TESTIMONY OF ANN RICHTMAN, J.D. / NORTHLAND NATURAL HEALTH RESOURCES, INC.

FOR WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY. MARCH 16, 2001. MINNEAPOLIS, MINNESOTA.

Thank you for this opportunity to speak. I am Ann Richtman. I am an attorney from northern Minnesota and Wisconsin and I was a legal consultant in the passage of the New Minnesota law 146A. I also coordinated publication of a 100-page book on natural health and related issues for distribution in our northern rural areas. I have read the transcripts of testimony presented to you in the past months and would recommend that everyone read Dr. Gordon's book of 1984 *The Healing Partnership*. I will limit my remarks today to three points.

Practitioner Accountability: I think that it would be fair to say that there is an assumption within the Commission that nationally established requirements of licensure or certification are a must for both practice and reimbursement. In Minnesota we did not let that assumption go unexamined. The demand for occupational licensing comes from practitioner organizations, not from consumer groups. We do want competence, accountability, and informed consumers. Our law incorporates consumer protection provisions -- both with regard to prohibited conduct regulated by the Department of Health, and the Client Bill of Rights which requires disclosure of practitioner information so clients can make informed choices.

Despite opposition from the ranks of the medical establishment, the bill passed 58 to 1 in the Senate and 110 to 23 in the House and became the first state law of its kind in the country. However, I want to point out something often overlooked. Most of the language of 146A is identical to a previously existing Minnesota statute for unlicensed mental health workers; one that also has compliance oversight history with the Department of Health. Decision-makers like taking the path of least resistance.

Before you make recommendations about national standards please give us an opportunity to test the merits of our model in its new context and make report in two years.

Informed Choice. As I read through the testimony, I ask myself what is the key issue here and how is it being addressed. "Therapeutic doctrines have important economic aspects." (Harris Coulter) People are sick and tired, and increasingly they are more sick and tired. In our region revenues from medical services industry are second only to iron ore; in the nation they are the largest sector. Our local hospitals have an advertising budget that is unrivaled only by the pharmaceutical companies. Between them there is constant and pervasive multi-level marketing of acute care services and prescription medications in our community –more and more packaged as "news" stories or public service announcements. In America we have an insidious inculturation process from industry and governmental policies that normalizes an expectation of pathological outcome and compartmentalizes self-care as a programmatic option. How will the medicalization

of our society be addressed in your report? Will you make available to us not only the testimony, but also the accompanying written documentation and research provided to you so that we can better inform the public of the wealth of information you are reviewing? And so that we can make an informed response to your recommendations.?

Informed Consent. You are aware that the doctrine of informed consent springs from tort law, although there are those who also see its importance in contractual application. The Supreme Court has told us we have a constitutional right to refuse treatment. But it has also told us that government may substitute it's judgment for ours when it come to having access to the treatment we think most suitable to our individual health needs. Our interests are further compromised by a statutory or judicial requirement that medical doctors advise their patients of "alternative treatments" that are not in any way inclusive of even those alternatives known to you, to us, and to many others outside the narrow confines of conventional medicine. Is patient consent truly informed without disclosure of documented beneficial alternatives?

Again, you are gathering information as part of your process that might broaden judicial, legislative and citizen understanding of "alternative treatments". One example of this, is the testimony presented by Blue Cross/Blue Shield on the cost effectiveness of the Dean Ornish program for cardiovascular disease as an alternative to surgical procedures. Or another is dietary supplements as an alternative to costly and toxic prescription drugs as described by Dr. Alan Gaby. Medical schools and doctors would have to expand their existing knowledge base for the benefit of the patient. We would do more than pay lip service to informed consent and informed choice.

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).

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[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").

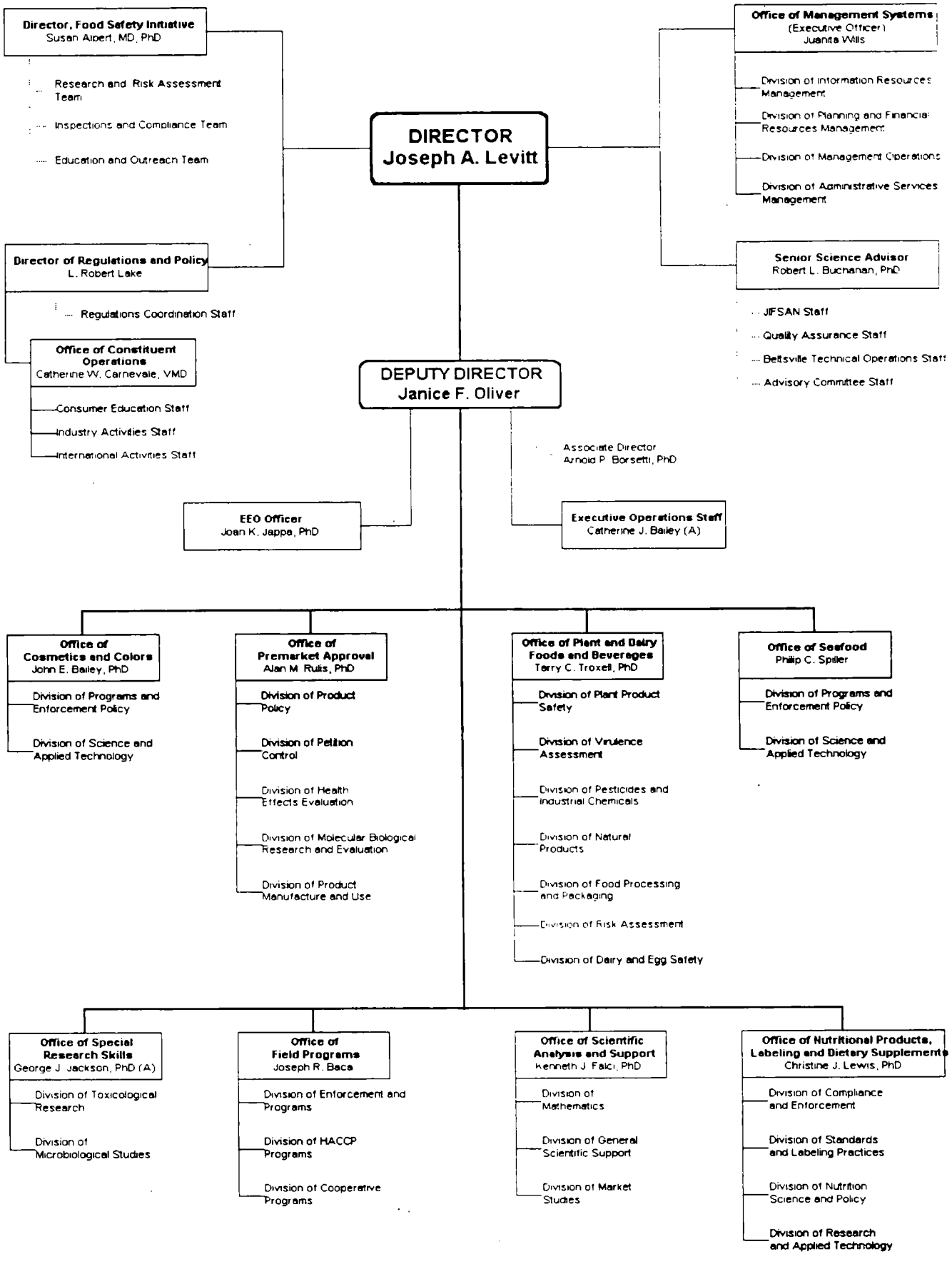
2. You will see a substantial list of goals in the cross-cutting program section regarding our move to College Park. As you may know, CFSAN personnel and laboratories in the downtown D.C. area have the good fortune to be moving to a new facility in College Park, Maryland, starting in the fall of 2001. 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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****
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

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

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Presentation

for the

White House Commission on Policy

for Complementary and Alternative Medicine

Town Hall Meeting

Minneapolis, Minnesota

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.

15th WONCA World Conference

'People and their family doctors - partners in care'

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ABSTRACT FORM

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WORLD CHANGE VIA PARTNERSHIP TECHNOLOGY

NAME(S) OF AUTHOR(S) (Underline presenting author)

INSTITUTE NAME AND ADDRESS

Milton Seifert
Eagle Medical P.A.
Excelsior, Minnesota USA

TEXT

START HERE: Introduction: Our medical practice began in 1972 with a belief in and a commitment to partnership health care. This has been maintained over time with an organizational strategy known as the 4C2A formula: comprehensive and continuing; coordinated and customized; accessible and accountable. Arising from this is a technology for health status assessment that has the capability of inducing systemic change.

Methods: Using the grounded theory approach, patients were enlisted as co-researchers; a language of negotiation was developed and tested; a spiritual health assessment was created; the SF36 was adapted to clinical practice; focus groups were conducted; the technology was tested in other clinics; and the final result was the design of the Health and Disease Questionnaire (HDQ). This questionnaire, influenced by researchers of health, promotes care for health with the same intensity it promotes care for disease.

Summary of Results: The HDQ, created with the integral involvement of patients, has meant empowerment for the patient role, assistance for the provider role, and support for their partnership activities. Functionality was measurable in the areas of physical, mental, social, emotional, and spiritual health. Known reliability and validity of the SF36 was confirmed by patients. Neglected patients from other systems were rescued. Populations were measurable. Health care and health care research merged into one entity.

Conclusions: This work, combined with the prior work of SF36 development, makes the HDQ a scientifically sound measurement device. Usefulness to partnership health care creates an opportunity for bottom-up systemic change. System economics based on measurable results for individuals and populations would, in time, change the world.

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DEADLINE FOR ABSTRACTS: September 30, 1997

Coordination of Patient Care:
Medical Practitioners with Alternative Care Providers

Author: Milton H. Seifert, Jr.

December 2000

Introduction: A report to the legislature, *"Complementary Medicine"*[1], was published on January 15, 1998 and sent to the Minnesota legislature. This report was published by the Minnesota Department of Health, and Commissioner Anne M. Barry writes the following: "The study of complementary and alternative therapies is a very important and relevant issue in the current health care market. The growth of complementary and alternative medicine in America seems indisputable. In a landmark study published in the New England Journal of Medicine in 1993, Dr. David Eisenberg and his colleagues found that one in three patients in the United States regularly use complementary and alternative therapies."

Commissioner Barry goes on to say: "As the legislature has indicated through mandating this report, it is important to begin to explore the potential implications of the increased use and acceptance of complementary and alternative medicine in Minnesota. The Minnesota Department of Health has an interest in assuring consumers' access to quality forms of health care. Our mission is to protect and promote the health and well being of Minnesotans." The *"Complementary Medicine"* report advanced a number of definitions, studied the efficacy and safety of complementary and alternative therapies, looked at the present state of complementary and alternative research, studied the importance of this movement in the U.S. and around the world, compared availability and utilization of complementary and alternative medicine in the U.S. compared with that of Minnesota, and ended with their thoughts on the purpose and types of regulation that should be considered. Commissioner Barry called this "one step" toward the goal of fully assessing and assuring that the health care delivery system meets the needs of the population.

Minnesota State Statute 146A was signed into law by Governor Jesse Ventura on May 11, 2000. Its title: Unlicensed Complementary and Alternative Health Care Practitioners and Clients[2]. This legislation had passed both houses of the legislature with large majorities. The grass roots support was called unprecedented. This law will have a substantial effect on the practice of medicine in Minnesota, as well as on the writing of this protocol.

State Statute 146A lists twenty-two specific complementary and alternative practices and commented that the domain was not limited to those listed in the legislation. The Office of Unlicensed, Complementary and Alternative Health Care Practice was created in the Minnesota Department of Health and given the responsibility to investigate complaints and to enforce disciplinary actions against unlicensed practitioners who violate prohibited conduct. This office was also expected to serve as a Clearinghouse on complementary and alternative health care practices. It has now been left to the commissioner to adopt rules necessary to implement, administer, or enforce the provisions of this Act.

However, in all health care delivery, regulated or not, licensed or not, the effectiveness and the safety come down to each individual practitioner-patient relationship. While some may still question the importance of this relationship, one group is absolutely clear about it's value. They are known as medical malpractice insurers. The loss prevention departments of these carriers have for some time recognized the value of employing techniques to increase patient understanding and satisfaction. They have long been telling practitioners to improve physician-patient relations and have provided a number of educational seminars as well. Thus, the practitioner-patient relationship will necessarily have a prominent place in the ensuing protocol.

Complementary and alternative providers are frequently referred to by the acronym CAM, so for the purposes of the remainder of this paper, CAM will be used to mean complementary and alternative medicine.

Informed Consent:

Michael H. Cohen, JD, MBA, MFA[3], writing in the journal *Complementary Health Practice Review*, Fall 2000, says the following: "Informed consent presents one of the major unresolved areas in the integration of complementary and alternative therapies into the health care system". He goes on to say that no court to date has expressly ruled that a physician must disclose the availability of complementary and alternative medicine alongside conventional care and that informed consent rules to date have failed to address the medical profession's growing exploration of complementary and alternative medicine. What is required are credible levels of scientific validation of specific therapies and these are yet to come. At the present time, Mr. Cohen would support a good faith attempt at disclosure, but within the physician-patient relationship.

It is difficult to conceive what kind of disclosure would be appropriate for a system of health care that has not yet emerged, such as the integrating of homeopathy, acupuncture and conventional medical practices. Similarly, we don't know the pharmacological interactions between conventional pharmaceuticals and Chinese or Tibetan herbs. One of the trademarks of CAM is its emphasis on factors outside biochemical, pharmacological, and scientifically accessible explanations. More frequently than not, CAM therapy is paradigmatically foreign to those with conventional medical training.

While it would be difficult for a medical practitioner to describe the "risks" of altering the flow of chi or the use of the low dilution medicines of homeopathy, Mr. Cohen recommends that there be deeper collaboration between physicians and CAM providers in order to create comprehensible disclosure rules. He also believes it is advantageous to bring CAM into the conventional physician-patient relationship. He believes that knowledge of CAM will loosen medical intolerance of therapies outside of orthodoxy, increase medical innovation, reduce misunderstanding, and lower malpractice risk.

Therefore, referral to a CAM provider by a medical practitioner will require at least two negotiation processes that reach consensus. The first negotiated process for informed consent will take place within a partnership of physician and patient and in an atmosphere of conversation and shared exploration. (This format is rapidly becoming a conventional

medical practice standard.)[4] The second negotiated consensus would occur between the medical and CAM providers, and also within an atmosphere of conversation and shared exploration. It is now clear that these steps are necessary for patient protection and absolutely necessary to achieve coordination of patient care.

Berkeley Rice[4], senior editor at *Medical Economics*, writes about "The New Rules on Informed Consent" in the June 19, 2000 issue. The author notes that recent court decisions have increased the demands for disclosure and that in a recent review of 85,000 malpractice suits, Physician Insurers Association of America found that one of the most common secondary claims was "failure to inform".

The old standard was what the average doctor thought his patient should know, while the new standard is what a reasonable patient would want to know before undergoing a proposed test or procedure. Now conventional physicians are being advised to solicit patient's opinions in reaching a joint decision on treatment in order that their patients can be truly informed and able to take part in the decisions that are ultimately made. Once again, this is the process of negotiated consensus.

