained needle technique (Japan)
	Kida et al Archives of Neurology 45: 831 (1988)	not specified	- minor sensory impairment after surgery - authors note rarity of occurrence given thousands of treatments and long history of acupuncture in Japan
	Isa & Sasaki, et al Surgical Neurology 23: 255 (1985)	2 cases not specified	- uneventful post operative course; slight loss of pain and temperature sensation remaining after surgery - retained needle (Japan)
Miscellaneous	Campbell British Journal of Radiology 55: 875 (1982)	acupuncturists (unknown if licensed or certified)	- persistent backache; no treatment undertaken - retained needle technique - seaman who had visited acupuncture practitioners around the world

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SAFETY RECORD OF ACUPUNCTURE

Complication	Author/Year	Practitioner	Note
Complications Due to Improper Clean Needle Technique or Improper Sterilization	Stryker et al Journal of Family Practice 22: 155 (1986)	D.C.	- all recovered - no set standards (Florida chiropractors)
Hepatitis B	Kobler et al Schweiz Med Wochenschr 109: 1828 (1979)	physician 3 cases	- no set standards (Switzerland)
	de Galocsy Acta Gastroenterol 45: 224 (1982)	unknown 6 cases	- no set standards (Belgium)
	Li & Shiang Journal of the American Medical Association 243: 1423 (1980)	none	- not a case report - letter re potential infection in China
	Boxal Journal of Medical Virology 2: 377 (1978)	non-M.D.	- all recovered - no set standards (England)
	Alexander et al British Medical Journal 2: 466 (1974)	none	- not a case report - letter re potential infection in China
	Hussain British Medical Journal 3: 41 (1974)	not specified	- author noted other possible causes - no set standards (England)
	Kent et al American Journal of Epidemiology 127: 591 (1988)	35 cases acupuncturist (licensed without examination)	- regulated jurisdiction (RI) but acupuncturist licensed without examination or clean needle technique standards and did not use acceptable CNT procedures
HIV	Vittecoq et al New England Journal of Medicine 320: 4 (1989)	unknown	- only M.D.s may perform acupuncture in France but there are no set standards of training - AIDS symptoms appeared 4 months after initial acupuncture treatment - too short a time for acupuncture to have been the cause of infection
Septicaemia	Pierik Rhode Island Medical Journal 65: 251 (1982)	2 cases not specified	- fatal - other significant health factors noted - acupuncture licensure (Rhode Island)
Subacute Bacterial Endocarditis	Lee & McIlwain International Journal of Cardiology 7: 62 (1985)	non-M.D.	- full recovery after hospitalization - no set standards (England)
	Jefferys et al British Medical Journal 287: 326 (1983)	not specified	- full and uneventful recovery - no set standards (England)

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SAFETY RECORD OF ACUPUNCTURE

Complication	Author/Year	Practitioner	Note
Petechiae	Bushta American Journal of Diseases of Children 123: 613 (1972)	acupuncturist	- no set standards (California 1972)
Auricular Chondritis or Perichondritis	Davis & Powell Arch Otolaryngol 111: 770 (1985)	not specified	- minimal deformity - no set standards (Illinois)
	Allison & Kravitz New England Journal of Medicine 293: 780 (1975)	not specified	- acceptable appearance after 2 weeks of treatment - no set standards (California 1975)
	Jones Journal of Laryngology and Otology 99: 1143 (1985)	4 cases not specified	- complete recovery without deformity - no set standards (Ireland)
	Baltimore & Moloy Archives of Otolaryngology 102: 572 (1976)	acupuncturist (unknown if licensed or certified)	- complete recovery without scarring - acupuncture licensure (Massachusetts)
	Trautermann H.N.O. 29: 312 (1981)	Heilpraktiker (similar to naturopath)	- no set standards (West Germany)
Osteomyletis	Jones & Cross Journal American Podiatry Association 70: 149 (1980)	not specified	- slight scar after antibiotics and surgery; no further symptoms - regulated jurisdiction (Korea) but no clean needle technique standards and little enforcement of licensing
Spinal Infection Mimicking Prolapsed Disc	Hadden et al Journal of Bone & Joint Surgery 64: 624 (1982)	D.O.	- uneventful post-op course; painfree 9 months later except when lifting very heavy weights - no set standards (U.K.)
Miscellaneous **Contact Dermatitis due to Allergy to Nickel in Acupuncture Needles**	Romaguera et al Contact Dermatitis 7: 156 (1981)	referred to as "the doctor"	- patient allergic to neomycin & nickel in permanent needle; cleared when both discontinued - no set standards (Spain)
	Romaguera & Grimalt Contact Dermatitis 5: 195 (1979)	not specified	- resolved in 18 days with conventional treatment and discontinuance of the acupuncture
	Fisher, Alexander CUTIS 50: 226 (1992)	acupuncturist (unknown if licensed or certified)	- regulated jurisdiction (NY) - author noted no problem with prior acupuncture treatments; assumed different needle composition
Complications with Cardiac Pacers	Fujiwara Chest 78: 96 (1980)	M.D.	- observations during surgery with acupuncture analgesia due to cardiac condition

