

# Report 12 of the Council on Scientific Affairs (A-97) Full Text

## Alternative Medicine

The terms "alternative medicine," "complementary medicine," or "unconventional medicine" refer to diagnostic methods, treatments and therapies that appear not to conform to standard medical practice, or are not generally taught at accredited medical schools. The scope of alternative medicine is broad, with widespread use among the American public of a long list of treatments and practices, such as acupuncture, homeopathy, relaxation techniques, and herbal remedies. In an editorial about alternative practices in the *New England Journal of Medicine*, Murray and Rubel comment, "Many are well known, others are exotic and mysterious, and some are dangerous."<sup>1</sup> This report will help to clarify and categorize the alternative medical systems most often used, create a context to assess their utility (or lack thereof), and discuss how physicians and the medical profession might deal with the issues surrounding these unconventional measures in health and healing. The Appendix lists various alternative systems and methods in common use.

At the turn of the last century, the effort led by the American Medical Association (AMA) to improve the quality of medical education and bring quality controls to curricula ultimately led to the landmark report by Flexner in 1910. Among other outcomes, the resulting changes in medical education led to the acceptance of the biological, disease-oriented models that dominate medicine in the United States today. State licensing boards, influenced by the AMA, limited the practice of medicine to graduates of accredited institutions, and research funding became the domain of the major teaching centers. All these factors put great pressure on smaller schools (and their graduates, many of whom were homeopaths) that could not meet the emerging requirements for medical education and practice. As a result, many schools that taught practices such as homeopathy were closed, homeopaths were shunned and stigmatized, and their therapies became the "alternatives" to the standards that evolved after acceptance of the Flexner reports. In contrast, Osteopathic schools like allopathic schools developed rigorous standards and practices.

### I. Alternative Systems and Techniques

Most observers from outside the fields of alternative or unconventional medicine find no common or unifying theory or basis for its use; indeed, it may be that the variety of treatments in itself enhances their popularity. Many such therapies are characterized by a charismatic leader or proponent, and are driven by ideology; some spring from folk practices or quasi-religious groups, while others are recognized elements of religions such as those practiced by Native Americans.

Many alternative practitioners are unlicensed (except for chiropractic, and in some states, acupuncturists, naturopaths, and homeopathic therapists) and unregulated, particularly those dealing in alternative nutritional therapy.

The adherents of these fields, however, state that "most alternative systems of medicine hold some common beliefs."<sup>2</sup> Many theories of alternative medicine attempt to pose a single explanation for most human illness; the therapy is thought to correct the source of the problem, not merely treat its symptoms. The recuperative power of the human body and the potential for certain stimuli to enhance this natural healing are central to many therapies. Other unifying threads include:<sup>2</sup>

- Importance of spiritual values to health
- Integration of individuals in the "stream of life"
- Attribution of a causal, independent role to various "manifestations of consciousness"

- Use of whole (unsynthesized) substances
- Maintaining the injunction to "do no harm"
- The philosophy that achieving and maintaining health is very different from fighting disease
- A belief that personal experience and anecdote are as reliable as scientific study in determining whether something is effective.<sup>3,4</sup>

John Renner, MD, a board member of the National Council Against Health Fraud, has proposed a set of definitions<sup>3</sup> that are useful in discussing of alternative therapies, treatments, and devices.

1. "Proven" products and services are those that have been scientifically tested, optimally through controlled clinical trials and double-blind studies, and found to be both safe and effective for the specific condition for which their use is proposed.

2. "Experimental" therapies or products are those undergoing controlled trials to determine their proper application, dose, frequency of use, general safety, and efficacy. Such trials should be conducted under the supervision of recognized entities such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH), or in academic medical centers, with proper human subjects review and full informed consent among any persons involved.

3. "Untested" methods are those that have never been subjected to rigorous clinical testing or evaluation under standard protocols and controlled conditions. Many of the herbal, homeopathic, and dietary products described in the previous narrative would fall in this category.

4. "Folklore" remedies have usually been passed down through cultural tradition and oral history, including many home remedies such as chicken soup for colds and honey and lemon tea for sore throat. Most folk medicine is not done for personal enrichment and is noncommercial.

5. "Quackery" or health fraud involves commercial marketing or use of therapies, products, or procedures with no proven effectiveness that could also cause physical harm; indirectly harms patients by delaying appropriate therapy or diverting care to unproven methods; and often involves financial fraud as well. Promises of cure for cancer, human immuno-deficiency virus (HIV), and other conditions for which little hope is present attract desperate patients willing to try anything. Anecdotal testimonials are the main basis for the "success" of these modalities.

The failure (real or perceived) of many physicians and medical specialties to understand and practice preventive medicine and to communicate effectively with patients, and conventional medicine's dependence on costly diagnostic and procedural interaction that ignores the human side of medicine may have helped spur public interest in alternative and unconventional therapy.

## **II. Theories of Alternative Medicine**

### **Mind-body interventions**

Much of alternative medicine deals with the relationship between the mind (as distinct from the brain and its biochemistry) and the body, with a chief goal of achieving a sense of psychological or spiritual well-being in persons and a feeling of wholeness even in the face of a disease process or condition. Patients with a wide range of conditions and disorders benefit from applications of techniques in this area; cancer, chronic pain and burns, chemical dependence, several neurological and psychiatric conditions, blood pressure and cholesterol reduction, home births, and other problems have been the subject of this set of treatments.

