concerns and fears. This is also why more people go on the web to look for information on health and disease than any other reason. Patients may often feel as if they have little choice, or say in their treatment. If they have cancer, they get a standard regime of surgery, chemo, and/or radiation. Rightfully, many patients are fearful of these procedures and have many questions about them that aren't always addressed within the current system. Herbal medicine and the choice of CAM therapies are often personal, discussed with friends and family, and allow for many more choices and much more personal control.
The issue of privacy is also relevant. Today, personal health information is often sold or sent to insurance companies, financial institutions, and made more or less public. This can create anxiety, a sense of powerlessness, and may influence insurers (Gostin and Hodge, 2000). Herbal remedies and other CAM modalities are available from practitioners who do not commonly share their records with insurance companies and others. In my acupuncture and herb practice in California, I was not required to share personal health histories, except for workman's compensation cases, and was able to respect the wishes of my patients regarding privacy.

2. Relative to the clinical effectiveness of herbs/botanical therapies, please summarize data regarding the following measures:

   - Specific health conditions

   Herbal medicine is appropriate for all kinds of health conditions, even pre- and post-surgery. Herbs often work to activate the body's own natural healing response (Wagner, 1999), through diverse pathways. The concept of "adaptogens" or "biological response modifiers" is evident throughout the history of herbalism and has been widely studied scientifically. These are mainly herbal substances that normalize the body's responses to all kinds of stress, reducing the overall impact on health (Wagner et al, 1994).
   A complete review of the literature concerning specific health conditions would take months and require hundreds of pages of text. My working group has been searching the literature and writing reviews for the last 14 months, funded by the consumer health division of a large pharmaceutical and chemical company. We are reviewing 100 top herbs, using standard MESH (medical subject headings) terminology. We have searched over 25 global electronic databases, and gathered over 50,000 references from a number of countries, translating documents when necessary. So far we have amassed over 2,000 pages of review text, which includes all biological effects, chemistry, clinical trials, side effects, contraindications, and interactions. This work will become available online within the next year.
   Many new works are already in print that review the efficacy and safety of herbs, though none of them to my knowledge critically review the literature. Several online sites do provide some critical reviews of herbs. Some of the better ones include www.tnp.com, www.factsandcomparisons.com, and www.thenaturaldatabase.com.
   Approximately 25-50 herbs have enough modern science to make a case for scientific support of efficacy and safety. Of these, only a handful, perhaps less than 10, have enough positive science to strongly support efficacy and safety. At the top of the list is *Hypericum*, St. John's wort. Although well-controlled studies are insufficient on most herbs to really satisfy a high-level medical researcher or research-oriented physician, the

fact that at least one herb could hold up under such modern scientific scrutiny indicates that this might be the case for other herbs as well.
As I've previously stated, just because an herb hasn't been proven scientifically to this extent doesn't mean that it isn't effective or safe--it may mean it hasn't been studied, or studied in the correct way. Herbs are not monosubstances and tend to work more slowly than drugs, and on many more pathways. For instance, new COX-2 inhibitors work only on one route the body uses to create inflammation and pain. A common herb like ginger works not only on the cyclooxygenase (COX) pathway, but also affects lipoxygenase and prostaglandins, two other pathways involved with the inflammatory response. Herbs sometimes work more slowly, but often these diverse effects mean less side effects and a more balanced reduction of inflammation and pain.

- Populations (age, sex, occupation, etc)

Herbal medicine is appropriate for all ages. For over 30 years I have observed safe administration of herbs and herbal products for infants, children of all ages, adults, and the elderly. Although no responsible herbalist would say that all herbs are safe just because they are natural, herbs, as a general rule, are as safe as many foods, *when used wisely*. This is where community education comes in. Community members should know when to use herbal teas and other remedies, and when to go to a physician. For colic in an infant, mild chamomile tea is perfectly safe and acceptable. If the condition persists or becomes worse, then medical advice should be sought.

- Practice setting, including whether herbs/botanical therapies only, or in conjunction with conventional medicine

Herbalists should be working directly with doctors. Most doctors are trained only in disease management and pathology--what can go wrong with the body. This knowledge is essential, for pathology will always exist, even when healthy habits are consistently practiced. Herbalists are trained in what can go right with the body, they are "health practitioners." A well-trained herbalist will be knowledgeable in the psychology of disease and health. They will encourage the patient to believe in their own innate healing abilities, and they will recommend diet and gentle herbal remedies that help assist this process. A deep knowledge of both health and disease is needed in today's society. Prevention, health education, and empowerment of the individual to value their health more profoundly will all save our society immeasurable suffering and costs.

- Type of Practitioner

Many types of practitioners and others can and do recommend and administer herbal remedies to people and patients, including medical doctors, naturopathic physicians, chiropractors, licensed acupuncturists, midwives, retail supplement department workers, and lay herbalists. The California acupuncture law specifically states that any person has the right to recommend dietary supplements and herbs to others, even if they are not licensed. By definition, only herbalists receive extensive training in the traditions and safe and effective use of herbal remedies. That is not to say that other kinds of

practitioners cannot safely and effectively recommend herbal remedies if they receive proper training. However, all too often today, health care practitioners read that ginkgo is good for circulation and memory, St. John's wort for depression, and saw palmetto for prostatic hyperplasia, without having the training to know how to *effectively* administer or recommend these products. They often have no training in holistic diagnosis, matching the safest and most effective herbal remedy specifically to a patient. This training, like other professional knowledge, requires years of study and experience to master. Because no standards and definitions exist for "herbalist," anyone can advertise themselves thus. Although traditional and lay herbalists are often adamantly opposed to regulations and licensure, fearing loss of freedom in their practice, I believe that some standards in education, training, apprenticeship, and practice for a class of "phytotherapists" (more science-based herbalists), as well as "community herbalists" (lay herbalists with high-quality training in the traditions of herbalism), is warranted. Consider that "Herbalist" is not a recognized or known profession in the U.S. This is not a profession that has any legal protection under the law. Some herbalists fear that only scientific herbalists will eventually be allowed to practice. While science-based herbalists, myself included, feel that a knowledge of modern medical practice such as pathology, anatomy, physiology, biochemistry, and pharmacology of commonly-prescribed drugs, is completely appropriate, even necessary for today's integration of CAM and modern medicine. I envision herbalists working together with physicians in hospitals and clinics.

However, I would like to go on record as stating unequivocally that lay herbalism, community herbalism, should not be interfered with. Community herbalism is growing rapidly in the U.S. I estimate that several hundred lay herbalists are trained in the U.S. every year, and this figure is growing all around North America, and really, all over the world. Community herbalism embraces the idea that a knowledge of local plants, cultivation of common herbs in gardens, and teaching community members how to take care of their health and to use simple and safe herbal remedies is valuable to the community and will spare suffering and reduce health care costs both locally, and ultimately, nationally. Community herbalists should have a more intimate knowledge of the health problems and tendencies of their local community members. They should still form working relationships with local physicians, if available. Community herbalists should still receive some training to help them discern when to refer to a physician. They should clearly know their limitations.

3. Describe the cost-effectiveness of herbs/botanical therapies provided as a stand-alone therapy with herbs/botanical therapies that is provided in conjunction with conventional medicine as part of an integrative approach.

Again, these studies and figures simply aren't available at present. My experience of over 30 years tells me that herbal medicine is entirely appropriate for use with drugs and conventional care. Herbal remedies can help reduce side effects of chemotherapy for instance. Ginger tea can help reduce nausea as a simple example. We simply need to learn how herbs interact with drugs and how best to apply them. At present, nearly 1/3 of Americans use herbal medicine. Of these, about ¼ also use prescription drugs. This amounts to about 25 million people or so. So far, despite many theories and numerous review articles

in the literature, only a few actual herb-drug interactions of any relevance have been reported. Still, we have much to learn in this arena.
Herbal medicine is also appropriate as a stand-alone modality for many everyday health problems that are self-limiting, like the common cold, as well as many chronic health problems where modern medicine has little to offer, such as chronic fatigue syndrome. The cost-effectiveness of herbal medicine as a stand-alone modality, or combined with conventional care, can be judged only in the context of a group's belief system. Ultimately, medicine is completely in harmony with the dominant paradigm of the society in which it exists. More people today are accepting the benefits of herbal medicine. I have detailed these above. I believe the most important aspect of herbal medicine, besides its long safety record (again, not just because it's "natural"), is the personal feeling of empowerment and freedom of choice that herbal medicine brings. When one goes to the doctor, the system is set up so that one is immediately whisked into a series of tests, procedures, operations, and drug therapy. These therapies and procedures are often quite fixed. Herbal medicine gives a person hope, which often leads to enhanced immune function and self-repair, because the individual, not the system, makes the choices. Many choices exist, many herbs and styles of herbalism, hydrotherapy, body work, deep breathing, yoga, meditation, diet disciplines, and faiths.

4. Compare the costs of herbs/botanical therapies with those of conventional medicine for the same or similar health conditions.

I would love to quote well-designed studies, but again, where are they? Only a few have been published, and these are far from definitive (White and Ernst, 2000). One study did find that patients who received acupuncture and self-care education were well-served and that these modalities were "cost beneficial in patients with advanced angina pectoris" (Ballegaard et al, 1999). The estimated cost savings was $32,000 per patient over a 5 year period, due mainly to a 90% reduction in hospitalization and a 70% reduction in surgery.

Cost-effectiveness of herbal therapies compared with drugs for specific ailments really depends on the practitioner. Some CAM practitioners I have come in contact with tend to load patients up with armloads of supplements and herbal products. One of their motivations in this might be profit, or simply a belief that if enough herbs and nutritional supplements are given, the desired effect is more likely to happen. Many community herbalists I know try to save their neighbors and clients money by encouraging them to grow their own herbs, make simple teas, and save money by eating well and simply, and exercising. These are the two extremes, with many practitioners falling somewhere in between. It is obvious that cost-effectiveness entirely depends on the skill and intentions of the practitioner, and the willingness of the patient to spend the time necessary to establish healthy habits such as exercising daily. Herbal teas are often inexpensive, when compared with standardized herbal extracts in capsules and tablets, but these offer greater convenience, and one usually pays extra for convenience.
My last 10 years of clinical experience shows me that health and healing can be served in most patients with the application of simple herbal remedies taken regularly, combined with health education and encouragement.

However, I will say that herbs and supplements are not always cheaper one to one than conventional drugs themselves (Marx, 1997), but they often are, especially compared with newer drugs still under patent protection. Take St. John's wort (SJW) as an example. If we assume that SJW is as effective as tricyclic and SSRI antidepressants, which current studies show may be true, then we can compare costs of say, Imipramine, or Prozac with the best brands of SJW/month.

- The average cost of a top brand of a standardized SJW product, 300 mg (0.3% hypericin), 3 x a day, is $15 a month. Few side effects are reported by patients, comparable with placebo in over 25 trials. Remember that overall costs are lower, too, because no physician visit is required to access SJW.
- The cost of Paxil is $62, and generic imipramine, $3.70 per month (plus doctor visit), though Tofranil, a branded product is $88 per month (Armstrong, 1997). Side effects of imipramine are reported to be over twice as high as with SJW (Hiller, 1999), and thus costs may be increased because of extra physician consultations and wasted medicine that is not finished because of switching meds.

5. Summarize patient satisfaction data, if available.

Some patient satisfaction data is available, and I can add a further review to this written testimony subsequent to the meeting in Washington if requested.
Ernst (1998) summarized three surveys on patients' attitudes towards CAM and concluded that, "on average, CAM is frequently used by rheumatology patients. The patients' level of satisfaction with CAM is often considerable and few adverse effects are being reported." On this basis he recommends more rigorous investigational studies be performed.
Perhaps the best satisfaction data is the steady growth, and at times, huge increases in sales and acceptance of CAM therapies such as herbal medicine over the last 10, or even 20 years. Not to mention that many of these remedies have been popular for centuries. St. John's wort was first recommended by the Greek physician Dioscorides for mania in the 1st century AD. It's just now that science has explained this use rationally.

6. Describe current significant barriers to the access and delivery of herbs/botanical therapies.

The lack of highly trained herbalists to serve many communities, the need for more high-quality educational and apprenticeship programs, and the natural resistance from competing modalities, products, and services.
Also a lack of understanding and acceptance of herbal medicine by physicians and pharmacists. Good scientific information is beginning to emerge on herbal remedies, and this should change as more science becomes available. Younger doctors are often quite interested in herbal medicine. I count a number of doctors among my students over the years.
Many of my patients are limited by cost. Herbal remedies are not paid for by health insurance in this country. In Germany, herbal remedies are paid for by national insurance. While this may be years away in North America, I believe this will eventually happen.

7. Discuss whether herbs/botanical therapies should be delivered as stand-alone care or should be integrated with more conventional therapies.

Herbal remedies are appropriate for use either as a stand-alone modality or completely integrated with conventional drugs and other therapies. This is the case in China. In 1996 I studied in a hospital of traditional Chinese medicine for a month. Herbal medicine was completely integrated with modern western medical tests and drug treatments. Doctors told me this system worked very well, because some people wanted herbs and believed in them, and some wanted antibiotics and other drugs. The doctor I studied with in internal medicine, Dr. Chen, had seen over 50,000 patients. During my time with him I observed that he would order an endoscopic exam to look for stomach irritation, gastritis, or actual lesions, then would take the patient's pulse, look at the tongue, and prescribe a traditional tea formula to be taken by the cup, twice daily. Whereupon the herbal pharmacy would make the prescription and have it ready for the patient before they left the hospital. If the patient wanted Tagamet or another drug, they had no problem with that. No philosophical, economic, or political conflict was involved. They believed in using whatever worked for the situation and the patient.

8. What should be done to prevent adverse interactions such as botanicals with prescription or OTC drugs, dietary supplements, or foods?

Absolutely the best way to solve this potential problem is to draw on the expertise of both herbalists and doctors working together as a team. Herbalists who are properly trained should have hospital privileges and work in medical clinics, especially as herbal remedies become increasingly popular. Helpful research has already been done. For instance, it is often known what major classes of chemical compounds are in a given herb, and some of their pharmacological actions are known. Some interactions have been observed, for instance in Germany. Hawthorn extract can potentiate the action of digoxin, and this is well-known. Not all herb-drug interactions are bad. In the case of hawthorn and digoxin, hawthorn could potentially reduce the dose of digoxin needed for the desired positive inotropic effect.
Studying the issue is challenging, but possible. The government should take responsibility to initiate and continue studies on the efficacy and safety of herbs, including the potential for herb-drug reactions. Pharmaceutical companies can't be expected to do this research partly because little patent protection is offered.