NATIONAL ACUPUNCTURE FOUNDATION
January 1, 2000

SAFETY RECORD OF LICENSED, CERTIFIED OR REGISTERED ACUPUNCTURISTS

Complaints and Disciplinary Actions Between July 1992 and May 1999

State	Injuries From Acupuncture	Injuries From Herbs	Injuries Due to Use of Acupuncture Instead of Medical Treatment	Other	Complaints & Disciplinary Actions
Alaska	0	0	0	0	Complaints not public inform'n 0 actions
California	16 complaints negl/incompet (2 with injuries), 2 actions	N/A	0	16 complaints sexual misconduct, 6 actions; 76 unprof conduct, 38 actions; 24 complaints unlicensed practice; 41 other, 5 actions	173 complaints 51 actions
Colorado	1 complaint	0	0	4 sexual harassment (one person), 1 action; 2 CNT complaints, 1 action; 9 unlicensed/beyond scope, 4 actions	16 complaints 6 actions
Hawaii				2 complaints of unlicensed practice; 10 other	12 complaints
Maine	1 complaint	0	0	1 complaint unethical practice	2 complaints 0 actions
Maryland	1 complaint, 1 revocation	0	0	1 complaint of sexual harassment, 3 of unethical practice (advisory letter issued)	5 complaints 2 actions
Massachusetts	0	0	0	2 complaints sexual harassment, 2 unethical practice; 3 other, 1 action	7 complaints 1 action
Minnesota	0	0	0	2 complaints of sexual harassment, 2 actions	2 complaints 2 actions
Nevada	0	0	0	1 complaint of sexual harassment, no action	1 compliant 0 actions
North Carolina	1 complaint, no action	0	0	1 complaint of unethical practice, 0 actions	1 complaint 0 actions
Oregon	0	Unknown	Unknown	Unknown	Unknown
Pennsylvania	2 complaints of incompetence, 1 of malpractice/negl	0	0	4 complaints outside scope/no referral, a action; 2 abuse/sex misconduct; 11 unlic pract; 13 other	33 complaints 3 actions
Rhode Island	2 complaints	0	0	0	2 complaints 0 actions
South Carolina	0	0	0	1 complaint of sexual harassment, 1 action; 5 other	6 complaints 1 action
Utah	N/A	N/A	N/A	N/A	N/A
Virginia	0	0	0	5+ complaints re: advertising, unlicensed practice (1 person)	5+ complaints 0 actions
West Virginia	0	0	0	0	0

Based on a survey by the National Acupuncture Foundation May 20, 1999

NATIONAL ACUPUNCTURE FOUNDATION
January 1, 2000

SAFETY RECORD OF LICENSED, CERTIFIED OR REGISTERED ACUPUNCTURISTS

Safety Record Survey July 1992

State	Licensure for Acupuncturists	Number of Acupuncturists	Number of Injuries Caused by Acupuncturists	Number of Injuries Attributed to Use of Acupuncture Instead of Medical Treatment
Alaska	2 years	7	0	0
Arizona	no licensing	3 Physician's Assistants	0	0
California	16 years	3700	unknown	unknown number
Colorado	2.5 years	99	0	unknown
Delaware	not licensed but permitted to practice under MD supervision for 6 years	Unknown	0	0
District of Columbia	6 years	42	0	0
Hawaii	18 years	252	9 complaints - 6 of misconduct or unethical practice, 2 of incompetence	unknown
Louisiana	17 years	0 at this time	0	0
Maine	4 years	38	0	0
Massachusetts	19 years	356	0	0
Michigan	none	Unknown	0	0
Minnesota	none	Unknown	2	0
New Jersey	9.5 years	45	0	0
New Mexico	14 years	236	0	0
New York	16 years	270	0	0
Rhode Island	12 years	23	0	0
South Carolina	18 years	3	0	0
Utah	9 years	20	0	0
Washington	7 years	136	0	0
Wisconsin	2 years	75	0	0

Based on a survey of state licensing agencies by Ralph Nesson, R.Ac. and Ralph Coan, M.D., July 1992

The White House Commission on Complementary and Alternative Medicine Policy
Town Hall Meeting: March 16, 2001
Humphrey Institute, Cowles Auditorium, Minneapolis, Minnesota

The Honorable James S. Gordon, MD
Commissioner George DeVries
Commissioner Wayne Jonas
Commissioner Linnea Larson
Commissioner Joseph Pizzorno

Thank you for allowing me to speak to you and others at this meeting today.

I am a board-certified Family Practice physician in private practice in Minneapolis. For several years now my practice has been limited to the use of various forms of acupuncture, mostly for the treatment of chronic pain, but occasionally for other conditions. The majority of my training has been through the UCLA Acupuncture for Physicians course and I expect to receive board certification from the American Board of Medical Acupuncture (ABMA) in the near future. I also have experience in the education of Licensed Acupuncturists having served in several capacities including that of Academic Dean at the Minnesota College of Acupuncture and Oriental Medicine of Northwestern Health Sciences University.

Reimbursement and the Effect of Coding Standards

In addition to the general problem of lack of reimbursement for CAM evaluation and treatment by both private and public health insurance, existing coverage is complicated by the use of coding systems (ICD-9 and CPT) poorly suited for describing conditions treated and treatments given by nearly all CAM systems. Although many patient presentations can be described by ICD-9 codes, its emphasis is on physician-centric Western diagnoses rather than the patient-centric symptoms and signs found in most CAM systems. Even the section of ICD-9 concerned with "Symptoms, Signs and Ill-defined Conditions" is badly lacking in concepts basic to a variety of CAM systems.

Similarly, the CPT system lists only two codes for acupuncture differentiated only by whether or not electrical stimulation is used. In practice, this is much less important than whether other, more time-consuming or therapeutically important but unlisted therefore unpaid acupuncture treatment modalities are used.

HCFA is in the process of defining new standards for documentation (and the definition) of Evaluation and Management service codes. In most non-Western systems, there is a heavy focus on a patient's history and review of systems and often the physical exam is fairly limited by Western medical standards. The decision making process is also considered limited and is usually of little risk. Because the E&M code is determined by the least intensive of history, examination and decision making, CAM E&M is usually undercoded, therefore under-reimbursed.

I would hope that this commission can recommend that the coding systems used for medical reimbursement and review be revised to better represent the very different paradigms of CAM systems..

Education and Regulation

In the laudable interest of providing high quality care for the public and in the struggle for legitimacy in today's medical system, a whole host of organizations have come into existence to define and control what is legitimate complementary and alternative medical care and training. This ignores what are significant differences in philosophy and therapies among what appear to be very similar groups of practitioners. In the push to regulate or otherwise categorize CAM too quickly, we may end up inhibiting legitimate methodologies or paradigms. In my own area, my training includes a number of techniques that are not based on Oriental medical principles yet look like acupuncture.. Most are not taught in acupuncture schools nor are they part of the NCCAOM board exam as far as I know. They are taught in the UCLA program and appear on the ABMA's board exam.

Both the NCCAOM and the ABMA have spent (and continue to spend) considerable resources on developing fair, accurate and comprehensive examinations and other requirements for what they and their related professional organizations believe define their somewhat different knowledge bases and core professional competencies. Less well defined are the fundamental differences in their assumptions about how that knowledge needs to be acquired. I'm sure similar issues divide other CAM professional groups.

I would hope that the commission moves carefully in suggesting paths to the future in this area. Perhaps the Department of Education's experience in accrediting higher education institutions can be of help. In some ways, professional competency standards organizations are not too different from institutions of higher education.