Some of the therapy sounds very familiar to orthodox clinicians--stress management through meditation, music and art therapy, hypnosis, focused relaxation, and psychotherapy are all known

to physicians as useful treatments. Biofeedback has been used for years in helping with anxiety and stress-related disorders, and for adjunctive therapy in blood pressure management. Some of the clinical applications of these techniques are, however, decidedly unconventional. Guided imagery to produce spontaneous remission of cancer, for example, or hypnotherapy for immune disorders and hemophilia fall into this category. Meditation is touted for its ability to increase intelligence and longevity, and yoga for better diabetic control. Advocates call for research into the "nonlocal effects of consciousness" as well as for more traditional kinds of review such as the effects of personal belief, values, and meaning on health and illness.

## **Diet/nutrition**

The knowledge that good nutrition and a balanced diet help maintain health is not new, or news. A cornerstone of belief in most alternative systems is the repudiation of the "modern, affluent diet" and its replacement with a diet rich in whole, "organic" products, often vegetarian in approach. Many healers maintain that certain diets promote anti-tumor immunity or cardiovascular health; other regimens advocate specific micronutrients or vitamins for particular conditions or overall longevity. There seems to be a continuum of beliefs ranging from promoting dietary supplements beyond the Recommended Dietary Allowances (RDAs), to elimination or addition of specific foods to "treat" specific conditions.

Much of the dietary intervention stressed by alternative healers is prudent and reasonable. The American diet is unarguably too rich in fat and empty calories. Dietitians and nutritionists are licensed in many states, and are an invaluable source of advice to physicians and patients alike regarding nutrition and dietary management of a host of conditions. But the approach taken by some alternative practitioners encourages what many consider the excessive use of health foods and dietary supplements, often of a proprietary nature and meant to enrich themselves while promoting several myths:<sup>4</sup>

1. it is difficult to get the nourishment one requires from ordinary foods
2. vitamin and mineral deficiencies are common
3. most diseases are caused by faulty diets and can be prevented by nutritional interventions
4. any use of food additives and pesticides is poisonous

## **Herbal remedies**

Herbal medicine is a booming industry in the United States. The American market for herbal remedies has doubled since 1985, to \$1.13 billion in 1993 (excluding homeopathic remedies and teas). Growth is expected to continue at 10% to 15% per year through 1997. Four-fifths of all people, worldwide, still rely to a great extent on traditional medicines based on plants and their components.<sup>5</sup>

The use of herbs in medicine is ancient in its origins, and several examples are well known to both physicians and the public: foxglove as the treatment for "dropsy" and later, the source for digitalis, and quinine's origins in *Cinchona* bark. New therapies such as taxol continue to show the usefulness of plants as a source of our pharmacopoeia. The director of collaborative services in the Department of Pharmacology at the University of Illinois at Chicago, a national botanical authority, states that only 90 plant species account for most of the plant-derived drugs in common use by physicians, about 120 drugs in all. Three-fourths of this list was discovered by following up on traditional folk medicine claims.<sup>5</sup>

Basic to the use of herbs in alternative medicine is the belief that whole plant material is superior to synthesized or isolated chemicals derived from plant sources. The material may be flowers, bark, roots, or leaves, used singly or in combination, often taken in the form of teas, or ground

and taken as tablets, or used in salves. These compounds are thought to produce fewer unintended or dangerous effects, and a "balanced" action as opposed to single drugs. There is little evidence for this belief, however and no standardization of the dose in herbal healing. The safety of many of the compounds is unknown, or the potential toxicity ignored.<sup>6,7</sup>

Folk healers, herbalists, naturopaths, traditional Chinese healers, homeopaths, and a host of others in alternative practices commonly use herbal remedies. As with other nutrition therapies, herbs are prescribed to prevent or treat specific conditions, and are consumed by many persons to maintain health. For example, a recent meta-analysis study on St. John's wort (*Hypericum perforatum*) suggests that this herb shows promise in treating mild to moderately severe depression.<sup>8</sup> An accompanying editorial points out several limitations in these interesting data, including the need for trials longer than 8 weeks, better patient selection and categorization of diagnosis, and comparisons with therapeutic doses of standard antidepressants.<sup>9</sup>

The conclusion that St. John's wort needs more study is distinctly different, however, from the one expressed by the president of Bastyr University, a school of naturopathy in Seattle, Washington. In an article written in a popular consumer magazine,<sup>10</sup> he describes common drugs he "personally would never take," offering "natural alternatives that help correct the underlying problem" that he describes as "safer, more effective, and less expensive" than such treatments as estrogens for menopausal symptoms, non-steroidal anti-inflammatory drugs, and conventional antidepressants. He advocates the use of St. John's wort or other herbs for mild to moderate depression. He does caution readers to consult with their doctor before beginning his suggested treatments, or making changes in current medication regimens.

Regulation of herbal and plant products in Germany has been assigned to a special commission within the Federal Health Agency that has produced a series of monographs on the safety of these products. More than 200 such products have been approved, some of which seem to have salutary effects. As opposed to the FDA requirements of evidence from randomized studies, the German commission demands a less stringent standard for efficacy, allowing material such as case reports, historical data, and other data in the scientific literature.<sup>11</sup>

The Dietary Supplement Health and Education Act of 1994 regulates the claims that can be made about the effects of herbal and nutritional products. The Act gives the FDA some controls over herbal supplements, vitamins, and amino acid preparations and similar products, classifying them as dietary supplements. Manufacturers cannot make claims as to the health or therapeutic benefits of their products on package labels and labeling without receiving FDA prior approval. However, general claims related to well-being and to the effect of a substance on the structure or function of the body can be made without any evaluation or approval by the FDA. The Act also shifts the burden of proof to the FDA to prove that a product in this category is unsafe prior to taking regulatory action, rather than requiring the manufacturer to obtain FDA approval by showing that the product is safe before offering the product to the public. New labeling requirements and an Office on Dietary Supplements in the NIH also are called for by the Act.