9. Please suggest specific policy recommendations that would improve the access and delivery of herbs/botanical therapies to consumers, including legislative or regulatory recommendations.

- The legislature should create a "traditional medicines" category, where herbal remedies that have a long and safe history of use and are widely known to be mild in action can include labeling about their traditional use.
- Make government grants available to support community herbalism and preventative health care in communities.

- Encourage educational programs in the schools to promote the importance of health to children, and how to maintain it throughout life. Support gardening projects in the schools where organic foods and herbs are grown. Herbalists promote the importance of taking care of our environment, and this should be emphasized in the schools.
- Support organizations that promote sustainable use of wild herbs like goldenseal and American ginseng which are overharvested in some states. As the popularity of herbs grows, we must pay special attention to conservation of our native medicinal plants. United Plant Savers is such an organization whose mission is just that, preserving native stands of wild medicinal plants by disseminating seeds, small plants, helping individuals to turn their land into "botanical sanctuaries," and through national seminars and classes. www.plantsavers.org.
- Support organizations that promote quality education for herbalists and responsible herbalism. The American Herbalists Guild (AHG), http://www.healthy.net/herbalists/, was founded in 1987, and is the only national organization for professional herbal practitioners. The organization's goals include: encouraging high levels of ethics and integrity in all areas of herbalism, integrating herbalism into community health care, promoting cooperation between herbalists and other health care providers, encompassing traditional wisdom and knowledge as well as current medical models, and developing a professional body that promotes and maintains excellence in herbalism, including individual and planetary health.

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Wagner, H. et al. 1994. Plant adaptogens. *Phytomedicine* 1:63-76.
White, A.R. and E. Ernst. 2000. Economic analysis of complementary medicine: a systematic review. *Complement Ther Med.* 8(2):111-8. (see abstract below)

Supplementary reading

Ashcroft DM; Po AL
Herbal remedies: issues in licensing and economic evaluation.
ABSTRACT:
In recent years, the use of alternative therapies has become widespread. In particular, there has been a resurgence in the public's demand for herbal remedies, despite a lack of high-quality evidence to support the use of many of them. Given the increasing pressures to control healthcare spending in most countries, it is not surprising that attention is being focused on the cost effectiveness of herbal remedies. We address the question of whether there is sufficient information to enable the assessment of the cost effectiveness of herbal remedies. In so doing, we discuss the current state of play with several of the more high-profile alternative herbal remedies [Chinese medicinal herbs for atopic eczema, evening primrose oil, ginkgo biloba, hypericum (St John's wort)] and some which have made the transition from being alternative to being orthodox remedies. We use historical context to discuss, on the one hand, the increasing commodification of herbal remedies and on the other, the trend towards greater regulatory control and licensing of alternative herbal remedies. We argue that unless great care is exercised, these changes are not necessarily in the best interests of patients. In order to identify cost-effective care, we need reliable information about the costs as well as the efficacy and safety of the treatments being assessed. For most alternative therapies, such data are not available. We believe that studies to gather such data are long overdue. Whilst we argue strongly in favour of control of some herbal remedies, we urge caution with the trend towards licensing of all herbal remedies. We argue that the licensing of those herbal remedies with equivocal benefits and few risks, as evidenced by a long history of safe use, increases barriers to entry and increases societal healthcare costs.
SOURCE: Pharmacoeconomics. 1999 Oct;16(4):321-8.

White AR; Ernst E
Economic analysis of complementary medicine: a systematic review.
ABSTRACT:
OBJECTIVE: To review systematically all reports of economic analysis of complementary and alternative medicine. METHOD : Searches were performed in Medline, Embase and AMED for reports of cost description, cost comparison, cost effectiveness, or cost benefit studies. Prospective studies that investigated comparative groups were considered to be of higher quality. RESULTS: A total of 34 reports was included. Retrospective studies in which a range of therapies are provided in primary care suggest that these may reduce referral and treatment costs,

but prospective studies suggest that complementary medicine is an additional expense and does not substitute for orthodox care. For individual therapies, one thorough but retrospective study suggests that carefully targeted acupuncture may reduce referral costs for musculoskeletal problems. One large pragmatic study of spinal manipulative therapy suggests that this treatment may reduce the societal costs of back pain, but four controlled trials found that manipulative therapy does not reduce the costs incurred by the back pain patients themselves or by their health insurance provider. CONCLUSION: Spinal manipulative therapy for back pain may offer cost savings to society, but it does not save money for the purchaser. There is a paucity of rigorous studies that could provide conclusive evidence of differences in costs and outcomes between other complementary therapies and orthodox medicine. The evidence from methodologically flawed studies is contradicted by more rigorous studies, and there is a need for high quality investigations of the costs and benefits of complementary medicine.

SOURCE: Complement Ther Med. 2000 Jun;8(2):111-8.

TITLE: Is alternative medicine more cost-effective?
AUTHORS: Weeks J
LANGUAGES:
Eng
SOURCE: Med Econ. 2000 Mar 20;77(6):139-42.

MED/20005632@@
TITLE: Addition of acupuncture and self-care education in the treatment of patients with severe angina pectoris may be cost beneficial: an open, prospective study.
AUTHORS: Ballegaard S; Johannessen A; Karpatschof B; Nyboe J
LANGUAGES:
Eng
ABSTRACT:
OBJECTIVES: A cost-benefit analysis of acupuncture and self-care education in the treatment of patients with angina pectoris. DESIGN: An open prospective study on an unselected group of patients. For comparison of risk three control groups were used: (1) published data concerning medical and invasive treatments; (2) an age- and sex matched group obtained from a randomly selected Danish population of 14,000 people; and (3) the 211 patients in this group with angina pectoris symptoms. SETTING: The treatment was carried out on a outpatient basis in a private research clinic. SUBJECTS: 105 patients with angina pectoris, 73 candidates for invasive treatment, and 32 for whom this was rejected. INTERVENTIONS: Acupuncture and self-care education was added to the pharmaceutical treatment. OUTCOME MEASURES: Healthcare expenses, a satisfactory medical status defined as New York Heart Association (NYHA) classification 0-I and/or no use of antianginal medication, and risk measured as cardiac death or myocardial infarction. RESULTS: The estimated cost savings during 5 years were $32,000 (U.S.) per patient, mainly due to a 90% reduction in hospitalization and 70% reduction in needed surgery. Compared to 8% before treatment, 53% of the patients achieved a life without limitations (NYHA 0-I) 1 year after treatment, as did 69% after 5 years. No increased risk for myocardial

infarction or cardiac death was observed. CONCLUSIONS: The addition of acupuncture and self-care education was found to be cost beneficial in patients with advanced angina pectoris. The results invite further testing in a randomized controlled trial.

SOURCE: J Altern Complement Med. 1999 Oct;5(5):405-13.

TITLE: A randomized experiment of the effects of including alternative medicine in the mandatory benefit package of health insurance funds in Switzerland.

AUTHORS: Sommer JH; Burgi M; Theiss R

LANGUAGES:

Eng

ABSTRACT:

OBJECTIVES: The present investigation focuses on the following questions: 1. Are complementary medical services paid for by a health insurer used in addition to orthodox medical services, or as substitute for them?; 2. If health insurers include complementary medical services in the basic cover, what will be the effect on costs?; 3. If complementary medical services as included in the basic cover, what will be the effect on the policyholders' subjective state of health? STUDY DESIGN: A randomized experiment was set up in which 7500 members of Switzerland's biggest health insurance fund, Helvetia, were offered free supplementary insurance for alternative medicine for 3 years. This simulated a situation in which the experimental group had access to the full range of complementary medical treatments under their health insurance policies. The remaining members in the scheme (670,000) people) formed the control group. To evaluate the effect on costs, we analysed the health insurer's cost and benefits data. In addition, a survey was carried out among random samples of subjects from the experimental group and from the control group using the 36-Item Short-Form Health Survey (SF-36) to examine the effects of including complementary medicine on subjective state of health. RESULTS: The analysis of the cost data shown that subjects used alternative in addition to orthodox medical services. It is also clear that alternative medical treatments are given in combination with orthodox medicine; less than 1% of the experimental group used exclusively alternative medical services. However, as only a very small percentage of experimental subjects (6.6%) took advantage of complementary medicine, no significant impact on overall health costs can be inferred. On the other hand, multiple regressions show that use of complementary medicine has a greater effect on treatment costs than sex, age or language region. Neither at the beginning nor the end of the experiment were any significant differences noted in the scales of the SF-36 between the experimental and the control group. Nor did multiple regressions reveal any effects on subjects' state of health due to the inclusion of complementary medicine in the basic insurance cover.

SOURCE: Complement Ther Med. 1999 Jun;7(2):54-61.

SECONDARY SOURCE ID:

MED/97203594

TITLE: Cost-benefit of combined use of acupuncture, Shiatsu and lifestyle adjustment for treatment of patients with severe angina

pectoris.
AUTHORS: Ballegaard S; Norrelund S; Smith DF
LANGUAGES:
Eng
ABSTRACT:
Sixty-nine patients with severe angina pectoris were treated with acupuncture, Shiatsu and lifestyle adjustments, and were followed for 2 years. Forty-nine patients were candidates for coronary-artery bypass grafting (CABG), whereas bypass grafting was rejected in the remaining 20 patients. We compared our endpoint findings with those of a large prospective, randomized trial comparing CABG with percutaneous transluminal coronary angioplasty (PTCA). The incidence of death and myocardial infarction was 21% among the patients undergoing CABG, 15% among the patients undergoing PTCA and 7% among our patients. No significant difference was found concerning pain relief between the three groups. Invasive treatment was postponed in 61% of our patients due to clinical improvement, and the annual number of in-hospital days was reduced by 90%, bringing about an estimated economic saving of 12,000 US $ for each of our patients. Despite the fact that the men in the present study, had significantly less positive expectations towards the outcome of the treatment, when compared to the women, there was no significant difference concerning the effect. The study suggests that the combined treatment with acupuncture, Shiatsu and lifestyle adjustment may be highly cost effective for patients with advanced angina products.
SOURCE: Acupunct Electrother Res. 1996 Jul-Dec;21(3-4):187-97.

http://www.naphsis.org/
Balancing Individual
Privacy and Communal
Uses of Health
Information
by Lawrence O. Gostin, J.D. LL.D. (Hon) and
James G. Hodge Jr., J.D. LL.M. 2000.

Introduction
Health records are among the most sensitive data that are acquired, used, and disclosed by government and the private sector. Health information reveals a great deal of personal facts about individuals which may lead to stigma and discrimination when possessed and misused by government officials, employers, insurers, and by friends and family. The increasing potential for disclosure of this information within a rapidly-developing national health information infrastructure, facilitated by massive computerization of records and other technological developments, presents significant risks to individual privacy.

Despite the highly-sensitive nature of individually-identifiable health information,

protecting the privacy and security of these records has been historically de-emphasized when compared with statutory protections allotted to other types of personal information (e.g., banking and investment records, consumer spending information, tax information, and video rental records). There are many reasons for the de-emphasis of health information privacy, including economic and political theories. However, modern legal developments are likely to improve privacy and security protection. As we develop a national health information infrastructure, the importance of privacy and security become crucial.

NLM CIT. ID: 98388539
TITLE: [Use of alternative medicine in oncology patients]
AUTHOR: Grothey A; Duppe J; Hasenburg A; Voigtmann R
AUTHOR AFFILIATION:
Abteilung fur Hamatologie und Onkologie, Universitat von Texas.
PUBLICATION TYPES:
JOURNAL ARTICLE
LANGUAGE:
Ger
REGISTRY NUMBERS:
0 (Minerals)
0 (Vitamins)
ABSTRACT:
BACKGROUND AND OBJECTIVE: Up to 60% of all oncological patients use methods of alternative medicine in the course of their illness. In earlier blinded studies demographic characteristics and the patients' motives of using alternative medicine had been recorded, but a correlation with individual illnesses had not been possible. PATIENTS AND METHODS: 142 patients of a oncological outpatient clinic gave their experience with alternative medicine in interviews and non-blinded questionnaires, 103 of them (72.5%; 46 men and 57 women; median age 58 years, range 18-91 years) returning questionnaires that could be evaluated. RESULTS: 46 patients stated that they had used alternative medicine. There was no difference between users and non-users regarding sex; age, profession, education, family status or religion. 58% of all patients with advanced disease used alternative medicine, compared with only 31% with partial remission or stable disease and 41% in complete remission (P = 0.042). Vitamins and mistletoe preparations were the most commonly used substances (50 and 45%, respectively). The predominant purpose was to stimulate the immune system (77%) and strengthen general physical capacity (64.5%). As main stimulus for using alternative medicine the patients came from their family doctor (56%), followed by family and friends (41%). Alternative medicine was used largely as complementary and not an alternative to conventional medicine. Health insurance met all or some of the costs of alternative treatment in 59% of patients. CONCLUSION: A large number of patients treated with conventional oncological regimens also use alternative medicine, most of them

because of a polypragmatic attitude to tumor treatment. Family doctors and health insurance companies are playing a more important role than had hitherto been assumed in spreading the use of treatment options without providing scientifically based evidence of their efficacy.

SOURCE: Dtsch Med Wochenschr 1998 Jul 31;123(31-32):923-9

NLM CIT. ID: 98305777

TITLE: Different standards for reporting ADRs to herbal remedies and conventional OTC medicines: face-to-face interviews with 515 users of herbal remedies.

AUTHOR: Barnes J; Mills SY; Abbot NC; Willoughby M; Ernst E

AUTHOR AFFILIATION:

Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, UK.