Michael Green, MD

Education of Health Professionals Panel

Testimony of Mary Jo Kreitzer PhD, RN
Director, Center for Spirituality and Healing
University of Minnesota

Honorable Commissioners - Welcome to Minnesota

Over the past several months as the Commission has held hearings, I suspect that you have often heard statistics quoted from the Eisenberg study on the high utilization of complementary and alternative medicine. Today I want to highlight a different study that will provide a context for my remarks and policy recommendations. Dr. Jon Astin in his study that that looked at profiles of people who use CAM therapies found that fewer than 5% of the population seeks access to CAM as an alternative. The remaining 95% are seeking care that draws from the best of healing traditions - both complementary and conventional. This has very significant implications for how we educate health professionals as well as CAM providers.

The University of Minnesota is strongly committed to preparing health professionals who are knowledgeable about CAM and who can help patients evaluate options. We believe that it is critical that nurses, physicians, pharmacists and other health care providers know how to make referrals to CAM providers and to work within an interdisciplinary team that includes providers from many different healing traditions. We recently were awarded an NIH grant to help expand our educational initiatives in this area.

Additionally, there are biomedical providers - physicians, nurses and others - who are returning to school to acquire new skills in CAM because they want to expand their knowledge base and repertoire of skills. Many of these health professionals are keenly aware of the risk of reducing these healing traditions to tools that are provided in a reductionistic way. They also recognize that many of these complementary and alternative systems of care are based on worldviews that are entirely different from the biomedical model in which they were educated. There is a need to educate healers who are capable of practicing in a way that embraces multiple worldviews.

From a policy perspective, there are four recommendations that I urge you to consider:

- To date, schools that are developing programs to educate health professionals in CAM are doing so as a result of demands from students, consumers and at times faculty. Curriculum is often optional and elective. Accreditation requirements and board exams need to be changed so that CAM becomes an integral part of required education.
- Academic Health Centers need funding to develop curriculum for both the basic training of health care providers as well as funding to develop specialized programs to educate health professionals who want to acquire additional skills in CAM. There are only a handful of graduate and fellowship programs in the

country. I serve on the policy board of a Foundation that provides fellowships to physicians seeking mid-career change. Over the past three years, 25-30% of all applicants are seeking training in CAM related areas. There are not enough training programs to prepare physicians in CAM.

- To create a health team that is interdisciplinary and integrated, we also need to address the need for training of CAM providers. Present CAM education programs often do not include information on working with biomedical providers or working within an interdisciplinary team. Federal funding to date has been limited to funding of conventional health professional education programs.
- There are very few clinical sites where students from different healing traditions can learn together. We need to create and fund models where students can observe, learn and work in tandem.

There is a poster that just went up at the University with many sets of eyes clearly reflecting different cultures and races - the poster has the words - "you, me, we - we walk the road together - fight racism". As we advance the vision of a health care system that embraces diverse healing traditions, we need to heal the "isms" that divide us. This is a call for education that unites rather then divides - that helps us to achieve something bigger and better than any of us can achieve alone.

Erin Colleen O'Fallon
University of Minnesota Medical School
Senior Medical Student

As a fourth year medical student, I have had limited experience with alternative and complementary medicine until this spring of my senior year. At that time I enrolled in the University of Minnesota's elective "Introduction to Alternative and Complementary Medicine".

The course lasts three weeks, and consists of visiting approximately 15 different alternative practitioners, meeting their patients, and observing their practice and/or training.

I took this class with seven other medical students. I believe I speak for all of us when I say this was one of the most powerful and thought provoking courses during our medical training.

We feel that every medical student would benefit from this exposure and training. We agree the course is valuable for a variety of reasons. Although focused on complementary and alternative medicine, it definitely enhanced our perspective on allopathic medicine. By glimpsing the world of allopathic practice from the outside, we more clearly understand the strengths and weaknesses of our chosen field. By considering the alternatives we developed critical thinking skills that applied not only to new and novel ideas, but developed our ability to look more critically at our own practices. Second, we feel our visits with different practitioners allowed us to begin build a meaningful understanding, rapport, and level of collegiality. Last, the course increased our interest and confidence in discussing alternative therapies with our patients. Since we know that many Americans now use a wide variety of healing practices, we think our ability to discuss them candidly and knowledgeably is vitally important.

Our brief exposure to the vast field of CAM served well to show us how much more there is to learn. We felt that continued courses during residency training, and as part of continuing medical education would be invaluable. Continued education is required because the scope of CAM is huge. We also recognize that at different times during our careers we would comprehend and integrate our knowledge of CAM in different ways. Of course as with the field of medicine as a whole, the continued expansion and evolution of knowledge and treatments demands keeping your information refreshed and up to date.

I personally plan to continue to educate myself about CAM and its relationship to allopathic medicine. I sincerely believe that my colleagues at all levels of their training would benefit from opportunities similar to the course I took. I hope the future of medical education holds an increase in understanding of CAM by allopathic practitioners. I also hope that collaborative training, dialogue and respect between our many fields and practitioners will enhance the medical care we can offer in the future.

White House Commission on Complementary and Alternative Medicine Policy
March 16, 2001

"Education of Health Professionals"

Patricia M. Cole, M.D.
Director, Family Practice Residency Program
Hennepin County Medical Center
Minneapolis, Minnesota

1. Physicians want to learn about CAM. Few have had formal training in either CAM knowledge or practice. Patients are increasingly using it and asking their doctors for advice. Physician faculty were surveyed in 1995 about their interest in CAM at a large mid-western inner city teaching hospital. [1]90% expressed interest in learning more about CAM. Residents and faculty in the Department of Family Practice were re-surveyed in 2000 and continue to show very strong interest. Physicians stated that they believed that it was their professional responsibility to be knowledgeable regarding CAM.

2. Many patients use CAM in addition to or exclusively for their medical problems. They do not tell their physicians. The efficacy of treatments cannot be fully understood when multiple treatments are being used and not fully discussed. Potentially harmful interaction effects cannot be discerned or responded to. Nor can potentially positive interaction effects be noted and used in practice.

3. Patients, especially minority and refugee patients have used CAM extensively and expect that physicians will be knowledgeable about it. With changing population demographics, knowledge of CAM principles and practices will be increasingly important for physicians.