Because this category of products can be marketed without FDA review or approval, standards for dosage and other manufacturing safeguards, or evidence of safety, some health fraud experts worry that this new law will make it easier for nutrition to be misused by hucksters, and will hamper the FDA's ability to effectively monitor safety among the growing number of herbal and nutritional remedies being offered to the public. The burden now rests with the consumer to interpret claims made by the manufacturers of these products. For example, persons with acquired immunodeficiency syndrome (AIDS) might believe a claim made by an herbal product of "boosting T-cells" is true and leads to an improvement in the course of the disease from using the product.

An example of FDA intervention in this area involves ephedrine alkaloid containing dietary supplements that have been promoted as euphoric agents that are safe alternatives to illegal

drugs, as well as for purposes such as weight loss, energy or body building. [NB: FDA has recorded very few adverse events with products marketed as euphorics.] Containing "natural" sources of ephedrine such as ma huang, ephedra, *Ephedra sinica*, or extracts of these substances, these compounds have been shown to have adverse effects such as headache, dizziness, palpitations, and possibly, clinically significant effects such as heart attack, stroke, seizures, and psychosis. The FDA considers marketing of these products, often aimed at adolescents looking for a "high," to be in violation of the Act, and is currently considering regulatory steps to ensure the safety of ephedrine-containing dietary supplements and what further action should be taken in this area.

Our ability to increase our understanding of the role of herbal remedies in medicine is hampered by deforestation, and the loss of knowledge held about plant therapies by indigenous people as the Amazon and other remote areas are developed. Activity in biodiversity is being supported by the NIH, the National Institute of Mental Health, the National Science Foundation, and the US Agency for International Development.<sup>2</sup> Both the traditional medical community and the adherents of alternative therapy have called for increased research into this area.

### **Manual healing methods**

The healer's touch has been considered a therapeutic instrument for the entire history of medicine, dating back to instructions by Hippocrates about therapeutic massage. Ancient Chinese medicine has strong roots in this system, and several areas of alternative medicine are associated with manual healing methods. The major fields of manual healing include (1) methods that use physical touch, manipulation, and pressure--chiropractic and osteopathic manipulation are primary examples; (2) therapies that use an "energy field" that can influence healing; and (3) mixed interventions that use both physical touch and energy field therapy.

### **Osteopathy**

Osteopathic physicians derive their theories from the work of Andrew Taylor Still (1828-1917), a physician's son who was trained as an apprentice to his father. After the Civil War, he began an empirical study of healing by manipulating bones and soft tissues to allow the free circulation of blood and lymph, and to restore the nervous system to what he considered a more normal function. Known as the "lightning bone-setter," he disdained the common practices of physicians in the last century such as venesection, emesis, and sedation with narcotics, preferring to use manipulation to enhance the body's innate ability to heal itself. Instead of using drugs, he believed that the solution to illness lay in treating the underlying condition, allowing the body's natural forces to return the patient to health. He proposed that much more than headache and back pain could be treated with manipulation, and set forth a regimen of therapy that included treatment for serious conditions such as pneumonia, dysentery, and typhoid fever.

The first school of osteopathy was opened in Missouri in 1892, teaching a variety of methods: manipulation of soft tissue, isometric and isotonic muscle techniques, manipulation with varying "velocity," the use of the percussion hammer to strike the body to alleviate "restrictions" in the joints and muscles that allowed internal processes to function normally, and other unorthodox therapies. Since that time, osteopathic education and its practitioners have become nearly indistinguishable from their allopathic cousins, with the exception of manipulation techniques that continue to be integral parts of osteopathic diagnostic and treatment modalities. Modern osteopathic physicians are considered to be in the mainstream of medical practice, with rigorous standards for education and specialty training. Osteopathic physicians commonly complete allopathic postgraduate specialty training, and are licensed to practice the full scope of medicine in all states, without restrictions. Some advocates of alternative medicine criticize modern osteopaths for abandoning the original scope and breadth of manipulation therapy.

## **Chiropractic**

As with many systems in alternative medicine, chiropractic holds that the innate ability of the body to heal itself can be optimized by achieving a "balance"; that proper function of the nervous system is key to this homeostasis; that "subluxations" of the spine and misalignment of joints impinge on nerves, causing imbalance in internal systems; and that manual release of these structural and functional joint pathologies can heal a number of conditions, and prevent illness as well.<sup>12</sup>

The theories behind chiropractic have been widely criticized. A 1968 study by the US Department of Health, Education, and Welfare concluded that chiropractic schools did not prepare students to adequately diagnose and treat patients, and recommended that their services not be covered under Medicare.<sup>2,12</sup> In 1972, Congress added Medicare benefits for "manual manipulation of the spine to correct a subluxation demonstrated to exist on x-ray." In 1974 the Council on Chiropractic Education was recognized to accredit schools of chiropractic, despite the absence of clear evidence of efficacy of chiropractic therapy.<sup>12</sup> Over the years, both political pressure and consumer acceptance has won licensure for chiropractic in all 50 states. Most of the nation's 45,000 chiropractors bill Medicare for services rendered, amounting to \$181 million in 1990.<sup>12</sup> Most third-party payers accept claims from chiropractors.

Manipulation has been shown to have a reasonably good degree of efficacy in ameliorating back pain, headache, and similar musculoskeletal complaints,<sup>13</sup> and some chiropractors limit their practices to these conditions. While precise statistics are not available, a majority of chiropractors adhere to the method's original theories, and continue to claim that chiropractic manipulation cures disease rather than simply relieving symptoms. (Personal communication, Denny Futch DC, Vice President, National Association of Chiropractic Medicine). They promote manipulation as useful in a host of conditions, ranging from infectious diseases to immune therapy, even claiming to prevent future conditions from occurring (even if years away) including menstrual irregularity, difficulty giving birth, and cancer.<sup>12</sup> Chiropractors commonly provide advice in nutrition and other preventive practices, and maintain that a regular series of "adjustments" is needed by most persons to maintain optimal health.