A study published in the *Journal of the American Medical Association*, December 1999, looked at 1,000 patient encounters to see if all the alternatives of conventional medicine were discussed and whether or not patients understood the clinical decisions affecting them. It was concluded that fewer than 10% of the clinical decisions met the standard for informed decision-making. So even though this is strictly conventional medical care, the contemporary requirements for informed consent now require a real dialogue within the context of a real physician-patient relationship.

Since informed consent within both conventional medical care and CAM health care requires better practitioner-patient relationships, it would be worthwhile to look at the types of relationships familiar with health care services as described by Richard Magraw, MD[5], in his book, *Ferment in Medicine*. These include the following:

> Activity/Passivity: This type of relationship is one in which the physician is active and the patient is passive. This has its origins in, and is entirely appropriate for emergency situations such as the treatment of severe injuries, the use of anesthesia, and undergoing appendectomy. Treatment takes place regardless of the patient's contribution. The relationship of the doctor to the patient is similar to that of the parent to the helpless infant.
>
> Guidance/Cooperation: This is the relationship of choice for acute myocardial infarction or an acute infectious process. The patient is aware, is capable of following directions and of exercising some judgement. The physician tells the patient what to do and the patient obeys. It is most like a parent-child relationship.
>
> Mutual Participation: In this relationship doctors help patients help themselves. Patients use expert help by means of partnership with their physicians. It is the relationship of choice for chronic illnesses, such as diabetes mellitus, coronary

heart disease or essential hypertension. The physician has an awareness of the patient in personal terms and, in the doctor's view, the disease is incidental to the person. It is most like an adult-to-adult relationship. It is the relationship type most appropriate to CAM referral, delegation, follow-up, and coordination of patient care.

CAM Provider Credentials:

The author has served on credentialing committees for organizations and systems for both conventional medical and CAM providers. The report to the Minnesota legislature, *Complementary Medicine*[1], notes that CAM practitioners have very diverse educational backgrounds and their training in some of the therapies may be obtained from several different sources and this training is certainly not the same for each practitioner, even within the same CAM specialty. The spectrum of education goes from formal education in an accredited institution to short courses and workshops. Thirty-four medical schools in the United States, including Harvard, Yale and Johns Hopkins, are offering coursework in alternative medicine. For all of the CAM professions in Minnesota, the only two that are licensed are chiropractic and acupuncture.

The field of CAM is very broad and diverse and includes many systems of care. The National Institutes of Health have established the Office of Alternative Medicine to promote and guide high quality research and to bring information on CAM to clinicians, researchers and consumers. The CAM projects that are being funded and the eventual publications are a beginning body of knowledge about CAM medicine.

Under State Statute 146A, CAM providers are required to provide the Client Bill of Rights to each patient before the treatment begins. This Bill of Rights provides the patient with seventeen areas of information, which include: name of provider, CAM health care title, business address, telephone number, training, experience, and degrees that have been achieved. This then would serve as one type of credential for the patient and the referring medical practitioner.

A medical practitioner seeking to refer to a CAM provider can learn about educational achievement, whether or not the provider is licensed, and perhaps find some literature in a peer reviewed journal, but otherwise the credentialing of CAM providers is not comparable to the credentialing of medical practitioners. Before State Statute 146A, CAM providers were frequently associated with other licensed professionals. That association was often relied upon as a type of credential and provided a way to judge safety and effectiveness.

The author was a member of the Infinite Health Network and a member of the Provider Board, which credentialed every new member. This very well conceived network of CAM providers reached 125 members and all went through the credentialing process. One could observe a great deal of diligence and integrity in this process, but associates, associations, and reputation were often as important in the final judgement as were education, training, certification or licensure. Once again, it appears that science, safety

and effectiveness still comes down to relationships and especially to the individual practitioner-patient relationship

Referral, Delegation, Coordination, Follow-up:
Referral, delegation, coordination, and follow-up are all key elements in the process of health care. Other key elements include the partnership of practitioner and patient and the health care system itself. Thus, an illness is seen within the context of the whole person and the practitioner-patient relationship is seen within the context of the whole health care system. W. Edwards Deming[6] has informed us that a system accounts for 80 percent of the human behaviors while the individuals account for only 20 percent.

A shorthand summary of this concept is the 4C/2A formula. These stand for comprehensive and continuing, coordinated and customized, accessible and accountable. CAM medicine arises out of a need of the patient for more comprehensive and more customized care. When this happens, a medical practitioner will have to rely on a CAM provider. This is difficult, as noted earlier, because CAM paradigms are often foreign to medical practitioners. Also, a CAM therapy may be awaiting scientific validation or it may not be accessible to the scientific training of a medical practitioner.

Therefore, the relationship between a medical practitioner and a CAM provider is decidedly different than the one between a referring physician and another medical specialist. It appears that the structure of the CAM provider-medical practitioner relationship will have an important effect on the outcome. It seems there are two distinct relationship types in this regard. They are:

1) Therapeutically Competent
2) Therapeutically Inadequate

Therapeutically Competent Relationship:
The therapeutic relationship is likely to be competent when the dynamics between a CAM provider and a medical practitioner are characterized by listening and caring and mutual respect. They agree to try trust and balance it with intentional accountability[7]. They share the power through a high degree of willingness to cooperate and to place the patient needs foremost (this is a high-grade relationship, but it needs to be, considering the great cultural gap between these professionals).

Therapeutically Inadequate Relationship:
The therapeutic relationship that is inadequate is characterized by lost or missing elements of the competent relationship. When too much is lost or unavailable, then delegation, coordination, and follow-up all will be impaired. Consequently, referral is likely to be too risky and integrative medicine is not possible.

When the relationship between a CAM provider and a medical practitioner is deemed therapeutically inadequate, then medical practitioners must inform patients of their

inability to not only assure the science, the safety, or the effectiveness of a CAM therapy, but that they are also lacking in a good and collegial relationship with the CAM provider. In that circumstance, medical practitioners can seek to establish better, more competent relationships with their patients and together seek out other comprehensive and customized health strategies using the process of negotiated consensus.

Given the above, one would conclude that the collaboration of a medical practitioner and a CAM provider in the care of a patient, could take place only within the context of a high-grade relationship. This would be especially true for the crucial elements of referral, delegation, coordination, customization, continuity, and follow-up.

"It's driving me nuts!" said a fellow practitioner in recent weeks. He went on to say that a patient with some serious diagnoses was seeking help in a frantic, uncontrolled way. All sorts of providers had been contacted (some questionable) through advertisements, the Internet, and by word of mouth. At the same time, the patient would not accept from this practitioner any advice or referral to a consultant with whom he was familiar. It had left the practitioner confused and worried.

In keeping with the approach we are describing here, a patient such as this could be advised of the nature of therapeutically inadequate relationships and at the same time be offered the elements of a therapeutically competent relationship. If the patient could try the element of trust, this plan could look appealing. In any case, the practitioner would have a safe way to navigate through this problem and possibly help the patient as well.

Integrative Medicine:
This term, Integrative Medicine, is now being used frequently, and in conjunction with, discussions about CAM medicine. This concept would incorporate the ideas of informed consent through the process of negotiated consensus as described above. It promotes research and publication in peer reviewed journals. It would support the development of Therapeutically Competent Relationships between all types of practitioners and their patients, and especially between CAM providers and medical practitioners. It is thought that the collaboration of CAM providers and medical practitioners will eventually lead to the provision of all of the elements of the 4C/2A formula.

Integrative Medicine is the goal of most CAM providers and its scholarly activity is the way CAM medicine can fully develop and achieve patient safety, scientific validation, and outcomes effectiveness. The concept of Intentional Law[8] could do much to promote this development. These ideas will be described next.

Intentional Law and Extensional Law[8]:
Extensional Law is best known to us in our everyday lives and works best when a "rate" can be attached to a violation. Rates of speed, blood alcohol, or pollution index can be determined with relative ease and their punishment is known to be effective in changing behavior. Extensional Law provides society with protection and restraint, but does not promote the pursuit of well being in society as a whole.

Intentional Law focuses on the systemic and seeks to better society and its institutions, such as security, education, and health care by promoting the achievement of a positive and enhancing environment, in addition to a restraining and governed one. Intentional Law would give the 4C/2A formula the force of law without legislation. It would provide a series of rewards instead of punishments. For example, health care practitioners could be reimbursed better when they achieved better health care outcomes. In the final analysis, Intentional Law leads to, and promotes, the much valued concept of "empowerment" for practitioners, patients, and their working relationship.

The report to the Minnesota legislature, *Complementary Medicine*[1], lists a number of guiding principles in the regulation of CAM medicine. For example, the legislative policy objective of state occupational regulation is protection of consumers. However, another guiding principle is that creative alternatives to regulatory approaches should be sought where possible. Also, regulation should not inhibit innovation in the health care market and in the development of alternative approaches to health care, except when necessary to protect the consumer. Similarly, consumers should have the broadest market access possible to complementary, cultural, and alternative health care practitioners as long as safety is assured. Regulation should interfere as little as possible with the availability of CAM providers.

It would appear that the concept of Intentional Law would apply usefully to the development of "creative alternatives" to regulatory approaches. It is known that regulation seeks the minimum acceptable standard, while accountability seeks the highest possible standard. Higher standards are doable when practitioners are involved in the process in an intentional way.[9]

Intentional Logic [7,8] leads to a form of governance that *requires* rather than *inhibits*. In health care, it would restore personal liberty to practitioners and patients and permit them to adopt the highest possible standards for themselves. It allows the freedom to attain the optimal result. Intentional accountability produces governance that creates individual liberty while fostering methods of accountability, including self-management, self-control, and self-governance.

A rational and efficient health care system that incorporates the principle of intentional accountability, while remaining congruent with societal values would design specifications and measurements of desired outcomes into the everyday health care practice in a way that makes results naturally and routinely visible to all the stakeholders, i.e., practitioners, patients, and purchasers. An intentional society might well require that patients and practitioners attach as much importance to the care of health as they do to the care of disease while measuring the outcomes for both.

Minnesota Department of Health:
As noted earlier, it has been left to the commissioner of the Department of Health to adopt rules necessary to implement, administer, or enforce the provisions of State Statute 146A. They continue to believe that creative alternatives to regulatory approaches should be sought where possible. At this point in time no rules have been adopted. Further, they

do not wish to develop or set standards for CAM practitioners. However, they will watch the experience of the unlicensed CAM providers and seek legislation if they become concerned.

The Pew Health Professions Commission:[10,11]
The Task Force on Healthcare Workforce Regulation surfaced a number of concerns, including the lack of uniformity in language among the states and the professionals which has had the effect of creating barriers to high quality health care as well as confusing regulators, legislators, professionals, and the public. They recommend that "scopes of practice" be eliminated because they draw boundaries among professions which create exclusive domains of control over the delivery of specific services. They articulated a number of principles for the healthcare workforce, regulatory system. These include the following: promoting effective health outcomes, protecting the public from harm, holding regulatory bodies accountable to the public, respecting consumers' right to choose their health care providers, encouraging a flexible, rational and cost effective health care system that allows effective working relationships among health care providers, and facilitating professional and geographic mobility.

In light of the earlier discussion on Intentional Law, one could visualize how intentional logic could address these concerns while promoting the development of a positive and enhancing environment, and ultimately the pursuit of well being. Since the nature of a health care system will have an 80 percent effect on the behavior of its practitioners, this is not trivial, but quite germane to the behavior of medical practitioners as they attempt to refer and integrate with CAM providers.

Assessment of Liability:
The bottom line of all of these ideas turns out to be personal, professional, legal, social, and economic liability. The stated intent by all has been consumer protection, even though we are now aware that some of our methods have been ill advised. We know this because we are developing many new technologies that will improve the performance of both practitioners and patients.

Whether licensed, regulated, certified, registered, inspected or not, the use of informed consent that goes deep into the relationships of health care is the most significant message of this paper. It speaks to consumer protection, comprehensive care, quality of care, and customization of care. At the same time, it addresses liability in all of its forms. In the end, all malpractice insurers, state and national, would be likely to support this conclusion.

Another conclusion relates to the large effect of a system (80 percent) on the behavior of its personnel. The health care system probably needs redesign, but in the meantime, its effect needs to be factored into these discussions.

A Medical Practitioner Advisory:
This section will summarize the content of this paper into some specific practical directives. They are as follows:

1) Ask your patient wishing to see a CAM provider to supply you with the information from the Client Bill of Rights. Also ask the patient to answer the questions of Exhibit B.

2) Practice Informed Consent
   a. By means of negotiated consensus with both your patient and the CAM provider.
   b. By developing a therapeutically competent relationship with your patient and the CAM provider.
   c. Complete the questions of Exhibit A

3) Don't refer if your relationship to a CAM provider is deemed therapeutically inadequate.

4) Consult with personnel at the Minnesota Department of Health regarding
   a. Health care policy for troubling cases
   b. Clearinghouse information

5) Develop colleague relationships at the University of Minnesota, Center for Spirituality and Healing for information on published literature and current research.

6) Obtain a subscription to a periodic, peer reviewed journal of CAM medicine.

7) Seek ways that your local health care system, i.e., your own practice, could be intentionally accountable. For example, seek measures of patient satisfaction, develop a complaint committee made up of patients, use before and after health status measures, develop a risk registry for follow-up and continuity, read the literature on process improvement programs by Edwards Deming, and read the literature on customization of health care by Boynton, Victor and Pine.

Respectfully submitted,

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Bibliography

1. Barry, A.M.; "Complementary Medicine: A Report to the Legislature". Minnesota Department of Health, Minneapolis; 1998.

2. Minnesota State Statute 146A; "The Office of Unlicensed, Complementary and Alternative Health Care Practice". Minnesota House of Representatives; St. Paul; May, 2000.

3. Cohen, M.H.; "The Role of Informed Consent in the Delivery of Complementary and Alternative Medical Therapies". Complementary Health Practice Review, Volume 6, Number 1, Fall 2000.

4. Rice, B.; "The New Rules on Informed Consent". Medical Economics, Montvale, New Jersey; June 19, 2000.

5. Magraw, R.; "Ferment in Medicine". W.B. Saunders Company, Philadelphia & London; 1966.

6. Deming, W.E.; "Out of the Crisis". Cambridge: MIT Center for Advanced Engineering Studies; 1982.

7. Seifert, M.H., Otteson, O.J.; "Health Care That Works: A Plan for Transforming Our National Health Care System". M.D. Publishing Co., Spring Park, MN; 1994.

8. Wheeler, H.; "Intentional Law for a Quality-Conscious Society". Santa Barbara: Center for the Study of Democratic Institutions; 1977.

9. Seifert, M.H.; "Accountability vs. Regulation". Minnesota Physician, Volume VIII, No. 5; August 1994.

10. Carpenter, E.; "Licensing and Credentialing in the Health Care Industry". No. 97-3; 1993.

11. Pew Health Professions Commission. "Reforming Health Care Workforce Regulation: Policy Considerations for the Twenty-first Century". 1-47; 1995.

Exhibit A

Negotiated Informed Consent:
Medical Practitioner Referring to a CAM practitioner
December 2000

Note: These are questions a practitioner should answer prior to a discussion with a patient requesting a CAM referral.

