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2011-0568-S
kc809

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**Criteria for Levels of Evidence for evaluation of botanical preparations –An approach**

**V.Srini Srinivasan Ph.D.**

Good afternoon. I would like to thank the White House Commission on Complimentary and Alternative Medicines for inviting me as representative of the United States Pharmacopeia to participate in this panel discussion.

USP was established in 1820 and we are in our third century. The first edition of the United States Pharmacopeia published in 1820, described standards for 217 botanical preparations . In the beginning all drugs were natural-animal, botanical and mineral. Over the next 100 years or so, USP added standards for nearly 700 botanical preparations. At the turn of the 20$^{th}$ century, with the availability of pure active constituents from plants drugs coupled with the synthetic organic medicinal compounds began to appear on the market, and prescribing habits of physicians began to change. As a result of this change, USP started establishing standards for modern drugs that were widely prescribed. This inevitably resulted in the removal of most of the botanical monographs from the pharmacopeia. . However with the recent resurgence of interest in natural medicines of plant origin and with the passage of the DSHEA in 1994, which classified botanical preparations as dietary supplements, the USP Convention adopted a resolution in 1995 encouraging the USP to establish standards and authoritative information for botanicals and other ingredients labeled and marketed as dietary supplements. Thus USP is engaged in the development of public standards for botanicals marketed as dietary supplements.

It is important to keep in mind that under the current USP and NF admission policies, the USP Information Experts Committees must first determine whether or not a botanical poses a safety concern.. If none are found, the standards setting process is set in motion. The next critical role of these Committees as defined by the policy, is to determine whether or not there is an FDA or USP identified or accepted use. If the answer is "Yes", the compendial standards will be published in the USP. If the answer is "No", the standards will be published in the National Formulary. The underlying rationale for this differentiation is 1) to maintain and protect the credibility of the USP and 2)to help dietary supplement purchasers make more informed decisions. During the period 1995-1997, prototype information monographs for four botanicals Ginger, Valerian , Feverfew and St.John's wort were published. They were not received well primarily because practitioners and manufacturers viewed USP's approach to developing information as being too "drug like". To respond to that expressed concern, in 1998 USP constituted an *ad hoc* Advisory panel on botanicals. The Panel was charged with the task of developing criteria for evaluation of evidence that could be used as the basis for determining safety and USP acceptance or non-acceptance of specific indications being claimed for botanicals. The Panel rigorously reviewed the information and various evaluative criteria and developed a Criteria of Levels of Evidence (see accompanying Table). These Criteria provide us with a more objective measure to determine whether or to admit botanicals in the USP-NF.

| | A | B | C |
|---|---|---|---|
| I | **RCT**<br><br>➢ Highest quality<br>➢ Adequately powered<br>➢ Comprehensively reported<br>➢ Well-designed and executed in all respects | **Meta-Analysis**<br><br>➢ A representative universe of RCT's that meet inclusion/exclusion criteria<br>➢ Results are based mostly on Level IA quality trials<br>➢ Comprehensively reported – pooling methods/statistical analysis well described | **Epidemiological Studies**<br><br>➢ For safety and drug adverse event associations of high scientific credibility<br>➢ Case-control, cohort or other appropriate design<br>➢ Case selection minimizes and controls for confounding factors<br>➢ No serious methodological flaws |
| II* | **RCT**<br>➢ Methodological flaws, if present, may not be serious enough to undermine the conclusions<br>➢ Methods of analysis or reporting may be less completely described | **Meta-Analysis**<br>➢ Universe of RCTs that met inclusion/exclusion criteria may be less representative<br>➢ Results are based mostly on Level IIA quality trials<br>➢ Comprehensively reported – pooling methods/statistical analysis well-described | **Epidemiologic studies**<br>➢ For safety and drug adverse event associations<br>➢ Uncontrolled long-term post-marketing surveillance studies |
| III | Inconclusive Studies<br><br>Non-randomized trial<br>Serious methodological flaws<br>Efficacy studies lacking an appropriate control<br>Inappropriate size or duration to be of any value | | |
| IV | Anecdotal Evidence<br>Case reports<br>Descriptive rather than experimental studies<br>Considered useful for hypothesis generation | | |

CRITERIA FOR LEVELS OF EVIDENCE

Level I: Randomized Controlled Trials, Meta-Analyses and Epidemiological Studies of Highest Quality

A. Randomized Controlled Trial (RCT)

The study is a randomized controlled trial that is adequately powered to show a treatment effect vs. placebo or an appropriate active or historical control. The report of the study must describe the objectives and design of the study, the endpoints measured, the method of randomization, the method of blinding, the assessment of outcome, and the statistical analysis employed, including the handling of dropouts and withdrawals (e.g., intention-to-treat vs. per protocol analyses). The results must be presented comprehensively, not selectively. Sponsorship of the study and the measures taken to assure the validity and integrity of the data (e.g., monitoring) should be noted. The study may not have a methodological flaw, or a potentially biased statistical analysis that is serious enough to undermine the conclusions of the study.

B. Meta-Analysis

The study contains a representative universe of RCTs in the worldwide medical literature that meet the pre-specified inclusion and exclusion criteria of the meta-analysis, at least some of which are Level IA in quality. The report of the meta-analysis must describe in detail the inclusion/exclusion criteria, the methods used to minimize selection bias, the method of pooling data, and the statistical analysis used. The study may not have methodological flaws sufficient to undermine the conclusions of the study.

C. Epidemiological Study

For the demonstration of drug-adverse event (AE) associations (but not drug efficacy), the study is a case-control study (or other epidemiological study of appropriate design) that demonstrates a drug-AE association of high scientific credibility, i.e., an association that is biologically plausible, has a non-marginal relative risk and a low probability of error. The report must describe in detail the method of selecting cases and controls and the measures taken to minimize selection bias and to control for confounding variables. The study may not have methodological flaws sufficient to undermine the conclusions of the study.

Level II: Randomized Controlled Trials, Meta-Analyses and

Epidemiological Studies of Moderate Quality

A. Randomized Controlled Trial

The study is a randomized controlled trial that is designed to show a treatment effect vs. placebo, an active control, or a historical control. However, the report lacks a sufficient description of the methods or analyses, particularly with respect to specified endpoints, randomization, blinding and/or the statistical analysis, to meet a IA level of quality. Evidence of quality control of the data though independent monitoring is usually lacking. The study may have significant methodological flaws, or uncertainties in the statistical analysis, but none that is overt and serious enough to undermine the conclusions of the study. Many clinical studies reported in the older medical literature or in non-peer-reviewed journals may meet this description.

B. Meta-Analysis

The study is a meta-analysis of a sample of trials that is less than the full universe of published trials meeting the pre-specified inclusion or exclusion criteria or is composed only of studies that are Level IIA in quality, but in other respects is appropriately conducted and reported.

C. Epidemiological Study

For the demonstration of a drug-AE association, the study is a case control study (or other epidemiological study of appropriate design) that would meet the standards of a Level IA study except that the relative risk and/or the P value marginal. Serious drug-related AE's identified in large, uncontrolled, long-term studies or in post-marketing surveillance belong in this category.

Level III: Inconclusive Studies

This level includes non-randomized trials, efficacy studies lacking an appropriate control group, studies with methodological flaws serious enough to render them uninterpretable, and studies that are too small or of insufficient duration to be of value. The conclusions of Level III studies are not necessarily incorrect, but they cannot be shown by scientific methods to be correct. Level III studies can be useful as hypothesis-generating studies but are ordinarily considered inconclusive in supporting the overall efficacy assessment of a drug.

Level IV: Anecdotal Evidence

This level includes case reports and/or papers reporting a series of cases. Such reports are not necessarily incorrect, but are generally considered as descriptive rather than experimental, and hypothesis-generating at best.

# V.Srini Srinivasan Ph.D.

Dr.Srinivasan serves as the Director of the Dietary Supplements program at the United States Pharmacopeia(USP). In this capacity he is responsible for assisting the USP Council of Experts in the development and establishment of public standards for dietary supplements that include vitamins, minerals, amino acids , botanicals and their preparations.

Dr.Srinivasan graduated from the University of Western Ontario, London, Canada with a Ph.D. degree in Natural products - Medicinal Chemistry.

He has numerous publications in leading national and international scientific research journals covering various aspects of medicinal chemistry, natural products, aerosol preparations, nutritional supplement preparations, etc. He served on the ad-hoc Advisory Panel to the Office of Dietary Supplements in the Strategic Planning for Dietary Supplements Research, ad-hoc Advisory Panel to the National Institutes of Mental Health in the identification of Hypericum products for clinical trials for mental depression, and on the Panel of Peer Reviewers for Evidence Reports/Technology Assessment, prepared by the San Antonio Evidence –based Practice Center of the University of Texas for Agency for Healthcare Research and Quality, on Botanicals Garlic and Milk Thistle . Dr.Srinivasan is a frequently invited speaker at national and international scientific meetings covering the above subjects.

His most recent interest is in the area of bioavailability of nutrients and botanical dosage forms.

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

David Schardt
Center for Science in the Public Interest

Most of the traditional media, such as television, radio, newspapers, magazines, and newsletters, are valuable for acquainting people with Complementary and Alternative Medicine (CAM) and for notifying them of new developments. However, these media have been less valuable for providing the kind of extensive, in-depth, objective, and practical information people and health professionals need to make informed decisions about whether to try CAM and, if so, which ones.

Many of the traditional media are constrained by:

* limitations of air time and column space
* need for newsiness
* need for visual images and human emotion
* need for conflict
* short shelf life
* lack of beat reporters

If the CAM community wants to foster better coverage in the traditional media, given these constraints, it should recognize that it is harder to produce good CAM stories than conventional medicine stories. The scientific literature is scattered and not easy to assemble, credible authorities and institutions are not as easy to identify and reach, and the latest news is not as easy to obtain.

The CAM community should establish a top-notch press office to make it as easy as possible for reporters to research, write, and record CAM stories. The office should be staffed by well-informed people who can promptly refer journalists to reliable background material and credible people to interview, who can answer simple questions, and who can help suggest stories.

**Testimony to the White House Commission on Complementary and Alternative Health Policy**
**By Susan Detwiler**
**President, The Detwiler Group**
**March 26, 2001**

Ladies & Gentlemen, I am honored to have the opportunity to testify before the White House Commission on Complementary and Alternative Medicine Policy. My name is Susan Detwiler, and I am President of The Detwiler Group, an independent information consulting firm, which specializes in the information needed by the health and medical industry. One of our goals is to not only stay aware of the quality of information available to these businesses, but also to evaluate the quality of health information available to the American public. To that end, we recently conducted a study of the timeliness of drug data on the Internet, which we released under the title, *The Medium Doesn't Get the Message* in January of this year. In addition, we conducted research on medical misinformation on the Web, much of which was published under the title, *Charlatans, Leeches and Old Wives*, in the March 2001 issue of *Searcher* magazine. I've submitted both of these reports to the commission for the record.

Although our specialty is health and medical information, our emphasis is on the information end of this phrase, rather than the health or medicine side. No one in The Detwiler Group is a physician, or a licensed health professional. However, we are experienced in finding health related information, as well as in evaluating how well different sources do at providing that information. Therefore this is where I will direct my remarks.

Studies at the Pew Internet and American Life Project have shown that more than half of all Americans with access to the Internet have used it to find information about health. While 70% search for specific illness related information, only 13% search for health or wellness related information. Instead of heading towards sites which had been recommended to them, 81% of the health seekers said they did a general search for the information they wanted. More than 60% said they had never heard of the sites they ultimately reached, and 30% checked four or more sites during their most recent search.

In other words, with all due respect to the information providers with high ethics and quality editorial standards, this Commission would be remiss if it ignored the reality of how the public seeks and finds its health information. We cannot focus on just the quality of top sites, or those with brand names. The Commission must be concerned with the broad spectrum of conflicting information which the public confronts when it conducts general searches for health advice. Therefore, in addition to a look at the CAM information presented by popular health sites like WebMD and drKoop, The Detwiler Group also reviewed the results of general searches on AltaVista, Google, and MSN, and sampled the message boards of AOL.

We emerged with three main findings:

- First, unlike information about mainstream or Western medicine, information about complementary and alternative medicine is frequently contradictory, often within the same website.
- Second, many general search engines are more likely to turn up spurious sites than they are to find balanced information, and the most popular results are not necessarily the most valid.
- Third, much of the information about CAM modalities is spread through chats and message boards, both on mainstream websites and in person-to-person systems.

Let's take these one at a time. First conflicting information on the same site. When it comes to acupuncture and homeopathy, much of the information on mainstream health websites, such as DrKoop.com and WebMD present balanced perspectives. They tend to be Western medicine based, but do indicate when there have been clinical studies indicating their effectiveness for particular indications. However, even within these balanced perspectives, they offer conflicting information. The public can easily become confused when a single health site offers information that is both positive and negative regarding a particular modality. For example, on DrKoop, the initial search for acupuncture turned up 50 results. At the top of the list was a news item from Reuters Health which talked about how useful acupuncture is as a treatment for tennis elbow. However, the following two items on that same list were two parts of a three-part story titled *Acupuncture Perspectives,* which calmly and precisely rips apart the science behind acupuncture, stating that "researchers have concluded...that acupuncture is no more effective than a placebo for weight loss, for smoking cessation, against pain (e.g., back pain), and against osteoarthritis."

A similar dichotomy of results emerged when we looked up homeopathy. The results on DrKoop.com include a number of Western based medicine perspectives on whether homeopathy is valid. The results also include an article which offers encouragement to try traditional Chinese medicine such as homeopathy, herbal medicine and DHEA for chronic fatigue syndrome.

Taking a look at WebMD, the first result for homeopathy is the balanced NIH overview of homeopathic medicine. Meanwhile, on the message boards, we see a diatribe against homeopathic remedies lifted directly from Dr. Stephen Barrett's Quackwatch site, followed by a WebMD sponsored chat with a practicing naturopathic physician and chiropractor who has specialized in homeopathic medicine for over 25 years. Other messages on the board are primarily touting the benefits of homeopathy for endometriosis, allergy, irritable bowel syndrome, asthma, learning disabilities and other chronic conditions. Several messages were commercial in nature, directing individuals websites for more information.

We now turn to the mixed results of general search engines. Since 70% of Americans search for a specific disease, we looked at the results they would get when searching for a cure. Using the words "cancer" and "cure," we tested Google, AltaVista, and MSN, three of the most popular search engines.

The first result in a Google search was the site of The Cancer Cure Foundation This Foundation is dedicated to the promotion of alternative therapies for cancer, including electrotherapy, hydrogen peroxide therapy, laetrile, herbal extracts and detoxification through homeopathic, chelation or other therapies. The reference to zapper and anti-parasitic herbals leads to a site promoting a Mexican based clinic to cure cancer. Doing a backwards link search, it appears that more than a hundred other sites link to the Cancer Cure Foundation.

Conducting the same very simple "cancer" "cure" search on AltaVista led to a similar result. The first site listed is a personal page covered with links to informative treatises with titles like "Mammography – Radiation Induced Breast Cancer!" At the top of the page is a link to "Cancer Therapies FAQ". This is a listing of alternative therapies ranging from parasite cleansing, to laetrile, to hydrogen peroxide therapy and scores of other alternative therapies.