## **Energy healing**

Biofield, or energy healing, is described by its proponents as "one of the oldest forms of healing known to humankind."<sup>14</sup> Theories related to this practice involve transfer of energy from healer to patient in unknown ways, either from a supernatural entity or by manipulating the body's own "energy fields." Over 25 terms are used in various cultures to describe this life force. Biofield practitioners incorporate a holistic focus into therapy, and promote their methods as useful for stress and general improvement of health; relief of pain, edema, and acceleration of wound and fracture healing; improvement in digestion, appetite, and various emotional states; and treatment of conditions such as eating disorders, irritable bowel syndrome, and pre-menstrual syndrome.

Some unique conditions are "diagnosed" by biofield practitioners, such as "accumulated tension" and "congested energy" that, when released, supposedly lead to improved health. A common form of this therapy is used by nurses, and is called "therapeutic touch." It involves moving the hands over (but not in direct contact with) the patient's body either to create a general state of well-being by enhancing "energy flow" in the subject, or to release "accumulated tension" and induce balance and harmony. At least one school of nursing has demanded that its faculty cease teaching these modalities as part of their curriculum (personal communication, John Renner, MD).

Therapies that combine manipulation and biofield therapy include "network chiropractic spinal analysis," which combines soft-tissue chiropractic and applications of the biofield, followed by

conventional chiropractic treatment; "craniosacral therapy," an offshoot of osteopathic medicine involving manipulation of cranial and/or sacral bones to relieve "restrictions" in motion of these bones that are thought to help persons with seizures, immune disorders, learning disabilities, and assorted other conditions; and "polarity therapy," in which touch, energy field manipulation, and other modalities correct distortions in one's "energy anatomy."<sup>15</sup>

### **Pharmacologic methods**

The area of pharmacologic treatment is rife with both opportunity and peril, since many of the modalities in unconventional medicine that use pharmacologic and biologic treatment may truly be deserving of clinical trials and well-funded investigation. At the same time, many therapies in this area represent true health fraud. Some areas under investigation include immunotherapies, including the use of antitumor antibodies; alternative strategies to treat menopausal conditions; the use of local anesthetic injection into autonomic ganglia and other sites, such as acupuncture points for chronic pain; and several cancer and HIV treatments.

Some methods proposed for study and further dissemination have been associated with proponents using questionable methods and possibly fraudulent research. Several of these are cancer therapies, including "antineoplastons," popularized by a physician named Burzynski who claims he can "normalize" tumor cells by shutting off their undifferentiated growth using peptides extracted from urine. A review of this method in JAMA<sup>15</sup> concludes that no objective evidence exists to support the experimental claims.

Chelation with EDTA for heart disease and other cardiovascular conditions is another questionable practice in this category. Described by proponents as a nontoxic way to flush "toxins" and fatty deposits from the arterial system, it has also been touted for emphysema, kidney and endocrine disease, and arthritis. Ozone therapy has been advocated by alternative healers, as has intravenous hydrogen peroxide. Therapies involving bee pollen (and other products from bees) are in widespread use, with no scientific evidence for efficacy--but a Senator who attributed improvement in his health to bee pollen spurred the creation of the NIH Office of Alternative Medicine (OAM).

Investigators worry that the Internet has become a bazaar for alternative therapies, whose purveyors can use overseas addresses for distributing products that are not subject to any sort of scrutiny. There are now more than 100 commercial outlets for shark cartilage, a substance that is promoted for cancer treatment and prevention, arthritis, and a host of other ailments. Hormones such as DHEA (dihydroepiandrosterone) get Internet claims for extending life, normalizing blood sugar and cholesterol, and sexual enhancement. Colloidal silver is said to be a "safe natural antibiotic" that "kills 650 disease causing organisms." Asparagus extract is said to "restrain and prevent metastasis of middle as well as late stage tumors," and the list goes on, with hundreds of alternative medicine home pages and links to mail order firms.<sup>17</sup>

Proponents of alternative pharmacotherapy argue that proper funding, well-organized trials, and modifications in FDA regulations for experimental therapy will help these therapies get a "fair hearing" by the traditional medical community. On the other hand, they have requested immunity from the FDA and other regulatory oversight, protecting investigators from fraud and licensing actions, raids, seizure of materials, import alerts, and other interventions for all clinical trials endorsed by the OAM.<sup>18</sup>

### **III. Alternative Systems of Practice**

Several distinct systems of alternative practice encompass many of the theories and methods described above.

## **Acupuncture**

Acupuncture is an ancient technique with its origins in traditional Chinese medicine. The internal study of the body was forbidden in China, so structural anatomy as defined by dissection was unknown. Twelve organs, or "spheres of function," were thought present, having minimal equivalency to anatomic definitions used in Western medicine. Body function was described in theories of energy flow, *orch'i*, from one organ to another. Each of these organs is described as having a superficial "meridian" with many numbered points, originally derived from Chinese astrologic calculations. By inserting needles into these points, acupuncturists believe energy flows can be manipulated or imbalance corrected, resulting in therapeutic effects on corresponding internal systems.