Name of CAM provider: _____

Circle one:

I am able to verify the scientific basis underlying therapy of this CAM provider. Yes No

I am able to provide data on the effectiveness of the therapy of this CAM provider. Yes No

I am able to provide data on the safety of the therapy of this CAM provider. Yes No

I have a colleague relationship (a history of professionally working together) with this CAM provider. Yes No

I have met this CAM provider in person. Yes No

I, or a member of my family, has been a patient of this CAM provider. Yes No

I can give you the name of someone who knows this CAM provider. Yes No

If yes, name of person: _____

Note: **All health care is done in relationships and the quality of that relationship will determine the quality of the outcome. A good relationship is characterized by listening, caring and mutual trust. There is also a high degree of willingness and intention to make the relationship work.**

Exhibit B

Negotiated Informed Consent:
Patient Requesting Referral to a CAM Practitioner
December 2000

Note: These are questions a patient should answer prior to a discussion with your doctor regarding a CAM referral (CAM means complementary and alternative medicine).

Name of CAM provider: _____

	Circle One:
I am able to verify the science, safety and effectiveness of this CAM provider.	Yes No
I plan to trust my doctor for these answers.	Yes No
I plan to trust _____ for these answers.	Yes No
I have met this CAM provider in person.	Yes No
I know a family member who has been to this CAM provider.	Yes No
I know how I will protect myself.	Yes No

Note: All health care is done in relationships and the quality of that relationship will determine the quality of the outcome. A good relationship is characterized by listening, caring and mutual trust. There is also a high degree of willingness and intention to make the relationship work.

Minnesota Physician

Volume VIII, No. 5

August 1994

Revised January 1995

Accountability Vs. Regulation

A practitioners approach to a key issue in redesign of health care delivery

by Milton H. Seifert, Jr., M.D.

Many years ago at the Education Committee of the Minnesota Academy of Family Physicians, we found ourselves learning how to design educational offerings for the membership. Our mentors at the time taught us that educational programs with the power to change behavior were preferred to all others. At about the same time, Paul Ellwood and his colleagues came to a consensus that *effectiveness* (i.e. a quality result) was a key ingredient in health system design. Similarly in 1978, the Institute of Medicine, after studying all of the known models of primary care worldwide, was able to list the principle elements of primary care, and one of these was accountability. Thus, it appears that a key component of a health care system has been variously expressed as behavior change, effectiveness, and accountability; and more recently, we have been calling the same component, outcomes measurement and management.

The Grounded Approach

Another useful way to think about educational design as well as health system design, is from the ground up. That means being thoroughly familiar with the basics, building a sturdy foundation, and having a lot of experience with practical application. As physicians, our training and experience teaches us to do the same thing so that we are able to find out what is really wrong with a patient. We want the diagnosis to be as accurate as possible so that the treatment can be as appropriate as possible.

The makers of Dove soap and Naprosyn have their own ways of getting to the basics, and one of the most useful is the focus group. Many of us have been participants. In any case, it is a good place to ferret out the truth and the real issues, and this leads to better marketing and hopefully more truthful marketing.

The scientist in us might feel ready to dismiss this kind of research, but if it is used to understand patient needs and if the information is used to improve our product, than services and marketing are both better and everybody wins.

In fact, there is a scientific method known as the *Grounded Theory Approach* where the investigator gets directly involved in the phenomenon that is being studied pretty much like an intern or an extern. This method allows one to see the nuance, the interplay, and the reality of what is being studied. This research is useful in itself, and it can also lead to follow-up research that is more quantitative, more objective, and more compelling.

What do you think those who use the grounded approach find most useful? They find the stories of people to be most useful -- the details of what made it better, what made it worse, how they coped, and what is the overall meaning. As you can see, it begins to sound a lot like the work of a practicing physician. It is also easy to see the more grounded we are, the more effective and accountable we will be.

The Comprehensive Component

As suggested above, most of us who spend our professional lives in medical care have participated in the "grounded approach", because that is what we do. Alexander Flexner recognized this back in 1925 when he said the mindset of clinicians solving the problems of their patients was pretty much identical to that of a research investigator.

Medical school prepared us to diagnose biochemical disorders, to seek out pathology, to repair trauma, to save lives, and to stamp out disease. That is one part, and it is the part most helped by the biomedical model. But when we became practitioners we learned there is another part. We learned how important the family, the job, the community, the church, and the economics are to the health and well-being of our patients.

We came to understand the psychosocial component of health and were amazed at how differently our individual patients handled stress and pain. Pharmaceuticals, procedures, and surgery (the tools of the biomedical model) were found to be much less useful with this set of problems. Instead, we learned to take an educational approach to teach about the use of support, humor, acceptance, forgiveness, willingness, and coping in general. Once again, the more comprehensive we became, the more effective and accountable we came to be.

With all of this in mind one wonders why these principles (accountability, comprehensive care, a grounded approach, and the integration of biomedical and psychosocial care) are not the basis of all proposals for current health care reform. Some of us think the debate is moving away from these principles, and others think the debate may be about other things such as power, control, money, special interests, and politics.

Intentional Accountability

There is a big difference between being accountable and being regulated. As physicians, we want to be accountable, not regulated. We want there to be system-wide accountability rather than a system-wide regulation and the bureaucracy that would go with it. But before we could get anyone to let us be accountable, we would have to show that we could be trusted and that we also had the means to prove it.

Regulatory pressures often force the physician to squeeze people into categories that are judgmental, pejorative, and even rejecting. These pressures also erode the process of careful, focused listening that comprises the heart of the doctor-patient encounter. We are slowly losing the healing power of the doctor-patient relationship which lies in the value patients derive from telling their stories to someone they trust as a healer. The inhibitory, controlling, regulating, and even punitive characteristics of the present governance system--reflects some outdated thinking.

"There is a big difference between being accountable and being regulated."

There are many models much better than this. For example, the early Native Americans formed confederacies and local systems of governance that promoted participative democracy, respect for individualism, and a harmonious relationship with the environment. Another model is the Deming method of replacing Quality by inspection with Quality by design. This promotes better quality, more teamwork, and higher self-esteem. When these items are combined with measurement, they create intentional accountability.

One can only conclude that the governance of our medical care system is among the most antiquated. This is the heart of the hurt for the principal stakeholders, namely practitioners, patients, and purchasers.

Accountable Cost Control

Health care costs have been cited as the most compelling reason for fixing the health care system by those who would reform it. Here again, we can choose between intentional accountability or inspection and regulation. Certainly, when our health care system is compared with other countries, we lose by those comparisons.

Barbara Starfield of Johns-Hopkins University did a study of the 10 western industrialized countries, including the United States, and compared them as to level of primary care, level of health status, and the ratio of satisfaction/expense. It turned out that the countries with the highest level of primary care also had the highest level of health status. The United States was the lowest in all three categories and the highest on expense.

If one were to take a grounded approach and visualize for a moment how health care is manufactured, one would see that this begins in a general medical practice, in little rooms with a couple of participants, negotiating the diagnosis and treatment for this particular episode of illness. It may lead to a referral, a procedure or surgery and when one added up the results of all those individual interactions across the country, that would be the output of our health care system for that day. Adding up the costs for those interactions would be the cost of the system for that day.

This would mean that health care is manufactured mainly within the practitioner-patient relationship. It would also mean that the practitioner and patient were in the best position to be intentionally accountable for the control of health care costs. The more they, by intention, did it right the first time, the less expensive it would be.

These two individuals would be guided by the basic principles of primary care. If they were not, it would be more costly. Here is why:

- ***Accessibility***. Lack of accessibility leads to untreated illness, delayed diagnoses, and increased costs.
- ***Comprehensiveness***. The lack of comprehensiveness leads to fragmented, incomplete forms of treatment and increased costs.
- ***Coordination***. A lack of coordination leads to an incomplete or improper mix of services, inefficiency, and increased costs.
- ***Continuity***. A lack of continuity leads to a reduced ability to recognize and revise a failing program and also to increased costs. Transfer of care to another provider increases costs and decreases continuity.
- ***Accountability***. Inability or unwillingness to measure and meet health care needs adequately, and to document that this is so, leads to governance by regulation and increased costs.

The Values Framework

Some voices in health care reform have urged us to be accountable for an explicit, defensible, agreed-upon framework of values that will help us evaluate reform proposals and establish criteria for assessing the efficacy of our health care system. If we are willing to be accountable for social values, it would seem that we need to do the following:

1. Reprioritize certain essential values, such as providing fair access.
2. Reinstate neglected ones, such as meeting the needs of underserved populations.
3. Add needed ones, such as promoting personal responsibility and social advocacy.
4. Rearrange others, especially those that conflict with each other.

Reinhard Priester, J.D., Center for Biomedical Ethics, University of Minnesota, has identified and defined five essential values that might guide the restructuring and reform of our health care system. They are as follows: fair access; quality;

efficiency; respect for patients; patient advocacy. In addition, the center has defined six other instrumental values that support the essential values: personal responsibility; social solidarity; social advocacy; provider autonomy; consumer sovereignty; personal security.

One would be hard pressed not to include these criteria in proposals for health care reform. However, adoption will require even further accountability.

System Reform Through Practice Design

Some of us think that practitioners and patients, if they could be heard, would contribute the most to meaningful reform. If patients had successfully participated in their own medical care and had a voice in how their primary care medical practice was managed, then no doubt they and their practitioners would have already constructed a working practice model by means of the ground-up approach. But, unfortunately, it is these voices that are the furthest from the debate and are very unlikely to be a part of the dialogue. So, what can we do if we want to have a voice?

Practitioners and patients could best join the dialogue by creating a workable practice design, characterized by collaboration and negotiation. Their combined and integrated voices would contribute to both practice management and patient care, and this would serve to educate and empower patients. When it became apparent that this is an attractive model, it would be duplicated and the practitioner/patient-voice would grow in other medical practices. There are further details, but the key to success is the understanding that this can be done with accountability, but not with regulation.

In the end, we would expect to see the development of a primary care practice model that avoids the mind-body dualism while meeting both the biomedical and psychosocial needs of patients integrated within the context of a strong practitioner-patient partnership. The core policies, procedures, and programs would rest on the five basic principles of primary care, the defining characteristics of community-oriented primary care (COPC), a values framework, and the conceptual elements of family medicine. All of these would fully integrate with the health care system as a whole.

The model, through a consensus negotiation approach, would promote greater patient responsibility, enhance the competence of physicians, and improve patient satisfaction. It would use a teamwork approach to address emotional, social, and spiritual health problems within the practice setting and would apply the principles of both science and ethics to the basic primary care issues. It could be the foundation of our health care system.

"Since the reform process is mostly governmental, perhaps we should define the proper role of government."

Practice based clinicians will be glad to know there are practical strategies to put these ideas into operation. In recent years, the Rand Corporation and the New England Medical Center have made major advances in developing the necessary technology. Important Minnesota developers include the following: InterStudy; The Health Outcomes Institute; The Minnesota Department of Health; and the Management Medicine Foundation. Hardware, software, short form questionnaires, and information systems are becoming useful for clinicians and hold the promise that one could be an autonomous but accountable practitioner.

The Reform of Health Care Reform

Since the current reform process is mostly governmental, perhaps we should define the proper role of government. The proper role of government is to stifle competition that is bad for its people; to facilitate the formation of structures, alliances, and services that are good for its people; to promote enlightened partnership management at all levels; and, most important, to manage the performance of those who do the performing.

The complimentary role of citizens is to perform well by intention and to have a data system that measures results. It will also require that we undertake change in our own personal health behavior in order to be fully accountable.

Summary

Accountability is the key to autonomy. It becomes easier to achieve the more we are willing to become intentional about it. The alternative to accountability is regulation which is inhibitory, inspectional, punitive, archaic and expensive. Good governance is possible with accountability while bad governance is probable with regulation. Regulation seeks the minimum acceptable standard while accountability seeks the highest possible standard. We want to see appropriate accountability for all levels of stakeholders and we want all levels to participate in developing the necessary policy. Finally, we want our health care system to operate with methods of accountability and information systems that will design and redesign health care delivery in a perpetual way.

Milton H. Seifert, M.D., is a principal and a practicing physician at Eagle Medical

This revision is based on an earlier article from Minnesota Physician, Volume VIII, No. 5. August 1994. It has been revised by the author.

THE QUALITY LETTER for Healthcare Leaders®

Volume 9 Number 10 November 1997

On Addressing New Issues in Patient Care

"Health status assessment gives you insights on patients' psychosocial lives that are often swept under the rug or missed entirely."

Harry Wetzler, M.D.
Senior Vice President
Health Process Management Inc.

On Changing the Prevailing Model of Clinical Care

"Effectively integrating patient preferences into treatment requires a fundamental shift in the way we deliver healthcare."

Robert Nease Jr., Ph.D.
Assistant Professor of Medicine
Washington University Medical Center

Featured in This Issue: Health Status Assessment

Also in This Issue

Health Status Assessment — A Vital Sign for Planning Patient Therapy

Patients' perceptions of their health status need to be weighed along with blood pressure and lab results to choose the best course of treatment, these physicians say. They're using health status surveys to get the information they need.

by Mary Darby

Milton Seifert Jr., M.D., a family practitioner in Excelsior, Minn., recalls the case of a 22-year-old man who came to see him for a seasonal allergy problem. Soon Dr. Seifert discovered that his patient had a host of other, potentially more serious problems, including work-related stress, alcohol abuse and smoking. He also learned that the man disliked his job intensely and often felt angry and depressed.

This information put the man's allergy symptoms in a new context, as a clearer and more comprehensive picture of his health emerged, Dr. Seifert says. "What I was looking at was the way he felt about life in general," he explains. "I told him, 'When you treat these other things, the allergy symptoms may not seem so bad.'" Dr. Seifert says he is trying to help the man solve his lifestyle problems.

How did Dr. Seifert become so attuned to his patient's inner life? The answer lies in his incorporation of health status assessment into his everyday clinical practice. Dr. Seifert routinely asks his patients to fill out a form called the SF-36 Health Survey (see box, page 3) and a health behavior survey he designed that includes questions on exercise, diet, sexual activity, work, seat belt use, safety and other lifestyle issues.

The two surveys, known collectively as the Health & Disease Questionnaire (HDQ), are loaded into a handheld computer. Patients take a few minutes to enter their answers on the computer, and Dr. Seifert quickly scores them, so that when he sits down to talk with a patient, he has concise, "real-time" information. He also has a clearer picture of what is going on with his patients' health — which he can flesh out as needed during his consultations.