Doing an MSN search, which is the default if you just put your search terms into the Internet Explorer URL locator, results in a similar set of sites. Here, the very first link is to The Gerson Institute, which describes itself as a non-profit organization dedicated to the holistic treatment of degenerative disease. MSN also gives you the opportunity to see the 10 most popular sites that match your words. Here we find "Alternative Cancer Cures and AIDS Cover-ups by Lorraine Day, MD". On this site, the health seeker finds sales literature for a video on "Sorting Through the MAZE of Alternative Medicines," as well as treatises on "The Government Cover-up of AIDS," "Why Condoms Don't Work" and similar topics. According to the counter on the site, I was visitor number 733332.

Finally, we looked at the information conveyed on person-to-person networks. Since so many people use AOL for its message boards, we tested the forums on its Alternative Medicine channel. AOL, with almost 88 million unique visitors in February, has an Alternative Medicine channel with several active message boards. In 4 weeks, the Herbal Remedies board picked up 136 subjects, each beginning with a plea from some individual for information about an herb or for herbal help with a disorder or disease. Most had several responses. In one case a respondent who suggested a Western medicine solution to a problem was chastised for posting on the Alternative Medicine Board.

All we know about the respondents are their email handles and the credentials which they list. Many state they are physicians or trained herbalists, but there is no way to check these credentials. Frequently, the advice of those who identified themselves as experts were contradictory, and in several cases the posted messages descended into an argument.

Based on this study of the Internet as a source for CAM information, I have to reiterate that the Commission cannot rely on the mainstream press and mainstream Web presences to convey accurate, balanced information about complementary and alternative medicine. In effect, what has developed is the Internet as an overgrown version of the village well. Any individual can state any item as fact, and there will be someone around to believe it.

Therefore, I have three recommendations to the Commission.

1) Acknowledge that mainstream health websites make up a small part of how complementary and alternative medicine information is spread on the Web, and plan accordingly. Turning a blind eye to the invisible networking that occurs among people on the Internet will undercut the effectiveness of any policy you put in place. Recognize that most people are NOT aware of the quality health sites. WebMD, the top ranked health website with 4.7 million unique visitors in December, still had less than 6% of the Web visitors. drKoop.com, with 981,000 unique visitors had 1.2%. Meanwhile, AOL Time Warner Network had more than 69 million unique visitors in February, almost 15 times as many as WebMD.

2) Once you have a policy in place, don't hide it. Create a public education campaign about how to benefit from this policy. Right now, much of the complementary and alternative medicine using public believes the government is deliberately fighting its use. There are whole websites devoted to conspiracy theories linking the pharmaceutical companies with the FDA in schemes to keep herbal remedies from the public. Create a website for CAM information, or build onto the NCCAM site, and invite conventional, integrative and alternative practitioners to link to it.

3) Create an educational campaign for use in the schools, probably at the middle school level, to teach critical thinking. The focus should be on how to evaluate information you get from your friends, strangers, people you 'meet' in Internet chat rooms and on message boards, and on various websites. This recommendation extends beyond the subject of complementary and alternative medicine, and perhaps should involve other entities in the Government. Students are taught how to use computers and how to find information on the Internet, but they are not taught how to evaluate that information. If they are fortunate to have instructors who teach about evaluating content, it is very unlikely that this lesson is extended to evaluating information received through emails and message boards. Students should be taught that anyone can claim to be a doctor or specialist and how to check out the "facts" they are told.

**Testimony to the White House Commission on Complementary And Alternative Medicine Policy**

**By Lee Rainie**
**Director -- Pew Internet & American Life Project**
**March 26, 2001**

Good afternoon. My name is Lee Rainie and I am the Director of the Pew Internet & American Life Project, a research organization fully funded by the Pew Charitable Trusts to do nonpartisan analysis of the social impact of the Internet. One of the major goals of the project is to assess the way Americans are using the Internet to get health information. Towards that end, the project has done several surveys of Internet users, one of them specifically focused on those who seek health information on the Web. We released those findings in November in a report entitled "The Online Health Care Revolution: How the Web helps Americans take better care of themselves." I have submitted a copy of that report for the record.

Our work on health care pertains to the activities and attitudes of Internet users, rather than to analyzing online health content, so I will focus my remarks on how users' experiences and expectations are relevant to your work. You will find that my comments add up to an encouragement that you consider Internet users as a distinct contributor on e-health issues.

## AN OVERVIEW OF THE E-HEALTH UNIVERSE

Almost 60 million American adults, or 57% of those with Internet access, have used the Web to get health or medical information. More than 6 million adults are getting such information on an average day. We call them "health seekers" and a majority of them go online at least once a month for health information. We have just come out of the field with a survey of teenagers and found that more than a quarter of children between ages 12 and 17 have consulted Web sources for health, fitness, and dieting information. (It's something girls do much more than boys, I should point out.)

The reason for all this activity is simple: Half of health seekers say access to information on the Web has improved the way they take care of themselves many report that the material they gather directly affects their decisions about getting care and treatment for their illnesses or the illnesses suffered by someone they love. In an era when many are not satisfied with the availability of their doctors, they are turning to the Web to provide the information they find hard to get from their caregivers. They are also increasingly interested in participating shared decision-making.

## HELP IN FINDING THE BEST INFORMATION

Perhaps the most important thing to know is that health seekers go online in a very action-oriented frame of mind. They are anxious to get information that will help them make important, even at times life and death decisions. In many cases, they feel they are getting more information about illness, prognosis, and treatment options from Internet sources than they are from medical professionals. Yet, even as they take this information to heart, 86% of health seekers say that they worry about getting health information from an unreliable source

online. This suggests that you would be making a vital contribution by fostering reliable guides to the best information.

Too often, health seekers are stumbling around cyberspace unaided. Fully 81% of health seekers told us they found the information they wanted through an Internet search, rather than through a search assisted by knowledgeable helpers. And 64% of health seekers say they had never before heard about the Web sites they ended up consulting. Since the majority of health seekers went online for information right before or right after a doctor's visit, there is an opportunity for health-care providers or other trusted intermediaries to supply lists of accurate and patient-friendly sites and guidance on sophisticated search strategies.

Under many circumstances now, patients get the exact opposite message from providers: "You are not helping yourself by getting more information and you are pestering me with all these Web printouts you want me to look at. I don't want to be bothered."

Dr. Tom Ferguson, the senior fellow for health research at my Pew Internet Project, argues that the places on the Internet where the most powerful searching and learning occurs are not necessarily health sites, but the disease-specific online communities and the disease-specific sites run by patients with condition X for other patients (and family members) of those with condition X. Within these forums, discussion of alternative and complementary approaches is most common for diseases in which conventional care has the least to offer and/or in which cultural mismatches between providers and patients make it harder for patients to get the kind of care they would like to get.

While opinions that many health professionals would probably label as "inaccurate" or "misinformed" are occasionally posted, (not as often as you might think because support group communities are impressively "expert" places), they almost never go unchallenged or uncorrected. In many cases differences of opinion boil down not into "right" and "wrong," but rather differing biases for a particular type of or approach to treatment. For instance, some end-users consider themselves "anti-drug and pro-natural" and consider most health professionals to be unconsciously "pro-drug" and "anti-natural." Thus by their lights they would prefer to begin with "natural" remedies and use "drug" remedies only as a last resort.

This suggests that efforts to encourage users to contribute to the assessment of online information would be a useful addition to the efforts that are being made by providers to establish ethical and quality standards for online health sites. Dr. Ferguson has done research suggesting that well-mediated and robust disease-support communities can often provide online health seekers more in-depth information, more details about cost-effective treatments, more emotional support, and more practical information about coping activities than professional health providers can. Of course, patients continue to say that doctors are better than support groups at diagnosing illness and setting up illness management regimes.

The other Internet sources for information quality assessment are the so-called qualityware search engines like google.com and consumer-oriented sites exemplified by gomez.com and epinions.com. The health-site report cards and ratings compiled by the staff *and* site users are a powerful resource for those asking fundamental questions: What are the best sites for my condition?

Sincerely concerned

## PRIVACY CONCERNS

Most users go to health sites for research and reference purposes and have been able to get the information they need without making any significant trade-offs by giving up personal information. Only 21% have volunteered their email address to a health Web site. Anonymity – or, at least, the *feeling* of anonymity – is enormously important to health seekers: 80% say that is one of the major appeals of getting health information on the Internet. A user can hunt for information on a sensitive subject and nobody has to know about it.

That partly explains why Internet users so strongly fear the prospect of such information falling into others' hands. A certain amount of shame might be a cause, but there are practical worries, too. Some 85% of health seekers are concerned that their insurance company might change their insurance status or raise rates if the firm finds out what Web sites a health seeker has visited. More than half of health seekers fear their employers might find out what sites an employee has visited and take action. This concern about privacy extends to the idea of online medical records: 63% of health seekers say that putting medical records online is a bad thing, even if the records are on a secure, password-protected site, because they worry about other people seeing their personal information.

Our sense is that this apprehension about medical privacy can be reduced. First, some of it will vanish as more and more people get more online experience. Those who have been online for several years exhibit noticeably less concern about privacy violations, probably because they have not had any problems and learn how to take steps to protect their privacy. Second, even with these expressed concerns about privacy, many Internet users have already shown that when the information-transaction suits them, they are willing to give up personal information in return for access to content that matters to them. My personal opinion is that if a doctor told her patients that creating an online medical record would result in better care, many would swallow their privacy fears and allow the record to be created. Third, many of these worries would dissipate if users were given assurances through anti-discrimination laws that information from their online medical searches could not be used against them on the job, in their insurance status, or in other key aspects of their lives. Concerns would also drop considerably if real penalties put in place for privacy breaches.

## NEXT STEPS

Our surveys suggest consumers and patients would appreciate this from you:

1) Encourage "buy in" from the medical establishment. Patients are going to hunt for medical information online whether their doctors sanction these searches or not. Internet users would like trusted allies to help guide them on these searches and no one should be better qualified to do that than providers. There is abundant evidence, too, that patients would love more opportunities for email interaction with their providers as well as the capacity to perform other online transactions with their providers such as appointment scheduling, prescription refills, and lab test reports.

2) Encourage transparency and patient privacy awareness. One of the reasons privacy fears run high is that Internet users don't know what is happening: 56% of Internet users don't know what a cookie is, don't know how to set the preferences on their browser, and don't

know the basics of tracking and profiling. They would appreciate education and technology tools to give them a better sense that they are in charge of their personal information and that they know what is being done with that information.

3) Facilitate methods for patients to apply their own expertise to online health matters. Internet-based support groups can play a very constructive role in providing advice to others about what web sites to visit, how to assess the validity of online information, and how to deal with illnesses. Their emergence online is one of the most important developments in health care. They embody the best open-source features of the Internet and the best kind of online communities.

## APPENDIX – ONLINE SUPPORT GROUPS

It's not always easy for visitors to just "drop in" on online support groups. First, they are rather like ongoing dinner parties and sometimes construct protective defenses against casual browsers. The technologies that support them also sometimes require cumbersome signup protocols, and passwords. Second, once you do "get in," it sometimes takes time to learn the peculiarities of the technical interface and/or the culture protocols and "netiquette" of each individual group.

Nonetheless, there are some easy and convenient ways of checking out postings on some of the online support groups. Here are a few starting places:

(1) Observers can check out the back issues of the ALS Digest (a support group for Amyotrophic Lateral Sclerosis -- Lou Gehrig's disease) at:
http://www.alslinks.com/alsdigestarchives.htm

(2) CancerHelp provides a gateway to a number of different cancer-related support groups:
http://cancerhelp.8m.com/

(3) To find a link to a support group on a specific topic, go to:
http://dmoz.org/Health/Consumer_Support_Groups/

(4) Another way to find a self-help group on a specific topic, log onto www.google.com and do a search for <name of condition> plus "support group."

# The White House Commission on Complementary and Alternative Medicine (CAM) Policy

## INFORMATION, DEVELOPMENT AND DISSEMINATION

## CAM in the Media: Newspapers, Magazines, Television, and Radio


## Testimony by Elmer E. Huerta, MD, MPH
## President and Founder, Prevención (*Wellness Through Media*)

## March 26, 2001

Good morning, my name is Elmer Huerta. I am a physician by training, specializing in internal medicine, medical oncology, public health and cancer prevention. I appreciate this opportunity to share with you my work in the Hispanic community. I am the founder and director of the Cancer Risk Assessment and Screening Center at the Washington Cancer Institute at the Washington Hospital Center in Washington, D.C. I have been appointed by the White House as member of the National Cancer Advisory Board and by the Secretary of Health and Human Services as member of the Advisory Panel on Medicare Education. In addition, I am member of the National Board of Directors of the American Cancer Society, the National Coalition of Cancer Survivorship and the American Legacy Foundation.

While working diligently as a practicing physician, in my native Peru, I realized the importance of informing the public on important health issues, through the media. Immediately after my arrival to the United States in 1989, I started a daily radio show on a local Washington, D.C., Spanish-language radio station. That isolated effort evolved into the founding of Prevención (the Spanish word for prevention), a non-for-profit organization started in 1996. Currently, Prevención produces and distributes a daily radio show on more than 80 radio stations in the U.S., Puerto Rico, Canada, Ecuador and Peru. The show, "Cuidando su Salud" (Taking Care of Your Health) has become the only health-related, daily radio show produced and hosted by a Latino physician in the United States. In addition, Prevención produces a daily, one-hour radio talk show, a weekly one-hour, live television program, and an Internet page entitled, Prevencion.org.

I use the media with the following four principles: First, consistency, meaning daily presence, which is used for weather or sports. Second, comprehensiveness, meaning to cover all sorts of medical themes. Third, using all communication channels that are available for the community, including radio, television, the Internet and print media. And, finally, gaining my listeners' trust through my medical messages. I do this without promoting products or even my medical services, on my programs.

Complementary and alternative medicine is an issue that I take very seriously in my shows. There are many reasons for this.

- First, Hispanics are descendants of people who used many forms of what is now called complementary and alternative medicine. They used these remedies long before Columbus landed on this American land. Native American Indians, Aztecs, Mayans, Incas and many other aborigine cultures were owners of a rich and millenary medical tradition. Present day Hispanic Americans are only inheritors of that millenary tradition and of the distinctive conceptions of health and disease of those populations. A recent survey of 542 patients attending 16 family practice clinics belonging to a community-based research network in San Diego, California, showed that use of traditional folk remedies was associated with Hispanic ethnicity. (1) Another study examined the use of complementary and alternative medicine among Hispanic patients attending the Emergency Department at Columbia-Presbyterian Medical Center in New York. Results showed that almost half had used traditional and alternative medicine methods for their symptoms or another health problem in the past year, most commonly in the form of medicinal plants and teas. (2)

- Secondly, use of traditional and alternative medicine methods may represent an easier "alternative" to the "harder-to-reach", formal American medical system. A community with so many barriers for obtaining access to basic medical care, such as lack of information, linguistic isolation, lack of health insurance and fatalism, may find it easier to rely on complementary and alternative medicine methods, versus mainstream medical methods. For Hispanics, the use of complementary and alternative medicine methods is more a necessity than an alternative.