Western practitioners have increasingly begun to use acupuncture, but many may not be using techniques that correspond to traditional Chinese teaching. The American Academy of Medical Acupuncture is a group of more than 700 physicians who offer training and continuing medical education, and set "standards of practice" regarding use of these techniques in medical practice. Most often, acupuncture is used for acute or chronic pain relief, but some proponents also use it for smoking cessation and substance abuse treatment, asthma, arthritis, and other conditions. Endorphin release, stimulation of the peripheral nervous system, and pain mediation through the effects of other neuropeptides are currently thought to be the most likely conventional explanations for the effects of acupuncture.

Several variations on the general theme exist, including the use of heated needles, passing low-voltage current into the acupuncture point, and applying lasers to acupuncture points. Proponents from different traditions (i.e., Korean vs. Chinese) often disagree as to the "correct" location of acupuncture points for treating a given condition. Recently, the FDA reclassified acupuncture needles as devices that do not require clinical studies, thus easing requirements for marketing. Critics contend that acupuncturists, including many traditionally trained physicians, merely stick needles in patients as a way to offer another form of treatment for which they can be reimbursed, since many insurance companies will do so. Critical reviews of acupuncture summarized by Hafner<sup>4</sup> and others<sup>19</sup> conclude that no evidence exists that acupuncture affects the course of any disease.

## **Homeopathy**

Homeopathy was begun in the early 1800s by Samuel Hahnemann (1755-1843), a traditionally trained German physician who renounced the practices of the day, such as bleeding and purging, taking an approach based in not inflicting harm. He studied the effect of drugs of the day on the body, and devised a new series of rules for their testing and later, their application. His primary theory is the "Law of Similars"--"like cures like." Coining the term homeopathy, he proposed that small amounts of a substance that could induce a set of symptoms in a patient could cure a disease with similar symptoms. This evolved into a highly structured, complex set of pharmacologic interventions or "provings" with formulation and administration of extremely dilute concentrations of substances and drugs, based in the "Law of Infinitesimals." Homeopaths believe that even extreme dilutions of a drug will have a salutary effect, and that the molecular structure of the diluent is somehow changed in the process of preparation, by vigorous shaking and striking the side of the flask containing the preparation. Then, the "memory" of the original drug is carried on even when, after multiple dilutions, none of the original substance could be theoretically present. Careful attention to the total history of the patient was emphasized, and the use of a single homeopathic remedy for a given condition or set of complaints was taught, based on detailed observations of the effects of these preparations.

Introduced into the United States in 1828, homeopathy spread and competed with traditional medicine, with results that were at least as favorable as bleeding and other customs of the day. By the turn of the century more than 14,000 homeopaths had been trained, and 22 schools taught



the theory in the United States. As mentioned previously, advances in medical education, scientific theory, and pressure from organized medicine led to the decline of homeopathy. In 1938, a homeopath in the US Senate, Royal Copeland (D-NY), succeeded in giving homeopathic remedies legal status, adding the drugs found in the *Homeopathic Pharmacopeia of the United States* to the list of articles that the FDA recognizes as drugs. This automatically designated these drugs as "safe," although their efficacy was never proven.

Today, homeopathy is practiced mostly by persons licensed as physicians or holding another license allowing the prescription of drugs. Some lay healers use homeopathy, and homeopathic remedies abound in health food stores and many supermarkets that feature "organic" products. Some homeopathic healers continue the tradition of extensive patient interviews and the use of a single substance as instructed by Hahnemann's original treatises; others use several compounds simultaneously, and add other modalities to their range of treatments, such as massage and skeletal manipulation, acupuncture, and aromatherapy.

While most homeopathic remedies are not known to have harmed anyone (probably because of the extreme dilutions involved), the efficacy of most homeopathic remedies has not been proven. Some think it a placebo effect, augmented by the concern expressed by the healer; others propose new theories based on quantum mechanics and electromagnetic energy.

A randomized clinical trial of homeopathic remedies has been touted as showing the effectiveness of homeopathic treatments in childhood diarrhea.<sup>20</sup> However, it has been criticized for inconsistent/incorrect data analysis; use of different diagnostic and treatment categories but combining them in the conclusions of efficacy; and lack of chemical analysis of different treatments. The clinical significance of the results, given the self-limiting condition being studied, has been called into question.<sup>21</sup>

Homeopathy's adherents propose new trials of these therapies, systematic review of standard pharmacologic agents subjected to homeopathic dilutions and therapeutic application, and investigation into clinical outcomes following homeopathic treatment.

## **Naturopathy**

Naturopathy is a term coined by John Scheel in 1895 to describe his methods of healing. A poorly developed set of principles and theories, naturopathy may have its roots in the spas of Europe that flourished at the turn of the century. About 20 schools of naturopathy were present in the United States in the early 1900s. The Flexner report and other pressures led to its decline. It never had the political and professional stature of other alternative methods, and until recently, education in naturopathy was available only through schools of chiropractic.

Currently, three naturopathic colleges have been accredited by the profession, led by Bastyr University in Seattle. Naturopathy is a four-year course of study that involves two years of anatomy, physiology, and basic sciences, and two years of applied courses. Naturopaths practice various treatments such as manipulation and massage, and use herbs, acupuncture, and traditional Oriental medicine. Its practitioners treat underlying causes of illness by facilitating the body's response to disease through its "life force." Questionable therapy such as prescriptions of colonic irrigation, and chelation therapy to "remove toxins" presumed present in the body are commonly used by naturopaths. Some naturopaths use "diagnostic" techniques such as iridology hair shaft analysis. Naturopaths are licensed in 11 states, but most third-party payors, including Medicare, do not cover their services. Recently, the King County, WA, governing council voted to subsidize a naturopathic clinic operated by Bastyr.

## **Ayurveda**

Ayurveda is a mind-body set of beliefs and principles that has its roots in ancient India, and has been practiced for over 5000 years. Disease is thought to arise from imbalance or stress in an individual's consciousness, and is exacerbated by unhealthy lifestyles. Three *doshas* determine one's unique "body type," and combined with diagnostic readings of the radial pulse, guides the healer to determinations of dysfunction and corresponding treatment.