Such health status assessment — the use of standardized, patient-based surveys to obtain information about different aspects of health — is slowly moving into the mainstream of clinical practice. For some time, researchers have recognized the value of patient behaviors and perceptions in measuring and assessing clinical outcomes and quality of life. Now, a few physicians are going a step further — making health status assessment part of their practice routine and using survey-based information to improve care for individual patients. No one really knows how widespread the practice is, but the peer-reviewed literature is an indicator. In the early 1990s, only six articles mentioned use of

BENEFITS OF HEALTH STATUS ASSESSMENT

A number of benefits accrue to practitioners using properly designed health status assessment techniques:

- ✔ Patient care is improved.
- ✔ Patients are able to participate more fully in disease management and health maintenance.
- ✔ Practitioners can help purchasers and business owners improve employee health and reduce costs.
- ✔ Practitioners acquire scientifically sound data useful in negotiations with other entities within the healthcare system.
- ✔ The technology is nonintrusive, preventing practitioner stress. The patient does the work.
- ✔ Healthcare and healthcare research merge into one process.
- ✔ The technology supports and improves the interaction of clinician and patient. This adds value to the service.

the SF-36; during 1996 and 1997, more than 100 articles on its clinical use were published.

This issue of THE QUALITY LETTER examines how a handful of physicians are using health status assessment to gain new insights into their patients' problems, communicate better with their patients, improve care and target their resources more efficiently. These physicians say that health status assessment has helped them bring their patients' needs and perspectives more fully into healthcare decisionmaking.

Viewing Care Through the Patient's Eyes

"We started out from a relatively skeptical point of view," recalls Klemens B. Meyer, M.D., director of dialysis services for Boston's New England Medical Center. Nephrologists spend a good deal of time with their patients, who generally come in several days a week for dialysis treatment. "We were very proud of giving personalized care to our patients, and we felt we knew our patients very well," Dr. Meyer says, adding that he and his colleagues expected the SF-36 results to merely reaffirm what they already knew intuitively. But that view changed after Dr. Meyer and his colleagues studied their experiences using the form among their dialysis patients.

For example, one patient felt he was doing significantly worse than did his physicians, who learned that they had greatly underestimated his disability during recovery after surgery to repair a fistula. Another patient perceived that he was doing better than his physicians did. It turned out that, unknown to his physicians, the patient had felt significantly impaired by hip pain. When the patient started taking ibuprofen on his own to relieve the pain, his overall view of his health improved substantially. "We had been attending to all sorts of things with great solicitude, but not the hip pain," Dr. Meyer notes.

Those and other experiences, Dr. Meyer says, illustrate that "there are a number of aspects of health that are hard to see through somebody else's eyes."

That is where generic health assessment surveys like the SF-36 come in. These instruments were designed to capture patients' perceptions of their health on a range of dimensions — systematically, effectively and efficiently.

ABOUT THE SURVEY INSTRUMENTS

The SF-36 Health Survey is a multipurpose survey that yields an eight-scale health profile (see page 4), as well as summary measures. The SF-36 — which stands for short form, 36 questions — has been used to monitor general and specific populations, compare the relative burden of different diseases, assess health benefits produced by different treatments and screen individual patients. Permission to use the SF-36 is routinely granted royalty-free to individuals and organizations for their own use by the Medical Outcomes Trust.

The Health Status Questionnaire (HSQ) by the Health Outcomes Institute in Minneapolis adds three items that are disease-specific mental health measures to the 36-item form.

Another survey almost identical to the SF-36 is produced as the RAND 36-Item Health Survey; this less-often-used version recommends a different scoring method on two of the eight scales.

Information on the SF-36 is available on the World Wide Web at http//www.sf-36.com, or call the Medical Outcomes Trust at (617)426-4046. For information on the HSQ, call (612)858-9188. Information about the RAND 36 is available from RAND at (310)393-0411.

Getting the Data Takes Only Minutes

Physicians applying health status assessment to patient care acknowledge its challenges, but they are not insurmountable. Generally, a standardized survey, such as the SF-36, is administered to a patient during an office visit. These surveys may be combined with disease-specific or other questions such as those Dr. Seifert developed. Patients can fill them out in a few minutes. The information may be processed through an optical scanner and

"If you get a graph of the scores and the two of you are looking at the graph and data trends, you can solve problems together and evaluate effectiveness of treatment."

Dwana Bush, M.D.
Atlanta Family Medicine
Atlanta, Ga.

translated almost immediately by computer into graphs (see "Graphing Health Status Can Help Pinpoint Patient Problems," pages 14–16) that illustrate a patient's scores in eight health-related domains:

- Physical function
- Role limitations as a result of physical problems
- Role limitations as a result of emotional problems
- Bodily pain
- General health perceptions
- Vitality
- Social function
- General mental health

Practitioners with limited computer capabilities can send completed survey forms to a service vendor by fax or telephone using voice recognition technology; the vendor's software computes the scores and transmits the results within minutes.

Low Scores Shed New Light on Problems

The choice of technology makes little difference, physicians say. What's important is to have those scores available to share with patients during consultation. And that, they say, is when the real discovery process begins. By clarifying patients' perceptions of the reasons for their low scores, physicians may unearth important information that places their patients' problems in a whole new context for diagnosis or treatment, says Donald Lum, M.D., president of a consulting firm called Living Lab Inc.

SAMPLE HEALTH & DISEASE QUESTIONNAIRE RESULTS

Sample Category/Questions*	Analysis of a Negative Response	Level of Concern
Disease impact:		
Pain	Pain with moderate limitation	Advise help
Social functioning	Fair social functioning	Advise help
I'd be a lot healthier if life hadn't been so unfair.	Spiritual health deficiency	Health hazard
I am willing to go to great lengths to improve my health.	Spiritual health deficiency	Health hazard
I minimize my intake of fats and oils.	Excess dietary fat	Health hazard
I am satisfied with my sleep pattern.	Dissatisfaction with sleep	Health hazard
I use a seat belt.	Seat belt deficiency	Mild concern
I have many financial worries.	Financial stress	Important problem

*Patient responds by indicating percentage of agreement on a scale.

"I used to say health status assessment paints a word picture of the patient," says Dr. Lum, who's also a practicing family clinician at the Allina Medical Group's River Valley Clinic in Northfield, Minn. "My new analogy is that it's actually like the picture frame that surrounds a presenting complaint or chronic illness with the mind-body connections."

Advocates say they're learning to understand their patients more completely, more efficiently and more effectively. They warn that administering forms such as the SF-36 to patients is not a substitute for talking with them. It is a tool for engaging in more productive dialogues.

"In the old days, we'd ask, 'How are you doing?'" says allergist Don Bukstein, M.D., of the Dean Clinic in Madison, Wis. "Now we have a much broader ability to really say how that patient is doing beyond just overt symptoms. And if people don't think that asking patients is important, they're wrong, because patients' answers are very accurate and sometimes lead to important questions."

Dr. Seifert says that combining the SF-36 with the lifestyle survey he designed has helped him probe into health and disease as "two interdependent topics." The SF-36, he notes, is a "good measure of the impact of disease," but he also wanted to assess lifestyle habits related to patients' health. Together, he says, the two instruments have enabled him to "create a language of health negotiation" with his patients.

One of his cases involved a 32-year-old woman with Crohn's disease, who, despite significant health-related problems, put on a show of optimism. Using the SF-36, Dr. Seifert says he quickly discovered that she had a low health perception and low vitality. "She said she thought she was going to die," he recalls. Upon hearing that, Dr. Seifert arranged for a team of providers — an internist, a nutritionist, a digestive disease specialist and a health educator who teaches life management skills — to work with her and get her back on track. The test scores will be used to mark her progress.

Like Dr. Meyer, Dr. Seifert says he initially had low expectations regarding the usefulness of health status assessment. "I wasn't prepared to know that there could be that much improvement," he says. "We are finding the test results to be very reflective of our patients."

Start a Dialogue

Systematic use of the SF-36 has helped Dwana Bush, M.D., a family practitioner with Atlanta Family Medicine, involve her patients more in their own healthcare by identifying health-related goals and deciding on steps to achieve them. The SF-36 scores serve as a basis for discussion between patient and clinician. "A graph depicting a patient's current health status is the most important 'vital sign' for planning patient care," she notes. "If you get a graph of the scores and the two of you are looking at the graph and at data trends, you can solve problems together and evaluate effectiveness of treatment." For example, a patient with a low vitality score may reveal that

INTERPRETING HEALTH STATUS ASSESSMENT RESULTS

The real value of health status assessment data comes into play when the physician shares the results with his patient and uses the assessment as a basis for discussion and decisionmaking, notes Donald Lum, M.D., president of Living Lab Inc., Northfield, Minn. Dr. Lum outlines four steps in that process:

1. Explain the meaning of each measure to the patient.
2. Identify measures in which the patient scored low.
3. Ask clarifying questions to determine the patient's perceptions of the reasons behind those low scores.
4. Use this information in clinical decisionmaking.

"Assessment," notes Dr. Lum, "is an interactive process."

she is feeling stressed by work. A new objective emerges: to minimize that stress and its effects.

Dr. Bush says that use of the SF-36 also has heightened her awareness of depression among her patients. The survey's depression screen (less than 60% of the total possible score for mental health) flags potential problems. As a result, she has redesigned her care processes to evaluate and treat depression and other mental health problems in the daily course of primary care. Dr. Bush notes that diagnosis of depression is particularly important in treating patients with chronic diseases, such as diabetes or asthma.

MEDICARE DEMONSTRATION PROJECT COLLECTS HEALTH STATUS INFORMATION THROUGH OASIS

Medicare home care providers say a new, standardized outcomes data set is helping them identify functional and other problems their patients are experiencing and design appropriate care plans earlier.

"We're asking questions that we've never asked before, and in areas that we've never asked about before," says Kitty Horton, R.N., B.S., former assistant vice president of patient care services at the Twin County Home Health Agency in Galax, Va. "This gives you a better picture of what's happening with the patient, which is helpful in setting up services to better meet patients' needs."

Fifty home health agencies throughout the country have been involved in Medicare's demonstration project using the Outcome and Assessment Information Set (OASIS), which elicits information on some 80 health status items, including physical and cognitive functioning. OASIS was designed to measure outcomes of Medicare home care patients over time, until they are discharged from home care.

HCFA Proposes Use for All Medicare Home Care

Although the demonstration project is still under way, the Health Care Financing Administration has proposed implementing OASIS data collection as a condition of participating in Medicare home care — creating, in effect, a mandatory outcomes-based quality improvement program.

Home care providers who have been using OASIS say there is a significant learning curve. "The nurses were a little shell-shocked at first," recalls Barbara Harlow, R.N., manager of performance improvement and support services for Providence Home Health Care of Novi, Mich. But with time, she and Ms. Horton say, administration of OASIS has become a part of everyday care.

Ms. Harlow and Ms. Horton say that OASIS makes patient assessment more consistent, objective and comprehensive. "It forces you to ask more questions up front," says Ms. Harlow. In the past, home care nurses may have waited to establish rapport with their patients before asking them questions about depression, thoughts of suicide or hopelessness. Now, these and other questions about health status are asked each new patient, then repeated every 56 to 60 days to recertify patients and again at discharge from home care.

"I think our nurses are aware much more quickly of their patients' needs," notes Ms. Harlow. "You can see very clearly in black and white how they're functioning."

Standardization Permits Benchmarking

Using a standardized system also allows agencies to benchmark their own performance against national averages. Agencies participating in the demonstration project have used OASIS to launch their own internal quality improvement initiatives too.

Twin County, for example, decided to focus on treatment of patients with shortness of breath, according to Ms. Horton. As a result, the agency stepped up staff education, examined how nurses were documenting and describing shortness of breath and started placing more emphasis on monitoring weight gain among at-risk patients. Ms. Harlow notes that use of OASIS showed that Providence was performing better than the national average in the areas of pain control and improvement in dyspnea but needed to work on ambulation.

Ms. Horton and Ms. Harlow advise other agencies that are gearing up for OASIS to start early and give themselves as much time as possible to prepare; it took them three months before the program was fully implemented. Internal office processes, policies and forms need to be revised and tested. Staff need to be trained on the purpose of OASIS and the new policies and processes. Staff should also talk with agencies that have participated in the demonstration project for insight into their experiences with OASIS, they add.

For more information about OASIS, contact Kathryn Crisler, M.S., R.N., assistant director at the Center for Health Services and Policy Research, University of Colorado, (303)756-8350, or the National Association for Home Care, (202)547-7424. Contact Ms. Harlow at (248)380-1200 and Ms. Horton at (800)719-7434.

The real payoff, physicians say, comes with time, after several rounds of scores have been compiled and patterns begin to emerge. "If your patient improves or deteriorates, you can do a process of discovery to find out what's making the difference either positively or negatively," explains Dr. Lum. In real life, he says, patients with complex problems often require a number of interventions, and figuring out which one made an impact can be difficult. For a patient with both depression and diabetes, a physician can use health status scores as a launching point to identify the relative effects of antidepressants, cognitive therapy, intensive insulin management and diet. "You will have your own perspectives about these things, and patients will have theirs," Dr. Lum says.

In addition, Dr. Bush notes that her use of routine health status assessment has helped her target her resources more efficiently. By zeroing in on patients' problems and responding to them earlier and more appropriately, she's reduced her use of diagnostic tests and referrals. She's been using the SF-36 for four years, and she can see patterns emerging and can quickly identify changes in a patient's status — and quickly respond.

Assessment Predicts Patient Use of Resources

Health status assessment can be extremely useful in managing risk, says John E. Ware Jr., Ph.D., senior scientist at the New England Medical Center's Health Assessment Laboratory and the principal architect of the SF-36. "A big part of managed care is risk management — deciding what a patient's care is going to cost, what her risks are and how she should be managed," he notes. "That's going to help with capitation a lot." Clinicians agree. Dr. Bush observes that patients who score low on the SF-36 tend to consume more healthcare resources. Dr. Bukstein says that scores are highly predictive of resource use among asthma patients. And Dr. Seifert notes that taking on intentional accountability buys clinicians reasonable and appropriate autonomy — which piques many practitioners' interest.

Dr. Bush has demonstrated in one managed care population that her patients' low initial mental health scores have, on the whole, improved by 20% — of interest to managed care administrators looking for quality outcomes documentation. "Functional health status measurement and identifying trends can get the patient, provider and purchaser all reading off the same page," she says.

FOUR KEYS TO SUCCESS

- ✔ **Unwavering support from local administrators.** This support empowers the team to effectively implement new clinical care processes by clearing roadblocks, gaining access to resources and sponsoring a mandate for innovation and change.
- ✔ **Well-organized clinical teams.** Respected opinion leaders from multiple disciplines, they act strategically to embed clinical innovation into the everyday work processes at the site.
- ✔ **Strong clinical champions.** Highly respected by their peers for excellent clinical skills, they demonstrate a high degree of interest and competence in teaching new clinical skills to other clinicians.
- ✔ **Clinical mentors.** Successful dissemination of the skills to clinicians depends on effective mentoring and coaching.

Invest for Long-Term Gain

One nagging question remains: If health status assessment is so beneficial, why aren't more clinicians incorporating it into their practices?

Consultant Harry Wetzler, M.D., M.S.P.H., a senior vice president at Health Process Management Inc., Doylestown, Pa., and a clinical outcomes specialist with the American Medical Group Association, has several theories.

First, he says, the clinical quality arena is crowded with activity. Many practices are caught up in efforts to keep up with accreditation requirements, contracting demands by managed care organizations and multiple pressures for data. In addition, health status assessment may seem vague to the uninitiated. "They're not sure what they can get out of this," Dr. Wetzler says. Chances are it won't be reimbursement.