- Thirdly, due to the same barriers, especially the linguistic isolation, Hispanics are the ideal target of sophisticated media-based quackery. There are many modalities of these frauds. There are naturopathy practitioners that broadcast nationwide by using edited tapes, on which they talk with callers. They diagnose and treat all sorts of conditions with a line of their own, manufactured products. These products are often extremely costly and ineffective. Acupuncture is unnecessarily offered for many conditions. I wonder if the Federal Communications Commission has ever monitored Hispanic media.

Given this reality, I provide a constant amount of information on traditional and alternative medicine methods on my radio and television programs. I always try to frame my comments into the above mentioned reasons for Hispanics' use of complementary and alternative medicine methods. I tell them that I know they believe in those methods, as do I, but to be careful. I inform them that I have seen many cases of advanced diabetes, cancer, or other conditions unsuccessfully treated by herbs and teas, until it is too late for doctors to help. I tell them to use their herbs, their massages, their meditation or their homeopathic prescriptions, but to please take advantage of what we all know about the modern diagnoses and treatment of diseases.

I select topics mainly from medical journals and articles published in respectable mainstream press media. I summarize the article, writing it in Spanish at a sixth grade literacy level. Occasionally I rely on other medical experts. Frequently, however, I talk to my many Hispanic patients about complementary and alternative medicine methods. They always give wonderful insight on these issues. I produced a ten show series based on the articles on complementary and alternative medicine methods, which were published in the November 11, 1998 Journal of the American Medical Association. I always try to balance the positive and negative results on complementary and alternative medicine methods. For example, I have written about reports on magnetic fields in relieving certain types of back pain, or the dangerous side effects of Gingko biloba.

Prevención does not have corporate sponsorship. When occasional pharmaceutical support has been accepted, an unrestricted educational grant is the only form of accepted support. No mention of the pharmaceutical companies' names is made on air. I would estimate that 90 percent of my work is done on a voluntary basis.

My target audience is the recently arrived Hispanic immigrant. Recent census data confirms that there are millions of Hispanics that fall into this category. My mission is to provide these recently arrived, hard working people with the necessary knowledge to prevent and detect disease, and not let them be the victims of organized quackery. I have seen modest laborers paying 700 dollars a month for some herbs, tonics and vitamin supplements.

Given the undoubted advance of complementary and alternative medicine methods, I will probably include more programs on this issue. They will always be framed on the principles described before.

I respectfully suggest the Commission to ask the Federal Communications Commission to carefully monitor Spanish-language media to break organized quackery. In addition, I would suggest designing and implementing programs to increase access to good quality medical care for the Hispanic population.

(1) The Use of Complementary and Alternative Medicine by Primary Care Patients. Lawrence A. Palinkas, Ph.D.; Martin L. Kabongo, MD, Ph.D.; The Journal of Family Practice. December 2000. Vol. 49, No. 12.
(2) Use of Complementary and Alternative Medicine Among Hispanic Emergency Department Patients. Am J Em Med 2000, 18: 51-54

## CHRISTINE GORMAN

My name is Christine Gorman and I'm a senior writer at TIME Magazine, where my primary responsibility is to cover health and medical topics. We've definitely increased the amount of alternative and complementary medicine news in our magazine over the past five years--primarily because we think our readers are interested in learning more about these topics.

Our coverage generally falls into one of two categories--either we're reporting on a scientific study that delineates apparent benefits or risks of a complementary therapy or we run a "trend story" that examines thegrowing popularity of a particular supplement or practice.

When deciding whether or not to report on a scientific study of complementary medicine we use the same standards we use for allopathic medicine. We consider where the study was published, how well it was designed and we talk to outside experts in the field to determine both the context and plausibility of the results. In November of 1998, for example, the Journal of the American Medical Association devoted an entire issue to studies of complementary medicine. We reported on a double-blind, placebo-controlled trial that found some benefit to traditional Chinese herbal medicine in the treatment of irritable bowel syndrome.

# Cathy Moxley, M.A.

Cathy Moxley, M.A., is manager of Health and Wellness for Marriott International, Inc. In this capacity, Cathy is responsible for the strategic development, implementation, and evaluation of Marriott's *Wellness & You!* health promotion program for approximately 4,000 Marriott corporate headquarters associates. In addition, she is the designated resource for Marriott field operations in the development of field-based wellness initiatives as needed.

Cathy has been involved with Marriott's *Wellness & You!* program since its early development stages and official introduction in 1993. As manager of the *Wellness & You!* program, Cathy povides a comprehensive schedule of programs on such topics as blood pressure, cholesterol, nutrition, smoking cessation, and stress management. In 1995, the *Wellness & You!* program received the C. Everett Koop National Health Award for its success in significantly reducing employee health care costs by improving health through wellness programs and education.

Cathy frequently speaks to lay audiences on the topics of stress and weight management, and to professional audiences on strategic and program planning at health promotion industry conferences. In addition, through Marriott's Executive Development Program, Cathy provides individual wellness consultations for Marriott executives.

Cathy currently serves as the president of the mid-atlantic regional chapter of the Association for Worksite Health Promotion, providing strategic leadership in this professional membership organization.

Prior to the introduction of the *Wellness & You!* Health Promotion program at Marriott in 1993, Cathy was the Program Coordinator for the Marriott Corporate Fitness Facility. She has a Master's degree in Exercise Physiology and a Bachelor of Science in Kinesiology, both from the University of Maryland, College Park.

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**Karen Prestwood**

Dr. Prestwood has been in academic medicine for over 10 years, including a fellowship in Geriatrics. Dr. Prestwood is well known in the field of geriatrics and aging research. She successfully competed for and completed several major career development awards in aging including the American Federation for Aging Research, The Brookdale Foundation and the Paul Beeson Physician Faculty Scholar in Aging Research Awards. She was awarded a prestigious National Osteoporosis Foundation grant and received several investigator-initiated grants from pharmaceutical companies.

Dr. Prestwood has a major role in the Claude Pepper Older Americans Independence Center at the University of Connecticut Health Center where she is principal investigator on one of the major intervention development studies of the center and the core leader of the Recruitment, Retention and Data Management Core. She was Associate Director of the Pepper Center from its inception in 1996 until October 1999, when she started sabbatical leave. Dr. Prestwood is the Associate Director for Research and the Assistant Program Director of the Geriatrics Fellowship Program. In addition, she has been the Director of the Research Curriculum for the Geriatrics Fellowship at UCHC since 1995. Dr. Prestwood is a senior mentor in both the Claude Pepper Older Americans Independence Center and Center for Interdisciplinary Research in Women's Health and is a member of the Scientific Advisory Committee of the General Clinical Research Center and the Selective Committee for Fourth year medical students (provides research training experiences for students). Dr. Prestwood mentors geriatric and endocrinology fellows, medical students and MPH-students in research.

Dr. Prestwood maintains a clinical practice where she sees primarily older adults with osteoporosis or other endocrine diseases. She developed an interest in CAM approximately 5 years ago and began to explore its use both from a personal and professional standpoint. In October 1999, Dr. Prestwood began a 1-year sabbatical leave. The purpose of the leave was to study complementary and alternative medicine with the goal to return to UCHC and develop a program in integrative medicine that includes clinical care, research and teaching. During the year, Dr. Prestwood immersed herself in study and attended major conferences in Integrative Medicine, Spirituality in Medicine, Alternative Medicine, and Botanicals in Clinical Medicine sponsored by Columbia University. She participated in several workshops on practical aspects of initiating an integrative medicine (one which integrates CAM with allopathic medicine) clinic. Dr. Prestwood took an introductory course in Chinese medicine and began training in Healing Touch through the American Holistic Nurses Association and Healing Touch International, Inc. During the year, Dr. Prestwood connected with various local CAM practitioners to better understand different approaches to diagnosis and treatment of disease as well as maintenance of health in older adults. Dr. Prestwood is a member of the American Holistic Medical Association and is on the AHMA research committee. She actively participates in the Connecticut Holistic Health Association where she can interact with CAM providers who are interested in collaboration in research as well as clinical care.

Since returning from sabbatical, Dr. Prestwood received training in Consciousness and Imagery in Healing (Achterberg, Rossman, Simeton) and she completed Mind-Body-Spirit Training for Professionals, lead by Dr. James Gordon. Dr. Prestwood continues her training in various forms of energy medicine. Her clinical practice is now an integrative practice and includes primarily older adults. She plans to further expand the practice so that she will work as part of a team with various CAM practitioners on site at the Health Center. Dr. Prestwood also developed research initiatives to evaluate various CAM modalities in maintaining and improving functional status in older women with osteoporosis- several of these initiatives are funded and will begin shortly.

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# *NUTRITION, CAM, AND WELLNESS FROM A CAM PERSPECTIVE*

**Testimony of M. Kushi**

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***The Cancer-Prevention Diet*** by Michio Kushi

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**Michio Kushi & Associates**
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**Issued: November 18, 1998**
**Revised: March 23, 2001**

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## ALTERNATIVE MEDICINE

### PAPERS BY DAVID EISENBERG AND OTHER RESEARCHERS

**1. January 28, 1993 (First Alternative Medicine Survey)**

Eisenberg, D. M, et al., "Unconventional Medicine in the United States," *The New England Journal of Medicine Vol. 328*: 245-252, Jan. 28, 1993

Prevalence and Frequency of Use among 1539 Adult Respondents in 1990: Lifestyle diets (eg. Macrobiotics): % who used in past 12 months: 4%; % who saw a provider: 13%; mean number of visits per user in past 12 months: 8 .

Extrapolation to the U.S. population suggests that in 1990 Americans made an estimated 425 million visits to providers of unconventional therapy. This number exceeds the number of visits to all U.S. primary care physicians (388 million). Expenditures associated with use of unconventional therapy in 1990 amounted to approximately $13.7 billion, three quarters of which ($10.3 billion) was paid out of pocket. This figure is comparable to the $12.8 billion spent out of pocket annually for all hospitalizations in the United States.

Conclusion: The frequency of use of unconventional therapy in the United States is far higher than previously reported. Medical doctors should ask about their patients' use of unconventional therapy whenever they obtain a medical history."

**2. November 11, 1998 (Follow-up of 1993 Alternative Medicine Survey)**

Eisenberg, D. M, et al., "Trends in Alternative Medicine Use in the United States, 1990-1997: Results of a Follow-up National Survey," *Journal of the American Medical Association* 1998 Nov. 11; 280 (18): 1569-75

Estimated total number of visits in 1997 to lifestyle diet practioner 1,774,000.

Extrapolations to the US population suggest a 47.3% increase in total visits to alternative medicine practitioners, from 427 million in 1990 to 629 million in 1997, thereby exceeding total visits to all US primary care physicians. An estimated 15 million adults in 1997 took prescription medications concurrently with herbal remedies and/or high-dose vitamins (18.4% of all prescription users). Estimated expenditures for alternative medicine professional services increased 45.2% between 1990 and 1997 and were conservatively estimated at $21.2 billion in 1997, with at least $12.2 billion paid out-of-pocket. This exceeds the 1997 out-of-pocket expenditures for all US hospitalizations. Total 1997 out-of-pocket expenditures relating to alternative therapies were conservatively estimated at $27.0 billion, which is comparable with the projected 1997 out-of-pocket expenditures for all US physician services.

Conclusion: Alternative medicine use and expenditures increased substantially between 1990 and 1997, attributable primarily to an increase in the proportion of the population seeking alternative therapies, rather than increased visits per patient."

**3. September 2, 1998**

Wetzel, M. S.; Eisenberg, D. M., Kaptchuk, T. J., "Courses Involving Complementary and Alternative Medicine at US Medical Schools," *Journal of the American Medical Association Vol. 280*, pp. 784-787, Sep. 2, 1998

- Conclusions. – There is tremendous heterogeneity and diversity in content, format, and requirements among courses in complementary and alternative medicine at US medical schools....
- As the discussion of incorporating complementary and alternative medicine topics appropriately into the medical curriculum evolves and broadens among medical faculties and professional organizations, we offer several suggestions based on information gathered in our survey and our experience with 5 years of offering an elective course in complementary and alternative medicine....
  *Include an experiential component.* Experiencing acupuncture or therapeutic massage or tasting a macrobiotic meal adds a dimension to the learning experience that a lecture or simple demonstration cannot. The deeper understanding that results should provide a better basis for responsibly advising patients.

## AMERICAN HEART ASSOC. COMMENTS ON MACROBIOTICS

AHA Internet Site: http://www.americanheart.org/Scientific/statements/1997069704.html

A Statement for Healthcare Professionals From the Nutrition Committee

"There is now overwhelming evidence that dietary factors influence risk of coronary heart disease (CHD) both favorably and unfavorably. The three most atherogenic dietary risk factors are saturated fat, cholesterol, and obesity. The Step I and Step II diets are recommended to address these problems and are aimed at reducing intake of total fat, saturated fat, and cholesterol. On average, blood cholesterol levels can be reduced an estimated 5% to 15% through the StepI-StepII diet approach, with some hyperlipidemic patients experiencing even greater reductions. Increased carbohydrate intake, especially complex carbohydrates, is also recommended to replace the majority of calories lost through reduced fat intake. Choosing fiber-rich carbohydrate sources may foster additional cholesterol lowering and other nutritional benefits beyond those derived from fat modification alone. Inconsistent findings from studies on fiber and lipids have recently contributed to some confusion regarding fiber's potetial benefits....

Several longitudinal observational studies have reported significant inverse associations between total fiber intake and both cardiovascular and all causes of mortality...Inverse associations between fiber and blood pressure have also been reported...Similarly, high-fiber vegetarian diets have also been associated with reduced risk of obesity. It has been hypothesized that high-fiber foods may favorably impact satiety and slow gastric emptying, thereby sustaining a feeling of fullness that prohibits overeating. Intake of high-fiber foods may also improve glycemic control in diabetic individuals and reduce risk of insulin resistance.

As a preventive strategy, it has been recommended that children older than two years should gradually adopt the Step I diet, reducing total and saturated fat intake to 30% and 10% of total calories, respectively. Children should also derive the majority of calories from complex carbohydrates...

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# CANCER

## THE DIETARY CAUSES OF CANCER

Summary of Combined Testimony from House of Representatives Government Reform Committee, June 10, 1999

& Asian Therapies for Cancer Conference, March 1-2, 2001

By Michio Kushi

If this food intake is exercised properly, in harmony with the changing environment – including its quality, volume, and cooking – then human life is in accordance with the environment, and it not only maintains its health, vitality, and happiness; but also a peaceful mind, and higher spirit.

The cause of cancer is not excluded from this universal rule. As all other physical, mental, and spiritual human affairs, human sickness and health fundamentally depend on our daily dietary practice.

During the 20th Century, the human diet has been drastically changed: there has been higher consumption of animal protein and fat, refined sugar, mass-produced artificialized food; together with unnaturally chemicalized agriculture. These changes have produced the complex and diversified phenomena of human sickness in modern, civilized society. Sickness includes physical, mental, spiritual, and social sickness. Among them, cancer is one of the most representative of chronic conditions.

When we continuously consume food beyond our daily capacity to eliminate it in the form of physical and mental activities, the excessive dietary components accumulate, and eventually produce excessive, abnormal increase and division of the cells. This is what we call cancer.