Specific lifestyle and dietary interventions are prescribed, as well as measures to rid the body of certain toxins and metabolic byproducts that are thought to accumulate, to the detriment of the body. Meditation, exercise, herbal oil massage, and other therapy are promoted, much of which is proprietary and marketed commercially.

## **Folk therapies**

Besides traditional Oriental medicine, other cultural systems within the United States use folk treatment and rely to at least some extent on self-care remedies. Some of the healers are shamanistic and blend religion with their efforts to heal, such as in Native American healing ceremonies or in Latin American and Caribbean culture. For physicians practicing in areas with significant ethnic populations, knowledge of these folk beliefs and cultural sensitivity in history-taking, physical examination, and instruction may enhance clinical interactions. Practitioners of traditional Chinese medicine use acupuncture, a host of herbal remedies, and sometimes include substances derived from sources such as the gallbladder of bears, tiger teeth and bones, and rhinoceros horn, increasing the hazards facing these endangered species.

## **The Office of Alternative Medicine (OAM)**

Because of the high prevalence of use of alternative medicine in the United States, Congress passed legislation in 1991 that created the OAM at the NIH, with a directive to begin a program of research on alternative therapies. Its purpose is to "coordinate and support evaluations and investigations that assess the scientific validity, clinical usefulness, and theoretical implications of health care practices that prevent or alleviate suffering or promote healing."

An initial budget of \$2 million has grown to \$5.4 million for FY 1995 and \$11.1 million for FY 1997. The OAM is funding a wide variety of investigator-initiated grant projects and creating a clearinghouse for information on alternative medical practices. Ten centers for research in complementary and alternative medicine have been funded with grants of about \$1 million each, to study specific health conditions, including cancer and women's health issues. Each center will develop a program infrastructure, establish research priorities, conduct small "collaborative research projects" within the first year or two, propose larger research projects for future funding, and create systematic reviews of specified areas of alternative medicine using rigorous standards.

The OAM is also re-evaluating its database and its methods for research development, including controlled trials of alternative therapies. As its evaluation director Carole Hudgings, PhD, states in the OAM's October 1996 newsletter, "...it is important that the scientific rigor applied in conventional medicine also be applied to complementary and alternative practices."

Critics of the OAM wonder why the NIH is putting its imprimatur on some of the more questionable alternative techniques, pointing out that doing so allows practitioners of such therapy to cloak themselves in legitimacy by such an association, claiming (often correctly) that their methods are "under study" at OAM. Initially, no rules were set up to guard against conflicts of interest by panel members, or to prevent them from using their panel membership in self-

promotion.<sup>22</sup> As previously mentioned, proponents of alternative therapy make no secret of their desire to use OAM sanction to obtain freedom from regulatory oversight.

In an essay in the *New York Times*, two university scientists who discuss the OAM conclude, "Should there be an Office of Alternative Medicine to evaluate unconventional practices? Not one that elevates magical notions to matters of serious scientific debate. ...It is important to distinguish these experiences [such as kindness or sunsets] from claims that ignore natural law."<sup>23</sup> Under its new director, it may be that the OAM will address these areas to the satisfaction of its critics.

### **The context of alternative medicine**

In a national survey, at least one-third of persons claimed to have used at least one alternative therapy in the past year, and one-third of these persons saw a provider of alternative medical therapy. Among those using an unconventional healer, 83% also saw a medical doctor for the same condition, but nearly 75% of them did not report the use of alternative care to their traditional physician. The survey data estimated that in 1990 the out-of-pocket cost of unconventional therapy in the United States, including the cost of herbal medicines and health food/nutrition therapy, exceeded \$10 billion. Another \$3 billion of these costs were borne by third-party payors. The total estimated cost, \$13.7 billion, exceeds the cost of hospital care in the United States in 1990 (\$12.8 billion) and is about half of all the out-of-pocket expenses to physician services (\$23.5 billion). The authors suggest that the total number of annual visits to alternative practitioners may exceed those to primary care physicians.<sup>25</sup>

The Oxford Health Plan, based in Norwalk, CT, is currently adding a network of about 1,000 holistic providers from which plan participants will be able to obtain chiropractic, acupuncture, and naturopathic treatment *without* prior approval of a "gatekeeper" at a cost of 2% to 3% added to the premium. Plan managers may believe that alternative therapies can decrease costs by decreasing utilization of conventional services. However, the Eisenberg study showed that the cost of alternative therapies averaged \$27 per provider visit, and totaled over \$500/year among those who used alternative methods, who usually sought simultaneous care from conventional physicians.<sup>25</sup> The Oxford group has instituted several advisory committees to determine the "highest quality" of alternative practitioners, and plans to obtain feedback from patient encounters to monitor the type of treatments offered for different complaints. Quality-control committees will gauge appropriateness of care and whether the modality used lies within the scope of practice of the alternative therapist. They also hope to conduct outcomes research on this project. This new venture may have the effect of shifting the burden of seeking effective diagnosis and treatment to the consumer, since the plan has no clear idea whether most of the alternative treatments have any credibility besides that being claimed by proponents.

In an editorial, *Campion*<sup>24</sup> cites several reasons for the public's "expensive romance with unconventional medicine." People have easy access to many options in medical care; disaffection with traditional care is widespread, fueled by media accounts of medical misadventures and uncaring managed care institutions; alternative practitioners often give people more time and attention than traditional providers; people want to feel in control of their bodies; and most of all, they want to feel well.