PUBLICATION TYPES:

JOURNAL ARTICLE

LANGUAGE:

Eng

REGISTRY NUMBERS:

0 (Drugs, Non-Prescription)

ABSTRACT:

AIMS: To determine whether adverse drug reactions (ADRs) to herbal remedies would be reported differently from similar ADRs to conventional over-the-counter (OTC) medicines by herbal-remedy users. METHODS: Face-to-face interviews (using a structured questionnaire) with 515 users of herbal remedies were conducted in six pharmacy stores and six healthfood stores in the UK. The questionnaire focused on the likely course of action taken by herbal-remedy users after experiencing an ADR associated with a conventional OTC medicine and a herbal remedy. RESULTS: Following a 'serious' suspected ADR, 156 respondents (30.3%) would consult their GP irrespective of whether the ADR was associated with the use of a herbal remedy or a conventional OTC medicine, whereas 221 respondents (42.9%) would not consult their GP for a serious ADR associated with either type of preparation. One hundred and thirty-four respondents (26.0%) would consult their GP for a serious ADR to a conventional OTC medicine, but not for a similar ADR to a herbal remedy, whereas four respondents (0.8%) would consult their GP for a serious ADR to a herbal remedy, but not for a similar ADR to a conventional OTC medicine. Similar differences were found in attitudes towards reporting 'minor' suspected ADRs. CONCLUSIONS: Consumers of herbal remedies would act differently with regard to reporting an ADR (serious or minor) to their GP depending on whether it was associated with a herbal remedy or a conventional OTC medicine. This has implications for herbal pharmacovigilance, particularly given the increasing use of OTC herbal remedies. The finding that a high proportion of respondents would not consult their GP or pharmacist following ADRs to conventional OTC medicines is also of concern.

SOURCE: Br J Clin Pharmacol 1998 May;45(5):496-500

FDA advisers tied to industry
Sept. 25, 2000

By Dennis Cauchon, USA TODAY
Realted stories

Approval process riddled with conflicts of interest

How the study was done

USA TODAY series on prescription drug costs

More than half of the experts hired to advise the government on the safety and effectiveness of medicine have financial relationships with the pharmaceutical companies that will be helped or hurt by their decisions, a USA TODAY study found.

These experts are hired to advise the Food and Drug Administration on which medicines should be approved for sale, what the warning labels should say and how studies of drugs should be designed.

The experts are supposed to be independent, but USA TODAY found that 54% of the time, they have a direct financial interest in the drug or topic they are asked to evaluate.

These conflicts include helping a pharmaceutical company develop a medicine, then serving on an FDA advisory committee that judges the drug.

The conflicts typically include stock ownership, consulting fees or research grants.

Federal law generally prohibits the FDA from using experts with financial conflicts of interest, but the FDA has waived the restriction more than 800 times since 1998.

These pharmaceutical experts, about 300 on 18 advisory committees, make decisions that affect the health of millions of Americans and billions of dollars in drugs sales. With few exceptions, the FDA follows the committees' advice.

The FDA reveals when financial conflicts exist, but it has kept details secret since 1992, so it is not possible to determine the amount of money or the drug company involved.

A USA TODAY analysis of financial conflicts at 159 FDA advisory committee meetings from Jan. 1, 1998, through last June 30 found:

At 92% of the meetings, at least one member had a financial conflict of interest.

TITLE: Economic evaluation of alternative therapies in migraine - adaption of a Canadian model [abstract]
AUTHORS: Schipp B; Behrens M
LANGUAGES:
Eng
ABSTRACT:
OBJECTIVE/PURPOSE: To develop a cost model for the German migraine market. METHODS: We analyze the basic model assumptions of the original Canadian model and perform an adjusted comparison with the market specifications in Germany. RESULTS: Up to now only one suitable cost-model (Evans et al., 1997,

Pharmacoeconomics, 12, 565-577) has been published. The results of the cost-effectiveness, -utility, and -benefit analyses have demonstrated the costs and consequences of migraine treatment comparing the new serotonin agonist sumatriptan s.c. and oral 100 mg with some of the competitors. A re-consideration of the corresponding decision-tree model and its assumptions was necessary because of the differences in the health-care systems. It yields four main results. One principle modification is related to the prices for the different factors (medicine, physicians, emergency room, in-patient care, wages etc.), raising the costs for the drugs and lowering the price for hospital stays. The second main difference was the introduction of a do-nothing alternative. We thought that a discussion of costs and consequences of migraine therapy is futile without a discussion of the most popular "therapy", namely the one without a sufficient drug. Thirdly we found, that only one competitor, i.e. Cafergot (R), is overserved because all the other pharmaceuticals under consideration in the basic investigation have no market registration in Germany. Finally, we had to omit the cost-utility analysis because of severe methodological problems in the main assumptions made for Canada. CONCLUSIONS: The inter-country adaptation of a cost-effectiveness and a cost-benefit model is possible despite large differences in the health-care systems if the basic assumptions of the main model are stated fairly and described in a way that allows a re-calculation of every single step.

SOURCE: Annu Meet Int Soc Technol Assess Health Care. 1999;15:143.

TITLE: Usage of complementary therapies in rheumatology: a systematic review.

AUTHORS: Ernst E

LANGUAGES:
Eng

ABSTRACT:
Complementary medicine (CM) is more popular than ever before. Rheumatology patients seem particularly keen to try CM. In this paper, surveys on rheumatology patients' use of CM are reviewed. The issues of perceived effectiveness, safety and costs are also addressed. In addition surveys of doctors' attitudes towards CM in rheumatology are summarised. Fourteen surveys on patients' use of CM and three on patients' attitudes towards CM were found and analysed. The results imply that the prevalence of CM varies between 30% and nearly 100%. Overall, patients perceive CM as being moderately effective. The survey contains only few data on adverse events of CM as perceived by these patients; collectively they suggest that adverse events are uncommon. Data on costs are similarly sparse; they imply that expenditure for CM is rarely high. Physicians seem to be more sceptical about CM than are their patients. It is concluded that, on average, CM is frequently used by rheumatology patients. The patients' level of satisfaction with CM is often considerable and few adverse effects are being reported. On the basis of these findings, a rigorous investigation of the effectiveness, safety and costs of CM in rheumatology seems desirable.

SOURCE: Clin Rheumatol. 1998;17(4):301-5.

Abstracts on Adverse Drug Effects

SECONDARY SOURCE ID:
MED/98289682
TITLE: Drug-related-injury visits to hospital emergency departments [published erratum appears in Am J Health Syst Pharm 1999 May 15;56(10):1020]
AUTHORS: Aparasu RR
LANGUAGES:
Eng
SOURCE: Am J Health Syst Pharm. 1998 Jun 1;55(11):1158-61.

2
SECONDARY SOURCE ID:
AHA/20052629
TITLE: Prescribed drugs: a major cause of ill health [letter; comment]
AUTHORS: Elliott R; Woodward M
COMMENTS:
Comment on: Aust Health Rev 1998;21(4):260-6
LANGUAGES:
Eng
SOURCE: Aust Health Rev. 1999;22(3):210-2.

3
SECONDARY SOURCE ID:
MED/20032797
TITLE: [Drug use in the elderly. Undesirable drug effects in the elderly: epidemiology and prevention]
AUTHORS: Doucet J; Capet C; Jego A; Trivalle C; Noel D
Chassagne P; Bercoff E
LANGUAGES:
Fre
ABSTRACT:
A COMMON PROBLEM: Adverse drug effects are common and severe in patients over 70. Most concern widely prescribed drugs or drugs with small safety margins. CLINIC: It is important to recognize the most frequently encountered modes of expression including cardiovascular, metabolic and neuropsychiatric manifestations. The effects of bleeding and low blood sugar are particularly severe. PREVENTION: Certain pharmacological favoring factors are closely related to the aging process. A large number of iatrogenic side effects could however be avoided if the patientis clinical situation is carefully considered in light of the risk of drug interactions, the patientis behavior (observance errors), or prescriber behavior (inappropriate prescriptions in light of the therapeutic goals).
SOURCE: Presse Med. 1999 Oct 23;28(32):1789-93.

4
SECONDARY SOURCE ID:
MED/20061422
TITLE: Iatrogenic drug dependence--a problem in intensive care? Case study and literature review.

AUTHORS: Taylor D
LANGUAGES:
Eng
ABSTRACT:
Use of sedative and analgesic pharmacological agents is a widespread practice in intensive care units (ICUs). Mainly, this involves opioid and benzodiazepine analogues, both known to induce dependence/tolerance states. This paper is based on a clinical scenario in which a patient treated with these agents developed problems when they had been discontinued, and exploration of the extent of such problems generally. The problems range across a wide range of domains and may include physical discomfort, difficulty weaning from respiratory assistance and the drugs, and the problems of short- and long-term psychological distress. Although there may be a recognition that these drugs can typically cause dependence problems, little emphasis has traditionally been given to assessing these problems in ICUs. Yet the ICU may be an area where these drugs are used in high volumes. The recognition, physiology, management and prevention of iatrogenic drug dependence/tolerance in critical care environments is elucidated, with reference to relevant literature.
SOURCE: Intensive Crit Care Nurs. 1999 Apr;15(2):95-100.

5
SECONDARY SOURCE ID:
AHA/99288635
TITLE: Prescribed drugs: a major cause of ill health [see comments]
AUTHORS: Mackay M
COMMENTS:
Comment in: Aust Health Rev 1999;22(3):210-2
LANGUAGES:
Eng
ABSTRACT:
Harm caused by ill-effects of prescribed drugs is largely unrecognised, but when looked for has been found to be an important cause of ill health. Perhaps 6% of all hospital admissions and some 800 deaths a year are caused by prescribed medication in Australia. The elderly, especially those in institutions, are particularly prone to injury by drugs. Attempts to use visiting pharmacists to influence the prescribing habits of doctors have resulted in unspectacular success. It is suggested that prescribing habits may more effectively be changed by visiting from specially trained practising doctors.
SOURCE: Aust Health Rev. 1998;21(4):260-6.

6
SECONDARY SOURCE ID:
MED/99015927
TITLE: Prevention of iatrogenic illness: adverse drug reactions and nosocomial infections in hospitalized older adults.
AUTHORS: Riedinger JL; Robbins LJ
LANGUAGES:
Eng
ABSTRACT:
Adverse drug reactions and nosocomial infections are two important aspects of iatrogenesis in hospitalized older adults.

Adverse drug reactions are related to changes in pharmacodynamics and pharmacokinetics that occur with aging as well as polypharmacy. Strategies for limiting iatrogenesis due to medications are discussed. Nosocomial infections continue to complicate older inpatients' care despite advances in understanding and treating institutional infections. In particular, urinary tract infections, nosocomial pneumonias, and Clostridium difficile-associated diarrhea are potentially preventable.

SOURCE: Clin Geriatr Med. 1998 Nov;14(4):681-98.

7

SECONDARY SOURCE ID:
MED/99232064

TITLE: [Iatrogenic medication: estimation of its prevalence in French public hospitals. Regional Centers of Pharmacovigilance]

AUTHORS: Imbs JL; Pouyanne P; Haramburu F; Welsch M; Decker N Blayac JP; Begaud B

LANGUAGES:
Fre

ABSTRACT:
The French network of Regional Centres of Pharmacovigilance has made an estimation of the occurrence of adverse drug reactions in a representative sample of patients in French public hospitals (departments of medicine, of surgery and of geriatrics). The study looked at one specific day in the spring of 1997. Each observed case of adverse drug reaction was validated. The total sample comprised 2132 patients of whom 969 were in a university hospital and 1163 in a general hospital. The hospitals and units concerned are representative of the country as a whole. One adverse drug reaction at least was present for 221 patients on the day of the investigation. This means a prevalence rate of 10.3 per cent (95 per cent CI: 8.7 to 11.9 per cent). In 33 per cent of cases (95 per cent CI: 26 to 42 per cent), the observed effects were rated as serious. From an incidence rate of 1.8 per cent (95 per cent CI: 1.0 to 25 per cent) on one specified day it can be estimated that in France an adverse drug reaction will occur in about 1,300,000 patients per year during a stay in hospital.

SOURCE: Therapie. 1999 Jan-Feb;54(1):21-7.

8

SECONDARY SOURCE ID:
MED/99232088

TITLE: [Prospective study on admissions for iatrogenic adverse effects in the emergency service of hospital university center in Poitiers]

AUTHORS: Perault MC; Pinelli AL; Chauveau I; Scepi M Remblier C; Vandel B

LANGUAGES:
Fre

ABSTRACT:
Hospital admissions resulting from an adverse drug reaction have been studied in the emergency unit of the university hospital in Poitiers during a 27-day period. This prospective study consisted in documenting all observations considered as an ADR by the medical practitioner in charge of the patient. There were 1235

hospital admissions to the emergency unit during the study period. Thirty-one (2.5 per cent) of admissions were considered to be drug-related. Women were more often affected than men. Patients with ADR were classified taking into account the type of pathology and the drug responsible for the effect. Dermatological and gastrointestinal reactions were predominant. Antibiotic and analgesic drugs were the most common drug groups implicated in causing an ADR.

SOURCE: Therapie. 1999 Jan-Feb;54(1):183-5.

9

SECONDARY SOURCE ID:
MED/99194383

TITLE: The nature and extent of drug-related hospitalisations in Australia.

AUTHORS: Roughead EE

LANGUAGES:
Eng

ABSTRACT:

In order to determine the nature and extent of drug-related hospitalisation in Australia, the Australian National Hospital Morbidity Collection, the Quality in Australian Health Care Study and Australian studies assessing drug-related hospital admissions were reviewed. The incidence figures, drugs and conditions most commonly implicated, and estimates of avoidability of medication-related problems were compared. The three data sources were found to provide consistent results, with all sources implicating cytotoxics, antirheumatics, anticoagulants, corticosteroids, antihypertensives and cardiovascular agents in medication-related hospitalisations. Estimates of the extent of the problem were also consistent, suggesting that at least 80 000 medication-related hospitalisations occur in Australia each year; between 32% and 69% of these hospitalisations were considered avoidable. It was concluded that medication-related hospitalisations are a major public health problem in Australia. The avoidability estimates suggest that much can and should be done to reduce this problem.

SOURCE: J Qual Clin Pract. 1999 Mar;19(1):19-22.

10

SECONDARY SOURCE ID:
MED/99194382

TITLE: Frequency, consequences and prevention of adverse drug events.

AUTHORS: Bates DW

LANGUAGES:
Eng

ABSTRACT:

Iatrogenic injuries are important because they are frequent and many may be preventable; those caused by therapeutic drugs are among the most frequent. While medication errors are common, most have little potential for harm. However, some errors, such as giving a patient a drug to which they have a known allergy, are more likely to cause injury. Error theory provides insights into the changes required to reduce medication error injury rates. Data from the Adverse Drug Event (ADE) Prevention study suggest that most serious errors occur at the ordering and dispensing stages, while another, smaller, proportion occur at the

administration stage. These data suggest that physician computer-order entry, where physicians write orders on-line with decision support, including patient-specific information and alerts about potential problems, has the potential to significantly reduce the number of serious medication errors.