The dietary causes of major cancers are the following, which are, of course, only briefly summarized here:

1. **Colon Cancer** – Over-consumption of meat and other heavy animal protein and fat
2. **Stomach Cancer** – Consumption of excessive animal protein, oily/greasy food, refined sugar, and spices
3. **Esophagus Cancer** – Over-consumption of dairy fat, with refined sugar and spices
4. **Prostate Cancer** – Excessive consumption of meat, eggs, and poultry, as well as cheese and other animal fat, with hard-baked flour products

5. **Pancreatic Cancer** – Over-consumption of poultry and eggs, shellfish, cheese, and hard-baked flour products
6. **Lung Cancer** – Over-consumption of animal protein and fat, including all sorts of meat, poultry, and eggs; as well as over-consumption of dairy fat, together with refined sugar, hot spices, and hard-baked flour
7. **Skin Cancer** – Excessive consumption of oily/greasy food, including dairy fat, refined sugar and sweets, and spices
8. **Malignant Melanoma** – Over-consumption of poultry, eggs, cheese, and other fat, together with refined sugar products
9. **Brain Cancer** – Either over-consumption of eggs, heavy meat, and other animal protein and fat; or, in other cases, over-consumption of dairy products and fat, and also excess of vegetable oil, such as in fried potatoes
10. **Thyroid Cancer** – Over-consumption of poultry, eggs, dairy fat such as in cheese, and hard-baked flour products, along with with refined sugar products and hot spices; fried food
11. **Liver Cancer** – Over-consumption of animal protein and fat, including meat, poultry, eggs, and fish & seafood; and dairy food high in fat. Excessive refined sugar and baked flour products, with greasy/oily cooking
12. **Bone Cancer** – Excessive consumption of salty animal food; poultry, eggs, hard-baked flour, and especially deep-fried foods; too many minerals
13. **Lymphoma** – Excessive dairy food and fat, with refined sugar products and refined flour products, for some cases. Excessive meat and other animal protein and fat, including poultry and eggs, combined with dairy fat and refined sugar products, for other cases
14. **Leukemia** – Over-consumption of refined sugar products, such as sugar, cakes, chocolate, and fruits and fruit juices; combined with oily/greasy foods

For the case of Women's Cancers:

1. **Breast Cancer** – Over-consumption of dairy fat, refined sugar and other simple carbohydrates, and refined flour products, along with oily/greasy foods. Excess of fruits will accelerate breast cancer, once it is caused by the previous foods
2. **Uterine Cancer** – Heavy animal fat and dairy products, including cheese; over-consumption of vegetable oils, refined sugar products, and baked flour products
3. **Ovarian Cancer** – Over-consumption of poultry, eggs, shellfish, and other high-fat animal food, and baked flour products
4. **Cervical Cancer** – similar to prostate cancer in men - Over-consumption of baked flour and salty foods; and oily/greasy fried foods, including heavy animal and vegetable-quality foods

Over-consumption of stimulants and aromatic substances, such as hot spices, alcoholic beverages, and caffeine, accelerate the spread of a cancer condition.

Of course, lifestyle factors, such as exposure to high electromagnetic fields or radiation or smoking may accelerate the development of cancer, as does consumption of unnatural chemically-treated food and water. Non-organic chemically-cultivated agriculture, irradiation, microwave cooking, and other such methods of unnatural food production and artificial processing, along with daily unnatural lifestyle, are seriously questionable as well.

The **Standard Macrobiotic Diet** can prevent these cancers naturally, if it is properly prepared. But it cannot only prevent, but it can also relieve these conditions. It may take 2 months to 2 years, depending upon how deeply undesirable foods have accumulated in the body. For some cases, it is helpful to supply for a few weeks to a few months some **Home Remedies**, prepared from grains, beans, vegetables, and sea vegetables, which are serving to neutralize and eliminate undesirable accumulations.

There are cases which are not effective by Macrobiotic practice, which are assumed (1) Inaccurate Practice; (2) Lack of Proper Information; (3) Lack of Family Support; (4) Confusing Practices of Various Approaches Combined with Macrobiotic Practice; and (5) Loss of Recovering Ability, as Seen in the Terminal Cases.

## AMERICAN CANCER SOCIETY

### 1. Prevention & Early Detection

a. ACS Internet Site: http://www2.cancer.org/prevention/index.cfm?prevention=1
"The Importance of Nutrition in Cancer Prevention"
This is an overview of nutritional recommendations, and supports USDA Food Guide Pyramid:

"The American Cancer Society publishes nutrition guidelines to advise the public about dietary practices that reduce cancer risk. These guidelines are developed by expert advisory committees and are based on existing scientific evidence that relates diet and nutrition to cancer risk in human population studies as well as in laboratory experiments.

This evidence suggests that about one-third of the 500,000 cancer deaths that occur in the United States each year is due to dietary factors. Another third is due to cigarette smoking. Therefore, for the large majority of Americans who do not smoke cigarettes, dietary choices and physical activity become the most important modifiable determinants of cancer risk. The evidence also indicates that although genetics is a factor in the development of cancer, cancer cannot be explained by heredity alone. Behavioral factors such as cigarette smoking, dietary choices, and physical activity modify the risk of cancer at all stages of development. The introduction of healthful diet and exercise practices at any time from childhood to old age can promote health and reduce cancer risk....

Many dietary factors can affect cancer risk: types of foods, food preparation methods, portion sizes, food variety, and overall caloric balance. Cancer risk can be reduced by an overall dietary pattern that includes a high proportion of plant foods (fruits, vegetables, grains, and beans), limited amounts of meat, dairy, and other high-fat foods, and a balance of caloric intake and physical activity.

Many Americans do not follow such healthful practices. Indeed, trends indicate an increase in caloric intake, greater use of high-fat convenience foods, and a decline in physical activity among Americans. We believe that such unhealthful trends are due in part to shifts toward consumption of food outside the home, to more sedentary lifestyle patterns, and to the advertising and promotion of high-calorie foods. The [American Cancer Society Advisory Committee on Diet, Nutrition, and Cancer Prevention] is especially concerned about the effects of such trends on the long-term health of children, who are establishing lifetime patterns of food intake and physical activity.

...The committee's recommendations are consistent in principle with the 1992 US Department of Agriculture (USDA) Food Guide Pyramid, the 1995 Dietary Guidelines for Americans, and dietary recommendations of other agencies for general health promotion and for the prevention of coronary heart disease, diabetes, and other diet-related chronic conditions. Although the committee recognizes that no diet can

guarantee full protection against any disease, we believe that our recommendations offer the best nutrition information currently available to help Americans reduce their risk of cancer.

**ACS Guidelines on Diet, Nutrition, and Cancer Prevention (excerpts)**

1. **Choose most of the foods you eat from plant sources.**
   - Eat five or more servings of fruits and vegetables each day.
     - Include fruits or vegetables in every meal.
     - Choose fruits and vegetables for snacks.
   - Eat other foods from plant sources, such as breads, cereals, grain products, rice, pasta, or beans several times each day.
     - Include grain products in every meal.
     - Choose whole grains in preference to processed (refined) grains.
     - Choose beans as an alternative to meat.
     - Grains such as wheat, rice, oats, barley, and the foods made for from them constitute the base of healthful diets as illustrated by the USDA Food Guide Pyramid. Healthful diets contain 6 to 11 standard servings of foods from this group every day.
     - Grains are an important source of many vitamins and minerals such as folate, calcium, and selenium, all of which have been associated with a lower risk of colon cancer.
     - Whole grains are higher in fiber and certain vitamins and minerals than refined flour products.
2. **Limit your intake of high-fat foods, particularly from animal sources.**
   - Choose foods low in fat.
     - Replace fat-rich foods with fruits, vegetables, grains, and beans
     - Eat smaller portions of high-fat foods.
     - Choose baked and broiled foods instead of fried foods.
     - Select non-fat and low-fat milk and dairy products
     - When you ear packaged, snack, convenience, and restaurant foods, choose those low in fat.
   - Limit consumption of meats, especially high-fat meats.
     - When you eat meat, select lean cuts.
     - Eat smaller portions of meat.
     - Choose beans, seafood, and poultry as an alternative to beef, pork, and lamb.
     - Select baked and broiled meats, seafood, and poultry, rather than fried.
     - High-fat diets have been associated with an increase in the risk of cancers of the colon and rectum, prostate, and endometrium. The association between high-fat diets and breast cancer is much weaker.

- Consumption of meat – specially red meats (beef, pork, lamb) has been linked to cancers at several sites, most notable colon and prostate.
- The evidence indicates that saturated fat may be particularly important in increasing risk for cancer as well as for heart disease.
- Emphasize beans, grains, and vegetables in meals to help shift dietary patterns to include more foods from plant rather than animal sources.

3. **Be physically active: achieve and maintain a health weight.**
   - Be at least moderately active for 30 minutes or more on most days of the week.
   - Stay within your health weight range.
     - An imbalance of caloric intake and output can lead to overweight, obesity, and increased risk for cancers at several sites: colon and rectum, prostate, endometrium, breast (among postmenopausal women), and kidney.
4. **Limit consumption of alcoholic beverages, if you drink at all.**
   - Alcohol consumption increases the risk of cancers of the mouth, esophagus, pharnyx, larynx, and liver in men and women, and of breast cancer in women.
   - Cancer risk increases with the amount of alcohol consumed...Studies show that the risk of breast cancer increases with an intake beginning at just a few drinks per week.

**Revised 05/11/99**

b. ACS Internet Site:
Http://www2.cancer.org/prevention/more_prevention.cfm
"Prevention and Early Detection"

"Many cancers that are related to a person's diet and level of physical activity can ... be prevented. Scientific evidence suggests that up to one-third of the 564,800 cancer deaths expected to occur in the US this year are related to poor nutrition or insufficient physical activity."

c. ACS Internet Site:
http://www2.cancer.org/prevention/index.cfm?preventionúctors
"Diet and Activity Factors That Affect Risks for the Most Common Cancers"

**Breast Cancer**

Breast cancer is the leading site for cancer cases among American women and is second only to lung cancer in cancer deaths...Many studies suggest that consuming alcoholic beverages may increase the risk of breast cancers, even when consumed in moderation. Some studies suggest that diets high in fruits and vegetables decrease the risk for breast cancer, although this evidence is much weaker than that for other cancer sites...

**Colorectal Cancer**
Colorectal cancers are the second leading cause of cancer death among Americans. Diets high in foods from plant sources (vegetables, fruits, whole grains, beans) have been associated with a decreased risk, whereas diets high in fat and red meat have been associated with an increased risk of colorectal cancer. Obesity and physical inactivity also appear to increase risk. Currently, the best approach to reducing the risk of colorectal cancer is to consume fewer high-fat foods. Limit intake of red meats, eat more vegetables, fruits, and whole grains, be physically active, and avoid obesity.

**Endometrial Cancer**
Studies of endometrial cancer consistently find that being overweight increases risk. The association may be due to the increase in estrogen levels that occurs among postmenopausal women who are overweight. To reduce the risk of endometrial cancer, maintain a healthy weight through regular physical activity and healthy food choices.

**Lung Cancer**
Lung cancer is the leading cause of cancer death among Americans. More than 80% of lung cancer cases occur as a result of tobacco smoking. Many studies have demonstrated that the risk of lung cancer among smokers and non-smokers is lower among people who consume recommended amounts of fruits and vegetables. To reduce the risk of lung cancer, do not smoke tobacco, and eat at least five servings of vegetables and fruits every day.

**Oral and Esophageal Cancers**
Tobacco – including cigarettes, chewing tobacco, and snuff – and alcohol, singly and together, increase the risk for cancers of the mouth and esophagus. Eating recommended amounts of fruits and vegetables decreases the risk.

**Prostate Cancer**
Prostate cancer is the leading cancer among Americans men. Scientists know that prostate cancer is related to male hormones, but are uncertain as to the exact mechanism involved. Intakes of animal fat, red meats, and dairy products have been found to be associated with an increase in the risk of prostate cancer, suggesting a role of saturated fat. To reduce the risk of prostate cancer, limit intake of foods from animal sources, especially saturated fats and red meat.

**Stomach Cancer**
The incidence of stomach cancer is decreasing worldwide, especially in the United States. Year-round consumption of fresh foods, refrigeration, and other improvements in food preservation methods have helped reduce risk. Infection with the bacterial species

Helicobacter pylori may increase risk. To reduce the risk of stomach cancer, eat at least five servings of fruits and vegetables each day.

**Revised 05/11/99**

b. ACS Internet Site:
http://www2.cancer.org/prevention/index.cfm?prevention=appendix
Appendix: "Members of the American Cancer Society 1996 Advisory Committee on Diet, Nutrition, and Cancer Prevention:

...
Lawrence Kushi, ScD, Associate Professor, Division of Epidemiology, School of Public Health, University of Minnesota, Minneapolis, MN"

c. Internet Site:
http://www2cancer.org/prevention/index.cfm?prevention=references
"References" (examples):

15. Willett, WC. Micronutrients and cancer risk. AM J. Clin. Nutr 1994; 59 (suppl 5): 1162S-1165S
18. Ames BN, Gold LS, Willett WC. The causes and prevention of cancer. Proc Natl Acad Sci USA 1995;92-5258-5265
19. Potter JD. Nutrition and colorectal cancer. Cancer Causes Control 1996;7:157-177
31. Hunter DJ, Willett WC. Nutrition and breast cancer. Cancer Causes Control 1996;7:56-68
34. Kushi LH, Lenart EB, Willett WC. Health implications of Mediterranean diets in light of contemporary knowledge. 2. Meat, wine, fats, and oils. Am. J Clinical Nutr 1995;61(suppl 6):1416S-1427S
70. Willett WC. Specific fatty acids and risks of breast and prostate cancer: dietary intake. Am J Clin Nutr 1997 Dec; 66(6 Suppl):1557S-1563S

**2. ACS Comment on Macrobiotics**
Internet Site: http://www.cancer.org/alt_therapy/overviews/uprpopu.htm
"Alternative Cancer Therapies Popular Today," from *Cancer (medical journal), March 15, 1996 / Volume 77/ Number 6* by Barrie R. Cassileth, Ph.D. (Dept. of Medicine, University. of North Carolina) and
Christopher C. Chapman, B.A., Duke University)

"Today's most popular anticancer diet is probably macrobiotics. As with many

alternatives, its appeal is enhanced by association with an ancient, foreign culture, in this case Japan. The popularity of macrobiotics can be traced to the efforts of Michio Kushi, a tireless proponent. Initially nutritionally deficient, the diet was enhanced and now derives 50-60% of its calories from whole grains; 25-30% from vegetables; and the remainder from beans, seaweed, and soups. (Reference: Kushi, M.: The macrobiotic approach to cancer. Wayne, NJ: Avery Publishing Group, 1982.) The diet avoids meat and certain vegetables, and promotes soybean consumption. The NIH Office of Alternative Medicine recently funded a pilot study of the cancer-preventive effects of the macrobiotic diet. The principal investigator is Lawrence Kushi, ScD, a researcher on the faculty of the University of Minnesota School of Public Health and the son of Michio Kushi."

**3. ACS Comment on Macrobiotics**
**Recommendation: University of Texas Website**
Internet Site: http://www.cancer.org/alt_therapy/resources.htm
"How Can I Learn More About Alternative and Complementary Methods?
Cancer Specific Websites"
University of Texas Center for Alternative Medicine Research in Cancer
(Please see below for an excellent summary of medical research about macrobiotics.)