Americans seek alternative care for a wide variety of conditions. In one national study, the most common complaints presented to unconventional practitioners were back complaints (36%), anxiety (28%), headache (27%), chronic pain (26%), and cancer or tumors (24%). About one-third of patients in the same survey reported using alternative healers for health promotion and disease prevention advice, or for nonserious conditions not related to their chief complaint.<sup>25</sup> A Canadian survey found that about 11% of children also attending a pediatric outpatient clinic in Quebec had been taken to chiropractic, homeopathic, naturopathic, and acupuncture practitioners, mostly for respiratory and ear-nose-throat problems. Parents assumed these

treatments to be more "natural," and to have fewer side effects, but did not seek alternative therapy to receive more "personalized" care.<sup>26</sup>

Alternative therapy for cancer treatment has attracted much attention. Recent surveys show that from 3%<sup>25</sup> to 9%<sup>27</sup> of patients with cancer sought alternative methods of treatment for cancer. Older surveys with smaller data bases found higher usage rates, showing that 13%<sup>28</sup> to about 50% of patients with cancer sought alternative treatments.<sup>29</sup> That nearly half of all cancer patients have sought or seriously considered unconventional cancer therapy has been reported widely in the lay press as well, and adds to the perception that such practices are quite common and might be useful. Many cancer patients change diet, use multivitamin therapy, take shark cartilage, Chinese herbs, homeopathic pellets, and such therapies as mistletoe or mushroom extract with the expectation that their disease will be mitigated. The whole gamut of unconventional therapists is utilized by cancer patients, ranging from acupuncturists to Gestalt therapists.

Buckman<sup>30</sup> points out that reports of success for many of the therapies being embraced by the public may be explained in several ways. The "cures" may have come from misdiagnosis, and when the anecdotes of healing are traced to the original sources, no data can be found. Patients may not have had the diagnosis for which they were "cured" or the data may have been falsified or misinterpreted by the healer. They may have experienced self-limiting or fluctuating illnesses, remission of which was wrongly attributed to the alternative treatment. After therapy, patients may not have been followed long enough to accurately assess cure or observe relapses. Concurrent conventional therapy is often being taken by patients who undergo alternative treatments, with inappropriate credit given to the unconventional method. Finally, misinterpretation of information by patients who believe themselves miraculously cured is often at the core of their success story. However, he points out that some of the clinical trials examining different areas of alternative therapy have raised enough questions to make further investigation of these methods desirable, in order to help answer the essential question in this debate: do these methods merely make one *feel* better, or do they really help one *get* better?

It is also interesting that in one survey of patients with cancer,<sup>27</sup> patients claimed little opposition by their physicians in seeking such care, but their physicians reported these encounters differently. Patients reported that their physicians recommended or approved their use of unconventional therapy 50% of the time, and 31% cited the physician as the source of information about alternative methods. Forty percent of patients in this group reportedly abandoned traditional therapy after finding alternative care. In the same study, 52% of physicians who treated this group of patients reportedly objected to unorthodox treatments, and only 2% said they had recommended such treatment, although 37% said they "went along with" the patients. Patients did not tell physicians about their alternative cancer care 35% of the time.

Other surveys report that for all uses of alternative medicine, up to 70% of patients may not reveal their use of unconventional treatment to their physician.<sup>25</sup> The former director of the OAM, Joseph Jacobs, MD, states that this lack of communication between doctor and patient about the use of alternative therapies "creates a very real challenge to the medical community, because not being able to understand what many [patients] are using outside of the medical mainstream presents a real barrier to good clinical care."<sup>31</sup>

On the other hand, many patients in the AIDS community, for example, have become quite vocal about the need for research in alternative medicine because they think many patients are being deceived by proponents of untested therapy, and have appealed to the OAM and others for definitive answers about unconventional AIDS treatments being offered.<sup>31</sup>

What do physicians think about alternative medicine? It is likely that most physicians are unaware of the scope, breadth, and extent of use of unconventional therapies in the United States.<sup>1</sup> The level of interest among physicians in learning more about alternative therapy, however, seems to be high. A regional survey of family physicians in the Chesapeake Bay area showed that more

than 70% were interested in training in such practices as herbal medicine, prayer therapy, acupressure, vegetarian and megavitamin diet therapy, acupuncture, and biofeedback.<sup>32</sup> The results of this study, however, are curious in that 26% of respondents claim to have had training in chiropractic methods, 22% in acupuncture, and nearly 10% report training in traditional Oriental or Native American medicine. While informal training courses in these areas may be available, the scientific basis for such instruction is weak to nonexistent, and not usually accredited by specialty societies or traditional organized medical associations that govern continuing medical education. It would be most unusual if over 20% of family physicians in this area actually use chiropractic in their practice.

In a national survey of referral patterns by board-certified family physicians and internists, 94% indicated willingness to refer for at least one alternative therapy, 90% for at least two, 85% at least three, 77% at least four, and 66% at least five such modalities. The list of therapies for which these physicians expressed a willingness to refer patients included: relaxation techniques-86%, biofeedback-85%, therapeutic massage-66%, hypnosis-63%, acupuncture-56%, and meditation-54%. By contrast, 47% said they would refer for chiropractic, 24% for "spiritual" healing, 15% for homeopathy, 14% for energy healing, and 6% would refer for megavitamin or herbal therapy. In the same survey, 22% of respondents reported personally providing relaxation therapy, 17% "lifestyle diet (vegetarian, macrobiotic, etc.)," 5% hypnosis, 3% massage or chiropractic therapy, and 1% homeopathic or acupuncture therapies.<sup>33</sup>

The authors of the Chesapeake Bay study<sup>32</sup> cite surveys of physicians in Great Britain, Israel, and New Zealand that show "similar interest" in studying alternative medicine. A more recent meta-analysis of European physicians and their attitudes about alternative medicine shows that on average, physicians view complementary medicine to have an "effectiveness rating" of 46± 18 on a scale of 0-100. There was no trend among these data to suggest increasing endorsement of alternative medicine by conventional practitioners, but the authors conclude that European physicians give these therapies a "considerable degree of acceptance."<sup>34</sup> They caution, however, that the perceived usefulness of such therapies by physicians or the public should not be equated with proven efficacy.