SOURCE: J Qual Clin Pract. 1999 Mar;19(1):13-7.

Community Herbalism and
Community-supported health care.

Not too many years ago, doctors made house calls. When your child was sick with the flu, you could count on a visit from a capable friend of the family to be with your child for some time and reassure you. Sometimes the psychological aspect of ilness is the most difficult. Today when we are sick, or have an accident, we often have to drive through busy traffic to a local hospital emergency ward, or "doc in a box" clinic, where more often than not, we have to fill out an inordinate amount of paperwork, wait, sometimes for extended periods, and then visit for a few minutes with an overworked doctor we don't know. According to national statistics published recently, the average doctor is interrupted when with a patient after 50 seconds.

Can we ever return to the more relaxed, personalized health care of the 1950s? That depends on whether we continue to move towards the creation and feeling of community, even within cities. Humans by nature tend to naturally seek out a feeling of friendship and community, according to the words of the Dalai Lama. I have a friend who has donated his large back yard in a city neighborhood for a community gardening project. Friends and neighbors on his block take turns growing vegetables and herbs for the benefit of the neighborhood. In thousands of smaller towns throughout the U.S., a strong feeling of community already exists as a resource.

When one thinks of the burden to our society of chronic illness today with the elderly, our parents, and then add to that millions of baby-boomers turning 50 and 60 within the next years, it's staggering. Will our present health care system be able to provide health care for all? Already we have heard of limiting the types and amount of health care to many. Many within our society have no health care.

Despite our booming economy, breakthroughs in medical research, and modern health care facilities, consider:

- Nearly 14% of women in the U.S., or 1 in 7, are without health Insurance.(1)
- The number of Americans without health insurance has been growing steadily. According to a new census bureau report, 43 million people are without coverage, the highest in 5 years.(2)
- Half of elderly Americans who have private health insurance covering drugs still spend $500 to $999 a year out-of-pocket on prescriptions, according to a new report from the AARP.
- Four out of 10 Americans used alternative medicine therapies in 1997; exceeded the visits to all U.S. primary care physicians. Americans paid an estimated $21.2 billion for services provided by alternative medicine practitioners.(3)

1. National Women's Law Center (NWLC), a nonprofit group, The University of Pennsylvania School of Medicine's
   FOCUS on Health & Leadership for Women and the Lewin Group, a health policy consulting firm.
2. NEW YORK (CNN).
3. November 11 issue of The Journal of the American Medical Association (JAMA).

What is needed is health education on a community level, along with more emphasis on prevention of disease and promotion of healthy habits. Herbal medicine encompases and teaches these living precepts.

Here is the basic model we have been working with in Santa Cruz, California, and now in Williams, Oregon, a small community of 1500 people near Grants Pass.

- Establish a non-profit community garden for growing food and herbs organically. The land can be leased from the city or county, or the purchase price can be raised from public or private donations or from a foundation. On-going classes teach community members how to grow food and herbal remedies in a sustainable way. Principles of propagation, cultivation, composting, cover-cropping,

crop rotation, and selecting the proper herbs for personal and family needs are stressed. These classes have been on-going in Santa Cruz, CA, and Williams, OR already for the last 15 years.

- 9-month "Community Herbalist" training programs teach all aspects of herbal medicine. Topics include local wild plant identification, plant conservation, harvesting, extraction, traditional diagnostic methods (like tongue and pulse diagnosis), and human physiology and anatomy. Training is given on how to apply simple herbal remedies and formulas to promote health and to work as part of a team effort with doctors and other health care providers to help relieve symptoms and assist the body to heal disease.
- Community herbalist training emphasizes learning about health and disease. And most importantly, how to effectively teach community members how to avoid chronic symptoms and illnesses in the first place by bringing together a knowledge of science and traditional healing methods. For instance, it is well-known that more fresh fruits and vegetables daily can help reduce the incidence of cancer and heart disease. People need to know how to incorporate more fresh fruits and vegetables into their diet, how much, what local kinds are best, and the best way to change harmful dietary practices.
- Herbalists learn when to work locally with complementary and alternative medicine (CAM) methodologies, and when to refer out to a physician or other practitioner.
- Taking into account all the many small herbal "trade" schools, apprenticeship programs, symposia, workshops, and classes offered in local community colleges, I estimate that between 300 and 500 community herbalists are being trained each year in the U.S. This education process is increasing geometrically. Teachers in my generation who started teaching herbal medicine in the 1960s and 1970s trained hundreds of students who began teaching classes in the 1980s and 1990s. Now I am seeing a 3rd generation of herbalists in training. In another 3-5 years, some of them will begin to emerge as teachers and practitioners in their own right. These young herbalists will be more medically-savvy. They will have some knowledge of western physiology and anatomy, chemistry, botany, in addition to the traditional knowledge of herbalism, blended with the concepts and herbal knowledge of traditional Chinese Medicine or east Indian Ayurveda.
- The American Herbalists Guild, the only national organization for herbalists, has over 120 professional peer-reviewed members. The organization is growing rapidly, and is discussing and helping to set new standards for herbal practice in America, including core curriculums for schools and training programs, and national registration. This is separate from the thousands of licensed acupuncturists and naturopathic physicians in the U.S. with herbal training that practice some form of herbal medicine as part of other CAM methodologies.

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Presentation by William C. Meeker, DC, MPH, Director of Research
Palmer Center for Chiropractic Research, Davenport, Iowa

To the

White House Commission on Complementary and Alternative Medicine Policy
Washington, DC
December 5, 2000

Questions for Session II: Clinical and Cost-Effectiveness of Selected CAM Services

Please provide references that best describe the clinical and cost-effectiveness data for access to and delivery of chiropractic practice.

A selected bibliography is appended to this report. Particular attention should be directed to two government sponsored monographs about the chiropractic profession. One was commissioned by the province of Ontario, Canada, (Manga, 1993) the other by the U.S. Agency for Healthcare Research and Quality (formerly Agency for Health Care Policy and Research). (Cherkin, 1997) Another major reference is the recent, "Job Analysis of Chiropractic," published by the National Board of Chiropractic Examiners, which is based on a major random survey of chiropractic practices in the U.S. (Christensen, 2000)

Relative to the clinical effectiveness of chiropractic practice, please summarize the data regarding the following measures: specific health conditions, populations (age, sex, occupation, etc.), practice setting (including whether chiropractic only, or in conjunction with conventional medicine), type of practitioner.

One indicator of chiropractic mainstreaming is the steadily increasing use by patients in the U.S., which has tripled in the last two decades from about 3.6% in a 1980 survey (Von Kuster, 1980) to an estimated 11% in a 1997 national random telephone survey. (Eisenberg, 1998) This translates to an estimated 190 million patient visits to chiropractors in a year, or about 30% of visits to all CAM practitioners. In surveys of patients seeking alternative care, chiropractors are utilized more often than any other CAM provider group. (Eisenberg, 1998) Payments for chiropractic services in the U.S. total approximately $8-10 billion annually.

Although spinal adjustment and manipulation is practically synonymous with chiropractic (chiropractors deliver over 90% of the manipulations in the U.S., (Shekelle, 1992)) chiropractors also provide a variety of other treatments and counsel to patients. Physical therapies such as heat, cold, electrical modalities, and rehabilitation methods are very commonplace. (Christensen, 2000; Mootz, 1997) Therapeutic exercises and general fitness recommendations are usually made to a majority of patients, and many receive advice about nutrition, vitamins, weight loss, smoking cessation, and relaxation techniques. (Hawk, 1995) Many chiropractors use other forms of CAM therapy, with emphasis on massage, acupressure, and mineral and herb supplements. (Hawk, 1999)

Studies demonstrate that chiropractic patients generally represent a cross-section of U.S. population demographics. Patients come from all age and occupational groups, economic and educational levels. Patients less than 18 years old account for approximately 12%, and patients 65 years and older make up approximately 15% of the chiropractic patient population. (Coulter 1996; Christensen, 2000)

Studies confirm that the chiropractic case-mix is predominately musculoskeletal in nature with about 50% of patients complaining of back pain; the remainder with head, neck and extremity complaints. (Christensen, 2000; Shekelle, 1991; Hurwitz, 1998) Approximately one-third of all patients who seek professional care for low back pain consult chiropractors in a primary health care role. (Deyo, 1987; Shekelle, 1995; Carey 1995; 1996) Furthermore, about half of the patients seeking chiropractic care have chronic symptoms. (Hurwitz, 1998; Hawk, 2000) Typically, approximately 5% seek care for other types of conditions. Recent studies also document that a proportion of patients attend chiropractors for general health concerns, prevention and a feeling of well-being, often receiving standard health advice, most often with regard to physical fitness and nutrition. (Hawk, 2000; Rupert 2000a; 2000b)

Clinically, chiropractors direct spinal adjustments to a dysfunctional joint "lesion" known as a subluxation. This is characterized as a form of joint strain/sprain with clinically associated hypomobility, malalignment, local and referred pain, inflammation, and muscle tension. (Gatterman, 1995) Subluxation in the chiropractic context primarily connotes a functional and not necessarily an anatomical entity. In theory, subluxation prevents the body from operating at an optimum healthy level. At least five mechanical and neurologic mechanisms have been proposed and these are listed below

Proposed Mechanisms of Spinal Manipulation

Action	Mechanism
Mechanical/anatomical	Alleviation of an entrapped facet joint inclusion or meniscoid, which have been shown to be heavily innervated (Giles, 1987; Bogduk, 1985)
Mechanical/anatomical	Repositioning of a fragment of posterior annular material from the intervertebral disc (Bogduk, 1985; 1981)
Mechanical/anatomical	Amelioration of stiffness induced by fibrotic tissue from previous injury or degenerative changes that may include adaptive shortening of fascial tissue (Arkuzewski 1988; Lantz, 1995)
Neurological/mechanical	Inhibition of excessive activity in the intrinsic spinal musculature or limbs and/or facilitation of inhibited muscle activity (Blunt, 1995; Bolton, 2000; Budgell, 2000; Suter, 2000).
Neurological/mechanical	Reduction of compressive or irritative insults to neural tissues (Haldeman, 2000).

Intriguing effects on neurophysiological and musculoskeletal function have been noted and these support the results from clinical trials. They include: increased range of joint

motion, [Miereau, 1988; Nansel, 1989] increased pain tolerance, [Terrett, 1984] reduced muscle activity, [Shambaugh, 1987] and muscle reflex responses. [Herzog, 1999] The nervous system may be affected by manipulation as suggested by experiments examining capillary blood flow, [Harris, 1987] serum levels of beta-endorphin, [Vernon, 1986; Christian, 1988] and substance P. [Brennan, 1992] A biomechanical picture of manipulation is beginning to emerge from studies on the forces involved and the resultant kinetics and kinematics. [Herzog, 1995] This is an area of intense scientific discussion and study.

There are numerous case-studies and observational outcome studies on the clinical effectiveness of chiropractic care. This summary will only focus on the experimental randomized controlled trial data. To date, at least 70 randomized clinical trials of a broadly defined spinal manipulation procedure can be found in the English literature. Most of these studies have been conducted on patients with low back, neck and head pain, with a few on other conditions. The clinical trials include placebo-controlled comparisons, comparisons to other treatments, and pragmatic comparisons of chiropractic management vs. common medical management. [Von Tulder, 1997; Hurwitz, 1996]

Results of RCTs of Spinal Adjustment/Manipulation (Please see list of references.)

Condition	# of RCTs	Positive, Equivocal, or Negative
Acute back pain	10	Positive
	3	Equivocal
Subacute and chronic back pain	8	Positive
	6	Equivocal
Mixed acute and chronic back pain	10	Positive
	4	Equivocal
Migraine headache	2	Positive
	1	Equivocal
Muscle tension headache	4	Positive
	1	Equivocal
Cervicogenic headache	1	Positive
Acute, subacute, chronic neck pain	4	Positive
	7	Equivocal
Dysmenorrhea	1	Positive
	1	Equivocal
Infantile colic	1	Positive
Enuresis	1	Equivocal
Asthma	2	Equivocal
Premenstrual syndrome	1	Positive
Carpal tunnel syndrome	1	Equivocal
Hypertension	1	Positive
	1	Equivocal

Forty-one RCTs of spinal manipulation for treatment of acute, subacute, and chronic low back pain have been published. Twenty-eight favored manipulation over the comparison treatments in at least a subgroup of patients, and the other 13 found no significant differences. No trial to date has found manipulation statistically or clinically less effective than the comparison treatment. Eleven of the low back pain trials included a

placebo arm and 8 of them demonstrated an advantage to manipulation. (Koes, 1996) Eleven RCTs of spinal manipulation for neck pain have been conducted, four positive and seven equivocal. Seven of 9 RCTs of manipulation for various forms of headache were positive.

The treatment effect sizes estimated by the majority of RCTs of manipulation on musculoskeletal pain appear to be clinically and statistically significant. Systematic reviews and meta-analyses in the early 1990s made cautiously positive or equivocal statements about the effectiveness of manipulation for low back pain, neck pain and headache, and called for higher quality studies. (Shekelle, 1992; Hurwitz, 1996; Koes, 1996; Anderson, 1992; Assendelft, 1995; Aker, 1996) A 1997 systematic review (Von Tulder, 1997) of manipulation for low back pain concluded that there was sufficient evidence to recommend manipulation for chronic back pain, but that there was weak evidence for acute back pain. The most recent review (Bronfort, 1999) used a slightly different method of analysis taking into account study design and quality, and concluded there was moderately strong evidence of benefit of manipulation for acute and chronic back pain. There was insufficient evidence for or against the effectiveness of manipulation for sciatica.

Using formal consensus processes, the Quebec Task Force on Whiplash-Associated Disorders in 1995, concluded that spinal manipulation had at least "weak cumulative evidence," and recommended that a short regimen of spinal manipulation may be used as a therapeutic trial for neck pain. (Cassidy, 1995) The U.S. Agency for Health Care Policy and Research in 1994 similarly concluded that spinal manipulation was safe and effective for acute low back pain. They reviewed all clinical trials available at the time and found no other treatment to have stronger evidence. (Bigos, 1994) Other countries for example, the U.K., Sweden, Denmark, and New Zealand, have also developed practice guidelines for the treatment of low back pain and have arrived at essentially similar conclusions.