# UNIVERSITY OF TEXAS WEBSITE ON MACROBIOTICS AND CANCER

## UNIVERSITY OF TEXAS~HOUSTON HEALTH SCIENCE CENTER

Internet Site: http://www.sph.uth.tcm.edu/utcam/

The Center for Alternative Medicine Research (UT-CAM) is dedicated to investigating the effectiveness of alternative/complementary therapies used for cancer prevention and control. It works in collaboration with M.C. Anderson Cancer Center. It was one of 11 centers established by the NIH National Center for Complementary and Alternative Medicine (old Office of Alternative Medicine) to evaluate alternative therapies.

- It is the only one focussed solely on cancer, and is co-funded by the National Cancer Institute.
- It also establishes a national network of alternative medicine practitioners, conventional practitioners, and researchers
- It supports critical evaluation skills among alternative medicine practitioners and researchers.

Macrobiotics, among other cancer therapies reviewed as a "Special Regimen/Integrated System" on 7/21/98. A summary follows. The entire 17 page Review will sent at the end of this transmission.

**U. of Texas Overview**

Definition of "macrobios." Yin & yang. George Ohsawa & Michio Kushi. Yin & yang spectrum of foods. Ohsawa's 10-stage diet vs. Standard Macrobiotic Diet: THIS RESTRICTIVE DIET IS NO LONGER ADVOCATED BY MACROBIOTIC COUNSELORS (!)

Books by Michio Kushi. Sattilaro's *Recalled by Life*. B12 and Vitamin D deficiencies. 1984 Subcommittee on Health and Long Term Care of the Select Committee on Aging, House of Representatives: "MB diet appears to be adequate mix of foods."

Feasibility of Reimbusement (insurance): None

Prevalence of Use:

- Cassileth reported that 63% OF CANCER PATIENTS WHO RECEIVED SOME FORM OF DIETARY THERAPY IN THE COMMUNITY RECEIVED OR WERE EXPOSED TO THE MACROBIOTIC DIET. (Cassileth BR, Lusk EF, Strouse TB, Bodenheimer BJ. Contemporary unorthodox treatments in cancer medicine: A study of patients, treatments, and practitioners. *Annals of Internal Medicine.* 1984;101:105-112)
- Kushi estimates that the standard macrobiotic diet has been practices daily by hundreds of thousands of people worldwide.

- The Office of Technology Assessment (OTA) found it to be "among the most popular unconventional approaches used by cancer patients (OTA. Macrobiotic Diets: Common Knowledge Press; 1990)

Estimated Cost/Expenditure/Reimbursement: comparable to that of a standard American diet, when all factors are considered.

**U. of Texas Science**

Articles citing the macrobiotic diet as a treatment for cancer. "Based on our review of the literature and other sources, 106 references were identified, or which 51 (48%) were applicable to cancer. Of these, 41 (80%) were retrieved and we classified the references in the following types of information:

| | |
|---|---|
| Retrospective Cohort Studies: | 2 |
| Best Case Series: | 2 |
| Case Reports: | 2 |

**U. of Texas Summary of Research**

1. Carter JP, Saxe GP, Newbold V., Peres CE, Campeau RJ, Bernal-Green L. Hypothesis: Dietary management may improve survival from nutritionally linked cancers based on analysis of representative cases. *Journal of the American College of Nutrition.* 1993;12:209-26

STUDY # 1: 23 respondents of 101 patients with pancreatic cancer who practiced a macrobiotic diet for at least 3 months.

- Mean survival was 17 months compared to 6 months for control group of patients.
- Macrobiotic patients had a 52% one year survival compared to 9.7% for control group.

STUDY #2: 18 Tulane Hospital patients with stage D2 prostate cancer.

- Mean survival was 177 months for macrobiotic, 91 months for controls. (Risk RR=1.6 for controls, survival curve differences were not significant)

CASE REPORT: 182 patients who sought MB counseling and responded to a subsequent nationwide mailed questionnaire. 10 cases are presented for patients with cancer of the pancreas, prostate, and uterus.

2. Review of the book *Cancer Free: 30 who triumphed over cancer naturally*, Japan Publications Inc. 1995 by Fawcett A. and Smith C.

Best case series of 28 patients selected because they had positive results using the macrobiotic diet.

3. Newbold, V. Remission of advanced malignant disease: A review of cases with a possible dietary factor. (as contained in the book *Cancer Free*, 372-5

Best case series of 6 patients with advanced or inoperable cancer who had recovered on a macrobiotic diet. Documented by a doctor whose spouse had inoperable cancer that improved following the adoption of a macrobiotic diet.

Proposed Mechanism of Action
Quotations from *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Relief and Prevention of Disease.*

Toxicity
"The American Cancer Society has stated that the macrobiotic diet provides inadequate nutrition for cancer patients, is unsafe and can cause malnutrition and death. The articles cited by one of these warnings concerned a case of scurvy which occurred while practicing the older, more restricted form of macrobiotics."

**U. of Texas Annotated Bibliographies**

Summary of 28 Cancer Patients Recovering with Macrobiotics from cancer of the prostate (3), melanoma (6), uterus (3), breast (5), stomach, leukemia, pancreas (2), colon (2), brain – astrocytoma, urethra, lung, brain, thyroid, leukemia – chronic myelocytic, bile duct, Hodgkin's disease, ovary

Summary of Vivien Newbold's 6 cases:

- Advanced or otherwise untreatable cancers who recovered using macrobiotics: pancreas metastasized to liver; malignant melanoma; malignant astrocytoma; endometrial stromal sarcoma; adenocarcinoma of the colon; abdominal leiomyosarcoma; Review of CT scans and other medical tests revealed no evidence of tumors after adherence to the macrobiotic diet. All of the patients (except one whose cancer came back after she discontinued macrobiotics) were reported to be working full time, leading very active lives, and feeling in excellent health. These cases were all reviewed independently and the diagnoses confirmed by the pathology and radiology departments of Holy Redeemer Hospital in Meadowbrook, Pennsylvania.
- Incurable colon cancer with no conventional treatment (Dr. Newbold's husband): "Eight months after being described as hopeless, he was feeling 'healthier than he ever felt in his life...a follow-up CT scan revealed that about 70 percent of the cancer was gone.'...

**U. of Texas Reference List**

Includes:

- Kushi, M. *The Macrobiotic Approach to Cancer: Towards Preventing and Controlling Cancer with Diet and Lifestyle*. Garden City Park, NY: Avery Publishing Group, Inc; 1991
- Kushi, L. Personal communication
- Sattilaro A. *Recalled by Life*. 1982
- Kushi, M. *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Relief and Prevention of Disease*. New York: St. Martin's Press

# NIH GRANT
# STUDY OF THE MACROBIOTIC APPROACH TO CANCER

## OVERVIEW

NATIONAL INSTITUTES OF HEALTH –

- OFFICE OF ALTERNATIVE MEDICINE (old name)
- NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (new name)

1. Internet Site: http://www.nccam.nih.gov/nccam/research/grants/rfb/grant-1/html
From chart of Office of Alternative Medicine-sponsored research from fiscal year (FY) 1993 – fiscal year (FY) 1997 Grant Award & Research Data
(This is our NIH Cancer Best Case Series, still to be completed)

| | |
|---|---|
| Grant Number: | R21RR09472 |
| Institution/Project Title: | University of Minnesota Twin Cities<br>Macrobiotic Approach to Cancer |
| City, State, P.I. | Minneapolis, MN; Kushi, Principal Investigator |
| NIH Institute | NCRR |
| Amount (FY 1993): | $29,964 |

3. Internet Site:
http://www.nccam.nih.gov/nccam/fcp/classify/index.html
For Consumers and Practitioners: Classification of CAM (Complementary and Alternative Medicine) Practice

IV. Biologically-Based Therapies

Special Diet Therapies: This subcategory includes dietary approaches and special diets that are applied as alternative therapies for risk factors or chronic disease in general:

Vegetarian, Fasting, High Fiber, MACROBIOTIC, Mediterranean, Paleolithic, Asian, Natural Hygiene, Pritikin, Ornish, McDougall, Gerson, Kelly-Gonzales, Wigmore, Livingston-Wheeler, Atkins, Diamond

# Withdrawal/Redaction Marker
## Clinton Library

| DOCUMENT NO. AND TYPE | SUBJECT/TITLE | DATE | RESTRICTION |
|---|---|---|---|
| 001. testimony | Michio Kushi (partial) (1 page) | 03/27/2001 | b(6) |

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

OA/Box Number: 43231

**FOLDER TITLE:**
WHCCAM Meeting Testimony, March 26, 2001 [2]

2011-0568-S
kc809

**RESTRICTION CODES**

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

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

**C. Closed in accordance with restrictions contained in donor's deed of gift.**
**PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).**
**RR. Document will be reviewed upon request.**

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

**b(1) National security classified information [(b)(1) of the FOIA]**
**b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]**
**b(3) Release would violate a Federal statute [(b)(3) of the FOIA]**
**b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]**
**b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]**
**b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]**
**b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]**
**b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]**

[001]

# *Nutrition, CAM, and Wellness from a CAM Perspective*
# *Panel #2 - Integrative Approaches to Wellness: Nutrition*

## White House Commission on Complementary And Alternative Medicine Policy Public Hearing on CAM in Self-Care and Wellness

Hyatt Regency Washington Hotel on Capitol Hill
400 New Jersey Avenue, N.W.
Washington, D.C. 20001
10:20 - 11:10 a.m. Tuesday, March 27, 2001

***Testimony of Michio Kushi***

(b)(6)

Dear Honorable Chairman and White House Commission Members,

The Era of Humanity is now beginning. Alternative and Complementary Medicine is one evidence of the processing of this transition from the Modern Age to the New Era of Humanity.

While we are appreciating the development of conventional medical technologies both in diagnosis and treatment, we also know that modern conventional medicine has been largely symptomatic and divisional approaches.

We are also appreciating all various Alternative and Complementary approaches to healthcare, including exercise, breathing, meditation, vibrational and electromagnetic treatments, herbal medicine, supplements, acupuncture,

moxabustion, shiatsu massage, polarity, traditional folk medicine, psychological and spiritual approaches, and various diets.

Diets alone vary from juicing, raw food eating, high protein, vegetarian, high and low fiber, low sodium, and many others; and conventional nutritional theories, with their concept of calories. Some of these approaches, however, while we are appreciating their temporary effectiveness for certain symptoms, still maintain a fragmental view of human life.

The Macrobiotic way of life and its recommended dietary practice are based upon human traditional eating, with natural organic foods and proper cooking, in harmony with the environment, which has been practiced for many centuries in different climactic and cultural adaptations. (A Pyramid form of the Standard Macrobiotic Diet in a temperate climate is herewith attached.) Through this practice in America, Europe, Japan, some Asian countries, and South America, uncountable numbers of people have regained their health, even from terminal sicknesses, and have restored their loving family life and peaceful relations with people and society.

The approach of Macrobiotics is to solve and correct the cause of physical and mental disorders in daily diet and lifestyle. As examples, dietary causes of some disorders are briefly summarized here:

1. CANCER
   Because cancer has diversified symptoms, its dietary causes are also diversified. For example:

   **Prostate Cancer** – is caused by over-consumption of heavy animal protein and fat; together with oily/greasy and hard-baked food.

   **Breast Cancer**- is caused by over-consumption of dairy fat and simple carbohydrates, such as sugar, chocolate and honey; together with oily/ greasy food

Other cancer symptoms are summarized in the attached papers of causes, case histories, and medical research papers related to the macrobiotic diet (which were presented to the House of Representatives Government Reform Committee in June 1999; and the Asian Therapies Conference in March 2001); and in the book *The Cancer-Prevention Diet.*

2. HEART DISEASE
   Though there are varieties of symptoms, the major causes are over-consumption of animal protein and fat, as well as hot spices, simple carbohydrates, and oily/greasy food, as detailed more in the book *Diet For a Strong Heart.* The Macrobiotic approach can secure Blood Pressure reduced by 10% from the national average, and cholesterol less than 150 (average for Macrobiotic persons is 126). These were studied already in 1976 by Harvard University Channing Laboratory and the Framingham Heart Study Center. A summary of medical research papers is attached.

3. ALLERGIES
   The cause is generally over-consumption of dairy food, stimulants, and simple carbohydrates; as well as oily/greasy food, in various degrees.

4. ARTHRITIS
   Several kinds of arthritis can be classified, such as osteo and rheumatoid; but overall, the causes are over-consumption of animal protein and fat, especially poultry, eggs, seafood, and dairy food, together with nightshade vegetables, fruits and fruit juices, simple carbohydrates, and stimulants.

5. DIABETES AND HYPOGLYCEMIA

For both, the underlying cause lies in a pancreatic hormone secretion disorder, which is caused by excessive eating of animal protein and fat, especially poultry, eggs, and cheese. Contributing are heavy baked flour consumption; and simple carbohydrates, stimulants, and oily/greasy food. Please see attached summary of medical research papers.

6. AIDS & VIRUS DISEASE
   Decline of natural immunity is caused by over-consumption of sugar, chocolate, and other simple carbohydrates, and refined flour; together with dairy food; tropical fruit and fruit juices; and stimulants.

7. EMOTIONAL DISORDERS
   Are caused by irregular eating. Some are more over-consumption of animal protein and fat, such as inwardly depressive paranoia symptoms. While over-consumption of sugar & simple carbohydrates, stimulants and spices, and soft drinks are causing more hyper-activity, excitement, irritability, and schizophrenia.

8. MENTAL DISORDERS
   Violence and children's psychological problems, such as Attention Deficit Disorder (ADD) are also caused by their dietary habits, which lack whole grain and vegetables as a major portion of their eating; and by excessive intake of animal protein and fat; sugar, oily food, spices, and stimulants. Please see attached summary of medical research papers, including a reference to the Tidewater Detention Center report.

9. BODY-MIND-SPIRIT RELATION
   Mind, Spirit, and Body should not be considered separate. Natural energy is received from the Universe, the Earth, and environment, forming our image, mental and spiritual nature, as well as chakras and meridians. In addition, food also releases energy and vibration, affecting mind and spirit.

Practically all physical, mental and spiritual disorders are caused by our food, our lifestyle, and our environment. Therefore, correction to proper diet, lifestyle, and environment should be the center of any health approach, regardless of CAM or conventional medical approach. Please see the attached diagram, where Diet is at the center of all health and wellness approaches.

We recommend the following as the policy of the United States for Alternative and Complementary Medicine, as well as for Wellness:

1. Allot and distribute available funds for **Research and Education** on the effectiveness of Alternative and Complementary solutions, for both prevention and recovery, with diet and lifestyle as the base. We also recommend a pilot plan for clinical trials in some hospitals and healthcare centers.

2. Establish **Community and School Educational Programs** to recover healthy lifestyles and proper home-cooking, which is whole grains- and vegetable-based: including adult education, and public schools in their home economics or health education programs.

3. Hold **Industrial Conferences** to guide food producers, distributors and servers, including agricultural and marine products.

4. Help facilitate the use of proper diet and wellness plan **in Public Dining Facilities and in Government Programs** such as meals-on-wheels for seniors and in our prisons.