4. Many people feel that attention to their sacred beliefs is essential to healing. There is deep yearning for relationship and feeling understood, or listened to by their doctors. Many patients want their doctor to pray for them, or with them.

5. CAM values are consonant with primary care values—patient centered, collaborative, comprehensive and wellness oriented.

6. Medical schools are increasingly exposing medical students to alternative healers and CAM principles. [2]Students enter residency eager to learn to integrate their conventional medical training with community needs.

7. Residency trains medical students to become doctors through application and practice. By caring for a panel of patients, they "put it all together". They learn the technical aspects of best practice well with our current system, but few learn to integrate CAM principles or practice into conventional medical care.

8. Little CAM training is offered in residencies across the country. [3]There are few fellowship-training positions. First year resident, Kara Parker MD, said, "I don't want to hold my breath for three years, until I am allowed to put CAM into my practice".

9. Economic pressures to see patients in brief time slots and fear of liability limit physicians willingness to collaborate with community CAM providers and healers. Residency training programs have these same constraints.

10. Time for building relationships and collaboration is not reimbursed. Few professional activities bring CAM practitioners and physicians together.

11. Physicians do not learn to care for themselves. Residency faculty are often poor self-care role models. Adequate rest, exercise, and nutrition is all put on hold while residents are expected to work excessively long hours (average work weeks 80 hours), with "on call" obligations to routinely work 36 hours consecutively. Many Residency Review Committees, (the graduate medical education specialty boards which determine content of residency programs), have adopted mandates for residents to have 24 hours off every 7 days. (The RRC for surgery is an exception to this). Although this is a step in the right direction, it fails to enable residents to care for themselves in any but the most basic ways.

    I recently encountered a family physician that trained with me 25 years ago. He values spending time with his patients and knows that they feel better when he simply listens to them. He practices in a small rural college town. He has had a quadruple bypass and knows his job is killing him. He is aging quickly and feeling burned out at 50. He knows that his patterns of self care (or lack thereof) coupled with his compulsive need to respond to people is killing him. He suspects there are answers in the CAM community. Taking a year's sabbatical, he is learning some CAM self care methods. He is deepening his spirituality to try to find ways to be fully present to his patients, and to himself.

12. We do a disservice to our healers with our current methods of training. We encourage idealistic, bright, hard working people to enter medicine and then burn them out with role models who work excessively, within a system that does not remember how to explicitly invite patient beliefs, experiences, practices, relationships, and intuitions into the exam room. The result is wide spread dissatisfaction with the best technical medicine in the world. Our current system does not serve doctors or patients.

Recommendations for policy change and action

National recommendations:

1. That CAM principles be taught in medical schools.
2. That cultural and spiritual assessments, essential in dealing with non majority patients, be taught to all care providers

3. That collaborative community efforts be encouraged so that chronic disease, domestic violence, chemical abuse can be de-medicalized. Patients and communities need to be encouraged to access their own healing skills to help heal themselves.
4. That residency educators convene to find ways to integrate CAM principles and skills into packed curricula.
5. That residency review committees require training in CAM curricula, which includes spirituality, and cultural assessment.
6. That self-care training be included in residency education. Physicians cannot adequately teach people to deal with stress of modern life, unless they can do it for themselves.
7. That physicians collaborate with community healers and CAM providers in caring for patients.
8. That a regional process of certifying competence be established, so that physicians can be relieved of liability worries.
9. That funding is provided for research projects to develop CAM demonstration clinics, to learn which methods are cost effective, and to measure the actual time and resources needed to facilitate collaboration.
10. That health maintenance organizations that develop innovative ways to include CAM in their systems be rewarded. Demand that outcomes measures, quality of care indicators, impact on medical personnel, and economic costs and personnel costs be made public.
11. That competency and knowledge regarding CAM be part of medical board examinations.

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I am honored to be here at this historic event with the wonderful commission members, my esteemed colleagues and the enthusiastic audience. I have been the program director and assistant professor at the College of St. Catherine-Minneapolis in the Holistic Health Studies program for the last eleven of the seventeen years it has been in existence. This professional certification while educating people from a wide variety of professions primarily focuses on the education of health professionals.

Nurses are the largest numbers of any of the health professions enrolled in the program. We have seen nurses who are disillusioned with the growing technological demands on their professions that have made a decision to discontinue conventional nursing. After being in the Holistic Health Studies program they become inspired and charged up to do nursing in a holistic framework.

I collaborated on a unique study conducted in 1999 aimed at the Health Professions faculty in twelve different programs at the College St. Catherine on both the Minneapolis and the St. Paul campuses. 78% of those returning surveys felt that graduating students from health professions need to have knowledge and expertise in the field of holistic and complementary health care to be adequately prepared for the changing demands of the health care market place.

To meet this demand to have health professionals educated in holistic and complementary philosophy, care, research, and practices, I have been part of a team that is in the final planning stages to develop a new Masters program in this field.

The following are important actions and policy recommendations I am bringing forth to the commission in order to impact and change the education of health professionals in the field of holistic, complementary, and alternative health.

- **Action Recommendation**: To enact federal policy and legislation that will make recommendations and mandates to the states which would require the licensing boards of the different health professions to examine and expand their professional practice acts to allow individuals within their professional scope of practice to legally practice and receive reimbursement for using complementary and alternative therapies.

- **Action Recommendation:** To establish a national financial incentive program to encourage academic institutions offering education to health professionals to develop programming and curriculum in the field of holistic and complementary health to

meet the growing demand. We know from the Eisenberg study published in JAMA in November 1998, that almost half the population uses CAM. Our academic institutions that offer health professions degrees need financial incentives to change curriculum to respond to the needs of the public. Academic institutions could apply to this fund for development of departments, programs, and courses in holistic or complementary health care. It could be modeled and structured in a similar way as the system that exists through the National Center for Complementary and Alternative Medicine at the National Institute of Health.

- **Policy Recommendation:** Because the philosophies and theories of some of the holistic health care practices are so different than those of conventional medicine, academic institutions need to root curriculum in the historical and cultural traditions from which many of the practices have evolved. This needs to include partnerships between academic institutions and centers that work to promote the health of cultural communities to guarantee that the voice of cultural ways of knowing are central to the agenda. As a movement that is working towards creating an integrative model of health, it is of utmost importance that we not appropriate or claim as our own, CAM practices that are rooted in cultural traditions

- **Policy Recommendation:** In order for the commission to avoid duplicating the Euro-centric model of health care as we design and envision a different model, it is absolutely necessary that the commission work harder to include cultural healing practices and cultural ways of knowing as central to its agenda and mission.