Clinicians also may be afraid of addressing new issues that will cut into their productivity. "There's no question in my mind that health status assessment gives you insights on patients' psychosocial lives that are often swept under the rug or missed entirely," Dr. Wetzler asserts. "There's a disinclination to deal with these issues out of concern that 'If I touch this, I'm tied up for 30 minutes.'" That, he believes, stems from a misconception of what productivity means in healthcare delivery. "Right now, physicians think in terms of 'How many people can I see?' We feel that productivity should be equated with 'How much health am I producing?'"

Some physicians say they consider health status assessment neither time-consuming nor difficult. Others say that although health status assessment does require a little additional time up front, it generally saves time down the road by helping them to focus on important problems early and prioritize treatment. "It is a time investment, but it is time-efficient," claims Dr. Lum.

Overcome Barriers to Implementation

But even staunch supporters of health status assessment in clinical practice say there are some nuances to it.

Dr. Lum led a collaborative group practice project in the Allina Health System that centered on health status assessment. Of seven sites that started with the project, only three completed it. Dr. Lum says those practices shared three characteristics: strong clinical champions, well-organized clinical teams and unwavering support from local administrators. "At the micro level, those three things are probably the most important transformation drivers," he notes. As a corollary, he recommends heavy emphasis on clinical mentoring and coaching for successful dissemination of the skills to clinicians. (Dr. Bush, he notes, was his clinical mentor.)

Dr. Meyer agrees with Dr. Lum about the need to train and educate physicians in health status assessment. "We're not taught how to interpret a change in physical functioning or in role limitations due to physical problems," he observes. "It takes some figuring out."

Explaining to clinicians what they should do with the results can be tricky. These practitioners offer four key steps to successful application:

EDUCATIONAL SERIES AVAILABLE ON HEALTH OUTCOMES SURVEYS

A new educational video series offers a primer on patient-based health outcomes surveys and their uses. The series, called *Understanding Health Outcomes,* is accredited for physicians, nurses and pharmacists by Tufts University School of Medicine and is designed for clinicians, hospital and managed care administrators, healthcare policymakers, employers, researchers and students of outcomes research.

Each program includes interviews with experts, examples of applications and graphics on specific teaching objectives. Each program consists of a videotape, study guide and diskette. Three of nine tapes for the first part of the series, "Health Status: Concepts, Measures and Applications," have been completed. Parts two and three will be developed and released in 1998; the others are in production. The second part of the series will focus on the use of patient-based measures for specific diseases, such as asthma, depression, migraine, dementia and sleep disorders. The third part will demonstrate how specific treatments affect patients' functional health status.

The series is being produced by HealthStat Productions Inc., with sponsorship by Searle, Glaxo Wellcome Inc. and Janssen Pharmaceutica. John E. Ware Jr., Ph.D., director of the Health Assessment Laboratory at the New England Medical Center, is chief scientific advisor for the series.

The tapes are being offered for sale individually or by subscription. The initial overview program is $95; programs in Series I, including the nine tapes, are $250 each. Subscriptions are also available for $1,350 (a 35% discount).

For information, contact Ken Nochimson of HealthStat at (732)636-6930; e-mail: HStatProd@aol.com.

❶ Start small. "Don't try to do too much too quickly," Dr. Wetzler says. Keep in mind the impact of assessment on staff, and don't lose sight of the fact that some financial investments are necessary. "Costs here don't have to be extraordinary, but you can't do it on a shoestring either," he warns.

❷ Be prepared to process the data. Technical needs can run the gamut. Dr. Meyer says at first it was a matter of remembering to have enough pencils for his patients to fill out their forms. Others describe their experiences with different types of scanners, computer programs and fax services. Dr. Bush says she believes that many people expend too much angst on high-tech hardware. "I tell people to invest in a little laptop that they can take around to process graphs on site," she says. Dr. Wetzler believes that technology — especially in the outpatient arena — needs more integration. "You want to automate this as much as possible by tying it in with appointment and billing systems," he notes.

Dr. Ware is upbeat about technology. The development of phone/faxback, computer, Integrated Voice Response and Internet technologies, which are currently being merged with television, he notes, has made seamless use of health status tools in practice "much more feasible." And some two dozen vendors now have software to process the forms.

❸ Put referral systems in place to support needed actions. Dr. Bush's experience with depression in patients is a case in point. "We found that approximately 30% of our patients have low mental health scores, which suggests that they need to be further evaluated for depression," she says. "You need to have an algorithm to follow for treatment and monitoring — and deal with the condition without creating a traffic jam." Referral systems need to be in place. "You need to have an individual and systemwide approach to dealing with mental health scores," Dr. Bush asserts.

Dr. Bush notes that "people tend to overmeasure and underrespond. You don't want to document that 30% of your patients have low mental health scores and then be unprepared to respond."

❹ Verify and understand the results. This interaction with patients "is the first thing you do," Dr. Meyer says. That means talking to patients and probing beneath the surface. Even then, "whether you do something about it depends on the information," he adds.

Dr. Ware is optimistic about the future of health status assessment in clinical practice. "We're on the verge of a whole new generation of tools," he predicts. The reliability and sensitivity of the instruments will improve and they will become even cheaper to use than they are now; a number of firms are marketing their assessment services for a few dollars or less.

Training programs in incorporating health status assessment into practice are also being developed, including the educational series produced by HealthStat Productions (see box, page 8) and a twice-yearly conference sponsored by the Integrative Health Institute in Atlanta.

"The real challenge is going to be: Who knows what to do with outcomes data and has the will to do it?" Dr. Ware says.❖

For more information ...

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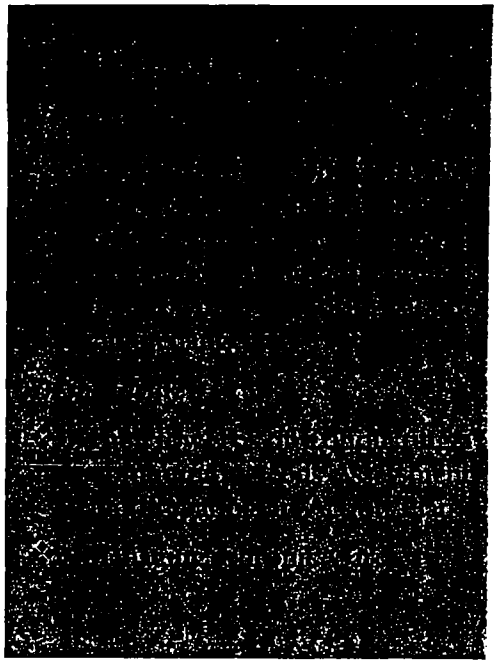

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"I don't mind filling out these forms, but it cuts into my time to read *People*."

THE QUALITY LETTER
for Healthcare Leaders ®

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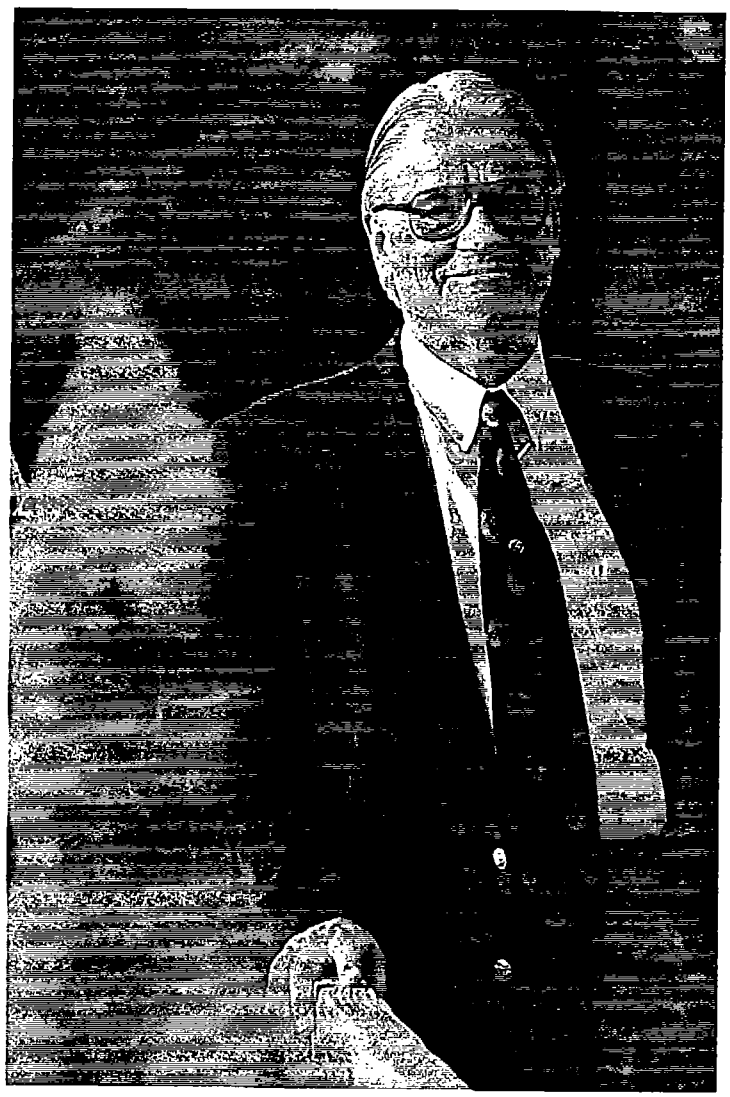
Published 11 times a year by Capitol Publications Inc., 1101 King Street, Suite 444, Alexandria, VA 22314. Subscriber services: (800)655-5597. Editorial: (703) 683-4100. E-mail: amiller@cappubs.com. Fax: (703)739-6517. Annual subscription rate (U.S. and Canada): $289. Multiple-copy rates available. ISSN 1047-5311.

Referenced in the American Hospital Association's *Hospital and Health Administration Index* and the *Cumulative Index to Nursing & Allied Health Literature.*

Could better care beat managed care?

This FP has bet his career that it can, though the odds are against him. His patients proclaim him the best doctor around.



FP Milton Seifert Jr. lets a patient advisory council guide his practice, including the setting of fees.

Photos by Layne Kennedy

By Ken Terry
SENIOR EDITOR

Excelsior, Minn., a suburb of Minneapolis, is the birthplace of the effort to make HMOs a major force in American medicine—and home to a medical practice of a kind that could make managed care obsolete.

For a quarter of a century, Excelsior FP Milton Seifert Jr. has been practicing a holistic brand of medicine that he calls "comprehensive care." It involves both traditional medicine and "health educators" who offer psychological counseling as part of the primary-care process. It recognizes the patient as a full partner in diagnosis and treatment. And, if many of Seifert's patients and an HMO survey can be believed, it's an approach that's highly conducive to patient satisfaction (see page 183).

While this system seems like the antithesis of assembly-line managed care, it grew out of the same impulse that gave rise to health maintenance organizations. Back in the mid-60s, Seifert, Paul M. Ellwood Jr., and four other health-care professionals coined the term HMO, to describe the prepaid concept that had been around for decades. As Ellwood and his group saw them, HMOs were the solution to America's health-care problems at the time. They were supposed to provide accessible, comprehensive, continuous, and effective care. Although they've fallen far short of those goals, Seifert says, he has tried to achieve them in his own practice. He's also strived to individualize care and make his practice accountable to the community.

In 1972, he made his commitment real by

forming his first patient advisory council. Now 50 members strong, the PAC deals with patient complaints, helps formulate practice policies, and advises Seifert and his two associates on business decisions (see page 184). It even decides how much the three family physicians can charge their 12,000 patients. During the past two decades, Seifert says, his basic office-visit charge has risen from $15 to $42, about average for the community.

While Seifert's Eagle Medical practice has struggled to survive financially, he attributes this mainly to external factors, rather than to the PAC. He views the PAC not as a limit on his freedom, but as a rock of support in a community that has depended on him and his family since the 1930s, when Milton Seifert Sr. began the clinic.

Where Seifert is out in front of the managed-care curve is in his emphasis on dealing with patients' psychosocial problems and measuring their functional health status.

Not surprisingly, Milt Jr. knows his patients well. While chatting with one young woman, for example, he remembers when her father was nearly run over by his own tractor. And, pointing to a batch of family-photo Christmas cards tacked to his office wall, he says proudly, "I delivered at least 13 of those babies."

That connectedness with his patients has been the foundation of Seifert's approach all along. As his partner Steve Kind notes, "In a sense, it's a throwback, and in another sense, it's out in front of things a little bit. It's a modern reinterpretation of what the old-time family doctor used to be about."

Experimenting with functional status

Where Seifert is "out in front" of the managed-care curve is in his emphasis on dealing with his patients' psychosocial problems and measuring their functional health status. (This outcomes measure looks at how patients feel and function before, during, and after treatment.) He has been employing the most widely used health-status survey, the SF-36, for three years. He combines this with additional questions on "life-management skills," including health behavior (smoking, alcohol use, diet, stress, and exercise) and other problem indicators (unsafe sex, harmful drug use, difficulties with marriage and work, etc.). Seifert uses this "Health & Disease Questionnaire" to identify problems, break down barriers to compliance, and track outcomes.

In this respect, Seifert is far ahead of most other primary-care doctors and right in synch with employers that are starting to view functional status as the key to measuring quality in health care.* With the help of a consultant, Seifert is developing software to analyze the results of his questionnaire. He hopes to sell employers on the idea and to begin using the survey in treating the 10 to 20 percent of employees who ring up the lion's share of health-care costs.

If he succeeds, he believes, he'll be pointing the way toward a new method of direct contracting between employers and physicians. In place of fee-for-service, Seifert envisions a system of "fee-for-results," in which outcomes will replace services as the basis of physician compensation. And in place of health plans, which he sees as bureaucratic middlemen with no real stake in patient health, he wants to form grassroots networks of small practices governed by PACs.

If this sounds like the late-night ruminations of a country doctor who's been in the trenches too long, consider this: The Minnesota Academy of Family Physicians named

*See "Can functional-status surveys improve your care?" Aug. 12, 1996.

Seifert Family Physician of the Year in 1990. He's a full clinical professor at the University of Minnesota. He has published a book, appeared on the "Today" show, and spoken at national conferences. Top academics like Barbara Starfield of Johns Hopkins and Arthur Caplan of the University of Pennsylvania sing his praises.

"What Milton's striving for is a way to make primary care user-friendly," says Caplan, director of Penn's Center for Bioethics. "That's a crucially important thing to be doing, not just because it's the right thing to do, but because when you do it, you'll get better results."

Few physicians have followed Seifert's lead, partly because the health-care market doesn't reward doctors for practicing that way. In fact, economic pressures may force this pioneering physician and his associates—Steve Kind and Milt's brother Greg—to break up their practice. But doctors in St. Paul, Minn., and Atlanta are applying his ideas, and he's influenced others through his teaching activities.

Is modern health care ready for Milton Seifert Jr.? That's hard to say. On the one hand, payers are ever more determined to cut costs, especially for mental health care, and health plans are pressuring doctors to process patients as quickly and efficiently as possible. On the other hand, there's an increasing recognition that the unmet psychosocial needs of many patients may be increasing their utilization of medical services. As a result, some HMOs are trying to integrate primary care with psychological counseling.*

*See "Will health plans make you play psychiatrist?" July 15, 1996.