The treatment of disorders not generally thought to be related directly to the musculoskeletal system by manipulation has been supported mainly by clinical experience and case reports. In the past few years, RCTs for primary dysmenorrhea, hypertension, chronic asthma, enuresis, infantile colic, and premenstrual syndrome have been completed with variable results. Two systematic reviews, one on extant trials at the time (Bronfort, 1996) and one recently on asthma sponsored by the Cochrane Collaboration (Hondras, 2000) concluded that the results so far do not argue convincingly for or against the utility of spinal manipulation for these kinds of conditions. Additional research is obviously needed in this area.

Although additional research is necessary, spinal adjustment/manipulation is already one of the most studied treatments for back and neck pain. (Bigos, 1994; Von Tulder, 1997) It should no longer be considered "investigational" in nature when compared to standard medical and other treatments in common use for common musculoskeletal conditions.

Describe the cost-effectiveness of chiropractic care provided as a stand-alone therapy with chiropractic care that is provided in conjunction with conventional medicine as part of an integrative approach.

To date, there are no formal cost-effectiveness studies that have compared chiropractic care to chiropractic care integrated with conventional medicine. Although settings exist where chiropractors work alongside medical doctors, these have not been subjected to this sort of analysis. In addition, typical chiropractic care is a case-management approach that emphasizes spinal adjustment, but also uses other procedures and lifestyle advice such as for exercise and nutrition, which might be considered "conventional." Finally, there are studies that indicate high rates of referral from chiropractors to medical physicians and a growing rate of medical doctors referring cases to chiropractors. (Curtis, 1992; Mainous, 2000) Patients fall into one of three categories: those that require only chiropractic care, those that need co-management, and those that need specialty medical care alone. Logically, co-management of patients only requiring chiropractic care would seem to be a waste of health resources, unless it can be shown that improved outcomes are the result.

Compare the costs of chiropractic care with those of conventional medicine for the same or similar health conditions.

The relative cost-effectiveness of chiropractic and medical care has not yet been convincingly demonstrated, although approximately 40 studies in this area have been published in the past three decades. Most studies have been retroactive and actuarial in nature, using claims databases that may not accurately reflect actual total costs, episodes of care and the clinical experience of doctors and patients. Furthermore, most studies have failed to compare equivalent patients, measure clinical outcomes, and include both direct and indirect costs in the analysis. Sophisticated economic analyses have been lacking. To date, there is still not a single prospective randomized trial comparing chiropractic care to conventional medical care with properly assessed economic and clinical variables as outcome measures.

However, despite variation in study quality, the preponderance of information from a number of studies indicates that chiropractic services are equal to or less expensive than common medical treatments. Cost advantages for chiropractic care, particularly for back pain patients appear possible. The most recent and best done single study indicates that chiropractic care substitutes for medical care in occupational low back injuries, and that there may be a cost advantage relative to disability expense as well (Johnson, 1999).

The most comprehensive review of the cost-effectiveness of chiropractic management of low back pain was undertaken by a team of health economists at the direction of the government of Ontario, Canada. (Manga, 1993) Conclusions strongly favored a much greater inclusion and integration of chiropractic services.

Fourteen of seventeen retrospective actuarial reviews from 14 different jurisdictions in the United States prior to 1981 concluded that the total costs for injured workers managed by chiropractors were lower than similar cases managed by other providers (Johnson, 1985). In 16 of the studies, less time loss from work was reported in patients under chiropractic care. (Johnson,1985) Publications after 1981 provide additional data regarding cost-comparison trends, and have improved on the descriptive methodology used in the earlier studies. A review of low back and neck sprain/strain claims data in Iowa reported average

case payments to medical providers at $352 and $223 for chiropractors. (Johnson, 1989) A review of Utah claims indicated that overall compensation costs were 10 times greater for medical physicians compared to chiropractors. Mean medical costs were $684 for medically managed claims versus $527 for those managed by chiropractors. (Jarvis, 1991) Additional studies from Florida in 1988 and Oregon in 1991 reinforce these trends. (Wolk, 1988a; 1988b; Nyiendo & Lamm, 1991) Similar data was also reported in Australia. (Ebrall, 1992)

A recent well-designed study from a private workers compensation carrier in California reported that for equivalent populations of patients, the health care costs of chiropractic and medical care were similar ($1044 vs. $1075). (Johnson, 1996a) However, indemnity costs (related to lost work time) under chiropractic care were substantially less making the average total claim costs (health care plus indemnity) under chiropractic care 20% less ($1526 vs. $1875. The most recent and sophisticated actuarial review of one California insurer's database on 185 closed claims between 1991-1993 concluded that medical and chiropractic management costs of non-surgical, low back work injuries is nearly equivalent. (Johnson, 1999) Medical costs, temporary disability, and permanent disability costs were considered.

Two years of large fee-for-service claims data records were examined in one study. Total health care costs as represented by third party payments were significantly lower for those patients treated by chiropractors. (Stano, 1993) Total adjusted cost differences ranged from $291 to $1722 over the two-year period. (Stano, 1994) Stano noted that outpatient costs tended to be slightly lower for patients exclusively using medical services, but lower hospital costs for patients under chiropractic care more than offset these additional costs. (Stano, 1994)

Stano & Smith (1996) subsequently compared health insurance payments and patient utilization patterns for episodes of low back conditions care, controlling for differences in clinical (eg, diagnosis, severity, episodes of relapse) and insurance coverage characteristics. They reported that costs were higher for episodes where the medical doctor was the first contact provider. Chiropractors were also more likely to retain the patient for subsequent episodes.

In contrast, Shekelle (1995) concluded that chiropractors had significantly more visits per episode, and the highest mean outpatient cost per episode. Disparity in the conclusions drawn between Shekelle and Stano may have resulted from differences in the data pool and study methods. Shekelle's study was observational in nature and reviewed evidence collected from the RAND Health Insurance Experiment data from the 1970's. Data on 1020 episodes of back care, totaling 8,825 visits by 686 different persons was evaluated.

Total health care costs for comparable cases of neck and back pain for members in a health maintenance organization (HMO) who sought chiropractic care and other treatment methods over a one-year period showed that care, prescription and imaging costs were lower in the group managed by chiropractors. Patient satisfaction and surgical rates were nearly identical for both groups. (Mosely, 1996)

Carey [1995] reported a comparison of outcomes (functional recovery, return to work, complete recovery from back pain, satisfaction) and cost of care for patient management by chiropractors, orthopedists and primary care physicians in both urban and rural regions of North Carolina. Clinical outcomes were assessed by telephone interview. Results were similar for all groups, although satisfaction was highest in those treated by chiropractors. Chiropractic costs were extrapolated from numbers of visits based on state-wide average costs per visit (not actual reimbursement). These estimated costs were highest for chiropractic and orthopedic care and lowest under management by primary care physicians. However, these differences may be accounted for by the fact that medical delivery was provided under managed care, while all of the chiropractic cases were fee-for-service.

The effects of dynamically evolving delivery systems of care severely complicate the design, implementation and analysis of true cost-effectiveness studies and will need to be dealt with in future efforts.

Summarize patient satisfaction data.

Chiropractors generate very high levels of patient satisfaction. A recent essay opined that much of chiropractic's success and perhaps its most important contribution to health care might have to do with the patient-physician relationship. [Kaptchuk, 1998] Analyses from anthropological and sociological perspectives have suggested that treatment by a chiropractor, especially for many patients with chronic pain, can generate a sense of understanding and meaning, an experience of comfort, an expectation of change, and a feeling of empowerment. [Coulter, 1995; Oths, 1993; Coulehan, 1985] The hands-on and compassionate "can do" clinical behavior of the typical chiropractor seems to be concrete, reassuring and immediately satisfying to many patients. Consumer-oriented surveys, observational studies and randomized trials leave little doubt that chiropractic patients are very satisfied with the treatment they receive, often at rates much greater than with other health professionals. [Cherkin, 1989; Sawyer, 1993; Carey, 1995; Cherkin, 1998] In one study, chiropractors were retained as primary provider by a much greater percentage of their patients (92%) who had a second episode of back pain care than were medical doctors. [Shekelle, 1995]

Describe current significant barriers to the access and delivery of chiropractic care.

Chiropractors have only marginal statutory roles in many integrated delivery care systems such as HMOs, the U.S. military, Federal government health plans, Medicare and Medicaid. Regulations should be examined and revised to be inclusive and equitable.

Chiropractors are only marginally included in studies of health care resources and delivery systems.

Chiropractic institutions receive virtually no financial support from Federal government programs designed to support and enhance health professions education and practice.

Please suggest specific policy recommendations that would improve the access and delivery of chiropractic care to consumers, including legislative or regulatory recommendations.

Increase funding for health services research that targets access and delivery issues with regard to the chiropractic profession.

Recommend that the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health, the Health Resources and Services Administration, and others develop research agendas that include consideration of chiropractic and other CAM professions.

Ensure that chiropractors are treated equitably in health delivery and reimbursement systems.

Prohibit discrimination based on type of practitioner license in all Federal health delivery and reimbursement systems such as Medicare, Medicaid, the military, etc.

Mandate the inclusion of chiropractors on all appropriate advisory councils, policy committees, task forces, etc. that deal with health issues at the Federal level.

Discuss whether chiropractic practice should be delivered as stand-alone care or should be integrated with more conventional therapies.

Both. Chiropractic care should be delivered as a stand-alone clinical practice AND it should be integrated in conventional health delivery systems that provide appropriate access and choice to patients. By history and habit chiropractors believe themselves to be primary health care providers, and chiropractic practice demonstrates many primary care attributes. However, this becomes a contentious point in the PCP gatekeeper vs. direct access issue in reimbursement and delivery systems when non-chiropractors control the flow of patients. Chiropractors and their patients are accustomed to direct access and chiropractors are trained to handle it appropriately.

Since chiropractic is a profession and not simply a procedure, the issue of chiropractic integration is a complex systems problem that must be examined at a variety of levels. CAM procedures and professions can be more easily integrated at some levels than others and there can be varying degrees of integration at the various levels. This is currently the case with chiropractic. These levels of integration include the following:

- The patient, or health consumer level
- The clinical management or health practitioner level
- The reimbursement and/or care delivery system level
- The regulatory and policy level
- The cultural, social and political level

Chiropractic is arguably very well integrated at the health consumer level in terms of use and satisfaction, and there is some evidence for a certain degree of integration at the clinical and reimbursement levels. Some examples can be cited.

On the other hand, chiropractic is not well-integrated in the sense of coordinated, interdisciplinary clinical behavior with conventional medical doctors. The following model of a continuum of integrative clinical practice makes this distinction clear, and it can be applied to most forms of CAM practice. It does not apply to the direct learning and use of CAM procedures by medical practitioners themselves. From top to bottom professional autonomy declines and shared expertise and professional communication increases.

- Parallel practice
- Collaborative practice
- Consultative practice
- Coordinated practice

Today, the majority of CAM is in the form of parallel practices. Patients choose and integrate their own health care and find ways to pay for it. Communication between practices is minimal. Some CAM is moving into a collaborative practice mode with case-by-case exchanges of information and referrals. There is evidence that chiropractic is increasingly moving into this stage with increasing referral rates both ways, but data are few. Consultative practice consists of the giving and taking of expert advice and integration occurs at the practitioner-to-practitioner level instead of at the level of the patient. Coordinated practice as it applies to CAM is very rare and undocumented. In this mode, a formal management function is added to the case-management decision-making process that may be subject to administrative review. PCP gatekeepers may function in this role. This kind of practice may only be feasible in large organizations with sufficient infrastructure to support it. Furthermore, excellent teamwork attitudes, values, and skills are essential.

Combining the integration level model with the continuum of practice model yields interesting observations that deserve additional study. For example, chiropractic is well integrated at the patient level, and increasingly so at the reimbursement/payor level. However, due to the nature of the way in which reimbursement systems are organized, chiropractic may continue to operate only in the parallel and collaborative practice modes. In other words, true multidisciplinary and interdisciplinary practice may be very difficult to obtain. Furthermore, whether or not this is a bad thing is debatable. Perhaps integration should be kept at the patient level; perhaps the dilution of professional autonomy necessary for consultative and coordinated practice will eliminate the attributes of CAM that make it attractive and effective. There is no data on this issue.

Finally, there are significant challenges to true interdisciplinary practice even within the established medical delivery system now, and CAM represents the special challenges of diverse disciplines, "turf" issues, non-standard practices, administrative and other resistance to change, history, habit and lack of experience, data, and knowledge. These

will all have to be addressed simultaneously in order for true integration to occur. (Bielinski, 2000)

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White House Commission on Complementary and Alternative Medicine
Testimony on Nutrition
Patsy M. Brannon, Ph.D., R.D.
December 4, 2000

Introduction:

Nutrition as a component of health care represents a broad continuum of approaches from self-selected diet or dietary supplement choices by consumers, in a free-living setting, without consultation with any health care professional to medical nutrition therapy within the conventional health care ambulatory or acute care settings. Distinguishing among the breadth of approaches is difficult. Further, the research on clinical effectiveness or cost effectiveness is variable across this continuum.

The IOM study (referenced below) identified two tiers of nutrition services. First is basic or general nutrition education or advice. Such care includes educating on basic diet principles and screening and reinforcing counseling provided by a nutrition professional. This may be incidental to other health services and may be provided by a variety of other health care professionals with a small amount of training in nutrition, such as physicians, nurses, dentists, pharmacists, chiropractors or others. In addition to general education by these nutrition and health care professionals, considerable nutrition information and education comes to the average consumer from mass media. The quality and accuracy of information through the mass media varies significantly.

Second is nutrition therapy (also known as medical nutrition therapy). This tier of nutrition service includes the assessment of nutritional status, evaluation of nutritional needs, intervention that ranges from counseling on diet prescriptions to the provision of enteral and parenteral nutrition, and follow-up care as appropriate. The IOM study recognizes registered dietitians as the single identifiable group with standardized education, clinical training, continuing education, and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy. Particularly in acute care settings, however, the dietitian functions as a part of a multi-disciplinary care team that includes physicians, nurses, pharmacists, psychologists, clinical social workers and others.

My remarks will focus primarily on nutrition therapy because this is the tier of nutritional services for which we have the most research-based evaluation of clinical effectiveness and cost benefit. However, the need to evaluate basic nutrition education remains high.

1. Please provide references that best describe the clinical and cost-effectiveness data for access to and delivery of nutrition-based approaches.