- **Action Recommendation:** That the commission addresses the serious issues of race and gender bias in medicine practice and research. This will include investigation and research to understand the mammoth scope and extent of this practice and to make recommendations for an action plan.

- **Action Recommendation:** That the commission include a strong emphasis on identifying environmental links to disease and illness and make legislative and policy recommendations to initiative corrective measures. This will include collaborating with current projects and campaigns already underway at the local and national levels aimed at stopping and preventing the continuation of environmental contamination and pollutants, which contributes to disease and illness.

Respecting Belief, Complementary Medicine and IRB policy

Robert Patterson, Ph.D.
University of Minnesota
March 2001

The belief of the practitioner and the patient may be very important for the success of the healing process. Western medicines standard for scientific research studies, the randomized, placebo-controlled, double-blind study, limits or minimizes the influence of belief. In most cases this requires telling the subject that he or she will be receiving the "real treatment" half the time or they have a 50-50 chance of getting the "real thing". This creates doubt in the mind of the patient, which in turn may affect the healing process.

At NIH conference on the placebo last November, many of the studies presented suggested that very real healing occurs from the placebo. I believe most traditional Western scientific researchers, think that the placebo only results in "imagined healing".

As the illustration of this, I would like to present an example of the difficulty I encountered in trying to carry out a qigong study on patients with torticollis treated injections of botulinum toxins every three months to relax the neck muscles. Torticollis is a painful condition in which the neck muscles become continuously active causing the head to be twisted. In our study we wished to have a Qigong master apply a non-touching treatment approximately one week before the patient's scheduled visit for the botulinum toxin injection. We had two outcome measurements. First using an electronic head tracking system, we would very exactly measure the change in head position before and after treatment. The second measure was the opportunity for the patients to cancel their scheduled botulinum toxin injection because it would not be needed due to the relief given by the Qigong practitioner.

The IRB would not approve the study. They required a sham control group. I responded in a letter describing the need to respect the belief process and arguing that since I am carefully measuring the outcome. They again rejected the study for the same reasons.

The following is in part is the written response I received. "We are, however, concerned about the apparent legitimization of a therapy by IRB approval of a study of the therapy, especially when the design of the study is flawed. The combining of IRB approval and a likely positive study outcome, even if the therapy is without effect, misleads both the current subjects and the general public (the latter through news reports, journal reports, and word-of-mouth). Being misleading about the efficacy of therapy is a risk." In my 21 years as a member of the IRB at the University of Minnesota I have never heard this argument being made about any other study before.

I appealed again in person to the panel and executive committee with the same arguments and again I was denied the right to conduct the experiment.

Just two months ago another similarly designed complementary medicine study was submitted to the IRB that I was a member of and the initial response was the same.

Guidance on this issue for IRB panels is given in the Federal OPRR institutional review board guidebook. In section 4 -1, the following question is raised "To what degree is it our responsibility to review the underlying science of the proposed research?" "Clearly, if it is not good science, it is not ethical. The federal regulations under which IRBs operate, however, do not clearly call for IRB review of the scientific validity of the research design." Later in the same document Robert Levine thoughts are given "Levine suggests that IRBs should establish their authority to criticize the scientific merit of protocols and to exercise that authority to require that investigators correct design flaws identified by the IRB before receiving IRB approval, but the IRB's should recognize their limits in this regard as well.

Suggestions for OPRR policies

1. **For minimal risk studies, the IRB shall not require changes in the study design.**
2. **The only risk considered shall be the risk directly affecting the subject.**

I suggest that the Federal OPRR policies be reviewed as they govern IRB procedures. Both complementary medicine and placebo research can be seriously hampered if traditional biases against the merits of these modalities limit the designs that can be used to investigate their efficacy.

White House Commission on Complementary and Alternative Medicine

March 16, 2001

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My clinical background is oncology nursing and my research expertise is CAM intervention research in the fields of cancer nursing and psychoneuroimmunology. I would like to address three components:

1. The need for rigorous, credible research in Complementary and Alternative Medicine to advance the science in the field.
2. Issues and barriers that continue to exist and interfere with conducting well-designed trials that determine efficacy and effectiveness.
3. Recommendations for integrating CAM research into practice and more quickly advancing the science of the field.

Although my written testimony addresses all three components, my talk focuses on recommendations.

I. The need for rigorous, credible research

Regardless of the level of acceptance in mainstream medicine, CAM therapies have infiltrated every aspect of health care.[1] Children with cancer use many different types of complementary and alternative medicine (CAM). Children around the world are using CAM, with 31% to 46% use in children with cancer in the Netherlands,[2] Finland,[3] British Columbia,[4] and Australia.[5] Similar rates are reported in the United States, with 59% use in the Midwest,[6] 65% in Florida,[7] and 84% in New York City.[8] The most common therapies used are prayer and spiritual healing, nutritional supplements, vitamins, massage, and mind-body therapies.[1,4,6,7] European countries are more likely to use homeopathy, bioelectric therapies[2] and micronutrients.[9]

Most of these therapies are employed as adjuncts to conventional medical therapy (complementary), as opposed to those that replace standard care (alternative). Parents of children with cancer often choose CAM as a way to participate in their child's care, manage side

effects, cope with emotional effects, feel more hopeful,[6] and reduce the pain and suffering of their children.[5] Parents are educated consumers who want to assume an active role in relieving symptoms and improving the well being of their child. They need assistance to sort out the myriad resources of varying quality and to evaluate the use of CAM in conjunction with standard cancer treatment.

Despite the prevalent use of CAM in both adults and children with cancer,[10,11] however, there are few published studies documenting the safety and efficacy of CAM therapies in cancer care, and determining whether they lead to improved quality of life and positive clinical outcomes. Integrative medicine in pediatric oncology seeks to improve the supportive care available to patients, and to determine, through scientific clinical trials, which adjuvant CAM therapies are medically sound and compatible with conventional chemotherapy and radiation.