5. Encourage **Hospitals, Clinics, Healthcare Facilities and Medical Schools** to add dietary and wellness studies, counselling, cooking classes, and serving facilities with healthful menus.

6. Apply adequate **Insurance Policies** to support Alternative and Complementary guidance, healthcare and dietary counselling, and learning.

7. Encourage the avoidance of daily consumption of food and water which are overly **Artificialized, Chemicalized, Irradiated**; encourage the proper evaluation of **Genetic Modification**; and encourage more respect for natural, organic, and traditional quality of food and drink.

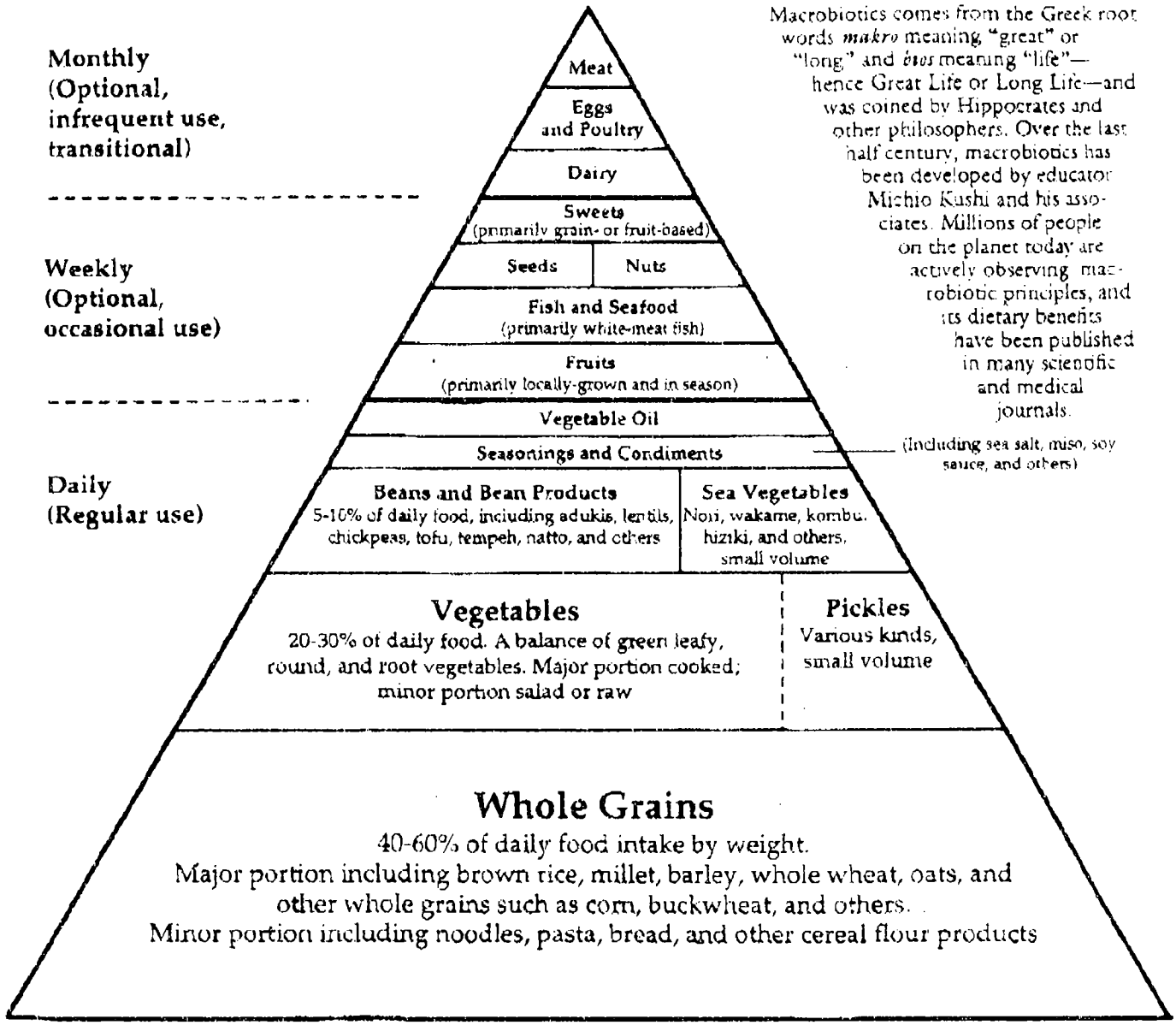
8. Promote improvements to secure a more **Clean, Natural Environment** of our air, water, and soil; and encourage avoidance of technology which is environmentally harmful.

We would be happy to cooperate with such governmental efforts by participating in research and education, and by dispatching well-experienced macrobiotic educators, counselors, and cooking instructors to any facilities.

These policies would inevitably result in a great turning in the healthcare systems. We need vision, courage, and tireless efforts. On the process of turning, we may face opposition, hesitation, doubt, and misunderstanding. However, to overcome our health crisis, we need to urgently proceed in all domains related to human life. Upon the achievement of this revolutionary turning, America will become a symbol of health, happiness, and well-being for the future of entire planetary mankind.

Thank you very much for this opportunity for presenting my humble statement.

# Macrobiotic Dietary Guidelines for a Temperate Climate




## Macrobiotics

Macrobiotics comes from the Greek root words *makro* meaning "great" or "long" and *bios* meaning "life"—hence Great Life or Long Life—and was coined by Hippocrates and other philosophers. Over the last half century, macrobiotics has been developed by educator Michio Kushi and his associates. Millions of people on the planet today are actively observing macrobiotic principles, and its dietary benefits have been published in many scientific and medical journals.

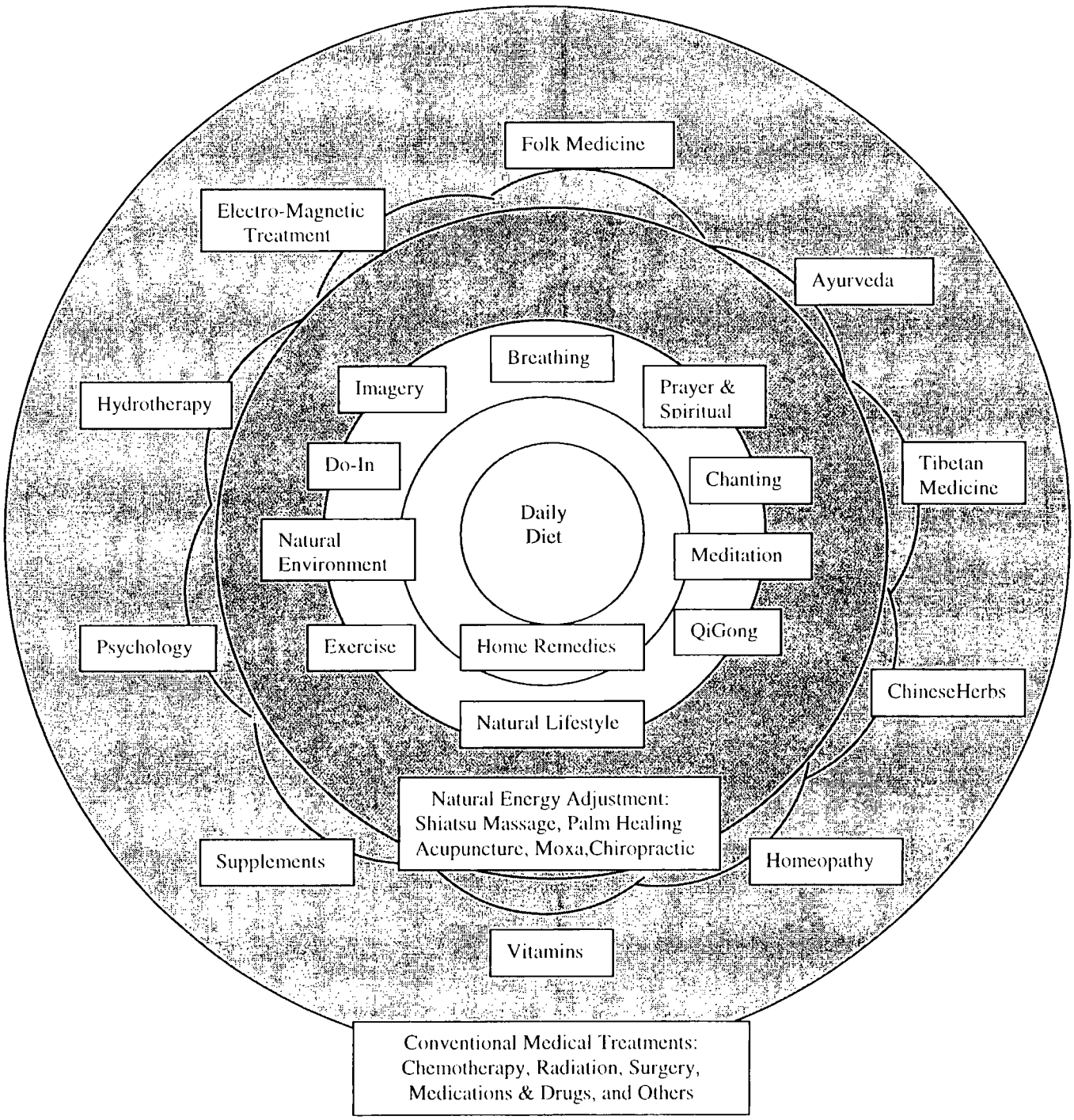
*Soup:* Grains, vegetables, beans, and sea vegetables may be consumed in the form of soup, 1-2 times daily or several times a week, in addition to the usual styles of preparing these foods

*Water:* non-stimulant beverages and natural, clean water, including spring, well, or filtered water for drinking and cooking

*Quality:* Food to be natural quality (non-genetically engineered), organically grown as much as possible, traditionally or naturally processed, and prepared using gas, wood fire, or other natural fuel

*Note: These are standard averages that may be adjusted for climate and environment, cultural or ethnic heritage, gender, age, activity level, individual condition of health and personal needs, and other considerations*

**Trial Draft of Overview of Health Approaches**




**Macrobiotic Overview for Health Approaches, with Macrobiotically-Oriented Diet as the Center of CAM and Conventional Treatments**

**= Diet & Lifestyle and Self-Care & Wellness**

**= Participation of Expert Practitioner & Specialist Required**

# ADDENDA TO TESTIMONY
# Of MICHIO KUSHI

**Biographical Sketch**

**Standard Macrobiotic Diet Brochure**

**Medical Research Papers Summary:** ResearchIndex3.23.01
- **Heart Disease**
- **Cancer**
- **AIDS**
- **Hypoglycemia & Diabetes**
- **Mental Illness**
- **Alternative Medicine & Diet**

**Cancer**
- **Summary of Causes** CausesofCancer3.23.01
- **American Cancer Society** ACSCommentsOnMBs3.23.01
- **University of Texas Best Cases** UTXCommentsOnMBs3.23.01
- **N.I.H. Best Case Series**
  - **Grant Overview** NIHGrantRef3.23.01
  - **Index of Cases** SummaryPlus2.01
  - **Summary of 6 Best Cases** SummaryPlus2.01

***Diet for a Strong Heart***
***The Cancer-Prevention Diet***

**Susan Schiller**
**CBS Evening News**

Susan Schiller is currently a producer at the CBS Evening News responsible for medicine and health coverage in addition to covering breaking news. Previously, she was Senior Producer of CBS This Morning where her duties included overseeing the health and medical unit. Ms. Schiller recruited the former head of the National Institutes of Health and current President of the American Red Cross, Dr. Bernadine Healy to serve as a consultant to CBS News on medical issues. In her capacity as a producer for CBS News she has produced reports on a wide range of medical topics including: Alzheimer's Disease, cloning, stem cell research, West Nile Virus, genetics, Attention Deficit Disorder, Parkinson's Disease, advances in spinal chord and heart research as well as alternative/complementary medicine.

Prior to joining CBS News in New York, Ms. Schiller held writing, producing and management positions at CBS owned television stations in St. Louis, Missouri and Philadelphia.

She has received numerous awards for her work including the American Women in Radio and Television Gracie Award in 2000 for a series on breakthroughs in fetal surgery. She has been honored by the American Heart Association, the American Cancer Association, the American Society of Dermatology, and the Epilepsy Foundation. Ms. Schiller has received 11 Emmy nominations for her work and won an Emmy Award for an investigation on fire safety in St. Louis housing.

**Susan Schiller**
**CBS News**

Mr. Chairman, Committee members thank you for allowing me to appear before you today. My name is Susan Schiller and I am a producer at the CBS Evening News with Dan Rather. I have been responsible for health and medicine coverage at CBS for nearly ten years at both the Early Show and currently the Evening News.

CBS News has a deep commitment to reporting on health issues. We know network television viewers rank health and medicine at the top of their "reasons to watch" list and as a topic, its more important to them than politics! They get more of their medical information from TV and other forms of media than they do from their own doctors. Stories on health and medicine directly touch the lives of our viewers and their families. As baby boomers age, and their own parents grow older, the appetite for health information continues to grow.

More Americans than ever before are turning to complementary and alternative medicine. They spend 15 billion dollars on herbs and vitamins in an effort to stay healthy. Alternative medicine is now mainstream.

Never before has the issue of complementary and alternative medicine been more central to our editorial process on what to report in the health field. What we cover and why can be complex.

At the CBS Evening News, we have tended to look at the issues of alternative and complementary medicine through a fairly critical journalistic lens. But sometimes, hard research is hard to come by. One of the most important areas of interest to the consumer: dietary supplements. Over the last decade, more and more people have started taking supplements as part of their overall wellness plan. Eating a well-balanced diet is considered the best way to get the essential vitamins and minerals needed for good health. But as Americans became obsessed with trying to improve their health, extend aging, fight cancer and cure the common cold the use of various supplements and herbs has exploded. Many viewers contacted us asking about the value of various forms of supplements. The problem was that our traditional forms of evaluating the legitimacy of the treatments were essentially non-existent in this area.

Typically, we've turned to the major medical journals as sources of information. These include: The New England Journal of Medicine, The Journal of the American Medical Association, the Lancet, among others. We know these journals have gone through rigorous review. We also turn to the NIH and other major medical research centers for information. But time and time again we learned that the same rigorous clinical evaluation of pharmaceutical drugs was not being conducted on dietary supplements. We found a lot of so-called "experts" making claims but often little evidence to back them up.

The Food and Drug Administration has limited authority over these products. On one hand, people pop supplements like candy thinking this vitamin or that herb will help them stay healthy. And if you can buy it off the shelf at the drug store or a health food store it can't be dangerous, right? But we found some products can actually be harmful, even kill. And what it says on the label isn't often reliable. Just this year, in evaluating independently a variety of supplements, some products contain less than the stated amount. Sometimes they contain other substances...like arsenic. In fact, the lack of regulation in this area appears to be a serious breach in public safety.

At CBS This Morning, now known as the Early Show, we did many reports on dietary supplements. We had a news/talk format which allowed us to address some of our viewers questions: What is St. John's Wort, Red Yeast, Echinacea, Saw Palmetto ? Did they work? Were they safe? Our medical correspondents were also physicians and could explain what we knew, what we didn't and heed a word of caution. But the Evening News is a hard-news broadcast based on facts and new advances. Did a treatment work or was it a placebo effect?