A. Basic Nutrition Education:

www.reeusda.gov/f4hn/efnep/tncba2.pdf

The cost-benefit of a nutrition education program through Cooperative Extension has been conducted in Tennessee. This community nutrition education program (Expanded Food and Nutrition Education Program; EFNEP) targets low-income families with children. Its goal is to change behaviors related to improve the nutritional quality of diets, handling food safely and stretching limited food dollars. Nutrition professionals and paraprofessionals in home and group community settings provide nutrition education. Ten nutrition-related chronic and acute diseases were evaluated in Tennessee for adults and infants. A cost-benefit ratio was found of $10.64 saved for each $1.00 invested.

B. Nutrition Therapy

1. Institute of Medicine, Food and Nutrition Board, Committee on Nutrition Services for Medicare Beneficiaries. The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population. 1999.

The Institute of Medicine (IOM) of the National Academy of Sciences conducted the study in response to a provision of the Balanced Budget Act of 1997. The IOM found that nutrition therapy has been shown to be effective in the management and treatment of many chronic conditions, which affect Medicare beneficiaries, including dyslipidemia, hypertension, heart failure, diabetes and chronic renal insufficiency. Medicare beneficiaries undergoing cancer treatment may also benefit from nutrition therapy aimed at controlling side effects or improving food intake.

Further, because of the comparatively low treatment costs and ancillary benefits associated with nutrition therapy, expanded coverage will improve the quality of care and is likely to be a valuable and efficient use of Medicare resources. Expanded coverage is likely to generate economically significant benefits to beneficiaries, and in the short term to the Medicare program itself, through reduced health care expenditures. IOM recommends that these services be reimbursed given the reasonable evidence of improved patient outcomes associated with nutrition care, whether or not expanded coverage reduces overall Medicare expenditures

The study estimates that the cost of providing nutrition therapy to Medicare beneficiaries for all diagnoses (physician referral required) for a five-year period, 2000 to 2004, would be $1.43 billion. For low utilization the estimated cost is $873 million while the high utilization estimated cost is $2.63 billion. Some of these costs will be passed on to Medicare beneficiaries through associated premium increases. Initial estimates indicate that savings could range from $52 to 168 million for hypertension, $132 to 330 million for diabetes and $54 to 164 million for dyslipidemia.

2. The Lewin Group, Inc. The Cost of Covering Medical Nutrition Therapy Under Medicare: 1998 through 2004, Final Report. 1997.

A study conducted in 1997 for The American Dietetic Association by The Lewin Group estimates net seven-year costs for coverage of medical nutrition therapy for all Medicare beneficiaries of $370 million. Savings from decreased hospitalizations and physician visits would be $1.2 billion from patients with diabetes and cardiovascular disease only. After the third year, savings were projected to exceed costs in each year. The study looked at the experience of Group Health of Puget Sound, which provided nutrition therapy based on self-referral.

3. The Lewin Group, Inc. The Cost of Covering Medical Nutrition Therapy Services under TRICARE: Benefit Costs, Cost Avoidance and Savings, Final Report. 1998.

A study completed by The Lewin Group for the Department of Defense estimates annual net savings of $3.1 million if medical nutrition therapy was included as a covered benefit in the TRICARE contracts (care provided to DOD beneficiaries of all ages by civilian health care organizations). The study showed that nutrition therapy is associated with a substantial reduction in health care spending for inpatient and outpatient services for persons with diabetes, cardiovascular disease, and/or renal disease. Cost of providing nutrition therapy for all nutrition-related diagnoses would be more than offset by reductions in health care spending for diabetes, cardiovascular disease and renal disease.

4. Focus on nutrition to improve chronic disease outcomes. Healthcare Demand & Disease Management. December 1997;3:177-184.

Following a successful pilot program in Brooklyn, NY, in which the health plan realized a tenfold return on investment, Oxford Health Plans broadened its nutrition program for at-risk elderly patients to all 160,000 Medicare members in New York, New Jersey, Connecticut, and eastern Pennsylvania. Oxford reported that for every dollar spent, it recognized $10 in savings.

5. Franz MJ, Splett PL, Monk A, Barry B, McClain K, Weaver T, Upham P, Bergenstal R, Mazze RS. Cost-effectiveness of medical nutrition therapy provided by dietitians for persons with non-insulin-dependent diabetes mellitus. J Am Diet Assoc. 1995;95:1018-1024.

The cost-effectiveness for nutritional care based on practice guidelines (averaging 151 min. with dietitian) compared to basic nutrition care (averaging 65 min.) was determined in a randomized clinical trial at the International Diabetes Center in Minnesota and related clinics in Florida and Colorado. The net cost effectiveness was $28.36 per patient per year (based on medication charges). Even such a small savings

per year becomes significant when applied to the 5-6 million American known to have Type II diabetes.

6. Gallagher-Allfred CR, Voss AC, Finn SC, McCarnish MA. Malnutrition and clinical outcomes: The case for medical nutrition therapy. J Am Diet Assoc 1996;96(4): 361-6.

This review summarizes the research available on malnutrition in hospitalized adults. In eight studies, 40 to 55% of hospitalized adult patients were found to be malnourished or at risk for malnutrition with as many as 12% severely malnourished. Nutrition support provided to malnourished patients across a broad range of medical conditions reduces complications, morbidity, length of hospital stay and mortality. The need for more clinical outcome studies is also highlighted. Estimate of cost savings through a team-care nutrition support approach was $4.20 benefit for every $1.00 invested.

7. McGehee MN, Johnson EQ, Rasmussen HM, Sahyoun N, Lynch MM, Carey M. Benefits and costs of medical nutrition therapy by registered dietitians for patients with hypercholesterolemia. J Am Diet Assoc. 1995; 95: 1041-1043.

This study of 474 outpatients with a primary diagnosis of hypercholesterolemia who were not taking lipid-lowering drugs and who were seen by a dietitian (at one of 20 hospitals or 3 HMOs) for at least 2 visits in a three year period were studied. There was a significant correlation of the reduction of serum cholesterol and the time spent with a dietitian ($r=0.118$; $p<0.001$). The more time spent with a dietitian, the greater the decrease in the patient's serum cholesterol. Mean total cost per patient for nutrition intervention by a dietitian was $163.

8. The Nutrition Care Management Institute. Cost Containment through Nutrition Intervention. Deerfield, Ill: Clintec Nutrition Company; 1996.

Tacker HN, Miguel SG. Cost containment through nutrition intervention. Nutrition Reviews 1996; 54:111-121.

This meta analysis of 22 published studies involving data from 70 hospitals over 15 years. The results suggest that nutrition therapy for patients at risk for malnutrition can decrease the length of stay and reduce costs.

2. Relative to the clinical effectiveness of nutrition-based approaches, please summarize data regarding the following measures:

Specific health conditions

Strong evidence (IOM report, McGhee et al.) from observational studies, consensus documents, systematic review and extensive clinical trials supports the value of nutritional therapy for:

dyslipidemia
hypertension
diabetes
osteoporosis.

Evidence (IOM report, Gallagher-Allfred et al., Tacher & Miguel) from observational studies, consensus documents, systematic review and some clinical trials (for heart failure and kidney failure) supports the value of nutritional therapy for:

heart failure
pre-dialysis kidney failure
undernutrition for Medicare beneficiaries.

The IOM report on The Role of Nutrition in Maintaining Health in the Nation's Elderly includes a critical and extensive review of the evidence supporting nutritional therapy in the above conditions. Multicenter clinical trials are included, such as the DASH studies and many others. Obesity, per se, is not addressed, but was considered in the review of evidence concerning dyslipidemia, hypertension and diabetes.

The IOM report concludes that limited evidence is available concerning the health benefits of nutrition related approaches, such as dietary supplements, botanicals, particular dietary regimens etc. for conditions such as Alzheimer's disease, osteoarthritis, and cancer.

Other critical reviews examine the data to support these conditions in specific populations as detailed below.

1. A position statement of the American Dietetic Association cites significant evidence that nutrition is a critical component of risk reduction and treatment, and must be included in clinical and preventive services for women (Women's health and nutrition -- Position of ADA and Dietitians of Canada. J Am Diet Assoc. 1999; 99:738-751.). The statement examines cardiovascular disease, cancer, osteoporosis, weight, and diabetes mellitus as significant health problems among women.

2. The ADA position statement on Nutrition services for Children with Special Health Needs -- Position of ADA (J Am Diet Assoc. 1995; 95:809) states, "Evidence of the benefits of nutrition intervention to the health and development of children with special health needs continues to accrue. This evidence is derived from treatment of conditions as diverse as metabolic disorders in which nutrition problems are primary,

and conditions in which the nutrition problems or risks result from biological, environmental, or psychosocial stressors. Improved nutrient and energy intakes, resulting in amelioration of growth and other nutrition markers, have been extensively documented. Economic benefits are derived from preventive and habilitative nutrition services."

3. Data supports the integration of nutrition education and nutrition intervention into the team treatment of patients with anorexia nervosa, bulimia nervosa, and binge eating during the assessment and treatment phases of outpatient and/or inpatient therapy. (Nutrition intervention in the treatment of anorexia nervosa, bulimia nervosa, and binge eating -- Position of ADA. J Am Diet Assoc. 1994; 94:902-907.)

Populations (age, sex, occupation, etc)

Evidence exists for the above disease conditions on the efficacy of nutritional therapy in both sexes across the adult life span (ages 17 to the elderly). The strength of the data varies for adults of different ages.

Practice setting, including whether nutrition-based approaches only, or in conjunction with conventional medicine

Evidence indicates that nutrition therapy is largely accepted as a component of conventional medicine in the treatment and management of many diseases and conditions. Most often nutrition therapy provided by a Registered Dietitian (RD) is currently provided as part of a team approach in conjunction with other therapies. The practice settings of the multitude of primary research reports summarized by these references include acute and ambulatory care.

The ADA position statement on medical nutrition therapy and pharmacotherapy (Medical nutrition therapy and pharmacotherapy -- Position of ADA." J Am Diet Assoc 1999;99:227-230.) cites evidence that "medical nutrition therapy and lifestyle counseling are integral components of medical treatment for the management of selected conditions for which pharmacotherapy is indicated. The Association promotes a team approach to care for clients receiving pharmacotherapy and encourages active collaboration among dietetics professionals and other members of the health care team."

Type of Practitioner

The reports and studies discussed above have largely focused on the registered dietitian as the primary provider of nutritional therapy. As discussed above, evidence supports the role of the dietitian as a member of the multi-disciplinary health care team. The IOM report recommends that the registered dietitian is "currently the single identifiable group with the standardized education, clinical training, continuing education, and

national credentialing requirements necessary to be directly reimbursed as a provider of nutritional therapy."

Many health-care practitioners in a wider variety of settings do basic nutritional education. These can include: physicians, nurses, pharmacists, dentists, chiropractors, nurse practitioners, physician assistants, and clinical social workers. The depth of training in nutrition varies tremendously among these health care providers

3. Describe the cost-effectiveness of dietary supplements provided as a stand-alone therapy with nutrition-based approaches that are provided in conjunction with conventional medicine as part of an integrative approach.

Little information is available on the cost-effectiveness of dietary supplements either as a stand-alone therapy or as a part of conventional medicine or nutritional therapy. Further, significant scientific consensus is lacking on the efficacy and safety of many dietary supplements.

Intriguing and frequently contradictory evidence is emerging on bioactive food components and botanicals. The potential impact of omega 3 fatty acids, gamma linoleic acid, flaxseed, green and black tea, flavenoids, antioxidants, supplemental vitamins and minerals, and many others needs to be evaluated. Efficacy, cost-effectiveness and safety need to be evaluated. As these studies are conducted, designs need to include a dietary assessment component. The interaction of nutrients and bioactive components has not been well-considered, but needs to be.

A cogent example illustrates this need. With the finding from epidemiological studies that the consumption of fruits and vegetables reduced the risk of cancer, the initial mechanistic hypothesis focused on beta carotene. However, results of several intervention trials with beta-carotene (and vitamin A) failed to support a role of beta-carotene in high risk populations and have suggested that there may in fact be an adverse effect of high levels of beta-carotene. We still do not know the active component(s) in fruits and vegetables in preventing cancer.

This example points out the need to study whole foods and dietary patterns. Recognition is growing that many bioactive components of foods and botanicals, whether nutrients or not, might interact to effect a particular health outcome. Understanding the mechanisms whereby dietary components or supplements act is important; but even in the absence of understanding such mechanisms, clinical effectiveness demonstrated through rigorous double-blind (when possible), random and placebo-controlled trials can be helpful in recommending healthy dietary patterns and practices.

Another example comes from weight-loss nutritional approaches. Clearly from decades of research, dietary caloric reduction and physical activity caloric increases are effective means of losing weight. Particularly in combination, the lost weight can be predominantly body fat as opposed to undesirable losses of lean body mass or ineffectual temporary losses of body water. What dietary patterns, however, are most effective in reducing calories and effecting weight loss is much more controversial. Many popular diets, prominently marketed in the mass media, have not been rigorously tested, but need to be. Importantly the weight loss needs to be evaluated relative to body fat loss.

4. Compare the costs of nutrition-based approaches with those of conventional medicine for the same or similar health conditions.

Nutrition therapy is increasingly recognized as an integral component of conventional medical treatment that can result in lower health care costs through reduced hospitalizations and physician visits, fewer complications and lower utilization of medication and more costly interventions/treatments.

Nutrition therapy has been incorporated into the treatment protocols for controlling diabetes, high blood pressure and elevated cholesterol, all of which often require the use of expensive drug treatments. Studies indicate that medical nutrition therapy provided by nutrition professionals, such as registered dietitians, can be used to help individuals successfully manage their disease conditions through dietary lifestyle changes. As a result, the need for drug treatments can often be substantially reduced or eliminated. Reducing the need for intensive drug therapy may also result in reduced cost and fewer side effects for the patient. This could improve adherence to the overall treatment program.

5. Summarize patient satisfaction data, if available.

Limited data exist. Results from Schiller et al. suggest a high degree of positive outcomes and patient satisfaction from nutrition counseling provided by dietitians. Nutrition counseling gives patients a greater sense of understanding and control of their conditions and helps meet emotional and interpersonal needs. (Schiller, M.R., Miller, M., Moore, C., Davis, E., Dunn, A., Mulligan, K., Zeller, P., Patients report positive medical nutrition therapy outcomes. J Am Diet Assoc 1998; 98: 977-982.)