At a meeting of his patient advisory council, Seifert listens to members express their concerns.

The time may be right for Seifert's grand scheme, after all. But whether it is or isn't, you can learn something from the extraordinary lengths to which he goes to serve his patients.

Negotiating care with patients

In explaining his approach to patients, Seifert uses a diagram in which lifestyle (unhealthy to healthy) is plotted against stage of disease (none to severe).

"When I see a new patient," Seifert says, "I'll show him the diagram and say, 'I'm totally dependent on you for my competence.' He'll say, 'Well, aren't you a doctor?' And I'll say, 'Yes, but I need you to have an independent role.' "

Seifert prefers to "negotiate" diagnoses and interventions with patients, rather than prescribe treatment. While this approach may not always help the patient right away, he maintains that it increases compliance in the long run.

Seifert stresses the importance of learning from difficult patients rather than ignoring their problems. "If a patient says the only

medicine that's helped him is a controlled substance, most doctors will dismiss his complaints because he's an addict," he notes. "By assuming the patient's at fault, you cut off your capacity to do anything about his problem."

According to the Department of Health and Human Services, says Seifert, lifestyle accounts for about half of the mortality from the 10 leading causes of death. That's one reason he feels physicians should pay more attention to what patients say, and not just to their clinical symptoms. Whereas most physicians identify only 5 to 10 percent of patient problems as psychosocial, Seifert figures the real percentage is about 20 percent.

"Doctors don't have time to talk with people for an hour about the stress in their life," says counselor Leigh Ostrander. "And it's very frustrating for doctors when they can't."

Like some other doctors and researchers, he's also noticed that stress can cause physical symptoms. He recalls one patient with pancreatitis, for instance, whose serum amylase level shot up whenever he became anxious. "We got to where we could recognize it early, before he got sick. In his case, stress was directly related to the recurrence of the pancreatitis."

Based on a patient's answers to Seifert's Health & Disease Questionnaire or his oral questions, the physician draws up a "problem list" that focuses on the patient's view of his health needs. Then he and the patient decide which problems to attack first.

So far, Seifert has given this survey to 300 patients when they came in for physical exams. Over time, he hopes to administer it to all of his patients. The biggest limitation right now, he notes, is that the data have to be entered into his computer manually.

Making counseling part of primary care

If a patient clearly needs help managing his life, Seifert will refer him to one of the two part-time health educators in the office. Until recently, they were practice employees. They were dropped from Eagle's payroll a year ago because of problems with insurance reimbursement. While the two, who both have master's degrees, now work for a mental health clinic, they still take Eagle patients on a private-pay basis. If patients are diagnosed with a definable mental illness, such as depression or panic disorder, insurance may pay for the counseling (see page 186).

The health educators help patients with a wide spectrum of problems, ranging from stress and depression to marital and job conflicts, family crises, and alcohol and substance abuse. Typically, they see a patient for no more than five to 10 sessions. If the patient needs additional help, the counselors will refer him to a psychiatrist or other mental health professional.

What's different about the Eagle approach, says health coordinator Leigh Ostrander, is that the psychological counseling grows out of the patient's relationship with his primary-care physician. "Also, we meet people in the doctor's office," she says. "So they feel safe. They've been here. It's not like sending them out to a specialist. And in some ways, we're an extension of the doctor, the way a nurse might be."

Health educators can take a burden off physicians, she adds. "Doctors don't have time to sit down and talk with people for an hour about the stress in their life," she says. "And it's very frustrating for doctors when they can't. I think they feel overwhelmed, to walk out of a room when they know someone's in pain."

FP David Ness, who used to work with Seifert and is now part of a five-doctor group in St. Paul, says that his own prac-

tice's health educator offers a great resource for "difficult patients and people who need short-term counseling or help changing behavioral patterns. I tell patients: 'We treat this kind of problem as we treat any other medical problem. I'll be monitoring your progress, and the health educator will be helping you on an ongoing basis.' That's very reassuring, and it's nonthreatening because patients don't have to go across town to some psychologist or psychiatrist.

"Milt's system saves you a ton of time. You need to identify emotional and mental health issues that people have. But you don't have to be the psychotherapist who deals with them. Before we had a health educator, if you got into those issues, you might be looking at an hour-long discussion. But now I can take care of those issues in a 15-minute office visit."

Seeing fewer patients and earning less

For Seifert, however, many visits do last an hour or more. In some cases, he says, it's because he attracts difficult patients and often "cleans up" after other physicians who don't want to deal with them. In addition, his low-key, approachable style encourages people to tell him their life stories. And he likes to do some counseling himself.

The upshot is that he sees only about 10 patients a day, half the number that his partner Steve Kind does. Of those, a third are there for level-4 or level-5 visits. So even though his approach may save money in the long run, Seifert himself isn't well-compensated for his work.

Last year, under his practice's income-distribution arrangement, which is based 75 percent on productivity, Seifert drew a salary of $36,960. (He wasn't paid anything for his work in running the practice.) Greg Seifert, who pays less attention to non-medical

What patients say about Seifert

Patients of Milton Seifert Jr. and his two associates, Steve Kind and Greg Seifert, are more satisfied than those in the average family practice, according to a recent Gallup survey of 1,000 doctors commissioned by Minneapolis' Medica health plan.

Seifert himself scored 4.36 overall, compared with a mean of 4.05 for all FPs in the survey. Sixty percent of the Excelsior, Minn., doctor's patients rated his care as excellent, the highest rating on a scale of 1 to 5. That compares with 36 percent for other FPs.

Translating these statistics into words, here's a smattering of remarks at a recent meeting of the practice's patient advisory council:

"I don't feel like just a patient, but more like a friend. Milt stresses the whole person, including your emotional and spiritual aspects, and all those are important aspects of health."

"Milt has always said, 'The patient knows more than the doctor does, because it's her body, and it's his job to listen well and form a wise diagnosis.' "

"I've never felt talked down to by Milt. All the care I've received from him has been negotiated care. We lay all our cards on the table and figure out what our next step is going to be."

"It's worth fighting to preserve this kind of treatment. It's a dying breed in this age of corporatized and impersonal medicine."

One patient recalled what happened when her husband died a year and a half ago. "I was impressed because Milt called me. And he talked about what the implications of my husband's early death could be for my three sons. It was important to him."

Another patient said she felt she could be anywhere in the world and call Milt about her problems. "He'll even take my collect calls."

A patient who owns a local restaurant said of Seifert: "I'm 40 years old, and his father delivered me, and I've been coming here ever since. I've been really happy." While Seifert treats specific medical problems very well, she added, he's also someone she can confide in. In fact, she and her husband came to Seifert when they were wondering whether they should have children.

Patients also say they like the fact that Seifert never makes them feel rushed. With most doctors, says one, "you just pull your number out and wait your turn, and you've got your allotted 15 or 20 minutes and you're out the door. It's nice to have a doctor who will take an hour and a half if you have two pages of questions. If you can't ask your family doctor, there's not a whole lot of other people you can talk to."

How this practice listens to patients

When Seifert started his patient advisory council in 1972, he viewed it as a kind of advisory board that would take up patient grievances and give him feedback on how he was running his practice. He also wanted to convince patients that he was on their side and was dedicated to promoting their health. So he decided to open his books to the PAC and seek its approval for his financial and policy decisions.

At the outset, Seifert sent postcards to all his patients, inviting them to join the PAC. Of the 200 people who responded, about 50 attended the council's first meeting, and that many still belong to the group.

About 15 PAC members turned out for a recent meeting. Several patients said they'd been PAC members for many years, but there were also a couple of new faces, according to Seifert.

The doctor says he typically recruits new members during office visits. "When they start beefing about health care," he says, "I'll ask them, 'You want to help us manage our practice? Join our council.' "

When a patient airs a complaint about the practice, the PAC acts as a mediator, presenting both points of view and trying to work out the parties' differences. Sometimes this leads to a policy change, as in the case of the practice's waiting-time policy.

For several years, the staff has been instructed to tell patients when there will be a long wait. Staffers are also supposed to ask patients about other engagements and make the doctor aware of those as soon as possible. The PAC recently decided that physicians should keep the staff better informed of expected delays, and that staffers should call some patients to warn them of delays.

In 1994, the PAC approved a policy that has reduced the practice's problem with no-shows and late cancellations. No-show patients are now fined $50 if they miss a physical, and $25 for other missed appointments. The fines are $35 and $15, respectively, for late calls to cancel visits.

Ann Benson, Eagle's bookkeeper, estimates that

problems, earned $50,333 for the same number of hours. And Steve Kind, who sees patients 33 hours a week and does more episodic care than Seifert, received $52,600.

(By comparison, the doctors in Dave Ness' practice make $90,000 to $120,000 working 3.5 to 4 days a week and seeing about 20 patients a day. Ness believes the Eagle physicians make so much less because of their payer mix and manual billing system.)

To make ends meet, Milton Seifert works at a local urgent-care center after hours. Seeing four or five patients an hour for "straight acute/episodic care," he earns four times as much as he would for the same amount of time in his office.

Eagle has actually been worse off than it is now. In the early '80s, when Seifert was practicing solo, he lost 25 percent of his patients and half his income in the first wave of managed care. Many of those who stuck with him couldn't pay as much, had less insurance, and had more health problems than those who left.

Since then, the practice's finances have improved and its patient load has risen to an all-time high. Seifert attributes that partly to his reputation for counseling patients and partly to the appeal of Steve Kind, who joined the practice in 1987 and attracted many younger patients.

(Greg Seifert also has loyal patients who've known him for many years. But he divided his practice from his brother's in 1972, sold out to a local hospital in 1988, and left town a year later. He didn't return until late 1994 and still isn't a partner.)

Over the past several years, the practice has contracted with a host of health plans but has been plagued by demands for ever-deeper discounts, not only from HMOs and PPOs but also from indemnity insurers. In 1994, Seifert says, his fees were discounted 28 percent; in 1995, he had to give up 33 percent, collecting $500,000 on charges of $700,000. So far this year, discounts are aver-

this policy probably saved one appointment a day in the year after it was implemented. Not many people actually paid fines, she adds, because most offered some kind of excuse. But the no-show patients became aware that their negligent attitude was hurting the practice financially, she says.

The PAC has also endorsed practice policies on such issues as hospital services and billing, prescription refills, and protecting patients and health workers from transmission of HIV and hepatitis B.

The PAC has input into the practice's financial decisions through its support-services committee, which includes Eagle's accountant and business staff. It meets to discuss such matters as staff hiring and salaries, use of outside labs, collection activities, and the practice's financial health.

When the physicians want to raise their fees, they propose charges that are average for the community. Over the past 20 years, says Seifert, the PAC has approved six raises—all the doctors have asked for. It has never capped his salary, he says, although he did follow its advice to take less out of the practice during one rough period.

The PAC also sponsored annual health fairs in Excelsior for 16 years, and it has found volunteers to help other patients with rides, light housekeeping, shopping, and respite care. Home-health-care agencies have taken over much of that, but the PAC still tries to plug holes in community support services.

One longtime Eagle staffer says she doesn't know whether the PAC has helped the practice run more efficiently. "It's hard, because the patients don't know all the circumstances that go into our decisions," she says.

On the other hand, bioethics professor Arthur Caplan of the University of Pennsylvania, who sat on the PAC when he worked in Minnesota, calls it "wonderful" and a refreshing contrast to what happens in most practices. "One of managed care's major flaws is that patients feel there's no accountability," he says. "They don't know who to go to if they don't like something."

aging 35 percent, he notes.

Meanwhile, Eagle's overhead has jumped to 70 percent from 60 percent a decade ago. Like many other physicians, Seifert blames managed care, which has forced the practice to hire three full-time-equivalent workers to replace the one bookkeeper it had before. (Altogether, the practice staff includes six full-time and four part-time employees.)

But he also admits that his own dedication to patients has driven up overhead. "I do a lot of level 5s, and episodic care is much more profitable," he says. "But the practice has to do a certain amount of comprehensive care."

His associates agree—to a limited extent. Greg Seifert rarely refers patients to a health educator, and Steve Kind, although he follows his partner's system in many respects, is dissatisfied with his own compensation. "This is really a fun practice," says Kind. "We do a lot of things well; patient care is really enjoyable here. But the financial side is a little difficult—in part, because of this marketplace. We certainly make some sacrifices to be small and independent."

Kind recently decided to take a full-time position in an FP residency program at nearby Methodist Hospital. He'd like to continue practicing at Eagle as part of his teaching job. Meanwhile, the Seifert brothers are discussing the possibility of practicing separately under the Eagle umbrella.

Giving health plans what they want

Seifert says the economic squeeze by payers has created this threatening situation. Yet, ironically, the health plans seem to like what he's doing. "They want patient satisfaction, and that's where I do well for them," he says. Partly as a result, he notes, Medica and the Blue Plus PPO returned all of Eagle's withholds last year. The doctors received $15,400 from Medica and $22,400 from Blue Plus.

Another factor in the return of their with-

What a "health educator" does for this family practice

Leigh Ostrander, one of the health educators for Seifert's practice, has a master's degree in counseling psychology and is working toward a psychologist's license. She began counseling patients part time for Eagle Medical in 1983. She left to work full time for Southwest Family Services, a mental health clinic, after insurance companies stopped reimbursing for her services through Eagle in 1994.

Nevertheless, Ostrander is continuing to see five or six Eagle patients a week in addition to her regular job. Once she gets her license, she says, she'd like to return to the practice full time if she can be assured of enough business to support herself.

She sees her role at Eagle as more educational than diagnostic. Using a form of cognitive-behavioral therapy, she teaches people coping skills that may help prevent them from wrecking their health.

Her patients range from people with serious mental illnesses to those who are merely stressed out. She has also been able to help patients with identifiable physical ailments. A woman with migraine headaches, she says, had far fewer of them and less pain after she learned how to cope with her emotions.

The patients initially come to see Seifert. They don't know that their doctor is going to send them to a counselor. Take George (we've changed all patient names), a 44-year-old account executive for a commodity brokerage. When he was having marital and job problems last year, he came to see Seifert because "I was at the end of my rope. I was fatigued and worn out and didn't know what to do. I've never felt that low before."

George just wanted Seifert to prescribe an antidepressant. He got what he was looking for, along with a suggestion that he set up an appointment with Ostrander. After hesitating for three months, George finally did. He visited her half a dozen times over 10 weeks, and now he's feeling much better.

He says that Ostrander helped him objectify emotions that he'd always tried to repress. Now, he says, "I can have one of these feelings and be analytical about it at the same time. There's something I can do with it, instead of just feeling it and not having anywhere for it to go. I can resolve it and go on."

Seifert referred another patient, Sarah, to Ostrander when she was having trouble dealing with the stress of caring for two young children and working under an abusive, alcoholic boss. Sarah says she didn't feel strange about seeing the counselor. "I knew it wouldn't be the kind of therapy where you talk about your mother. This was just about what was happening, and what I could do." What Ostrander taught her, she said, was how to say No to her boss "without being confrontational about it." Now, she says, her stomach is no longer upset all the time, she's embarked on an exercise program, and she's feeling better about herself.

holds was their low utilization, says Seifert, adding that this amazed the plans. "They said, 'Gee, you do a lot more referrals and yet you still have lower numbers.' They don't see that those two could be related—that we're doing better because we use consultants effectively," he points out.