In 1998, when the New England Journal of Medicine published a study on the potential use of an herbal combination called PC-Spes for prostate cancer it was a watershed. The results were a way to demonstrate to the public that herbal medicines are powerful—as powerful as any prescription drug. It was used by prostate cancer patients in combination with conventional medicine or after conventional treatments had failed.

That study represented to some extent a sea-change in the attitudes of many physicians we spoke to. Previously when we would contact doctors, many viewed the world of alternative medicine with disinterest if not disdain. They considered it almost quackery. The reporting of this research in the New England Journal of Medicine gave not only this herbal supplement credibility but alternative medicine in general. It opened a door.

In the past five years or so, we have been inundated with press releases and materials pitching stories related to alternative medicine. Some go as far as claiming a cure for cancer. We still get press releases for shark cartilage. Often these come for various public relations firms hired by the company which makes a product. This is a big red flag to us. We still seek out research done by a major academic center or the National Institutes of Health because we believe that the results were properly researched regardless of the outcome. If it comes on a press release over the fax machine it will get a large degree of scrutiny.

Corporate sponsorship of research is another concern to us. In the past, studies that were funded by the corporate money were often disregarded. Inherent bias is obviously a concern. Today, many drug studies are funded by large pharmaceutical companies and we will often point that out in our report. However, in the area of alternative medicine,

there are relatively few double-blind, placebo controlled studies and they are often done in a small patient base. If the company that stands to benefit from favorable results paid for the research, we would take extra steps to insure that the research was done in a scientifically solid and unbiased way.

Why do we choose the stories we do? Clearly, complementary and alternative medicine is high interest to our viewers. We know the public is interested in advances for major medical illnesses such as cancer, heart disease and diabetes. There are some general guidelines that we follow: the first and single most important question is: what's new here? how significant is the finding, who will benefit –a large or relatively small group? If the advance is a treatment rooted in alternative medicine its as important in our mind as any new chemotherapy or heart procedure. In general, we don't target any specific racial or ethnic group but clearly in our reporting on medical findings ethnicity and race may be a factor.

Over the next few years, our reporting on alternative and complementary medicine will only grow. Congress has approved additional research dollars for this area of medicine. Consumers want more definitive answers. Can taking an Omega –3 supplement daily increase your protection against cancer or heart disease or both? Is ginkgo baloba really effective in maintaining memory? Is it false hope for an Alzheimer's patient?

Stories on complementary and alternative medicine are among the most interesting ones we do. On the CBS Evening News we've reported on the benefits of acupuncture for pain, neurofeedback for attention deficit disorder, magnetic therapy for depression and the power of prayer and healing. Just this month we reported on a new treatment option at a major medical center in New York. Holistic therapy combined with surgery. A strumming musician playing guitar right in the operating room as a woman is about to undergo surgery for breast cancer. Both the holistic therapist as well as the surgeon saw benefit in this combination of both complimentary and conventional medicine. For the patient undergoing her second mastectomy, it helped relieve her stress and helped her cope with a very difficult situation. While the guitarist may be an odd site in the o.r. today...tomorrow he'll be considered routine personnel in some procedures.

But we need to remember that while aromatherapy may not kill, other alternative medicine practices might. People often using alternative medicines along with conventional treatments and the combination may put them in a life-threatening situation. Some interfere with chemotherapy. Patients aren't always honest with their doctors about their use of alternative medicines. The interaction of medicines whether conventional or alternative is a serious problem.

At the CBS Evening News we will continue to investigate complementary and alternative medicine. We recognize that science is an evolving process.
As journalists we need reliable data to be reliable reporters. Consumers have a right to know about a treatment: does it harm, does it help or is it simply a waste of money?

Testimony to
The White House Commission
on Complementary and Alternative Medicine Policy

by Craig Stoltz
Health Section Editor, The Washington Post

March 26, 2001

It is a commonplace among journalists to declare, from the midst of some noisy controversy, that "if people on both sides are complaining about our coverage, we must be doing something right."

I've always found this facile and fatalistic--and, much scarier, as evidence that some journalists don't realize it's possible to antagonize people in two opposing camps and still be dreadfully wrong.

Still, we at The Washington Post Health section do indeed find ourselves taking heat for our coverage of CAM from "both sides," which is to say, from supporters of complementary and alternative medicine on the one hand and advocates of mainstream practice on the other. I've come to regard this crossfire as evidence of nothing more (or less) than the fact that we've found ourselves on the battlefield of a culture war where the stakes--individual lives, the public imagination, a view of commerce, the future of science, the meaning of history, technology or humanity, and, not least, money--are extremely high.

It's a battlefield we entered on purpose. When I became editor of thesection in January of 2000 I sat down and looked for places where our coverage wasn't meeting readers' needs and interests. CAM was first andmost important topic area on that list. It was clear that our readers were far ahead of us in terms of using dietary supplements and herbs, visiting alternative practitioners, finding non-mainstream complements to their doctors' orders or pursuing wellness and preventive campaigns never mentioned by their private physicians. It was time we engaged this area of health fully, via the application of our established tools and techniques: multiple-source reporting, skeptical questioning, ideologically neutral analysis and an essential mission of serving the public rather than any institution or special interest.

Here's what we've done.

1. We replaced a weekly question-and-answer column written by a mainstream physician with a feature called Treatment of Choice. Each week we take a common, non-life-threatening condition and explain the treatments likely to be offered by both conventional doctors and by alternative practitioners. We try to devote an equal amount of space to each and indicate how much scientific support lies behind each. Though an interesting argument can be made that this binary formula mitigates against an integrative approach, we find that most householders perceive these two distinct paths and want to know about each. We chose to assign a pair of reporters write the reports rather than having experts write the pieces, in order to keep our reports

broad-based and free of any one practitioner's judgment or limitations. I don't think a week has gone by when we or our reporters haven't been accused of some horrendous bias, oversight, simplification, dismissal, gullibility or servitude to either (1) the dangerous, morally bankrupt, money-grubbing academic-medical-pharmaceutical-insurance complex, or the (2) dangerous, morally bankrupt, money-grubbing dietary supplement-pseudoscience-herbalist-antiestablishment cabal. These charges, I should say, have come almost exclusively from people who are fighting the larger cultural war and who feel their army had been ill-served.

2. We introduced a new feature called Findings of Fact, in which we examine the quality and quantity of science behind some product, claim or treatment our readers are likely to have become familiar with. Many topics we've taken on--magnets, various herbs and dietary supplements, prayer, etc. are drawn from alternative practice. When we drill all the way down to the bedrock upon which these treatments are based, we generally have found an intriguing but inconclusive body of research, and a small possibility of danger. In the marketing of these treatments we often have found overbroad inferences, generous interpretations of limited data, suspicious omissions of fact and, sometimes, acts of outright deception. All of this we have reported to our readers as plainly and dispassionately as we can. Like Treatment of Choice, Findings of Fact often upsets the cultural warriors, who feel we have exaggerated or ignored some vital fact or perspective.

3. To bring order to our reporting of medical research into both conventional and alternative treatments, we present highly formatted, boiled-down reports published in peer-reviewed scientific journals. We choose reports of sufficient quality and rigor that a reader may be advised to consider, in consultation with medical professionals, a change in their behavior or treatment. This editorial discipline ensures we don't highlight animal or test tube work, even when those studies make good copy, or narrow studies from which a broad interpretation is not responsible. For every study we list the important caveats, including information about the study's funding. Quick Study is one of our section's most widely praised features.

By introducing these new types of stories into the Health section, we've created mechanisms to ensure we deliver regular reports on CAM and related topics. It has been fascinating and successful, but often punishing. Internally, there has been great trepidation, and some open hostility, to these efforts. Cultural warriors on both sides send us long, passionate letters, often accompanied by annotated versions of what we've written, illuminating our purported errors, biases and weak-mindedness. Along the way we have indeed made mistakes, both in fact and in judgment.

To do this work we have had to develop an entirely new set of sources to help us navigate the world of CAM, and have discovered in both human experts and published data the expected variations in quality, dependability, bias and intellectual honesty. Economic interests are both hidden and obvious, just as they are in conventional medicine. Sophisticated operations controlled by entrenched institutions try to manipulate our coverage. Scholars who protest intellectual independence are revealed to have long devotion to proving or disproving the very thing they are studying. When reporting on a conventional treatment for a well-known

condition, we start with a sense for who to turn to and who to trust. When reporting on alternative approaches, by contrast, the territory is not well marked and many land mines are still hidden. Any journalist's CAM source list is very much a work in progress.

I'd like to believe that this task we've taken on is as easy as some people, particularly those on the conservative side of medical practice, suggest: That we should simply hold "alternative" treatments to the same standards expected of "conventional" ones--that until something is proven safe and effective by repeated gold-standard science, it's quackery and beneath the dignity of The Washington Post or a well-educated public to accept. I suspect everybody in this room realizes the fallacy in this sort of thinking--due to the sobering fact that so little conventional medical practice is based on first-rate science, whether the topic is the appropriate amount of sodium in the diet or the efficacy of various treatments for prostate cancer. If we wrote only about treatments that passed over the highest gold-standard bar--including complete financial, professional and ideological independence--I'm afraid we wouldn't have much to fill our pages with, from either conventional or alternative sources.

In the end, we find ourselves in the position of standing between a demanding public seeking information about something they have equal parts fear and hype, and a field of battle that's noisy, contentious, unsettled, in flux and colored by the fog of war. In short, it's the kind of place journalists often find themselves. We like to think that, when things get hairy, we need only to remember that readers trust us for reports about CAM and conventional medicine that are accurate, well-informed and free of commercial interest or other bias. If we deliver that, we'll have earned our readers' faith, and--call me an idealist--maybe served the resolve the greater war too.

Looking back at our efforts in the past year, I'm struck by this: Most of the complaints we've received about our coverage of CAM, while often constructive and educational, have come from people who are deeply invested the cultural war between alternative and conventional approaches. Our readers, by contrast, have little investment in the war and have mostly been grateful and enthusiastic about our reporting.

I'm tempted to say it: We must be doing something right.

# Nutrition, CAM and Wellness: Achieving Optimal Functioning

Mark A. Hyman M.D.
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**Overview**

1. Health Promotion vs. Disease Prevention and Treatment. The acute care model is not effective for chronic illness.
2. Nutritional Intelligence is a key element of health creation.
3. What are the educational, research and public policy imperatives that derive from this necessary shift from a disease focused health care system to a health-based model?

## The Nature of Health Promotion vs. Disease Prevention and Treatment

Consider this for a moment. How many of us were born with an operating manual strapped to our thigh, an instruction book for the care and well being of our bodies and souls? How many of us know what will make our bodies function optimally, what will give us energy, vitality and longevity? How many of us know what will make us thrive based on our gender, race or age? How many of us truly know what elements of our behavior, habits, diet, exercise, social relationships or spiritual beliefs impede or support our health?

The attainment of this knowledge for each individual is the promise of the revolution in medicine. The revolution spreads through the halls of the laboratory, the hospital wards, the clinic and a new generation of health centers and health resorts. In the pages of our medical journals a new story is being told. The body is one wholly functioning organism. To thrive it must receive the basic elements that give life – essential amino acids, essential fatty acids, specific carbohydrates, fiber, vitamins, minerals, accessory or conditionally essential nutrients, physical and intellectual activity, air, water, light, love, touch and rhythm. Those things that impede our vitality must be identified – anti-nutrients (trans fats, refined sugars, unnecessary food additives, hormones, antibiotic and petrochemical and endocrine disrupting residues in our food supply), inactivity, excessive stress, environmental toxins, infections, isolation, lack of community and more.

revolution, the consumer demand for a new kind of care, and over burdened physicians must give way to a new road map, a compass for navigating the task ahead of us.

My perspective emerges from five years of intensive work and study, testing and treatment within a unique setting -- a health resort. It is a place where people come to promote health and wellness, to work with over 60 health care practitioners – doctors, nurses, nutritionists, exercise physiologists, physical therapists, behavioral therapists, movement therapists, practitioners of homeopathy, traditional Chinese medicine and Aryuveda. Those practitioners interface with hundreds of massage therapists, yoga teachers, qi gong and tai qi teachers, fitness trainers and others. Over 50,000 people per year come through our doors to seek what should be available to a larger population. One quarter of Americans now seek treatment at spas. This is a consumer driven revolution.

Three forces of change in our healthcare system were identified in Price Waterhouse Coopers Report Healthcast: 2010. The first force is the consumer driven shift in demand for a new type of health care and health care delivery system. The second force is the electronic spread of health information and the third is the revolution in genomics and biotechnology that will shift the healthcare system from cure to prevention.

How must we deal with the human and economic burden of nearly 100 million chronically ill people when our health care system is focused on the acutely ill? A recent JAMA article reviewed the status of US Health. "Of 13 countries in a recent comparison, the United States ranks an average of 12$^{th}$ (second from the bottom) for 16 available health indicators." The application of an acute care model to chronic illness creates an enormous burden of suffering (accounting for 225,000 deaths per year or the third leading cause of death after heart disease and cancer) and an economic disaster of $77 billion in extra costs from the adverse effects of outpatient care alone. (JAMA, 2000;284). We are must ask why. We must shift from simply treating disease, to defining, measuring and creating health. (JAMA, 1999;281:1030-1033). We in fact must shift away from the transitional distinctions between complementary, alternative and allopathic medicine to just plain good patient-centered medicine. As William Osler instructed us, "it is more important to know the person who has the disease, than the disease that the person has."

EO Wilson, the Harvard sociobiologist, describes a new ground for the evolution of human knowledge based on "Consilience: The Unity of Knowledge". He outlines the progress from reductionism to synthesis in all disciplines, from the sciences to the humanities. Emerging from the advances in molecular biology, nutritional biochemistry, genomics and proteomics is a new vision – it is the body's little instruction book. It defines health, not disease. A model based on health will supplant the model of health care based on diseases.

# Nutritional Intelligence
# Optimizing Functioning/Fitting into your Genes

Our public policy and government regulations must reflect "Nutritional Intelligence", a concept that has grown from our work at Canyon Ranch and was given birth by Kathie Swift, our nutrition director.

A local Berkshire educational center, a local school for children who are wards of the state has a clear written nutrition policy. Children less than 12 can have a cheeseburger, small fries and a small coke, and children over 12 can have two cheeseburgers, a large fries and a large coke. We wouldn't feed French fries to our dog. Why do we feed them to our children? The top two vegetables eaten by children are French fries and ketchup.

The USDA reported that the top nine foods eaten by Americans are:

1. Whole cow's milk
2. 2% milk
3. Processed American Cheese
4. White bread
5. White flour
6. White rolls
7. Refined sugar
8. Colas
9. Ground beef

Nutrition is a key foundation for health creation. Conversely, over consumptive under nutrition can cause severe disturbances to our health and accounts for the most of the morbidity and mortality in this country. Food must no longer be seen as simply calories to fuel the body, but information and instructions for the body to achieve health or to promote imbalance and disease. The genomic revolution is converging with the advances in nutrition to disclose the power of nutrient gene interactions. The Pima Indians of Arizona, extensively researched by the NIH, illustrate the power of nutrient-gene interactions in determining health. In one generation they have been transformed from a fit, vibrant, adapted community of desert dwellers to one of the most obese populations on the planet with a rate of diabetes of nearly 80% and a life expectancy of 46. Shifts away from essential fatty acid consumption toward trans fats, and the abundance of refined sugars and a cessation of their physically active life produced the gene expression phenotype of insulin resistance. Nutrition – amino acids, peptides, essential fatty acids, fiber rich carbohydrates, phytonutrients dense foods, vitamins, mineral and accessory nutrients – play a critical role in cell signal regulation, enzyme function, gene transcription, and post-translational modification of gene products --- all critical steps in creating the dynamic balance of physiology and biochemistry that support health.