The majority of children with cancer participate in national clinical trials. In one large study, conducted by Kara Kelly and colleagues in New York, 85% of children receiving CAM were simultaneously enrolled in clinical trials for the primary treatment of their cancer.[8] How will the use of CAM therapies affect the findings of these studies? For example, is the fact that some of these children are taking the herb "milk thistle" for liver function going to influence the tolerated dose of chemotherapy agents or the incidence of veno-occlusive disease of the liver seen in some children taking thioguanine?

A debate currently rages about the appropriate role of anti-oxidants in the treatment of children with cancer. Although antioxidants appear to have a role in cancer prevention in adults,[12] the role is less clear in children and in patients already diagnosed. Anti-oxidant use often is encouraged by CAM practitioners to help combat side effects of cancer therapy. However, both radiation and certain chemotherapeutic agents (e.g. anthracyclines) exert their anti-cancer effects by causing oxidative damage. Therefore, controversy exists regarding if and when to use anti-oxidants during chemotherapy and radiation. There are few controlled studies, especially in children, and results are contradictory.[13] At the present time, many oncologists recommend that anti-oxidants (above those amounts found in a children's multi-vitamin) not be taken during anthracycline therapies or during radiation. Do we have evidence to support these practices?

The push towards integrative medicine has primarily come from patients and parents, who perceive CAM as being more patient-friendly and more natural. This natural approach is appealing because of the debilitating side effects of chemotherapy and radiation. However, because most pediatric cancers are curable with conventional treatment, the health care team must stress that CAM therapies may be at best positive adjuncts to conventional treatment. There is currently no cure for any type of cancer with complementary therapies alone and there is little scientific evidence that CAM therapies increase survival, extend life, or improve quality of life. Nonetheless, preliminary and anecdotal evidence suggests that some therapies offer relief of symptoms associated with cancer treatment.[14,15,16]

The aim of evidence-based practice is to provide the best care based on the best available research.[17] Research on CAM is needed to determine efficacy and outcomes, dosage (especially for children), provider effectiveness, cost, and mechanism of action. Pediatrics must be included in the Integrative Medicine research agenda. It is inaccurate to assume that studies of adult patients will be applicable to children.[18] Many CAM therapies are effective for symptom management of terminally ill children, and CAM options for patients with advanced disease should be expanded.[19,1] Research in these areas is especially needed.

I believe that CAM research, at this time, should focus on:

a. determining select interventions and their specific effects/outcomes under certain conditions in select populations (ie efficacy studies of those CAM practices that have preliminary evidence),
b. comparing primary or adjunctive CAM interventions to standard care in larger randomized trials in which specific CAM therapies have shown efficacy (ie acupuncture for n/v related to cancer chemotherapy),
c. establishing databases for all CAM and Integrative clinical programs so that outcomes are assessed and documented for each patient who uses any form of CAM in that institutional setting (and analyzed retrospectively for use, trends, and outcomes), and perhaps most importantly,
d. conducting studies to determine the mechanism of action of interventions on specific outcomes and testing models that include the multiple factors involved in responses to CAM interventions.

Of importance in the methodologies to study CAM is the inclusion of qualitative analysis to capture how CAM affects individuals as a whole as well as specific outcomes that aren't easily measured with standardized self-report instruments. Qualitative analysis also can help provide the clinical constructs in which to develop sensitive and valid instruments.

An example would be the assessment of the role of spiritual beliefs in health and healing. Spirituality is not easily "measured" although many have tried to do so. Assessments of spirituality naturally involve the whole person and not just a specific religious or spiritual belief system. However, global indices of health such as health related quality of life often are not specific and sensitive to CAM interventions. They are more functional rather than spiritually related. Our assessments need to reflect this integration of beliefs within the spiritual being of the individual, from the perspective of adults as well as children.

II. Issues and barriers interfere with conducting well-designed trials that determine efficacy and effectiveness.

Research in psychoneuroimmunology has provided much of the scientific evidence for the interaction among the body, mind, psyche, and spirit. Evidence for the negative effects of stress on the immune system, the relationship of stress to illness, and the ability to condition physical outcomes with psychological expectations directly emanates from PNI research. In my view, CAM research is the "intervention model" for PNI research. Whether the intervention being tested is prayer, imagery, massage, aromatherapy, herbals or nutritional supplements, a conceptual model of how the specific therapy might work drives the selection of the population studied, the mediating variables, and outcome measures. Research in CAM requires the same rigor as PNI research. Both efficacy and effectiveness studies are needed, as well as studies testing mechanism of action of individual CAM therapies.

However, CAM intervention research has many unique characteristics that make standardization of the intervention more challenging, control of patient self-practices difficult, and randomization sometimes unethical. Some of the methodological issues of conducting CAM intervention research include:

a. The level of control isn't the same. We still need randomized controlled trials, but we can't always have double-blinded conditions, and we may need to rely on statistical methods of controlling for differences, rather than restricting use of other supportive interventions used by subjects.
b. Randomization should be used when appropriate. However, adding a randomized control group would require eliminating access to the intervention. How ethical is this when your child is dying and you want to do everything possible to smooth the transition?
c. Maintaining consistency of the intervention across subjects is important. However, some level of "tailoring" of the intervention must be allowed. Energy therapies require that the practitioner be responsive to the specific condition of the patient at that moment in time. And homeopathy defies the principle of treating everyone the same.
d. Interventions aren't generalizable. What works for one individual often is not helpful to another individual. Despite the scientific strength in randomization, the power of the intervention lies in "matching" that intervention with the strengths and beliefs of the individual.
e. Recruitment is challenging. The level of commitment is often high in CAM intervention trials (Richardson, Post-White et al, 1998), and the drop-out of the "control" arm is higher than that of the intervention arm. Cross-over designs reduce drop-out, but carry-over effects are likely for some CAM interventions for specific outcome measures (ie pain – preliminary analysis, Post-White et al).
f. CAM interventions are often used in combination. New methodologies are needed to look at whole systems. Just as chemotherapy is synergistic; CAM also may be more effective when used in combination. However, we first need to demonstrate efficacy of therapies alone.
g. Ideally, efficacy studies precede effectiveness studies. It won't matter if it's cost effective if it doesn't make a difference! It is the efficacy studies that will create organizational, policy, and insurance changes.