Both Seifert and Ness claim that addressing their patients' psychosocial problems reduces the need for tests and procedures. For instance, Seifert notes, a referral to a neurologist for a headache almost always leads to a CT scan; so if he doubts a patient's headache reflects a serious condition, he'll look at whether it might be related to a psychological problem. He also cites a patient who complained of severe stomach pains and nearly ended up having exploratory surgery for pancreatic cancer. Seifert headed this off at the last minute by urging the patient to get therapy for his repressed anger first. The patient did,

and his pain vanished.

Not that Seifert would discourage a patient from getting a necessary test or undergoing needed surgery. But if there's time to scrutinize the problem from another angle, he says, he'll suggest that.

While researchers at Kaiser Permanente and elsewhere have shown that comprehensive care reduces utilization, says Seifert, he himself has no hard evidence that it saves money. But he notes that it shouldn't be hard to track costs from billing data and compare them with the functional-status data he's amassing. Partly for that purpose, he's developing outcomes software with Minneapolis pediatrician and informatics specialist Gerald Werth.

Catering to employers with health-status data

That software would allow users to tabulate and analyze data from Seifert's Health & Disease Questionnaire. It could be used to break down the health status of a company's insured employees and dependents, and it could help doctors customize services to fit each patient, according to Werth.

Since large corporations are already looking into such a system on their own, Seifert and Werth are pitching their software to small and medium-sized companies. The basic idea is to identify employees with unhealthy lifestyles and help them change their behavior. Both employers and workers would benefit, and physicians would be rewarded accordingly.

"We'd take the 3 to 5 percent of workers who are the most difficult patients, and we'd change them" by using health counselors and rehab specialists, says Seifert. "This would be a big boost to my practice, it would get me away from dependence on the health plans, and I'd have very satisfied business customers."

Eventually, he envisions a network of family practices held together by this information technology and contracting directly with payers. "Nobody would have to own us, and each physician would be free to encourage seatbelt use or smoking cessation in whatever way he wants."

Milton Seifert Jr. may never bring that vision to life. But to those who know him and his work, he's something of a saint. "He's truly a remarkable man, and I think that when the medical profession looks back, it will realize that," says FP Mary Tuohy, a former student of Seifert's who now works in a primary-care clinic in Stanley, Kan.

FP Dave Ness thinks Seifert has touched something very important that shouldn't be ignored. "Health plans are way behind the curve in dealing with mental health issues," he says. "When you consider how much of what we see in primary care is emotional illness, ignoring 60 or 70 percent of those problems isn't very smart."

Seifert, who says he's had "nothing but success" with his approach since 1972, is convinced it will outlast managed care. He doesn't deny that he's worried about his financial situation. But he's determined to stay the course, regardless. "To do otherwise would be soul-searing," he declares. "And I've seen this happen to some of my colleagues—they've sold their souls to the devil, and they haven't been happy doing it.

"I feel good at the end of the day. I feel I've done good work. The numbers are troublesome, but I'm usually thinking about what I've done or haven't done for patients." ■

"Must you always have the upper hand, Ferguson?"

Comments Presented to:
The White House Commission on Complementary and Alternative Medicine Policy
Minneapolis, Minnesota
March 16, 2001
By: Marilynn R. Anderson, G.C.F.P., The Feldenkrais Guild of North America®

Dr. Moshe Feldenkrais defined health as "the capacity of a person to live out his or her avowed and unavowed dreams." I want to live in the dynamic world populated by these healthy people. As a Feldenkrais Practitioner, my role is not to work with specific maladies and conditions - but to teach and encourage comfortable, efficient, and effective functioning of people in their environments.

Feldenkrais Practitioners meet people in whatever state of functioning and health that they are, and assist them to move gently and easily towards where they want to be. Those desires may be as basic as breathing more fully in a wheelchair or as complex as surviving a day comfortably while sitting attentively (maybe at a meeting). Through a series of guided, often developmental, movement sequences, either privately or in a group setting, the Feldenkrais Practitioner encourages fluid systemic movement patterns. The client learns to notice how they interfere with and detour from their intention, while learning how to safely experiment and discover alternative routes and strategies that are both more comfortable and fruitful. This same process holds true for the person recovering from a stroke and the high performance athlete.

The Feldenkrais Method® and other somatic education modalities, are an essential component of the Health and Health Education Systems. However, we are not part of the Medical System as it is conventionally defined. Now it often happens that through the Feldenkrais process, as the client becomes more self-integrated and organized, that a shoulder may "unfreeze", a knee stops swelling, a jaw softens, an ankle quits chronically spraining, blood pressure lowers, or a back aligns better. These symptomatic events create interesting borderlines between the Medical System and Somatic Education Systems and warrant exploration and research. But, to a Feldenkrais Practitioner, those would be merely incidental asides to the successful functional acts of a person spontaneously playing with a grandchild on the floor, delighting in a walk around a lake, simply rolling over in bed, sleeping well, shoveling snow without a three-day recovery, or comfortably persisting at a computer until the book is complete. People productively follow their dreams with pleasure when functioning fully and confidently in their lives. They are healthy.

Whatever policies arise from this Commission, The Feldenkrais Guild requests that you approach each modality respectfully and in consultation with its professional organizations. Please be cautious about placing non-medical practices into a medical framework. The most healthful practice around may be a walk on the beach – but certainly no one wants to need a prescription to do it along with a "qualified" walker. We have an enormous amount to contribute towards the healthy functioning and injury prevention of the citizenry. We welcome the shift in the Medical System towards the Health and Health Education Systems, and look forward to a continued blossoming relationship within that context.

Hmong Shamanism in America
The Medicine Healer

by Chu Y. Wu
Presentation to the White House Commission
on Complementary and Alternative Medicine Policy

Shamanism is one of the oldest spiritual healing that is still practiced by some indigenous people around the world. Shamanism is very much alive with the Hmong people, the new immigrants in the United States. Since the late 1970's, the Hmong people from Southeast Asia have been granted permission to settle in America. My family members were among those who fought along with the United States military in Vietnam and were able to bring one of the richest traditions of healing with us to this country: the shaman. To the Hmong people, shamanism is an ancient method of healing, but to the Western mind, it is a new alternative method of treatment.

According to the Hmong shaman belief, all living species have a body, soul and spirit. When a person becomes ill, the shaman believes the problems are either caused by organic disease, lost soul or because the spirit of the person departs from the body. The human body is somehow out of balance; therefore it needs the medicine healer to conduct healing ceremonies in which to determine the cause of the problems. A shaman is someone who is chosen by the creator and possesses the power to heal throughout his or her lifetime. No one decides to be a shaman. When the spirit enters into the person, other shamans come to assist him or her in starting the process for one or two days. He or she begins to practice the ceremonies within the family and then eventually is invited to help others in the community. The shaman's role is to cure the soul and the spirit, to drive demons out of the body and out of the family and then to help in bringing back the spirit and soul to the body in order for the person to become well again. Almost all the shaman I have known during the last twenty years and those whom I interviewed in the "Shamanism in Minnesota and Patient Choices" research project are working to cure the soul and spirit, not the disease. He or she is not a medical doctor that attended school, learned about the subject and obtained a degree. Their knowledge and skills are gifts from God. Their services are voluntary and free.

As Hmong people in the United States come in contact with Western medicines and science, many conflicts have risen between Hmong patients and their doctors. Some of these conflicts have been documented in articles, medical records, lawsuits, and social service cases over the last twenty years. An article written by Charles Numrich, "Among the Hmong" published in the Bulletin of The Park Ridge Center for Health, Faith and Ethics, Fall, 2000. "Since the Hmong came to the United States from Southeast Asia after 1975, they have struggled to survive and retain their culture. Families are torn between preservation of ancient traditions and assimilation. Many Hmong see the shaman as a symbol of cultural stability and make regular visits for spiritual, medical, and cultural guidance."

As an interpreter for the Hmong community during my college years, I witnessed one of the most complex cases from the Rochester Municipal Court in Rochester, Minnesota. A four-years-old child had a ligament growing in one of his eyes. When the social worker discovered the disease, the child was immediately ordered to seek medical attention and told by the doctors that he must have his eye removed immediately. However, the child's grandfather was a shaman and performed a ceremony to determine the causes. He knew the child had inherited the spiritual healing and would continue the traditional shaman practice after his term. The social worker and doctors took the case to the court. The judge sided with the doctors' recommendations. The child was removed from the parents and the family members.

Another case involved one of the shamans I interviewed in the research project. The shaman is seventy years old. When the doctors detected cancer in his stomach. They told him and his family that he had four weeks to two months to live. The man knew that he still had much life to enjoy. He returned home and asked other shamans to perform the healing ceremonies and to take any herbal medicines that he could find to save his life, because he had nothing to lose. Almost a year later, this man still lives.

Pahoua Vue, another Hmong shaman I interviewed, recognizes the importance of including the entire community in his work. I quote from his interview with a St. Paul Pioneer Press reporter: "Doctors don't always recognize what we do. We are sure we can help the doctors and patients but hospitals and clinics always turn us away." Dr. Gregory Plotnikoff, is medical director of the center for Spirituality and Healing and Co-principal Investigator of the shaman research project. He believes "Every physician knows that care is enhanced when working with a patient's belief system. Care is diminished when working against a person's belief system."

In conclusion, I recommend that healthcare in this country should be more open to alternative medical treatments and recognize the important values and healing systems of all cultural practices. We shall all continue to find new ways to cure human beings. We need more study of the different types of treatments in order to develop more available resources for human needs before some of those valuable healings are lost forever. Healthcare providers and churches in this country should not abandon the different types of religious treatments, herbal medicines, and cultural practices, but they should work together to save lives. Shamanism is alive and still has much to offer to the modern world. We need to find ways to balance the system and to invite other healers to be part of the medical treatment team. In the words of Pahoua Vue's statement, "The shamans and doctors are always trying to find good ways to save lives. They must work together."

Summary Statement:

Jeffery A. Dusek, PhD, Mind/Body Medical Institute, Harvard Medical School (Speaker #63)

Dr. Gordon and distinguished commissioners, thank you for allowing me to speak to you today on behalf of the Mind/Body Medical Institute, which was founded in 1989 by Dr. Herbert Benson. The Mind/Body Medical Institute is located in the Beth-Israel Deaconess Medical Center, one of Harvard Medical School's teaching hospitals. Over the past decade researchers at the Mind/Body Medical Institute have been conducting evidenced-based research examining the medical interaction between mind and body.

Over the past decade, two national surveys indicate that Americans are increasingly relying on the use of alternative medical treatments alone or as a supplement to traditional medical treatments. Given that many Americans are already using alternative treatments that have not been adequately tested, researchers must continue to explore the safety and proposed efficacy of these treatments.

To do adequately achieve this aim, my recommendations are that:

1. CAM therapies must be required to adhere to the same scientific rigor expected of traditional medicine. Contrary to the belief of some CAM practitioners, current clinical research tools can be used to objectively and fairly examine the efficacy of CAM treatments.

2. In this process, it is imperative to examine whether the CAM treatments themselves are effective in treating illness, or whether the belief in the CAM treatments plays a fundamental role in treating illness.

3. Until clear scientific evidence of safety and efficacy of CAM treatments is obtained, safeguards should be implemented to protect Americans from potential harm. Simply accepting that a treatment is safe, based on anecdotal and not clinical evidence, is not only unacceptable, it is dangerous.

4 Specifically, it will be important to determine the safe and effective doses of treatments, an acceptable duration of treatment, and identifying which patient population may be best suited for a given treatment.

5 Mind/body medicine is an excellent example of how non-traditional research can adhere to the scientific method employed in traditional medicine. Positive results from mind/body medicine research are based on scientifically collected clinical evidence, not anecdote.

6 Although the National Center for Complementary and Alternative Medicine's budget has dramatically increased over the last several years, additional and adequately funded research initiatives are desperately needed to carry out this important work.

Thank you.

Goal of clinical trial - use for future patients

Chris

Testimony of

Richard R. Pavek,

Director of the SHEN Therapy Institute, Sausalito, California,

on Health Care Options

before the

White House Commission on

Complementary and Alternative Medicine Policy

March 16, 2001

National need for a Minnesota type Health Care Freedom Act

Richard Pavek, Director of the SHEN Therapy Institute, Sausalito, California

There are two major groupings of Complementary and Alternative health care practices; each has different goals. The more established, such as acupuncture, chiropractic and homeopathy are attempting to convince medical science that they are effective so that they may be accepted into mainstream medicine. Since their operating principles cannot be explained within medical science's rigid and imperfect understanding of the human being, this will require a great many expensive, double blind controlled clinical trials. This need is slowly being met, at the insistence of Congress and the American people, by the National Center for Complementary and Alternative Medicine (NCCAM) in association with other centers.

However, a number of health care options, by their very nature, can never be brought into mainstream medical practice. Some require more time than licensed practitioners could provide, some are highly individualized to the client and others defy accepted medical explanation, relying on empirical evidence of efficacy for proof. NCCAM has limited funding and few of these options are on NCAM's list of possible candidates for investigation.

For years mainstream medical science has, without proof, dismissed these methods as being merely the results of 'imagination,' or 'placebo'. The public, being unversed in medical dogma, uses what works; whether it works by a valid physical effect presently unrecognized by medical science, or by imagination, placebo, the practitioner's personality or hair coloring is of little matter. The fact that it works is enough.

Many of these systems, such as mine, work to promote emotional health, noticing that when emotional health improves, physical health improves – a principle vaguely understood in medicine but which medicine has no means to effect. Maintenance of emotional health is not a part of the standard medical curriculum; these CAM therapies fill that gap.

All CAM therapies lie in a vaguely defined area surrounding mainstream medicine's excessively broad and monopolistic territory. When CAM options have been effective enough to be noticed by the medico/legal authorities, they are often fined and put out of business, not for causing harm or endangerment, but because they were in competition with, and sometimes more effective than, standard medical practice.

Minnesota's Health Freedom Act protects the rights of its Citizens to receive the health care options each of them determines suits them best. The act appropriately defines what the unlicensed health care practitioner may safely do and not do, and legally enforces ethical responsibility and full disclosure, actions not presently required of the medical profession.

Freedom of health care choice should be the personal right of every American Citizen. Without protecting the practitioner's freedom to deliver CAM practices to those who desire them, the public's freedom to exercise their health care options will be lost.

I urge this Commission to strongly endorse national legislation similar to the Minnesota Act – it is vital to the future of these health care options and, clearly, is in the best interests of the American people.

Thank you.

Richard R. Pavek, Director of the SHEN Therapy Institute Sausalito, CA 94965 415/332-2593 SHENmaker@MSN.com

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

Traditional Chinese Medicine: Its Practice, Education and Research in the United States

Changzhen Gong, Ph.D., MS

American Academy of Acupuncture and Oriental Medicine (Minneapolis)
Asian-American Acupuncture Association (Chicago)

Traditional Chinese medicine is a science of Eastern wisdom of health and healing. It is a complete system of medicine, not just a therapy. It covers the whole range of health conditions, not just a few health problems. It is in the best interest of both the professionals and the public to preserve the integrity of this time-tested medicine, keep a high standard of professional education and develop valid research protocols on acupuncture and Chinese medicine.