6. Describe current significant barriers to the access and delivery of nutrition-based approaches.

Lack of recognition of dietitians and nutrition professionals as providers of nutrition therapy in Medicare/Medicaid and the private sector health plans remains a barrier to

nutritional care in the acute and ambulatory settings. The net impact is that consumers are currently not able to receive the life saving nutrition therapy as a benefit in many circumstances. Current factors contributing to this challenge are multiple. There is no consistent definition of nutrition services within the insurance industry. Coverage varies from state to state, making it a challenge to implement nutritional therapy. We lack a universal procedure for payment of nutrition services. Claims/billing examiners lack sufficient familiarity with dietitians and their services and are unable to distinguish which parts of nutrition care are reimbursable. Insurers lack adequate cost/benefit and cost-effectiveness data to justify the benefit of nutrition treatment.

Other health care providers do not understand the expertise or training of the dietitian. A recent study examined the practice of chiropractors concerning nutrition counseling and referrals to registered dietitians (Walker B et al. Provision of nutritional counseling, referrals to registered dietitians and sources of nutrition information among practicing chiropractors in the United States. J Am Diet Assoc 2000; 100:928-933). Although 90% of responding chiropractors provided nutrition counseling, most were not aware of the educational requirements for registered dietitians and did not refer their patients to registered dietitians. Compounding the problem is the inadequate training received by other health care professionals to identify potential nutrition problems and determine when to refer patients to dietitians for comprehensive nutrition services. The position paper of the American Dietetics Association ("Nutrition education for health care professionals -- Position of ADA."J Am Diet Assoc. 1998;98:343-346) states, "The shift in health care to earlier intervention and increased ambulatory care services makes it necessary that health practitioners be able to identify nutrition risk and recognize when it is necessary to refer a patient to a registered dietitian for medical nutrition therapy and intervention. The majority of health care providers need initial and continual lifelong learning about comprehensive nutrition services to enhance the nutritional health of the public." The IOM report concurs.

In terms of basic nutrition education, consumers regularly turn to sources other than dietitians, nutrition professionals and health care providers when it comes to information about health and nutrition. In fact, ADA's 1997 Nutrition Trends survey found that most Americans get their nutrition information from mass media outlets—57% from television, 44% from magazines, and 23% from newspapers. Only 5% of people surveyed received nutrition information from dietitians.

News media are the most visible messengers of health and nutrition information. Consumers are relying on information provided in audiovisual or print media to make food purchasing decisions. Nutrition misinformation is compounded by the Internet and food advertising in magazines, which tend to promote foods that are not necessarily have nutritional or health value. Advertising media contain health and nutrition claims, which influence consumers food choices. Consumers are not relying on dietitians to provide them with expert nutrition advice and services. (For more details, see "Comparison of food groups and health claims appearing in food advertisements in 3

popular magazines" J Am Diet Assoc 2000; 100:1396-1398. and "Status report on nutrition in the news" J Am Diet Assoc 2000: 1001298-1299.)

The importance of the food or supplement label as a source of nutritional information to the consumer must be recognized. The impact of the Pearson decision on health claims on labels is yet to be determined. Many contradictory results can be selectively cited to validate a claim. An example would be supplemental vitamin E use to reduce the risk of cardiovascular disease. A consensus view is not available, leading the IOM to conclude that insufficient agreement exists in the present data to evaluate the clinical effectiveness of this practice.

7. Discuss whether nutrition-based approaches should be delivered as stand-alone care or should be integrated with more conventional therapies.

Nutrition therapy works best when utilized in an integrated approach to the prevention, management and treatment of disease. Most of the evaluation of nutritional therapy presented in my testimony focuses on the management and treatment of disease.

A major concern for the future is the focus of nutrition approaches on disease prevention. Growing evidence is highly suggestive that diet and nutrition is one of the key risk-reducing factors for cancer, osteoporosis, cardiovascular disease and hypertension under an individual's control. Understanding how to motivate individuals early in their life to adopt healthy dietary and nutritional practices that will prevent the chronic diseases discussed remains a major challenge in nutrition. Simply put, we understand too little about diet and behavior. Public health and community nutrition need a greater focus. The U.S. Dietary Guidelines represent a strong, albeit not unanimous, consensus on the key aspects of a healthy diet. The cost-benefit analysis of the Tennessee EFNEP program suggests considerable benefit to be gained by preventative nutrition education.

8. Please suggest specific policy recommendations that would improve the access and delivery of nutrition-based approaches to consumers, including legislative or regulatory recommendations.

Legislative Recommendations:

Legislation is currently before Congress to provide outpatientMedicare coverage of medical nutrition therapy. The bills, H.R. 1187 and S.660, have gained the support of 292 Representatives and 37 Senators. A limited medical nutrition therapy benefit to cover individuals with diabetes or kidney disease is included in the package of Medicare Balanced Budget Act revisions and enhancements approved by the House of

Representatives. Passage of this legislation would increase access to nutritional therapy.

Depending on the outcome of this Medicare legislation in the current Congress, efforts need to be renewed to gain Medicare Part B coverage of medical nutrition therapy. If passed, efforts to expand coverage beyond diabetes and renal disease to cardiovascular disease, osteoporosis, cancer and HIV/AIDS need to be pursued.

The IOM recommendation to reevaluate existing reimbursement systems and regulations for nutrition services in acute care, ambulatory care, homecare, skilled nursing and long-term care would greatly expand access to nutritional therapy to vulnerable populations.

Regulations:

Health claim labels on dietary supplements and foods should be evidence based. If health claims are permitted that do not meet the current standard of 'significant scientific agreement', such claims must be truthful and not misleading. Regulations need to find a way to ensure that a single study is not the validation of a health claim when contradictory evidence exists in the literature.

Policy:

NIH should stimulate and support nutrition research to evaluate the efficacy, safety and cost-effectiveness of various nutrition and dietary interventions, especially those related to dietary supplement use and the interaction of nutrients and bioactive food components.

NIH, with other relevant federal agencies such as USDA, should stimulate and support nutrition research on diet and behavior so that theoretically based and sound research can inform nutritional education and nutrition therapy for the most effective clinical outcomes.

Coordinate nutrition research occurring within NIH and other government agencies with efforts in the private sector.

Develop programs to educate the public and health care providers about the importance of nutrition and nutrition services in the prevention, treatment and management of chronic diseases.

White House Commission on Complementary and Alternative Medicine
Testimony on Nutrition
Patsy M. Brannon, Ph.D., R.D.
December 4, 2000

Introduction:

Nutrition as a component of health care represents a broad continuum of approaches from self-selected diet or dietary supplement choices by consumers, in a free-living setting, without consultation with any health care professional to medical nutrition therapy within the conventional health care ambulatory or acute care settings. Distinguishing among the breadth of approaches is difficult. Further, the research on clinical effectiveness or cost effectiveness is variable across this continuum.

The IOM study (referenced below) identified two tiers of nutrition services. First is basic or general nutrition education or advice. Such care includes educating on basic diet principles and screening and reinforcing counseling provided by a nutrition professional. This may be incidental to other health services and may be provided by a variety of other health care professionals with a small amount of training in nutrition, such as physicians, nurses, dentists, pharmacists, chiropractors or others. In addition to general education by these nutrition and health care professionals, considerable nutrition information and education comes to the average consumer from mass media. The quality and accuracy of information through the mass media varies significantly.

Second is nutrition therapy (also known as medical nutrition therapy). This tier of nutrition service includes the assessment of nutritional status, evaluation of nutritional needs, intervention that ranges from counseling on diet prescriptions to the provision of enteral and parenteral nutrition, and follow-up care as appropriate. The IOM study recognizes registered dietitians as the single identifiable group with standardized education, clinical training, continuing education, and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy. Particularly in acute care settings, however, the dietitian functions as a part of a multi-disciplinary care team that includes physicians, nurses, pharmacists, psychologists, clinical social workers and others.

My remarks will focus primarily on nutrition therapy because this is the tier of nutritional services for which we have the most research-based evaluation of clinical effectiveness and cost benefit. However, the need to evaluate basic nutrition education remains high.

1. Please provide references that best describe the clinical and cost-effectiveness data for access to and delivery of nutrition-based approaches.

A. Basic Nutrition Education:

www.reeusda.gov/f4hn/efnep/tncba2.pdf

The cost-benefit of a nutrition education program through Cooperative Extension has been conducted in Tennessee. This community nutrition education program (Expanded Food and Nutrition Education Program; EFNEP) targets low-income families with children. Its goal is to change behaviors related to improve the nutritional quality of diets, handling food safely and stretching limited food dollars. Nutrition professionals and paraprofessionals in home and group community settings provide nutrition education. Ten nutrition-related chronic and acute diseases were evaluated in Tennessee for adults and infants. A cost-benefit ratio was found of $10.64 saved for each $1.00 invested.

B. Nutrition Therapy

1. Institute of Medicine, Food and Nutrition Board, Committee on Nutrition Services for Medicare Beneficiaries. The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population. 1999.

The Institute of Medicine (IOM) of the National Academy of Sciences conducted the study in response to a provision of the Balanced Budget Act of 1997. The IOM found that nutrition therapy has been shown to be effective in the management and treatment of many chronic conditions, which affect Medicare beneficiaries, including dyslipidemia, hypertension, heart failure, diabetes and chronic renal insufficiency. Medicare beneficiaries undergoing cancer treatment may also benefit from nutrition therapy aimed at controlling side effects or improving food intake.

Further, because of the comparatively low treatment costs and ancillary benefits associated with nutrition therapy, expanded coverage will improve the quality of care and is likely to be a valuable and efficient use of Medicare resources. Expanded coverage is likely to generate economically significant benefits to beneficiaries, and in the short term to the Medicare program itself, through reduced health care expenditures. IOM recommends that these services be reimbursed given the reasonable evidence of improved patient outcomes associated with nutrition care, whether or not expanded coverage reduces overall Medicare expenditures

The study estimates that the cost of providing nutrition therapy to Medicare beneficiaries for all diagnoses (physician referral required) for a five-year period, 2000 to 2004, would be $1.43 billion. For low utilization the estimated cost is $873 million while the high utilization estimated cost is $2.63 billion. Some of these costs will be passed on to Medicare beneficiaries through associated premium increases. Initial estimates indicate that savings could range from $52 to 168 million for hypertension, $132 to 330 million for diabetes and $54 to 164 million for dyslipidemia.

2. The Lewin Group, Inc. The Cost of Covering Medical Nutrition Therapy Under Medicare: 1998 through 2004, Final Report. 1997.

A study conducted in 1997 for The American Dietetic Association by The Lewin Group estimates net seven-year costs for coverage of medical nutrition therapy for all Medicare beneficiaries of $370 million. Savings from decreased hospitalizations and physician visits would be $1.2 billion from patients with diabetes and cardiovascular disease only. After the third year, savings were projected to exceed costs in each year. The study looked at the experience of Group Health of Puget Sound, which provided nutrition therapy based on self-referral.

3. The Lewin Group, Inc. The Cost of Covering Medical Nutrition Therapy Services under TRICARE: Benefit Costs, Cost Avoidance and Savings, Final Report. 1998.

A study completed by The Lewin Group for the Department of Defense estimates annual net savings of $3.1 million if medical nutrition therapy was included as a covered benefit in the TRICARE contracts (care provided to DOD beneficiaries of all ages by civilian health care organizations). The study showed that nutrition therapy is associated with a substantial reduction in health care spending for inpatient and outpatient services for persons with diabetes, cardiovascular disease, and/or renal disease. Cost of providing nutrition therapy for all nutrition-related diagnoses would be more than offset by reductions in health care spending for diabetes, cardiovascular disease and renal disease.

4. Focus on nutrition to improve chronic disease outcomes. Healthcare Demand & Disease Management. December 1997;3:177-184.

Following a successful pilot program in Brooklyn, NY, in which the health plan realized a tenfold return on investment, Oxford Health Plans broadened its nutrition program for at-risk elderly patients to all 160,000 Medicare members in New York, New Jersey, Connecticut, and eastern Pennsylvania. Oxford reported that for every dollar spent, it recognized $10 in savings.

5. Franz MJ, Splett PL, Monk A, Barry B, McClain K, Weaver T, Upham P, Bergenstal R, Mazze RS. Cost-effectiveness of medical nutrition therapy provided by dietitians for persons with non-insulin-dependent diabetes mellitus. J Am Diet Assoc. 1995;95:1018-1024.

The cost-effectiveness for nutritional care based on practice guidelines (averaging 151 min. with dietitian) compared to basic nutrition care (averaging 65 min.) was determined in a randomized clinical trial at the International Diabetes Center in Minnesota and related clinics in Florida and Colorado. The net cost effectiveness was $28.36 per patient per year (based on medication charges). Even such a small savings

per year becomes significant when applied to the 5-6 million American known to have Type II diabetes.

6. Gallagher-Allfred CR, Voss AC, Finn SC, McCarnish MA. Malnutrition and clinical outcomes: The case for medical nutrition therapy. J Am Diet Assoc 1996;96(4): 361-6.

This review summarizes the research available on malnutrition in hospitalized adults. In eight studies, 40 to 55% of hospitalized adult patients were found to be malnourished or at risk for malnutrition with as many as 12% severely malnourished. Nutrition support provided to malnourished patients across a broad range of medical conditions reduces complications, morbidity, length of hospital stay and mortality. The need for more clinical outcome studies is also highlighted. Estimate of cost savings through a team-care nutrition support approach was $4.20 benefit for every $1.00 invested.

7. McGehee MN, Johnson EQ, Rasmussen HM, Sahyoun N, Lynch MM, Carey M. Benefits and costs of medical nutrition therapy by registered dietitians for patients with hypercholesterolemia. J Am Diet Assoc. 1995; 95: 1041-1043.

This study of 474 outpatients with a primary diagnosis of hypercholesterolemia who were not taking lipid-lowering drugs and who were seen by a dietitian (at one of 20 hospitals or 3 HMOs) for at least 2 visits in a three year period were studied. There was a significant correlation of the reduction of serum cholesterol and the time spent with a dietitian ($r=0.118$; $p<0.001$). The more time spent with a dietitian, the greater the decrease in the patient's serum cholesterol. Mean total cost per patient for nutrition intervention by a dietitian was $163.

8. The Nutrition Care Management Institute. Cost Containment through Nutrition Intervention. Deerfield, Ill: Clintec Nutrition Company; 1996.