Additional recommendations for conducting rigorous research in CAM require that:
a. outcomes are embedded in a theoretical framework
b. measures are sensitive to the intervention
c. multiple data sources and multiple methods are used to reduce bias of self-report
d. interventions are standardized, but allow for tailoring to specific client needs
e. interventions and outcome measures are sensitive, relevant, and meaningful to different cultural and ethnic groups
f. the dose, intensity, frequency, and actual practice/utilization of the intervention is defined and measured
g. new methods of analysis are developed that consider individual outcomes, not just group means (Hierarchical Linear Modeling and Growth Curve Analysis)
h. instruments are replicated across samples with sufficient power
i. mechanism of action are studied within a framework
j. the inclusion of biological outcomes tests mechanism of action and supports a PNI framework for CAM intervention studies

Study designs measuring PNI outcomes of CAM interventions require large sample sizes to accommodate extraneous factors and huge individual intra- and inter-variability. This increases the cost of the study and oftentimes reduces the chance for competitive funding (either the study is too expensive for the value of the findings or it is underpowered to test the expected outcomes). Much more funding is needed to accommodate large scale, powered, efficacy and effectiveness studies. This funding is needed now, before CAM therapies become "standard care" and patients are unwilling to be randomly assigned to groups or forego favored therapies in a randomized controlled design. And because of the methodological challenges, funding education and training for CAM intervention researchers is just as critical as the monies to fund the studies themselves.

III. Recommendations for integrating CAM research into practice and more quickly advancing the science of the field.

It is difficult in CAM intervention research to obtain large enough samples sizes that provide power and generalizability beyond a homogenous sample. Funding is one barrier, particularly when the elements of control and randomization are absent in the design. Other barriers include access to a unique population (children at the end of life in a given region), travel distances to obtain and offer interventions by select practitioners, and time commitment by participants reducing participation in trials.

Multi-site research is becoming standard when sample sizes are small. Although multi-site research brings its own issues of lack of control and standardization by site, integration of CAM interventions within Cooperative Group Clinical Trials is one way to test the efficacy and effectiveness of CAM interventions more efficiently. Mechanisms for the inclusion of biological outcomes are often already established and the clinical trial structure facilitates standardization of the intervention and procedures (by protocol). Unlike medical trials, however, CAM interventions in clinical trials would require cross-training of practitioners to ensure consistency among the interventions offered at each site.

In the forthcoming grant renewal for Children's Oncology Group (COG), funded by the National Institutes of Health, the CAM subcommittee of the cancer control group is designing group wide protocols to test the effects of specific CAM interventions on outcomes in children with cancer. The goal is to test adjunctive complementary modalities as well as specific individual agents.

Cooperative group research is credited with the doubling of survival from childhood cancer. As a cancer CAM researcher and mother of an 8 y.o survivor of leukemia (ALL), I can assure you that it is the clinical trial mechanism that saved son's life, which I am deeply appreciative of and thankful for. However, these children, as well as many adults, who survive cancer, have late effects that persist throughout their life. They learn to live with physical limitations and changes in cognitive function and school performance as a direct result from surgery, cranial radiation, or intrathecal chemotherapy. They also relive the fear and feelings of lack of control over their bodies. Siblings too are affected in many ways we do not yet understand - because they haven't been studied as much.

Imagine what differences we could make in not only continuing to improve survival rates, but also in reducing toxicities and late effects, and having a direct effect on the lives of

children, families, and adults who survive cancer. Many of the clinical trial protocols for acute leukemia in children are inching survival rates upward, trading off the benefit with sometimes increasing associated toxicities. It's a very fine balance.

Imagine the effect on clinical outcomes if we could identify CAM therapies that could reduce these specific toxicities and allow for more effective use of appropriate treatments/agents. For example, adding carnitine or Co-Q10 as a cardio-protectant to reduce the cardiac toxicity that some of these children and even more adults experience secondary to anthracycline therapy. Or investigating an herbal supplement that influences neurotransmitter and glutamine levels and reduces the neurotoxicity of intrathecal methotrexate. Or perhaps investigating specific anti-oxidant levels and supplemental dosages to reduce recurrence rates.

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Multi-site trials exponentially increase the sample size and generalizability (with some sacrifices to intervention control that would need to be standardized). Collaborating with cooperative groups ensures access, credibility, increased sample sizes, and efficiency in recruitment, data collection, follow-up and analysis. Cooperative group trials also increase intellectual resources and provide opportunities for research questions that might be underpowered at one site or not studied at all. Think how far we have come in pediatric cancer survival since the 1970s. Think how much more of a difference we could make in the lives of children, adults, and families with cancer. Imagine where the science of CAM could be in the year 2030... It is time to critically test some of our more promising CAM therapies.

Brennan Robert White, Survivor of ALL

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March 16, 2001

Honorable Commissioners:

It is my belief that the greatest benefit that complementary and alternative medicine has to offer us is in the opportunity to see ourselves from other perspectives. In Chinese medicine it is said that nothing brings greater suffering than the stagnancy engendered by attachment to a single point of view. There is great wisdom in adopting another perspective when it is appropriate to do so and there is great advantage in having a collection of ready perspectives from which to draw.

CAM represents a diverse collection of perspectives on a wide range of human health issues, from the treatment of illness and the prevention of disease to the optimization of health and well-being. This diversity of perspectives is the very definition of CAM and is its greatest value. It is perspective that guides the CAM practitioner in making a diagnosis and forming an appropriate treatment strategy. It is perspective that directs the safe and effective use of treatment modalities. It is perspective that helps to shape, guide and provide focus for the healing intention. It is perspective that is ultimately responsible for whatever benefits a system of medicine is capable of yielding.

Yet, as important as perspective is in defining a paradigm, it is seldom acknowledged and CAM paradigms often remain unarticulated and poorly understood. If we hope to create policy that will ensure the maximum benefit of CAM in an integrated system of health care we must recognize where this benefit lies. The benefit is in the perspective. We must do everything we can to clearly define and understand CAM perspectives so that we do not lose sight of them in the process of integration.

As we develop methods of research to determine safety and efficacy, we must do so in a way that maintains the integrity of CAM perspectives.