Many persons who are proponents of alternative medicine understand and acknowledge the role of traditional Western medicine for such problems as surgical intervention for appendicitis and fractures, or antibiotic therapy for specific infectious diseases. However, many in the alternative medical community spend a good deal of energy denigrating the role of allopathic intervention as dangerous, expensive, and impersonal. In the "deconstructionist" mode, they often change the vocabulary to make their methods seem rational and reasonable. In a critique of alternative medicine, Wallace Sampson, MD, points out that an editorial in *Alternative Therapies* poses:

"a non sequitur: present knowledge is adequate to dismiss the utility of most alternative methods; but [the editorial claims] there are ineffable qualities that [conventional] methods cannot detect and alternatives cannot define; therefore, alternative methods must be accepted, their practitioners licensed, and their services paid for by public funds and health insurance."<sup>35</sup>

In an unpublished survey of all 125 US medical schools, Sampson has found that just over 50 schools offer elective, for-credit courses on alternative therapy, and 18 other schools offer lecture series or seminars on the subject. His survey reveals that most are being given by "supporters or proponents of alternative methods," and that the "scientific view" is offered in only 7 courses.

In an editorial,<sup>36</sup> Alpert argues that alternative medicine should not be "condemned out of hand," but suggests that traditional medicine approach alternative therapy based on five principles. Convinced that many unconventional treatments will eventually become mainstream, he proposes that physicians:

1. Maintain an open-minded attitude about all potentially new therapeutic interventions that include those commonly referred to as alternative.
2. Encourage carefully performed and appropriately controlled studies of these new therapies.
3. Do not ignore or ridicule the potential of the placebo effect to produce marked therapeutic benefit.
4. Do not accept all new therapies as efficacious on first acquaintance. Practitioners of quack medicine continue to abound as in all earlier times. Claims of therapeutic efficacy should be rationally examined and tested.
5. Avoid hubristic and arrogant attitudes toward alternative medical practices because one might be embarrassed by the subsequent demonstrations of their clinical efficacy.

Alpert says that these statements are guiding the University of Arizona as it sets up a program to "integrate and evaluate valuable alternative medical practices into routine allopathic care." Andrew Weil, MD, who has written several books on alternative medicine, is heading the new program.

It is clear that in the quest for wellness, the public is seeking new approaches to medical care. Some of the reasons may be understandable, such as the desire to find a healer with time to listen, to receive compassionate care, and to establish a partnership with a provider in seeking health.

In "Turning From Science and Reason," an address at the 1996 AMA National Leadership Conference, Jeremiah Barondess, MD, stated that many physicians may not deal effectively enough with illness, elements he identifies as those symptoms, anxieties, and concerns that make people feel sick, as opposed to our emphasis on disease, defined too often in biochemical and molecular terms that are far removed from the person being examined. Patients, he says, are increasingly taking more responsibility for their own health. Many are disaffected with medicine in general, as part of a trend of public suspicion of authoritarian, insular sections of society.

Some of the interest in alternative medicine may be due to an "outbreak of irrationalism" that includes New Age interest in "channeling" and astrology.<sup>37</sup> Television talk shows and the proliferation of books and tapes on alternative therapies are gobbled up by an uncritical public that does not understand how to sort quack theories from what might be reasonable. Carl Sagan has recently lamented the phenomenon of our increasing scientific illiteracy and the rise of pseudoscience and superstition, noting that "baloney, bamboozles, careless thinking, and wishes disguised as fact...ripple through mainstream political, social, religious, and economic issues in every nation."<sup>40</sup>

Political decisions allow licensing of alternative practitioners without any scientific basis for accreditation of their schools or the methods used by their practitioners. Congress has recently dismantled its own scientific oversight section, the Office of Technology Assessment. Political pressure from the health food and vitamin supplement industry has hampered the FDA's ability to monitor their products, and legislative proposals have been advanced to allow such products to be covered by food stamps--in effect, paying for pills instead of food<sup>38</sup> There is, indeed, reason for concern.

Given the growing interest in alternative medicine by the public, accurate, even-handed education about alternative medicine is vital for both the public as well as for physicians, who should be familiar with unconventional therapies and be able to advise patients on their use. Sound, good quality research is needed to determine the potential benefits and avoid the risks inherent in unconventional therapy.

## RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted as AMA Policy at the 1997 AMA Annual Meeting.

1. There is little evidence to confirm the safety or efficacy of most alternative therapies. Much of the information currently known about these therapies makes it clear that many have not been shown to be efficacious. Well-designed, stringently controlled research should be done to evaluate the efficacy of alternative therapies.
2. Physicians should routinely inquire about the use of alternative or unconventional therapy by their patients, and educate themselves and their patients about the state of scientific knowledge with regard to alternative therapy that may be used or contemplated.
3. Patients who choose alternative therapies should be educated as to the hazards that might result from postponing or stopping conventional medical treatment.
4. Courses offered by medical schools on alternative medicine should present the scientific view of unconventional theories, treatments, and practice as well as the potential therapeutic utility, safety, and efficacy of these modalities.

<http://www.ama-assn.org/ama/pub/category/1800.html> Council on Scientific Affairs Home Page

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