Preserve the Integrity of Traditional Chinese Medicine

The vitality of traditional Chinese medicine relies on the holistic foundation, pattern differentiation and clinic effectiveness.

Holistic Foundation: Chinese medicine views the human body in a very different way from other medicine. The system is internally consistent, coherent and built practically upon the "cosmological basis" of Yin/Yang, and Five Elements. This also provides the basis for Chinese medicine to be able to offer many unique and highly effective therapies for many conditions.

Pattern Differentiation: Stressing treatment of different individuals based on their specific clinical manifestations and response to diseases serves as the core of Chinese medicine diagnosis. Any simplification by giving up pattern differentiation will reduce the clinical effectiveness.

Clinical Effectiveness: Clinical effectiveness has made the Chinese medicine flourish and thrive several millennia. This depends on the consistence of the theory, treatment principles and treatment modalities. Without a systemic knowledge of Chinese medicine, it is impossible to provide the best Chinese medicine care with the maximum effect.

Keep High Educational Standard

Entry Standard: NCCAOM has developed certification standards in acupuncture and Chinese herbology. Practitioners are prepared to have a complete and systematic basis of Chinese medicine theory and the basic skills for diagnosing and treating commonly seen

conditions. We support that NCCAOM certification standards should be used as a general standard for the professionals who provide acupuncture and Oriental medicine services.

Complete TCM as the Base for Doctoral Program: World-wide, only the system of traditional Chinese medicine, its institutional establishment and educational structure are parallel with and equivalent to modern Western medicine. Practice-oriented doctors of Oriental medicine should be able to analyze and treat common and complicated health conditions with major Chinese medicine modalities, based on a solid and complete knowledge of Chinese medicine theory.

Develop Valid Research Protocols

Western Medicine Research Approach to TCM. Western medicine based research provides some insight toward demystifying this thousand year healing tradition. But this research is limited in discovering the working mechanism of Chinese medicine which is rooted in holistic concept and pattern differentiation.

Eastern Medicine Research Methodology. Beyond traditional Chinese medicine research tools and conventional Western medicine research paradigm, researchers should develop new research protocols to validate those effective treatment procedures. Those research methods should incorporate the fundamental principles of traditional Chinese medicine: holistic concept and pattern differentiation. The involvement of highly trained Chinese medicine professionals is very necessary.

Chinese Medicine Literature Translation. Five thousand years of medicine accumulated a vast amount of literature from classical texts, anecdotes to modern research. Translating the existing research literature from Chinese into English will benefit both the profession and the public.

治未病

HIGHLAND ORIENTAL MEDICINE

Jennifer Blair, LAc

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White House Commission on Complementary
and Alternative Medicine Policy
Minneapolis Town Hall Forum
March 16, 2001

Traditional Chinese Medicine. Medical Models vs. Tools.

Jennifer Blair Licensed Acupuncturist, Dipl. (NCCAOM) AC, CH

My Name is Jennifer Blair. I practice Traditional Chinese Medicine and am licensed by the state of Minnesota as an Acupuncturist. Herein lies the problem. I diagnose and treat patients according to a complete and logical system of medicine, developed and refined over thousands of years of clinical observation. Yet the state licenses me and the public defines me based on a single tool in my medical practice. In the struggle for acceptance, our professional organizations, academic institutions and private clinics have even conceded to label themselves in this limited way.

The terms *complementary* and *alternative* limit our progress in providing a healthcare model that benefits the patients we serve. They are the result of cultural and political biases that place biomedical medicine, a system with a relatively brief history, at the center of our medical dialogue. As a result of this limited perspective, we borrow tools from other medical paradigms, without understanding them contextually. Using the sharply focussed lens of biomedical disease differentiation, we all too often find that the adopted tools are reduced in their scope and efficacy. They simply do not fit neatly in our paradigm and become easily discarded, misused or disparaged. Not recognizing the importance of a medical language different from our own places us at the same risk that any other isolationist behavior would. We must find models with which we can communicate between our paradigms for the most effective outcomes for our patients.

Chinese medicine is a complete and distinct system of medicine that has an important place in the healthcare landscape of this country. Chinese medical diagnosis offers a truly holistic view of the body, providing patients as well as practitioners with an understanding of how disparate symptoms within their body interact to create a complete picture of health. The resulting diagnostic clarity leads to more effective treatment outcomes, whatever tools are applied. I am not a technician. I do not simply use herbs and acupuncture to treat patients. By using the diagnostic perspective of Chinese Medicine, a different medical language, I am able to apply diagnostic clarity and effective treatment to promote health.

By forcing other paradigms to be measured by biomedical standards, we risk losing valuable wisdom in a morass of misleading statistical analyses. While I recognize that there are no easy answers for insurance reimbursements, research or educational models, I believe we must embrace the value of other paradigms before we can make substantial headway on the complex issues that face our healthcare system. Working with representatives from our national and state organizations, The NIH can serve the public as a sort of health care United Nations. We need voices within the NIH and other governmental agencies that speak from the perspective of Chinese Medicine, Ayurvedic medicine and other complete systems. It is not enough to have Western trained MD's with knowledge of the tools of other paradigms.

Regardless of what the government decides in terms of public policy, it is clear that Americans no longer believe that biomedical medicine has all the answers. We can ignore that 95% of the population (according to Harvard Medical School) is seeking alternatives to the biomedical model, we can try to control the dispensation of healthcare through financial constraints or we can choose to find ways to support what our patients are telling us. I believe we all can win and our patients benefit if instead of co-opting the tools of other paradigms, we instead focus on finding ways we can communicate *between* our paradigms.

Thank you for your time and interest.

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

Ike Rodman
Minnesota College of Acupuncture and Oriental Medicine
of Northwestern Health Sciences University
Bloomington, Minnesota

We in oriental medicine feel that use of acupuncture needles by practitioners who have not been trained in the complete paradigm subjects the public to ineffective treatment and *confuses the public* about what acupuncture and oriental medicine are.[1] This may be one result of naming the treatment for the tool, and leaving diagnosis, the heart of the medical care, out of the definition. There is confusion among Congress and third-party payers about qualifications of different providers who use acupuncture needles.

A bar to Congressional consideration of access to, and wider third-party reimbursement for, acupuncture and oriental medicine treatment is the lack of agreement among practitioners about who is competent to use acupuncture needles. In order to learn which providers are competent to help what patients, I **recommend** that a study be funded to compare courses of study and outcomes skills of AAMA and ACAOM-trained providers. Find the areas that are unique to each, the areas they have in common, and their levels of competency and safety. Practical clinical skills and patient outcomes must be assessed. This is not easy, but it will lead to understandings that will enhance possibilities of cost-effective integration of patient care.

For this study, you must find a committee of people with disparate views and interests. The members must all be strong people who will insist on the integrity of their paradigms, but who agree to agree on what can be agreed upon--people who can examine their own assumptions in good humor and appreciate the assumptions of others. This group will not be easy to find, but it must be found. A philosopher of language should perhaps be included because deciding upon definitions will be central.

I believe that mutual respect and increased referral will result. Whatever the results, I am ready for them in my belief in the value of the search for understanding.[2]

APPENDIX 1: NOTES

[1] There sometimes seems to be an assumption that CAM is an undifferentiated soup waiting for definition. It is important to understand that the profession of oriental medicine in the United States already has a professional structure, with national accreditation of master's-level education, national certification of competency, and state licensure and regulation of practice.

The oriental medicine schools and colleges are nationally accredited, state approved, degree-granting institutions of higher education offering first-professional master's degree programs.

The Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) is recognized by the U.S. Department of Education and by the Council on Higher Education Accreditation (CHEA).

The National Commission for Certification of Acupuncture and Oriental Medicine (NCCAOM), which gives national board exams, is a member of the National Organization for Competency Assurance (NOCA) and is accredited by the National Commission for Certifying Agencies (NCCA).

The practice of oriental medicine is licensed and regulated in most states, where it has been found to be safe and effective. Most states use the NCCAOM national board examination as part of their licensure requirements. I **recommend** that you view the licensure of oriental medicine practitioners as a states' rights issue the federal government should walk gently around.

Oriental medicine, with national standards for education and certification (national board exams), may be seen as a model for other CAM professions, but there are still different rules in each state. Practitioners across the country hunger for uniform national standards and reciprocity of licensure. Recognition by all states that national standards of accreditation and certification are the appropriate standards for education and licensure would greatly help practitioners who want to move to another state. The public too would be greatly helped in understanding what is available because titles and scopes of practice would be more uniform.

On the other side of the coin, practitioners who have been in practice for years are often prevented from moving from one state to another because they began to practice before national standards existed. Reciprocity of licensure should be encouraged. Because it is in the public interest, I **recommend** that the NIH's CCAM gather state regulators to discuss the feasibility of agreement on national standards and reciprocity of licensure.

Oriental medicine is, in the words of the Minnesota statute,

> a comprehensive system of health care using Oriental medical theory and its unique methods of diagnosis and treatment.

Many patients come to oriental medicine practitioners after exhausting standard treatment possibilities. Often these patients are the very ones oriental medicine treats best. That is, the systems really are complementary. They see the body and health with different metaphors and have different answers to questions that are conceived differently.

Because oriental medicine is a comprehensive system, the parts (the tools) are less effective than the application of the whole paradigm. Use of the tools without the paradigm *confuses the public*. Patients feel, for instance, that they have "had acupuncture," and it didn't help, so they do not seek a practitioner of oriental medicine who may be able to help.

[2] I **recommend** that after the study is completed, the federal government report to itself through the government printing office and make the reports available to the public to educate the public on modalities. I believe this report will show the breadth and depth of oriental medicine, and will help the public understand the difference between licensed oriental medicine and medical acupuncture.

APPENDIX 2

CLINICAL RESEARCH

Two models perhaps define the spectrum of research, with randomized double-blind clinical trials on one end, and Albert Einstein's thought experiments on the other. RCT were developed to test pharmaceuticals--single-agent medications for specific conditions. We who follow can surely think up something relevant and still "scientific" to test holistic medicine.

As a creative approach to cost-effective and ethically-perceptive research, I **recommend** that research be funded to scour patient records and compare outcomes to standard care. Many patients have exhausted standard care, so this study will be relatively easy for the some conditions.

Patient satisfaction surveys will be relevant. Patients are being helped. We need research because we all need information to help patients. I **recommend** that instead of waiting to see if research proposals come up to standard expectations, the CCAM meet with ACAOM schools to discuss creative ways OM can be investigated. Let's make this a mutual search for understanding rather than applying the same western scientific paradigms to OM. Work together for creative research design. We have the practice records. You have the research experience. Let's work together in our mutual quest for understanding.

APPENDIX 3: THE COMMISSION'S QUESTIONS

1. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions.

> What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?

A research database exists in the patient files of oriental medicine practitioners (called Licensed Acupuncturists in most states). These patient files should be surveyed and the outcomes compared to usual care. Many patients who come to oriental medicine come as a last resort after exhausting bio-medical treatments. The relief they experience as a result of oriental medicine treatment is often dramatic. These patient files are a natural for comparisons to standard care.

> What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?

We need creative ways of thinking that are designed to elicit information rather than to adhere rigidly to protocols that were developed for drug trials. Drugs are single refined ingredients produced for a single purpose. That is the opposite of holistic care, which looks for patterns of conditions in order to craft the most efficient treatment for the complex presented by a single patient on a particular day. Research should be relevant. The data exist in the patient files of practitioners. These data could be gathered and compared to standard care.

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

> How can uniform standards of education, training, licensure and certification be applied to all CAM practitioners?

Uniform standards should not be applied. Relevant standards to protect the public should be applied, such as accreditation of schools, certification of competence of practitioners, and establishment of state boards to protect the public.

> What training and education should be required of all health care providers to assure access to safe and effective CAM practices and interventions?

APPROPRIATE training should be required for the scope of practice. Assurance of appropriate education and testing for professional competence are the areas of expertise of professional accreditation and certification commissions. In other words, the patterns exist. Do not seek to reinvent the wheel.

Gregory Schmidt, testimony for President's Commission on Complementary and Alternative Medicine Policy in Minneapolis, Minnesota March 16, 2001

My name is Gregory Schmidt. I am an artist, a carpenter and the vice president of the Minnesota Natural Health Legal Reform Project.

I am here because:
#1) I believe natural health practitioners recognize, in fact celebrate, the uniqueness of the individual and the body's own healing abilities, and because they recognize that we are not interchangeable machines with interchangeable parts.

#2) because I am ultimately responsible for my own health and well-being. I will be the judge of where I will go, what path I will choose and who I will work with in that pursuit.

I believe I am qualified to speak about these matters because I am a person and because it is we the people who should be in charge, not the associations, not the boards, not the schools, not the HMO's, not the doctors, not even the natural health practitioners. It should be WE THE PEOPLE.

I believe I am qualified to speak because my experiences in my degreed field and also in my business relate to two of the main questions that were constantly asked of us during our legislative endeavors.
#1)"Standards, what about standards?"
#2) Fairness, "Well, under this bill, anybody can just hang up a shingle and call themselves a natural health practitioner and all of these other professionals have all of this education,all of this training, and all of the liability, and is that fair?"

I believe I am qualified to speak because we the people did pass a bill that at least partially guaranteed our freedom of access.

The commission has asked us to present ideas on what we learned from that process and how to duplicate it. In other words, where do we go now.

QUESTIONS ABOUT STANDARDS:

Where did this seemingly unquestioning reverence for standards come from? Is it our birthright/responsibility as humans or is it a byproduct of the industrial age and machines and mass production and marketing?

My goal as an artist or a carpenter is to do the best I can, to treat others like I would like to be treated. It may sound quaint, but if I do not respect myself, my work, and my clients, and if humility, openness, fairness, honesty and love are not enough, how can one do more? I am six feet, two inches, and I will never be 6 foot 6 inches no matter how hard I try, how much education I get or what governing body may wish otherwise. Until people are standardized, I do not see how any relationships between them can be standardized, either. Each interaction is totally unique and special in it's own right.

REGARDING FAIRNESS:

THE FOCUS SHOULD BE ON THE CLIENT.This should not be about one group or belief or one's schooling verses another groups beliefs or schooling.

This reminds me of the story of the farmer who paid the workers hired later in the day the same as the workers hired earlier in the day even though the workers hired in the beginning of the day agreed to their wages. The workers hired in the beginning of the day complained that the workers hired later in the day earned they same pay and it was not fair. It is not about the pay or the work, it is about the commitment to help.

The focus should be, did the person get better? Not who helped them or how or by what method.

Maybe a lot of the problems we are seeing would be helped if practitioners only got paid for results. I know I do not get paid if I do not satisfy my customer. I have virtually no formal training as a carpenter, yet can honestly say that I am one of the most skilled in my field. Why? It is because of the respect I have for my clients, their investment and the work itself. I have never met a natural health practitioner who is not equally dedicated foremost to the clients interest.

Thank you.