This will probably be very difficult to do using standard research models that tend to focus on mechanism. If we are to determine the validity of any CAM perspective it is my opinion that we must not do so in terms of conventional medicine. The validity of a perspective rests not in how well it agrees with our own, or whether we can even understand it in terms of our own, but whether or not it consistently leads to positive outcomes. Safety and efficacy of a given therapy are dependent upon its appropriate use. Appropriate use, in turn, is determined by the guiding principles of the perspective. We must encourage and support CAM research within the CAM community itself so that CAM perspectives can first demonstrate the validity of their guiding principles. If the guiding principles of a CAM perspective can be demonstrated to be internally consistent, then it may be much easier to go on to demonstrate safety and efficacy without having to research the mechanism. In this way, we may be able to meet the standards set by our society for the safe and competent practice of health care without having to compromise the integrity of CAM perspectives.

Thank you.

I am working on a research study entitled The Effects of Therapeutic Massage and Healing Touch on Cancer Patients. Through this study, I have gained a great appreciation for the scientific process, and the subjective comments from scores of our research subjects support its value in their lives. In fact, one woman could not wait to tell her story, when, after receiving Healing Touch, she rapped on my door and burst into the office saying, "Look at me. Look at me!! Today is the day in my chemo cycle when I am always admitted (to the hospital)...but that's not what it's about. It's not about the diarrhea or the nausea or the vomiting or the mouth sores. Can you see it? I am *living* for the first time since I was diagnosed. It is my spirit, Mary Ellen-- my spirit. Look at me!" She spread her arms and twirled in front of me. In addition to recognizing and appreciating her obvious vitality, my thought was "What am I witnessing here? And just how do we measure that?" How do we measure the ineffable using the construct of our current scientific methodology?

The goals and philosophy of CAM include wholeness, wellness, and healing. These are inherently expansive concepts that lead to questions of consciousness, interconnectedness, transcendence, healing, and spirituality. If we ask the questions that CAM prompts, then a methodology that supports the research to find the answers is required. The current methodology of the randomized double-blind study is serving us well in some arenas, but it is based on a reductionist model, and reductionism and wholism do not resonate.

When we look at the woman in my office, the results we obtain from a randomized controlled trial may be valid, but they are certainly incomplete. We can measure her episodes of diarrhea and vomiting, the number of antiemetics and pain medications she uses, and measure her endorphin, T cell and cortisol levels. We can measure length of inpatient stay and even quality of life, but if we listen carefully to what she told us, we still will not capture measurement of what she identifies as the underlying key to her experience-her spirit. This calls for advancement to another level of reliability and validity in research methodology.

We are already practicing and benefiting from an integrative medicine and our healing practices are moving beyond what can currently be measured in a reductionist manner. Science must evolve along with medicine to continue answering the questions and assuring safety and efficacy for the people seeking wholeness. I have great hope and confidence science will answer the call.

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Presentation

for the

White House Commission on Policy

for Complementary and Alternative Medicine

Town Hall Meeting

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March 16, 2001

Excelsior

The Argument for Bottom-up System Change:

I am a mainstream, family physician in general practice, in the town in which I was raised. My office and high school and ancestral home are all within a 50 yard radius. In one sense, I am a domain expert on localness. The localness of Peter Senge.

The town is Excelsior and means "ever upward." It is the title of this testimony and an image for bottom-up system change.

When the work of this White House Commission is completed, I assume, it will have created a set of policies that address: care, education, outcomes research, organization, systems and governance. These policies will need to be integrated and cohesive and, definitely not, at cross purposes with one another.

Guidelines for the research and development of each policy will be chosen and I would like to suggest some options, mostly based on bottom-up strategies.

For organizations and systems, the 4C2A formula: comprehensive and continuing, coordinated and customized, accessible and accountable. Services and programs will be built on this basis.

For care and education, the emphasis would be on partnerships where the partners have equal power. Also, there will be replication of the 4C2A formula.

For outcomes research, a health status assessment that measures and treats both health and disease with equal intensity. Policy would direct that this be a part of daily care.

For governance, the intentional logic of Harvey wheeler where a system of rewards largely replaces regulation and punitive methods while it produces higher performance and greater patient safety. It would give concepts like the 4C2A formula the force of law.

PRIORITY OF PARTNERSHIP:

A project supported by an NIH, SBIR grant, asked patients how they got well and they said: we got better because you and your staff listened and cared; this allowed us to put in trust (and become a partner in the relationship); and this led to willingness to change our lifestyle and our lives.

A recent review of the literature on informed consent found both mainstream medicine and complementary medicine saying the same thing, i.e., the practitioner and the patient would approach a negotiation about proposed care within an atmosphere of conversation and shared exploration until they came to a negotiated consensus. To do otherwise, would make the practitioner liable. The good news is that the need for this kind of partnership extends across the whole spectrum of practitioners and could assure integration, collaboration and greater safety. This idea is already supported by the malpractice insurance carriers.

THE GROUNDED THEORY APPROACH:

The Grounded Theory Approach takes place when one goes to where the phenomenon is taking place, and becomes immersed in that environment. Examples would be: an internship, a focus group on the use of Dove soap, or a practitioner and patient negotiating a treatment plan

based on a current health status report.

Patients can be research colleagues either individually or collectively. One patient group pointed out that the SF36 (Ware, et.al.) was lacking in a spiritual health measure. Another group of patients helped develop a language of negotiation, and when this collaboration of practitioners and patients was done, the practice no longer had hypochondriacs, neurotics, schizophrenics or psychopaths.

THE LABORATORY PRACTICE:

The laboratory practice using the Grounded Theory Approach, patients as research colleagues, and the multimethond research of Miller and Crabtree, might well be the preferred option for the development of health policy that would support integration and collaboration of CAM and Medical Practitioners and their patients. Also, this method is more likely to support the CQI processes of Demming and the Mass Customization of Boynton, Victor and Pine.

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Patients can be research colleagues either individually or collectively. One patient group pointed out that the SF36 (Ware, et.al.) was lacking in a spiritual health measure. Another group of patients helped develop a language of negotiation, and when this collaboration of practitioners and patients was done, the practice no longer had hypochondriacs, neurotics, schizophrenics or psychopaths.

THE LABORATORY PRACTICE:

The laboratory practice using the Grounded Theory Approach, patients as research colleagues, and the multimethond research of Miller and Crabtree, might well be the preferred option for the development of health policy that would support integration and collaboration of CAM and Medical Practitioners and their patients. Also, this method is more likely to support the CQI processes of Demming and the Mass Customization of Boynton, Victor and Pine.