Tacker HN, Miguel SG. Cost containment through nutrition intervention. Nutrition Reviews 1996; 54:111-121.

This meta analysis of 22 published studies involving data from 70 hospitals over 15 years. The results suggest that nutrition therapy for patients at risk for malnutrition can decrease the length of stay and reduce costs.

2. Relative to the clinical effectiveness of nutrition-based approaches, please summarize data regarding the following measures:

Specific health conditions

Strong evidence (IOM report, McGhee et al.) from observational studies, consensus documents, systematic review and extensive clinical trials supports the value of nutritional therapy for:

dyslipidemia
hypertension
diabetes
osteoporosis.

Evidence (IOM report, Gallagher-Allfred et al., Tacher & Miguel) from observational studies, consensus documents, systematic review and some clinical trials (for heart failure and kidney failure) supports the value of nutritional therapy for:

heart failure
pre-dialysis kidney failure
undernutrition for Medicare beneficiaries.

The IOM report on The Role of Nutrition in Maintaining Health in the Nation's Elderly includes a critical and extensive review of the evidence supporting nutritional therapy in the above conditions. Multicenter clinical trials are included, such as the DASH studies and many others. Obesity, per se, is not addressed, but was considered in the review of evidence concerning dyslipidemia, hypertension and diabetes.

The IOM report concludes that limited evidence is available concerning the health benefits of nutrition related approaches, such as dietary supplements, botanicals, particular dietary regimens etc. for conditions such as Alzheimer's disease, osteoarthritis, and cancer.

Other critical reviews examine the data to support these conditions in specific populations as detailed below.

1. A position statement of the American Dietetic Association cites significant evidence that nutrition is a critical component of risk reduction and treatment, and must be included in clinical and preventive services for women (Women's health and nutrition -- Position of ADA and Dietitians of Canada. J Am Diet Assoc. 1999; 99:738-751.). The statement examines cardiovascular disease, cancer, osteoporosis, weight, and diabetes mellitus as significant health problems among women.

2. The ADA position statement on Nutrition services for Children with Special Health Needs -- Position of ADA (J Am Diet Assoc. 1995; 95:809) states, "Evidence of the benefits of nutrition intervention to the health and development of children with special health needs continues to accrue. This evidence is derived from treatment of conditions as diverse as metabolic disorders in which nutrition problems are primary,

and conditions in which the nutrition problems or risks result from biological, environmental, or psychosocial stressors. Improved nutrient and energy intakes, resulting in amelioration of growth and other nutrition markers, have been extensively documented. Economic benefits are derived from preventive and habilitative nutrition services."

3. Data supports the integration of nutrition education and nutrition intervention into the team treatment of patients with anorexia nervosa, bulimia nervosa, and binge eating during the assessment and treatment phases of outpatient and/or inpatient therapy. (Nutrition intervention in the treatment of anorexia nervosa, bulimia nervosa, and binge eating -- Position of ADA. J Am Diet Assoc. 1994; 94:902-907.)

Populations (age, sex, occupation, etc)

Evidence exists for the above disease conditions on the efficacy of nutritional therapy in both sexes across the adult life span (ages 17 to the elderly). The strength of the data varies for adults of different ages.

Practice setting, including whether nutrition-based approaches only, or in conjunction with conventional medicine

Evidence indicates that nutrition therapy is largely accepted as a component of conventional medicine in the treatment and management of many diseases and conditions. Most often nutrition therapy provided by a Registered Dietitian (RD) is currently provided as part of a team approach in conjunction with other therapies. The practice settings of the multitude of primary research reports summarized by these references include acute and ambulatory care.

The ADA position statement on medical nutrition therapy and pharmacotherapy (Medical nutrition therapy and pharmacotherapy -- Position of ADA." J Am Diet Assoc 1999;99:227-230.) cites evidence that "medical nutrition therapy and lifestyle counseling are integral components of medical treatment for the management of selected conditions for which pharmacotherapy is indicated. The Association promotes a team approach to care for clients receiving pharmacotherapy and encourages active collaboration among dietetics professionals and other members of the health care team."

Type of Practitioner

The reports and studies discussed above have largely focused on the registered dietitian as the primary provider of nutritional therapy. As discussed above, evidence supports the role of the dietitian as a member of the multi-disciplinary health care team. The IOM report recommends that the registered dietitian is "currently the single identifiable group with the standardized education, clinical training, continuing education, and

national credentialing requirements necessary to be directly reimbursed as a provider of nutritional therapy."

Many health-care practitioners in a wider variety of settings do basic nutritional education. These can include: physicians, nurses, pharmacists, dentists, chiropractors, nurse practitioners, physician assistants, and clinical social workers. The depth of training in nutrition varies tremendously among these health care providers

3. Describe the cost-effectiveness of dietary supplements provided as a stand-alone therapy with nutrition-based approaches that are provided in conjunction with conventional medicine as part of an integrative approach.

Little information is available on the cost-effectiveness of dietary supplements either as a stand-alone therapy or as a part of conventional medicine or nutritional therapy. Further, significant scientific consensus is lacking on the efficacy and safety of many dietary supplements.

Intriguing and frequently contradictory evidence is emerging on bioactive food components and botanicals. The potential impact of omega 3 fatty acids, gamma linoleic acid, flaxseed, green and black tea, flavenoids, antioxidants, supplemental vitamins and minerals, and many others needs to be evaluated. Efficacy, cost-effectiveness and safety need to be evaluated. As these studies are conducted, designs need to include a dietary assessment component. The interaction of nutrients and bioactive components has not been well-considered, but needs to be.

A cogent example illustrates this need. With the finding from epidemiological studies that the consumption of fruits and vegetables reduced the risk of cancer, the initial mechanistic hypothesis focused on beta carotene. However, results of several intervention trials with beta-carotene (and vitamin A) failed to support a role of beta-carotene in high risk populations and have suggested that there may in fact be an adverse effect of high levels of beta-carotene. We still do not know the active component(s) in fruits and vegetables in preventing cancer.

This example points out the need to study whole foods and dietary patterns. Recognition is growing that many bioactive components of foods and botanicals, whether nutrients or not, might interact to effect a particular health outcome. Understanding the mechanisms whereby dietary components or supplements act is important; but even in the absence of understanding such mechanisms, clinical effectiveness demonstrated through rigorous double-blind (when possible), random and placebo-controlled trials can be helpful in recommending healthy dietary patterns and practices.

Another example comes from weight-loss nutritional approaches. Clearly from decades of research, dietary caloric reduction and physical activity caloric increases are effective means of losing weight. Particularly in combination, the lost weight can be predominantly body fat as opposed to undesirable losses of lean body mass or ineffectual temporary losses of body water. What dietary patterns, however, are most effective in reducing calories and effecting weight loss is much more controversial. Many popular diets, prominently marketed in the mass media, have not been rigorously tested, but need to be. Importantly the weight loss needs to be evaluated relative to body fat loss.

4. Compare the costs of nutrition-based approaches with those of conventional medicine for the same or similar health conditions.

Nutrition therapy is increasingly recognized as an integral component of conventional medical treatment that can result in lower health care costs through reduced hospitalizations and physician visits, fewer complications and lower utilization of medication and more costly interventions/treatments.

Nutrition therapy has been incorporated into the treatment protocols for controlling diabetes, high blood pressure and elevated cholesterol, all of which often require the use of expensive drug treatments. Studies indicate that medical nutrition therapy provided by nutrition professionals, such as registered dietitians, can be used to help individuals successfully manage their disease conditions through dietary lifestyle changes. As a result, the need for drug treatments can often be substantially reduced or eliminated. Reducing the need for intensive drug therapy may also result in reduced cost and fewer side effects for the patient. This could improve adherence to the overall treatment program.

5. Summarize patient satisfaction data, if available.

Limited data exist. Results from Schiller et al. suggest a high degree of positive outcomes and patient satisfaction from nutrition counseling provided by dietitians. Nutrition counseling gives patients a greater sense of understanding and control of their conditions and helps meet emotional and interpersonal needs. (Schiller, M.R., Miller, M., Moore, C., Davis, E., Dunn, A., Mulligan, K., Zeller, P., Patients report positive medical nutrition therapy outcomes. J Am Diet Assoc 1998; 98: 977-982.)

6. Describe current significant barriers to the access and delivery of nutrition-based approaches.

Lack of recognition of dietitians and nutrition professionals as providers of nutrition therapy in Medicare/Medicaid and the private sector health plans remains a barrier to

nutritional care in the acute and ambulatory settings. The net impact is that consumers are currently not able to receive the life saving nutrition therapy as a benefit in many circumstances. Current factors contributing to this challenge are multiple. There is no consistent definition of nutrition services within the insurance industry. Coverage varies from state to state, making it a challenge to implement nutritional therapy. We lack a universal procedure for payment of nutrition services. Claims/billing examiners lack sufficient familiarity with dietitians and their services and are unable to distinguish which parts of nutrition care are reimbursable. Insurers lack adequate cost/benefit and cost-effectiveness data to justify the benefit of nutrition treatment.

Other health care providers do not understand the expertise or training of the dietitian. A recent study examined the practice of chiropractors concerning nutrition counseling and referrals to registered dietitians (Walker B et al. Provision of nutritional counseling, referrals to registered dietitians and sources of nutrition information among practicing chiropractors in the United States. J Am Diet Assoc 2000; 100:928-933). Although 90% of responding chiropractors provided nutrition counseling, most were not aware of the educational requirements for registered dietitians and did not refer their patients to registered dietitians. Compounding the problem is the inadequate training received by other health care professionals to identify potential nutrition problems and determine when to refer patients to dietitians for comprehensive nutrition services. The position paper of the American Dietetics Association ("Nutrition education for health care professionals -- Position of ADA."J Am Diet Assoc. 1998;98:343-346) states, "The shift in health care to earlier intervention and increased ambulatory care services makes it necessary that health practitioners be able to identify nutrition risk and recognize when it is necessary to refer a patient to a registered dietitian for medical nutrition therapy and intervention. The majority of health care providers need initial and continual lifelong learning about comprehensive nutrition services to enhance the nutritional health of the public." The IOM report concurs.

In terms of basic nutrition education, consumers regularly turn to sources other than dietitians, nutrition professionals and health care providers when it comes to information about health and nutrition. In fact, ADA's 1997 Nutrition Trends survey found that most Americans get their nutrition information from mass media outlets—57% from television, 44% from magazines, and 23% from newspapers. Only 5% of people surveyed received nutrition information from dietitians.

News media are the most visible messengers of health and nutrition information. Consumers are relying on information provided in audiovisual or print media to make food purchasing decisions. Nutrition misinformation is compounded by the Internet and food advertising in magazines, which tend to promote foods that are not necessarily have nutritional or health value. Advertising media contain health and nutrition claims, which influence consumers food choices. Consumers are not relying on dietitians to provide them with expert nutrition advice and services. (For more details, see "Comparison of food groups and health claims appearing in food advertisements in 3

popular magazines" J Am Diet Assoc 2000; 100:1396-1398. and "Status report on nutrition in the news" J Am Diet Assoc 2000: 1001298-1299.)

The importance of the food or supplement label as a source of nutritional information to the consumer must be recognized. The impact of the Pearson decision on health claims on labels is yet to be determined. Many contradictory results can be selectively cited to validate a claim. An example would be supplemental vitamin E use to reduce the risk of cardiovascular disease. A consensus view is not available, leading the IOM to conclude that insufficient agreement exists in the present data to evaluate the clinical effectiveness of this practice.

7. Discuss whether nutrition-based approaches should be delivered as stand-alone care or should be integrated with more conventional therapies.

Nutrition therapy works best when utilized in an integrated approach to the prevention, management and treatment of disease. Most of the evaluation of nutritional therapy presented in my testimony focuses on the management and treatment of disease.

A major concern for the future is the focus of nutrition approaches on disease prevention. Growing evidence is highly suggestive that diet and nutrition is one of the key risk-reducing factors for cancer, osteoporosis, cardiovascular disease and hypertension under an individual's control. Understanding how to motivate individuals early in their life to adopt healthy dietary and nutritional practices that will prevent the chronic diseases discussed remains a major challenge in nutrition. Simply put, we understand too little about diet and behavior. Public health and community nutrition need a greater focus. The U.S. Dietary Guidelines represent a strong, albeit not unanimous, consensus on the key aspects of a healthy diet. The cost-benefit analysis of the Tennessee EFNEP program suggests considerable benefit to be gained by preventative nutrition education.

8. Please suggest specific policy recommendations that would improve the access and delivery of nutrition-based approaches to consumers, including legislative or regulatory recommendations.

Legislative Recommendations:

Legislation is currently before Congress to provide outpatientMedicare coverage of medical nutrition therapy. The bills, H.R. 1187 and S.660, have gained the support of 292 Representatives and 37 Senators. A limited medical nutrition therapy benefit to cover individuals with diabetes or kidney disease is included in the package of Medicare Balanced Budget Act revisions and enhancements approved by the House of

Representatives. Passage of this legislation would increase access to nutritional therapy.

Depending on the outcome of this Medicare legislation in the current Congress, efforts need to be renewed to gain Medicare Part B coverage of medical nutrition therapy. If passed, efforts to expand coverage beyond diabetes and renal disease to cardiovascular disease, osteoporosis, cancer and HIV/AIDS need to be pursued.

The IOM recommendation to reevaluate existing reimbursement systems and regulations for nutrition services in acute care, ambulatory care, homecare, skilled nursing and long-term care would greatly expand access to nutritional therapy to vulnerable populations.

Regulations:

Health claim labels on dietary supplements and foods should be evidence based. If health claims are permitted that do not meet the current standard of 'significant scientific agreement', such claims must be truthful and not misleading. Regulations need to find a way to ensure that a single study is not the validation of a health claim when contradictory evidence exists in the literature.

Policy:

NIH should stimulate and support nutrition research to evaluate the efficacy, safety and cost-effectiveness of various nutrition and dietary interventions, especially those related to dietary supplement use and the interaction of nutrients and bioactive food components.

NIH, with other relevant federal agencies such as USDA, should stimulate and support nutrition research on diet and behavior so that theoretically based and sound research can inform nutritional education and nutrition therapy for the most effective clinical outcomes.

Coordinate nutrition research occurring within NIH and other government agencies with efforts in the private sector.

Develop programs to educate the public and health care providers about the importance of nutrition and nutrition services in the prevention, treatment and management of chronic diseases.