From the small microcosm of our health care center, I have witnessed the power of nutrition to reverse diabetes, create sustainable weight loss, arrest or relieve chronic

inflammatory diseases including, arthritis, chronic allergy, sinusitis, eczema, food allergy and recurrent infections, reverse lipid disorders, improve cognitive function, relieve depression and anxiety, improve hormonal chaos experienced by women as PMS and menopausal symptoms, end decades of bowel dysfunction from IBS, and dramatically improve fibromyalgia and chronic fatigue. Even in the absence of disease nutrition has the power to improve vitality, function, energy and longevity when combined with improvements in lifestyle.

## Implications for Healthcare Policy and Public Health: The Obstacles and the Imperatives

### The Obstacles

What are the political, personal, economic and social obstacles to implement the scientific advances of the last half-century connecting nutrition and health? Just as Eisenhower in his final days implored, "beware the military industrial complex", I suggest that the "medical-industrial complex" dangerously impacts our health. It is a loosely defined force of commercial food producers, fast food purveyors, pharmaceutical corporations, health care institutions and the media that unwittingly (or perhaps consciously), contribute to hundreds of thousands of premature deaths and billion's of dollars of preventable health care expenditures. Dr. Willet "estimates conservatively that 30,000 premature deaths per year in the United States are attributable to consumption of trans fatty acids. Because there are no known nutritional benefits of trans fatty acids and clear adverse metabolic consequences exist, prudent public policy would dictate that their consumption be minimized and that information on trans fatty acid content of foods be available to consumers." Am J Clin Nutr 1997;66(suppl):1006S-10S. The obesity and diabetes epidemic is perfectly correlated to the increased consumption of refined sugars that are freely available. The average boy has 36 teaspoons of sugar per day, the average girl 24. The average American consumes half a pound of sugar per day, or 150 pounds per year. The science exists to support labeling our food supply with health warnings, just as we label cigarettes. The economic forces impeding the clear flow of knowledge and science are larger than the tobacco lobby.

In addition to the "medical-industrial complex", a natural resistance to change exists within the medical community. An entire shift in medical education, practice and belief is needed to shift from a disease based model, to a health based model, from the pharmacologic management of disease to methods that uncover the underlying cause of illness and support the body's optimal function and enhance the healing system. How do we encourage practitioners to implement advances in science such as nutritional modulation of cytokines? A recent review in the New England Journal of Medicine highlighted key elements of this approach. The strategy of creating cytokine balance emphasized preventing gut derived endotoxemia, inhibiting TNF alpha activity, inhibiting inflammation, decreasing the production of reactive oxygen species; reduction of liver lipids and improving insulin sensitivity supported the use of "probiotics", herbs, vitamins, "prodrugs" to boost glutathione. (NEJM 2000: 343; 1467-1476) The food we

eat, the substances we ingest, and the phytonutrients and other "pro" substances available to the practitioner today can affect these processes and are supported by peer-reviewed research. There are 500,000 references in the NIH database on dietary supplements. The science of medicine must become the practice of medicine, what we know must become what we do.

The limitations of randomized controlled trials to answer the questions posed by chronic illness have recently come to the forefront. (NEJM). We cannot create a patient centered research agenda as long we focus solely on disease. We must look collectively at the strategies for measuring, and creating new tools to measure the deviations from health, the imbalances and disturbances in physiological and molecular function, and the distortions of cell signaling that precede clinical illness. The single drug, single disease model does not speak to the complexity of biologic function that creates health.

We must consider "prodrugs" rather than "anti-drugs" and study how they can be used to restore normal function in the key systems of the body. For example, insulin sensitivity can be modified by the new class of drugs, the thiozolidinediones, that act on a nuclear receptor (PPAR alpha and gamma) and affect gene transcription. Insulin sensitivity can instead be regulated by nutritional modulation. Trans fatty acids act as analog inhibitors of PPAR, while conjugated linoleic acid (CLA) and the omega three fatty acids EPA and DHA as well as antioxidants act as PPAR agonists. Cell membrane physiology and insulin receptor conformation is also directly affected by the essential fatty acids that form the phoshoplipid cell membrane, as well as specific nutrients including vitamin E, alpha lipoic acid and vanadium. Creatine increases GLUT4 receptors and improves glucose metabolism. Dietary fiber and slowly digested starches modulate intestinal glucose uptake and reduce peripheral insulin production. Strength training and aerobic conditioning also improve insulin sensitivity. From this brief and incomplete description of the effect of diet, exercise, nutrients, essential fatty acids and "prodrugs", it is clear that globally enhancing function can be collectively more potent pharmacologic therapy. It is estimated that 50% of hypertensive patients have insulin resistance as the causative factor. Certain classes of anti-hypertensives (beta- blockers) actually exacerbate the underlying pathology while lowering blood pressure (NEJM). The impediments to integration of this model in health care delivery include insufficient or inappropriate allocation of resources for education of practitioners and the public. Compounding this lack of education is the frequent misrepresentation or misinterpretation of medical information by the media and the influence of marketing by the pharmaceutical and food industries. (NEJM)

## Implications for Healthcare Policy

### Education of Practitioners

New and innovative strategies must be developed that grow from a cohesive understanding of health, from a synthesis born from many disciplines and fields integrated into a fuller understanding of optimal functioning. The goal of these strategies must be to equip the practitioner, the patient and the media with accurate and clear knowledge of how to care for the human body, how to enhance the web of life to maximize health and vitality.

The educational imperatives before us include the development of a focused medical school and postgraduate curriculum on nutritional and lifestyle management of chronic illness and the creation of health. This must include the principles forming a new theoretical foundation for medical care outlined in the paper by Dr. Jeffrey Bland. These emerging principles include 1) biochemical individuality based on genetic and environmental uniqueness or functional genomics, 2) a patient-centered versus disease centered model, 3) an understanding of the dynamic interaction between the internal and external environment, 4) the complex relationships and connections among physiologic factors and 5) health as positive vitality, not merely the absence of disease.

Specific modules are needed on intake and assessment from a patient centered perspective to elucidate the antecedents, triggers, mediators and effects of illness. The teaching modules must include new laboratory diagnostic and functional measurements of health and imbalance focused on early intervention, non-pharmacological management of illness, use of pro-therapies including nutrition, dietary supplements, herbal therapies, exercise, stress management and environmental therapies. These educational imperatives must filter down to all the allied health professions to prevent a patchwork quilt of complementary therapies that have no cohesive framework for practice.

**Education of Children**

Three of the most important things in life we do not learn in school: the care of our children, and relationships, the care of our finances, and the care of our bodies. Public schools provide the foundation for future life skills – this should include the way to properly feed, nourish and enhance the body and the mind throughout life, how to prevent future illness that we now know begins in childhood such as heart disease, cancer and osteoporosis. Schools can give the children we entrust to them the operating manual for their bodies.

**Education of the Public**

Public health campaigns are required to highlight "Nutritional Intelligence" and to dispel myths and misconceptions about nutrition and health. Use of the media, television, Internet, the enrollment of modern sports and entertainment icons in the task of public education is crucial. We grew up believing that eggs cause heart disease, milk is nature's perfect food, and margarine is better than butter. How long did it take for the government to recognize the dangers of smoking and adequately label cigarettes? Perhaps the bag of potato chips, or a dish of French fries, or a can of cola should have a warning label: "this product contains trans fats and sugars that can cause obesity, coronary artery disease, cancer and premature death." How many decades was it clear that folate was critical to prevent heart disease, neural tube defects and cancer before public policy mandated its

**White House Commission on Complementary and Alternative Medicine Policy**

**Testimony**
**March 26, 2001**

**Dale A. Ogar, Managing Editor**
**University of California, Berkeley Wellness Letter**

I want to thank the members of this Commission for inviting me to join you in this discussion of complementary and alternative medicine. In order to examine the way in which we, at the University of California, Berkeley Wellness Letter examine, analyze and disseminate information, it helps to know a little bit about the way this publication came into existence and what we see as our primary role in educating the American public about matters which concern health promotion and disease prevention.

The Wellness Letter was launched as a collaborative effort between a New York publisher, Rodney Friedman, a marketing expert, Richard Benson and the School of Public Health at the University of California, Berkeley. Editorial control of all content was vested in the faculty of the School and specific responsibility for the scientific accuracy was assumed by Sheldon Margen, M.D, then Professor of Public Health Nutrition and Joyce Lashof, M.D., then Dean of the School of Public Health.

The first issue of the Wellness Letter appeared in October 1984. Now in our 16th year, the principles of accuracy and integrity still the guide everything

we produce. The Wellness Letter, which is published monthly, covers a wide range of topics. We try to balance every issue with articles on nutrition, exercise, general wellness, stress management, safety and a number of short facts and tips. More and more over the last several years, we have also included at least one article per month on some aspect of complementary and alternative medicine (CAM), including nutritional supplementation.

As the "business" of CAM and particularly nutritional supplementation has grown, so has the interest - one could almost say obsession - of the American people with finding the magic bullet, or the one-stop solution that many of these therapies promise. There is absolutely no shortage of available information in the area of CAM. However, to a large extent, the quality and reliability of that information is every bit as questionable as the quality, reliability and safety of many of the products and therapies themselves. Traditionally, the general public has received most of its information on health and medical care issues from daily newspapers, magazines, television, radio and now, increasingly the internet. At one time there were more than 25,000 websites on these subjects and the number is probably still growing.

The advent of publications such as ours, which are driven, not by advertising revenue or the sale of products and services, but by subscriber support, and which do not have to produce eye-catching headlines on a daily basis, has allowed for the creation of places in which the mountain of

information available can be sorted, analyzed, evaluated and then shrunk down to a manageable size.

Our goal has been to provide the public with an independent, reliable summary of available scientific information regarding CAM. Our selection process for what articles to write begins with what we read and see elsewhere and then is reinforced by questions from our readers. By staying current on what is being promoted and what kinds of confusing information our readers are receiving from other sources, we are able to help them navigate through the murky waters of all health information and particularly CAM.

When we begin the process of writing an article, we search the literature as completely as possible to find both the science-based and non-science based reports. We look at the studies that showed positive results and the ones that showed negative results. We examine the methodology and the statistical procedures used and, if necessary, go directly to the author(s) for clarification of any unreported data. All supporting material is carefully analyzed before it is distilled into an article.

We also try to encourage our readers to be careful consumers by educating them about the meaning of what they read or hear in the media. We periodically publish guidelines to help them understand the language of science. What are clinical intervention trials? What are epidemiological studies? What is a case control study? What is a cohort study? What words indicate certainty or uncertainty? "May" does not mean "will" "Breakthroughs" don't really happen

very often. "Contributes to" does not mean "causes". A single study is no reason to buy anything or change health habits. Don't make decisions by listening only to somebody who has a pocket full of pills to sell you.

We have, historically, been very cautious in recommending any alternative therapies or nutritional supplementation that had not been subjected to rigorous scientific testing to demonstrate efficacy and safety. The Wellness Letter is produced by the University of California, Berkeley without the use of any state funding, but our position as a major public university obligates us to educate without bias and to reach out into the larger community by providing reliable and helpful information.

In covering the area of CAM, we have focused largely on the nutritional supplements because, with the passage of DSHEA in 1994, the marketplace became flooded with products which promised a great deal but had nothing more than advertising hype and anecdotal reports with which to back up those promises. While simply separating people from their hard earned money for no discernible benefit is at worst fraudulent and at best unethical, the bigger issue for us is one of safety.

By having an unregulated industry like this grow at such an astonishing rate, Americans have become participants in a huge social and biological experiment for which they were never asked to give informed consent. The products which are hyped to consumers need not be tested for efficacy, for safety, or for interactions with conventional drugs. And unfortunately, in the

case of many products there is no standardization of ingredients. The promises are unbelievable, yet oh so tempting.

We believe that our role in all of this is to take a careful look at whatever science-based evidence is available and determine whether these products (assuming they contain what they say they contain) have any likelihood of doing what they are supposed to do and, more importantly, whether they are likely to be dangerous.

In response to overwhelming interest in the subject, in August of 1998 we published what we referred to as the "Supplement Supplement" which listed and discussed several of the most commonly used nutritional supplements. Since that time the Wellness Letter has contained dozens of articles on various therapies and supplements. When we put up our website in April of last year, we included, as a service to our readers, an updated version of that information and we have continued to build that resource on our website. In your briefing books you will find a print out of the most recent version. You will also find a copy of the Wellness Letter from September, 1997, in which we led off with our first article on St. John's Wort and included a two-page special report on herbal medicines. This special report summarizes our concerns about herbs and the larger field of CAM.

In reading the outline of what was to be covered in this testimony, I see a question regarding the barriers people have to accessing CAM information. We believe that there are no barriers to accessing information – only accessing

reliable information. People need to be able to find the places, like the Wellness Letter, that will weed out snake oil and present balanced and accurate information. Perhaps, if some highly credible organization produced a widely publicized directory of such sources, this would help people make better and more informed choices.

While, the dissemination of better information and warnings to the American public are extremely important, we also believe that there are some legislative and regulatory actions which are essential if we are ever to control the proliferation of unsubstantiated claims and unregulated products and procedures. Two of our recommendations could be implemented in the near term.

- **Enforce existing rules covering claims made on labels and claims made in other advertising. Make adequate resources available to FDA and FTC to enforce claims that are currently being made.**

- **Require FDA to finalize the Current Good Manufacturing Practices which should include quality control, standardization and accurate labeling.**

Two others will require more time and substantial effort to accomplish:

- **Repeal or amend DSHEA to give FDA the power to regulate nutritional supplements as they now do OTC drugs and thus require scientific proof of efficacy and safety.**

- **Require mixtures of herbs or other "natural products" to present new proof of safety for every combination of ingredients to insure that there is no adverse interaction between the ingredients.**

The field of CAM has the potential to produce positive health outcomes under certain circumstances. However, it also has the already realized potential to do great harm, as the list of supplement-related deaths continues to grow. We call for research by the scientists, restraint by the sellers, regulation by the government and caution by the consumers to make sure that in the end we heed the warning of Hippocrates and first, do no harm.

Thank you very much.

## JOEL R. NEEL

JOE R. NEEL has reported on medicine and health for 20 years. Since 1995, he has served as Deputy Science Editor and Health Correspondent for National Public Radio. In these roles, he reports on numerous issues affecting health care and oversees coverage of medical and health policy issues for *Morning Edition, All Things Considered, Weekend Edition* and *Talk of the Nation.* Prior to joining NPR, Mr. Neel reported for *Physician's Weekly, Medical News Network,* International Medical News Group and *Modern Medicine*. He did graduate work in neurophysiology at Washington University School of Medicine and received bachelor's degrees in biology and German literature and language from Washington University in St. Louis.